TECHNICAL REPORT

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Conformity assessment — Example of a certification scheme for tangible products

Évaluation de la conformité — Exemple d'un schéma de certification pour des produits tangibles

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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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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 TR 17026 was prepared by the *ISO Committee on conformity assessment* (CASCO).

Introduction

Product certification is used ever more widely to provide confidence that products, processes and services fulfil specified requirements.

This Technical Report is intended to provide useful information to those involved in product certification on the application of ISO/IEC 17067. It provides an example of a type 5 scheme, as outlined in ISO/IEC 17067, related to the certification of tangible products.

There are many different ways in which product certification is operated in practice. This Technical Report does not prevent scheme owners, in consultation with other stakeholders, from adopting other measures or using them in different combinations to achieve a fit-for-purpose scheme.

In particular, the range of activities used, and the intensity with which they are applied, need to be proportionate to the consequences and likelihood of a product in service failing to fulfil specified requirements. Factors such as the particular characteristics of the marketplace, the product technology and the production methods related to the products also need to be taken into account.

The principal stakeholders, who are most affected by the rules, procedures and management of the scheme, are the following:

— the scheme owner;

— the certification body/bodies;

— the manufacturers of certified products;

— users of the certified product and entities that rely on certification.

NOTE Where a certification body runs its own scheme, the certification body is the scheme owner.

Other stakeholders include, but are not limited to:

— regulatory authorities;

— specifiers, purchasers and users of certified products;

— conformity assessment bodies, such as testing laboratories and inspection bodies, involved in the product certification process;

— accreditation bodies and peer assessment groups;

— international certification schemes that facilitate the recognition of certification status from one scheme owner to another;

— consumers.

This Technical Report contains neither normative requirements (expressed by “shall”) nor recommendations (expressed by “should”). It is intended solely as an example of a type 5 product certification scheme.

Conformity assessment — Example of a certification scheme for tangible products

1 Scope

This Technical Report provides an example of a type 5 product certification scheme for tangible products as described in ISO/IEC 17067.

NOTE 1 The example provided in this Technical Report relates to a certification scheme for products. However, if applicable, it can also be used as a basis for developing certification schemes for services and processes (see type 6 as described in ISO/IEC 17067).

NOTE 2 In the context of this Technical Report, the assessment of a management system as part of product certification does not constitute the certification of the management system.

NOTE 3 This Technical Report is intended to provide useful information to those involved in product certification on the application of ISO/IEC 17067.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

ISO/IEC 17067:2013, *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17067 and ISO/IEC 17065 apply.

4 General description of the example scheme

4.1 Development and operation of a product certification scheme

General provisions for the development and operation of a product certification scheme are stipulated in ISO/IEC 17067:2013, Clause 6. This Technical Report provides an example of how those general provisions are implemented in a particular type 5 product certification scheme. The example is not intended to limit in any way the decisions of scheme owners when developing and operating their own schemes. They may develop alternative product certification schemes including those described in ISO/IEC 17067.

4.2 Outline of the example product certification scheme

This example of a product certification scheme reflects a type 5 product certification scheme as explained in ISO/IEC 17067. It includes the following functions, activities and elements, which are further described in this Technical Report:

a) selection (see 4.5), including:

   1) specified requirements for the products covered by the scope of the scheme (e.g. those in a standard or other normative document);

   2) elements of the production process to be assessed and of the management system to be audited;

   3) determination activities, and the basis on which those activities be undertaken (e.g. reference ISO/IEC 17065 for product certification bodies, and to the applicable requirements of ISO/IEC 17025 for testing, ISO/IEC 17020 for inspection and ISO/IEC 17021 for management system auditing);

   4) sampling methods and frequency;

   5) requirements which the client has to fulfil in order to gain and maintain certification of the product (e.g. signing a certification agreement, the ongoing operation of a management system, maintaining control over the use of the mark of conformity, advising the certification body of changes affecting product conformity);

   6) any other certification requirements;

b) determination (see 5.2), including:

   1) evaluation of the product;

   2) assessment of the production process and audit of other elements of the client's management system critical to managing product conformity through document review and onsite assessment;

c) review of the evaluation results;

d) decision on certification and attestation of conformity (see 5.7 and 5.8);

e) licensing and control of the mark (see 5.9), including:

   1) mark of conformity;

   2) publicity to clients;

   3) misuse of certificate and marks of conformity;

f) surveillance (see 5.10), including:

   1) testing and inspection of product samples;

   2) assessment of the production process and audit of the management system;

g) suspending or withdrawing a certification and license (see 5.9.5);

h) managing changes affecting certification (see Clause 7).

NOTE These functions are consistent with the requirements specified in ISO/IEC 17065, in which the functions selection and determination are together referred to as "evaluation". A description of the functions listed above appears in ISO/IEC 17000:2004, Annex A.

4.3 Scope of the scheme

The scope of the scheme is defined in terms of the types of product, the product requirements and other requirements specified by the certification scheme and the geographical areas within which it operates.

4.4 Parties involved in the scheme

The main parties involved in the operation of the scheme are:

a) the scheme owner;

b) the certification body;

c) the organization that has a certification agreement with the certification body, or that has applied for (this organization is referred to as "the client").

NOTE 1 For further information on the certification agreement, see ISO/IEC 17065:2012, 4.1.2.

All product certification schemes have a scheme owner. The scheme owner can be a certification body, a regulatory authority, an industry group, a group of certification bodies or others. The scheme owner is responsible for the rules, procedures, management and integrity of the scheme.

NOTE 2 Further information on scheme owner can be found in ISO/IEC 17067.

The certification body may outsource some activities to other organizations but always retains responsibility for the outcome. The review, decision and attestation cannot be outsourced.

The client is often the manufacturer, who may use sub-contractors for some of the production operations, but sometimes the manufacturer's agent or another organization in the supply chain (e.g. a distributor) can act as the client and seek certification. In such cases, the client may not have control of the manufacturing processes nor access to the production facilities. Before signing a certification agreement, the client needs to be able to ensure that the certification body can perform all necessary assessment activities of the production processes and the manufacturer's quality management system.

4.5 Selection elements in the scheme

Within the declared scope (see 4.3), the scheme specifies the requirements that the products, production process and management system are intended to fulfil. These requirements are specified by reference to standards, technical specifications or other normative documents that have been developed in accordance with the guidance in ISO/IEC 17007.

Certification requirements are comprised of:

— product requirements (as defined in ISO/IEC 17065:2012, 3.8);

— other requirements for the client to fulfil, including the following:

  — signing a certification agreement;

  — meeting arrangements for the selection and sampling processes, testing, assessments and auditing;

  — payment of necessary fees;

  — signing a licensing agreement for the use of the certification mark on their products;

  — providing product information.

The product requirements are a subset of the certification requirements.

4.6 Sampling processes in the scheme

This scheme specifies the sampling method(s) to be used for evaluation. Sample(s) need to be:

a) representative of products to be certified;

b) made using components and sub-assemblies approved for use in production;

c) made using production tools and assembled using methods established for the products to be certified.

Where evaluation is performed on prototype samples, further evaluation of subsequent production sample(s) is necessary.

4.7 Determination procedures of the scheme

This scheme provides details of the procedures to be used for determination activities, e.g.

a) sampling, testing and other evaluation activities, where these have not been adequately specified in the product requirements or other normative documents;

b) assessing the production process;

c) auditing those elements of the client's management system which are identified as critical to ongoing product conformity.

5 Sequence of a certification cycle and involved activities

5.1 Application for certification and certification agreement

The certification body provides the potential client with all information necessary to understand and follow the rules for the specific certification scheme. These rules are publicly available.

The client makes an application to the certification body for certification of its specified products. The application provides the certification body with all necessary information to enable it to plan the evaluation and certification process.

ISO/IEC 17065:2012, 7.2, gives examples of the information needed and it constitutes the basis for the application information listed in Annex A.

Once the application is received from the client, the certification body checks that the information provided by the client is clear and sufficient and, if it is not, asks the client for the necessary clarification or additional information.

The certification body establishes a legally enforceable agreement with the client (see ISO/IEC 17065:2012, 4.1.2).

5.2 Determination

5.2.1 General

During this function, the certification body gathers information to determine the extent to which the client demonstrates its fulfilment of certification requirements.

5.2.2 Evaluation plan

From the information provided in the application, the certification body ascertains that it has the competence and capability to undertake the work.

Based on the requirements of the scheme, the certification body prepares an evaluation plan setting out:

a) the product type (e.g. model identification) for which certification is sought;

b) the standards and other normative documents that specify the product requirements;

c) the evaluation methods and procedures to be used where these are not specified in the standards;

d) the product samples and/or the sampling procedures required for evaluation;

e) the methods and procedures to be used when assessing the production process;

f) the coverage and the extent of the auditing of the management system;

g) the personnel and other resources, including outsourcing, to be used for the evaluation.

The evaluation plan can be a generic plan that can be used for all certification evaluation activities under this scheme, or an individual plan for each client or individual evaluation.

The certification body advises the client of the plan, including any financial and timescale aspects required by the scheme, and ensures that the client has completed, or has undertaken to complete, the certification agreement (see Annex F for the suggested content of a certification agreement that includes the matters identified in ISO/IEC 17065:2012, 4.1.2).

After confirmation of the acceptance of the application, the certification body makes the necessary arrangements with the client for the initial assessment in accordance with the evaluation plan.

Under this certification scheme, the following determination activities are used:

— initial testing and examination of the product;

— assessment of the production process;

— audit of the elements of the management system that are critical to product conformity.

The certification body is responsible for all actions included in the particular certification scheme, including sampling, testing, assessment of the production process, auditing of the management system, and surveillance of the certified product.

5.2.3 Acceptance of conformity results generated prior to the application or provided by the client

This scheme accepts conformity assessment results (including such items as test results and management system certification) which are generated prior to the application, or are provided by the client. In accordance with ISO/IEC 17065:2012, 6.2 and 7.4.5, the certification body takes responsibility for these conformity assessment results.

In order to cover this responsibility under this scheme, the certification body:

a) checks that the conformity assessment results relate to the certification requirements;

b) identifies whether the conformity assessment results come from a body that fulfil the applicable requirements of ISO/IEC 17020 or ISO/IEC 17021 or ISO/IEC 17025, or are accredited or peer evaluated to these standards with a scope relevant to the certification requirements.

5.2.4 Initial product evaluation

The product evaluation is carried out in accordance with the methods specified in the applicable standard(s) or requirement(s), and with the procedures specified by the scheme. The objective is to ascertain if the product fulfils the specified requirements.

Testing facilities used in product evaluation demonstrate to the certification body that they meet the applicable requirements of ISO/IEC 17025. This can be demonstrated by:

a) the testing facility having a current accreditation as fulfilling the requirements of ISO/IEC 17025 with a scope of testing covering the test methods established by the normative document for the product being certified; or

b) the assessment of the competence of the testing laboratory by the certification body using a suitably competent laboratory assessor, including the witnessing of testing on a periodic basis; or

c) the testing laboratory having a peer assessment recognition by a competent organization with a scope covering the product being certified.

If test results are accepted, test reports and samples are examined together to ensure that test results are applicable to product samples under consideration.

5.3 Assessment of the production process and audit of the management system

5.3.1 General

Assessment of the client's production process and audit of the elements of the management system critical to product conformity forms part of the initial assessment in accordance with this product certification scheme.

The client designates:

— a responsible person as the main contact with the certification body;

— a person(s) with management responsibility for the technical performance of the production processes and management system.

5.3.2 Initial document review

The first stage of undertaking an assessment of the production process and audit of the management system is a document review.

The certification body conducts a document review of the client's management system in order to determine the readiness for the onsite assessment.

To facilitate the document review, the client provides information on the management system pertinent to the production process. An example of the pertinent information is shown in Annex B. The client makes available to the certification body records that demonstrate the effective implementation of the management system.

The certification body may, at its discretion, take into account the client's current management system certification, provided that the certification covers:

a) the scope of products being considered;

b) the sites where the activities take place.

Consideration is also given to the extent that the management system certification is mutually recognized, through it originating from a certification body that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021 and/or ISO/IEC 17040).

The certification body evaluates the information provided, requests additional information as needed, and determines whether the application can proceed to the onsite stage of the determination function.

