GUIDE 28

Conformity assessment — Guidance on a third-party certification system for products

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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 Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

ISO/IEC Guide 28 was prepared by the ISO *Committee on conformity assessment* (CASCO).

This second edition cancels and replaces the first edition (ISO/IEC Guide 28:1982), which has been technically revised.

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Introduction

This Guide serves to provide a model for a third-party certification system for products, but does not exclude the existence of other useful models for third-party conformity assessment systems. There are many types of possible systems depending on the type of product requiring certification.

The usefulness of ISO/IEC Guide 28:1982 as a model third-party certification system for products has been well recognized. This revision confirms the status of this Guide as an authoritative and reliable, though not exclusive, model of a product certification system.

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Conformity assessment — Guidance on a third-party certification system for products

1 Scope

This Guide gives general guidelines for a specific product certification system.

It is applicable to a third-party product certification system for determining the conformity of a product with specified requirements through initial testing of samples of the product, assessment and surveillance of the involved quality system, and surveillance by testing of product samples taken from the factory or the open market, or both. This Guide addresses conditions for use of a mark of conformity and conditions for granting a certificate of conformity.

This system corresponds to system 5 product certification system as described in ISO/IEC Guide 67.

A model checklist of requirements for a third-party certification system is given in Annex A.

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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.

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ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*

3 Terms and definitions

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

4 Application for certification

The application is made on a special form obtainable from the certification body. An example of such a form is given in Annex B.

The application relates to the specific product or group of products for which certification is requested by the applicant and as determined by the product certification scheme.

On acceptance of a completed application form and receipt of the deposit, if required, the certification body provides the applicant with an estimate of the time required for conduct of the initial evaluation, and any further information necessary for the processing of the application.

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5 Initial assessment

5.1 General

To operate this model product certification system, the certification body shall comply with the requirements of ISO/IEC Guide 65.

After confirmation of the acceptance of the application, the certification body should make the necessary arrangements with the applicant for the initial assessment in accordance with the product certification scheme.

The certification body is responsible for all actions included in the particular certification scheme, including sampling, testing, assessment of the production process or quality system, and surveillance of the certified product. The certification body may accept existing conformity assessment results in accordance with the product certification scheme.

The certification body should inform the applicant of the results of the initial assessment and testing.

If the certification body is not satisfied that all the requirements have been fulfilled, it should inform the applicant of those aspects which do not comply with applicable requirements.

If the applicant can show that corrective action has been taken to meet all the requirements within a specified time limit, the certification body should repeat only the necessary parts of the initial assessment and testing.

Where a cost limit is specified by a certification body as part of its application procedure, the filing of a new application or an extension of the cost limit may be required.

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Repeat of the assessment may not be needed for subsequent submittals of the same product.

5.2 Assessment of production process and quality system

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Assessment of the applicant's production process or quality system forms part of the initial assessment in accordance with the product certification scheme.

A model of facility assessment is given in Annex C.

All records produced from implementation of the quality system related to certification should be readily available for assessment by the certification body.

The applicant should ensure that the question of responsibility to the certification body for the quality system is clearly defined. This could be by appointing a designated person who is independent of the production management as far as the technical performance of this function is concerned, and who is qualified to maintain contact with the certification body.

5.3 Initial testing[1)]

5.3.1 Sampling

The sampling for tests and examination is based on the product certification scheme.

Samples should be representative of the entire line or group of products to be certified, and should be made using components and sub-assemblies identical to those used in production, made from production tools and assembled using methods established for the production run.

1) As used herein, “initial testing” refers to testing carried out by the certification body before granting or extending a licence. It is sometimes called “type testing”.

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Where testing is based on prototype samples, confirmation tests or examination, as appropriate, should be made on production samples.

5.3.2 Conduct of initial testing

The initial testing should be carried out in accordance with the applicable standard(s) or requirement(s) and with the product certification scheme.

5.3.3 Use of test data produced by other than the certification body

Where the certification body chooses to use test data produced by others (including supplier laboratories under certain conditions), the body should ensure that the requirements for the suitability and competence of the party conducting the testing, as specified in ISO/IEC 17025, are met.

6 Evaluation (review)

The evaluation should be carried out by determining if the results of the initial assessment of the production process or quality system and initial testing meet the specified requirements.

7 Decision

When the evaluation (review) has been completed, a decision on conformity should be made. The statement of conformity as the result of the decision may take the form of a report, a declaration, a certificate (see Annex D for an example) or a mark, and conveys the assurance that the specified requirements have been fulfilled.

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8 Licensing

When the certification decision (attestation) has been made, the certification body should provide a certification decision to the applicant, and should submit a licensing agreement to the applicant for signature. When the licence agreement has been signed, the certification body should issue a licence. An example of such an agreement and a licence are included in Annexes E and F.

NOTE If the provisions addressed by the licensing agreement are incorporated in the application then “licensing agreement” may not be necessary.

The agreement should address conditions under which the mark or certificate is to be used, and should establish rules in the case of misuse.

9 Extension of the scope of certification

A licensee wishing to extend the scope of certification to additional types or models of products, to the same specified requirements as the products for which a certification is already granted, should apply to the certification body using the application form (Annex B). In such cases the certification body may decide not to carry out an assessment of production process or quality system but to require test samples of the additional types of products to determine that they comply with the specified requirements. If the tests are successful, the scope of certification should be extended and the licence agreement may be modified.

If the licensee wishes to apply the certification to additional types of products, but to different specified requirements, or if the licensee wishes to apply for certification to be used in an additional facility that is not covered by the earlier license, it will be necessary to carry out those parts of the original application procedure which do not cover the new circumstances.

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10 Surveillance

The certification body should exercise surveillance of the products on the basis of the requirements of the relevant standard and on the basis of the elements or requirements of the product certification scheme. The certification body should exercise surveillance of the production process or quality system on the basis of the requirements relevant to the product certification scheme. The certification body may accept existing conformity assessment results according to the product certification scheme.

In some cases it may not be necessary to base surveillance on a repetition of all the elements of the initial conformity assessment. This could be the case with custom-built products and could be applied to cases where the initial testing is very complicated or where the samples are very expensive. In such cases, the surveillance may be based on examination only, or combined with more simple identification tests which ensure that the product is in conformity with the tested sample. Such identification tests should be described in the product certification scheme.

The licensee should be informed about the results of the surveillance.

The licensee should inform the certification body about any intended modification to the product, production process or quality system which may affect the conformity of the product. The certification body should determine whether the announced changes require another initial testing and assessment or other further investigations. In such cases, the licensee should not be permitted to release products resulting from such changes until the certification body has notified the licensee accordingly.

The licensee should keep a record of any complaints and their disposal relative to the products covered by the licence, and make these available to the certification body on request.

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11 Use of a certificate or mark of conformity

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11.1 Certificate or mark of conformity

ISO/IEC Guide 23 and ISO/IEC 17030 should be considered. Such a certificate or mark of conformity should be distinctive and should at least

— be proprietary in nature, with legal protection as regards composition and control of use,

— be so coded or otherwise designed as to aid in the detection of counterfeiting or other forms of misuse, and

— be non-transferable from one product to another.

A mark of conformity should be directly applied to each individual product except where the physical size of the unit or the type of product does not permit this, in which case the mark may be applied to the smallest package in which the unit is marketed.

11.2 Marking

In certain circumstances, it may be appropriate to use other marking in association with the certificate or mark of conformity, such as

— the name or trademark of the certification body where such cannot be determined from the certificate or mark of conformity used,

— the name of the product classification where such is not completely obvious, and

— identification of the relevant standard(s).

Such certificate or marking should be in accordance with the product certification scheme.

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In the event of revision of a standard on which a certification scheme has been based, it is important that the marking, or related information, clearly indicates the appropriate edition of the standard in question or a date code marking where applicable, so that the user is informed correctly of the requirements laid down for the product.

12 Publicity by licensees

A licensee should have the right to publish the fact that it has been authorized to issue a certificate of conformity or apply a mark of conformity for products to which the license applies.

In every case the licensee should take sufficient care of its publications and advertising that no confusion arises between certified and non-certified products.

The licensee should not specify any function or make any claim or the like in user information that could lead purchasers to believe that performance of the product or its use is covered by the certification when in fact they are not. Instruction books or other user information accompanying the product and related to the certification scheme should be approved by the certification body if so required by the product certification scheme.

13 Confidentiality

The certification body should be responsible for ensuring that confidentiality of information is maintained by its employees and those of its subcontractors concerning all information obtained as a result of their contacts with the licensee.

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14 Misuse of a certificate or mark of conformity

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The certification body should take action when unauthorized, incorrect, or misleading use of the certificates or marks of conformity is found.

Incorrect references to the certification system or misleading use of certificates or the mark found in advertisements, catalogues, etc., should be dealt with by suitable actions, which could include legal or corrective action or publication of the transgression.

In cases of misuse of certificates or the mark of conformity by licensees, corrective action should be taken (see ISO/IEC Guide 27).

15 Suspension of a licence for a product

The applicability of the licence to a specific product may be suspended for a limited period, for example in the following cases:

— if the surveillance shows nonconformity with the requirements of such a nature that immediate withdrawal is not necessary;

— if a case of improper use of the certificate or the mark (e.g. misleading publications or advertisement) is not solved by suitable retractions and appropriate corrective actions by the licensee;

— if there has been any other contravention of the product certification scheme or the procedures of the certification body.

The licensee should be prohibited from identifying as certified any product that has been produced under a suspension of the licence as applicable to that product.

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