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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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).

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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5.3.3 On-site assessment

5.3.3.1 General

The certification body arranges a date for a visit to each of the client's site(s) where the certified product is manufactured and forms an assessment team that includes persons competent in:

a) the applicable product requirements;

b) appropriate test and/or inspection procedures and techniques;

c) conformity assessment procedures;

d) the management system requirements and audit methodologies as included in the scheme.

NOTE For additional information on audit activities and knowledge and skills of auditors, reference can be made to ISO/IEC 17021.

The matters to be investigated by the assessment team at the client's facilities include:

— determine that all information provided in the application is correct and complete;

— assessment of the production process;

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

Annex B provides an example of information to be provided on production process and management system.

5.3.3.2 Production process

Assessment of the production process includes direct observation and examination of the production line and communicating with production personnel to demonstrate:

a) that the client has the necessary facilities, equipment, personnel and procedure for carrying out the tasks associated with producing the product in accordance with the product requirements;

b) the client's capability and competence to monitor, measure and test the product during and after production so as to ensure conformity with the specific product requirements used in the scheme;

c) that the client sampling and testing (whether it be in-house or outsourced) is undertaken in accordance with the certification requirements (including the specific product standards and methods of tests) and the applicable requirements of ISO/IEC 17025 and the certification requirements;

d) quality control of the product through the production process in accordance with the certification requirements, from the receipt of inputs, through all transformation processes, through to dispatch of the completed products;

e) the ability of the client to identify and quarantine nonconforming product and to maintain product traceability where there is a certification requirement.

The certification body takes samples from the production line for subsequent verification.

5.3.3.3 Elements of the management system critical for product conformity

Matters to be covered in the audit of the elements of the management system critical for product conformity include reviewing the following:

a) procedures covering the production processes, including quality control, production resources and personnel competence that can affect product conformity;

b) documents and records control in relation to production processes and product conformity;

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c) existing management system certifications and associated audit reports;

d) internal audits and management reviews;

e) procedures and records associated with product nonconformance, corrective and preventive actions;

f) the identification, marking, and marketing of conforming products in accordance with certification requirements and license agreements.

NOTE The certification body gives consideration to the amount of audit time when the client's management system is certified by an accredited or peer assessed quality management system certification body.

5.4 Nonconformities

It is important that the scheme specifies how nonconformities are managed resolved.

If the certification body does not have sufficient evidence that the client has demonstrated that certification requirements have been fulfilled, it informs the client of those aspects which do not comply with applicable requirements as nonconformities.

If the client undertakes corrective actions these have to be completed within a specified time limit set by the certification body. The certification body may repeat the necessary parts of the initial product evaluation, assessment and audit to verify the nonconformity has been adequately addressed.

5.5 Evaluation report

Following the initial product evaluation, assessment of production process and audit of the elements of the management system, and after satisfactory action on any nonconformities, a report on the assessment team's findings is prepared. The report will be considered as part of the total package of evidence to demonstrate compliance with the certification requirements by the certification body's person or group responsible for making the certification decision.

5.6 Review

Once all determination activities have been completed, the results of initial product evaluation and the on site assessment are reviewed to ensure that they provide a suitable, adequate and effective demonstration that the product and the system for managing product quality fulfil the specified requirements. The review is carried out by a person (or group of people) who has not been involved in the determination activities. If the evidence is sufficient, a recommendation for certification is made.

5.7 Decision

When the outcome of the review is positive, a decision is made to grant certification. When the outcome of the review is negative, a decision is made not to grant certification. The client is informed with the reasons for the negative decision. The decision is made by a person (or group of persons) who has not been involved in the evaluation activities. The review and decision may be made by the same person or group of persons.

5.8 Attestation

Following the decision to grant certification, the certification body issues a statement of conformity.

Under this scheme, the statement of conformity is in the form of a certificate and a subsequent listing of the certificate on the scheme owner's website by the certification body, and on the certification body's website if the certification body wishes.

Annex C gives an example of information to be included in a certificate of conformity.

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In addition the certified client may place the scheme's certification mark on the product subject to a licensing agreement being entered into with the certification body.

5.9 Licensing use of certificates and marks of conformity

5.9.1 General

The use of the certificate and mark of conformity is controlled through a licence issued by the certification body to each organization which uses them on, or in conjunction with, certified products. The organization holding the licence (referred to in this clause as the licensee) may be different from the client to which the certificate was issued. Circumstances under which a different organization might be involved include the following:

a) the client sub-contracts the manufacture of the product, including the placing of the mark on the product, to another organization (the manufacturer would need to be a licensee);

b) a customer of the client applies its own label, including the mark, to the product under an agreement with the client (the customer would need to be a licensee);

c) other cases.

In all cases, the client ensures that the certification body has access to the licensee's premises for the purposes of assessment of the production process and audit of the management system, initially and during surveillance.

5.9.2 Mark of conformity

In accordance with ISO/IEC Guide 23 and ISO/IEC 17030, the certificate and mark of conformity are distinctive and are:

a) proprietary in nature, with legal protection as regards composition and control of use, and

b) so coded or otherwise designed as to aid in the detection of counterfeiting or other forms of misuse.

The mark of conformity is 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.

5.9.3 Other labelling

In certain circumstances, it may be appropriate to use other labelling in association with the certificate or mark of conformity, e.g.

a) the name or logo of the certification body where such cannot be determined from the certificate or mark of conformity used;

b) the name of the product classification where such is not completely obvious;

c) identification of the relevant standard(s).

The certificate and labelling are used in accordance with the product certification scheme.

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5.9.4 Issuing of a licence

The certification body submits a licensing agreement to the licensee for signature. When the licence agreement has been signed, the certification body issues a licence. An example of the information to be included in an agreement and a licence are included in Annexes D and E.

NOTE If the provisions addressed by the licensing agreement are incorporated in the application form (if the scheme requires an application form) or the certification agreement, the "licensing agreement" might not be necessary.

The licensing agreement addresses conditions under which the mark or certificate will be used, and establishes rules in the case of misuse.

5.9.5 Suspending or withdrawing a licence

5.9.5.1 Suspension

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

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

b) 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;

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

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

A licence may also be suspended after mutual agreement between the certification body and the licensee for a limited period of non-production or for other reasons.

An official suspension of a licence is confirmed by the certification body in a registered letter to the licensee (or by equivalent means).

The licensee may give notice of appeal, and the certification body when considering the appeal may or may not (depending on the nature of the case) decide to proceed with its decision to suspend the licence.

The certification body indicates under which conditions the suspension would be removed, such as for example corrective action taken in accordance with 5.9.6.

At the end of the suspension period, the certification body investigates whether the indicated conditions for re-instituting the licence have been fulfilled.

On fulfilment of these conditions, the suspension is removed by notifying the licensee.

5.9.5.2 Withdrawal

Apart from the suspension of a licence, a licence is withdrawn in the following cases:

a) if the surveillance shows that the nonconformity is of a serious nature;

b) if the licensee fails to comply with the due settlement of financial obligations;

c) if there is any other contravention of the licensing agreement;

d) if inadequate measures are taken by the licensee in the case of suspension.

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In the above cases, the certification body has the right to withdraw the licence by informing the licensee in writing. Concerning the specification of a time limit, see j) of the example licensing agreement (Annex D).

The licensee may give notice of appeal, and the certification body when considering the appeal may or may not (depending on the nature of the case) decide to proceed with its decision to withdraw the licence.

Prior to withdrawal of a licence, the certification body decides upon the consequences in relation to products certified under the licence, whether the mark of conformity needs to be removed from all products in stock, and perhaps even, if practicable, from products already sold, or whether a clearance of the stock of marked products is permissible within a short period of time. The certification body decides if other actions are required, including (if necessary in cases of a serious nature) informing the clients of the licensee, by the licensee or by the certification body.

Furthermore, the licence may be withdrawn in the following cases:

— if the licensee does not wish to maintain the licence;

— if the standard or rules are changed and the licensee either will not or cannot ensure conformity with the new requirements (see 7.1);

— if the product is no longer made or the licensee goes out of business;

— on the grounds of other provisions specified in the licensing agreement.

5.9.6 Misuse of the mark

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

Incorrect references to the certification scheme or misleading use of certificates or the mark found in advertisements, catalogues, etc., are 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 clients, corrective action is taken in accordance with ISO Guide 27. Withdrawal of a licence due to misuse of the certification mark may be published by the certification body

5.10 Surveillance

The certification body carries out surveillance as defined in the scheme in order to provide confidence that products manufactured after the initial certification continue to fulfil the specified requirements. The surveillance activities are selected according to the nature of the product and the consequences and probability of non-conforming products. The frequency with which the activities are carried out is specified in the scheme and can be adjusted in the light of the results of previous surveillance cycles. For example, if non-conformities in products or the management system have been found, surveillance may be carried out more frequently until the necessary level of confidence is restored.

Surveillance activities cover all sites where manufacturing takes place and include one or more of the following:

a) inspection of product samples taken either from the point of production, or from the market, or from both for conformity with the certified type;

b) testing of product samples taken either from the point of production, or from the market, or from both to check that they fulfil the specified requirements;

c) assessment of the production process and auditing of the management system, including examination of the client's quality records relating to the production process.

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It may not be necessary to repeat all of the elements of the initial product evaluation. 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 certified type. Such identification tests are described in the product certification scheme.

The client is informed about the results of the surveillance.

If surveillance reveals nonconformity with the certification requirements which cannot be readily remedied by the client, the certification body considers what action to take.

The client keeps a record of any complaints relating to compliance with the certification requirements and documents the remedial actions taken. The client makes the records available to the certification body on request. If non-conforming products have been released onto the market, the client informs the certification body so that it can agree on the action to be taken.

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6 Publicity by clients

The client has the right to publish the fact that:

a) an identified product has been certified;

b) the client has been authorized to

- use a valid certificate of conformity, and
- apply a mark of conformity for products to which the licence applies.

In every case, the client takes sufficient care of its publications and advertising so that no confusion arises between certified and non-certified products.

The client does 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 it is not.

In this example the scheme requires the certification body to approve instruction books, manuals and other user information accompanying the product.

7 Changes affecting certification

7.1 Changes to product requirements

When a standard or another normative document that is part of the certification requirements is changed, there are a number of factors that have to be considered by the scheme owner when he fixes the date on which the new product requirements of the changed document will come into force (effective date reflecting the transition period).

NOTE See also Clause D.2, bullet k).

The effective date of obsolescence of a standard or other normative document is communicated by the certification body to all applicable clients to allow them adequate time to take appropriate action.

In those cases when the standard development organization responsible for the standard or other normative document defines the transition period until which the superseded document is valid, this date defines the obsolescence of the superseded document unless otherwise stated by law or by the scheme.

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Further factors that are considered when choosing the effective date include, but are not necessarily restricted to, the following:

a) compliance with regulations or contractual obligations;

b) the urgency of complying with revised health, safety, or environmental requirements;

c) the length of time and financial costs for retooling and manufacturing a product complying with the revised requirements;

d) the extent of stock on hand and whether it can be reworked to meet the revised requirements;

e) avoidance of unintentional commercial advantage given to a particular manufacture or design;

f) operational constraints of the certification body.

7.2 Changes to other scheme requirements

The scheme owner advises the certification bodies, and their clients if necessary, of other changes to the scheme requirements, such as:

a) test and examination procedures where these are not contained in the standards or other normative documents that specify the product requirements;

b) criteria and procedures for assessment of production processes and audit of management systems;

c) conditions for licensing of the certification mark;

d) qualification criteria and procedures for conformity assessment bodies participating in the scheme.

7.3 Changes by client

The client informs the certification body about any intended modification to the product, production process or management system which may affect the conformity of the product. The certification body determines whether the announced changes require another initial testing and assessment or other further investigations. In such cases, the client is not permitted to release products under the certificate resulting from such changes until the certification body has notified the client accordingly.

A client 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, applies to the certification body using an application form (Annex A). In such cases, the certification body may decide not to carry out an assessment of production process or management system but to require or select 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 is extended and the licence agreement may be modified.

If the client wishes to apply the certification to additional types of products, but to different specified requirements, or if the client wishes to apply for an extension of the certification to cover an additional facility that is not covered by the earlier licence, it will be necessary to perform only those parts of the original application procedure which do not cover the new circumstances.

8 Confidentiality

The certification body is 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 client; this applies also to information obtained at the application stage.

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9 Product liability

In this scheme, all questions related to product liability are dealt with on the basis of the relevant legal system(s).

10 Complaints and appeals

The client has a right to complain to the certification body about aspects of the service provided. The client may also appeal to the certification body against its decisions on issuing, maintaining, extending, suspending and withdrawing certification. In all of these cases, the certification body's complaints and appeals process will apply, as described in ISO/IEC 17065:2012, 7.13.

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Annex A
(informative)

Example of information provided with an application for product certification

A.1 General

The information given in this annex is based on ISO/IEC 17065:2012, 7.2, Note 1. The information could be collected by various methods and media such as completion of an application or by inputting to an online database.

A.2 Example of information provided

A.2.1 Date of application

A.2.2 Information regarding applicant

— Legal name of the applicant, address of its registered office, contact details

— Name and function of the person acting as contact to the certification body and authorized to sign on behalf of the applicant

— Business address and contact details

— Role of applicant organization (manufacturer, designer, distributor, agent, etc.)

A.2.3 Information regarding intended certificate holder (if different from applicant)

— Legal name of company, address of registered office, contact details

— Name and function of the person acting as contact to the certification body and authorized to sign on behalf of the applicant

— Business address and contact details

— Role of intended certificate holder (manufacturer, designer, distributor, etc.)

A.2.4 Designation of product(s) for which certification is requested

— Description of product(s), including catalogue number(s), type designation(s) or other descriptive identifier(s)

— Standard(s) and other normative document(s) to which certification is requested: number, title, year of issue

A.2.5 Manufacture of product(s)

— Place(s) (physical address(es)) of manufacture of the product(s)

— Name and title of person responsible for product quality

— Business address and contact details

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A.2.6 Certification and licensing agreements

— Declaration of willingness, on satisfactory completion of evaluation, to conclude the applicable certification agreement and licensing agreement, if not previously concluded

— Name (in block letters, of the person nominated in A.2.2 or A.2.3)

— Signature

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Annex B
(informative)

Example of information on production process and management system

B.1 General

This example provides preliminary information on the production process used to manufacture the products for which certification is sought and on the management system which is used to control activities critical to product conformity. It is intended to help the certification body in its preparation of the initial on site evaluation the facility or facilities involved. If the product is manufactured at different locations, the information for each location is supplied.

The amount of preliminary information to be provided by the applicant depends on the nature and complexity of the product/production process.

B.2 Example of information provided

B.2.1 General

In this example, B.2.2 and B.2.3 list possible aspects where information can be provided on the production processes and management systems.

B.2.2 Production process

B.2.2.1 Production companies

— All information about the manufacturing sites necessary for the certification body to plan the assessments

— Organization having the product ownership and bearing overall responsibility for the product to be certified (including contact persons and contact details)

— All sites where the final product to be certified is manufactured (addresses and contact persons and contact details)

NOTE Where applicable, this information is required also for subcontracted manufacturers.

— Principal activities carried out at all these locations

B.2.2.2 Production organization

— Relationship of all production sites to the product owner organization

— Information about the production organization having the product ownership

— Organization chart showing key personnel involved in production and their roles

— Authorization and training of personnel managing production activities

— Information about the initiation and control of production

B.2.2.3 Purchased materials, components and services

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— Main materials, components and services purchased, relating to product(s) to be certified

— Purchasing specifications

— Supplier qualification process

— Control of quality of incoming materials, components and services

B.2.2.4 Production

— Description of production process (key stages, flow chart)

— Sub-contracted operations (description of operation, name and address of sub-contractor, details of contract relevant for product conformity)

— Description of production resources and equipment (principal items only) (proprietary and specially made or adapted)

— Control of inventory

— Control of work in progress

— Control of finished products

— Control of defective materials, components, sub-assemblies and finished products

B.2.2.5 Quality control inspection and test and existing conformity assessment attestations

— Inspections and tests carried out on purchased major components during manufacturing-processes and on finished products

— Inspection and test equipment

— Calibration of the measurement equipment

— Responsibility for inspection and test

— Existing conformity assessment attestations from internal or external laboratories, inspection bodies or certification bodies for the product to be certified or for essential components

B.2.2.6 Documentation and records

— Product and production specification (drawings, parts lists, work instructions)

— Control of changes to the product and production process

B.2.2.7 Certificates and control of marks of conformity

— Stage at which mark is applied to the product

— Control of the products ensure that only those covered by the certificate are marked

— Copies of existing certificates of conformity issued by a certification body

B.2.3 Management system

B.2.3.1 Management system specification

— Conformity with ISO 9001 or equivalent (provide reference)

— Copy of quality manual and/or quality management system documentation

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— Certification of management system (name of certification body, scope of certification, site(s) covered (related to production of product(s) to be certified), copy of certificate(s))

B.2.3.2 Organization

— Management structure

— Key personnel

— Responsible quality manager

— Competence records for key personnel

B.2.3.3 Management system maintenance

— Documentation and records

— Internal audit

— Management review

— Improvements (corrective and preventive action)

— Change management

B.2.3.4 Product realization

See B.2.2.

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Annex C
(informative)

Example of information to be included in a certificate of conformity

- Certificate number or other unique identification
- Name of scheme under which the certificate is issued
- Name and address of certification body
- Name and address of client (certificate holder)
- Reference to certification agreement
- Statement of conformity, including:
  - name and unique designation of product
  - standard(s) and other normative document(s) (including dates of publication) the requirements of which the product is attested to fulfil
  - production sites and other details of assessment, e.g. quality system, production inspection
- If applicable, reference to the accreditation or recognition status of the certification body
- Date of expiry of certificate (if necessary)
- Date of issue of certificate
- Legally binding signature(s) of person(s) authorized to sign on behalf of the certification body

NOTE In some economies, legally binding authorization of document is accomplished by other means, e.g. by legally binding seals.

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Annex D
(informative)

Example of contents of a licensing agreement for the use of a certificate and mark of conformity

D.1 Parties

— Certification body (name, address, contact details)

— Licensee (name, address, contact details)

NOTE In some schemes, the scheme owner is a party to the licensing agreement.

D.2 Grant of licence

To use certificate of conformity and mark of conformity on products listed in the licence under the following conditions.

a) **Regulations for certification and assessment**

Reference to the general rules for the certification scheme as well as the standard(s) and the specific rules specified in the licence.

b) **Rights and obligations of licensee**

Certified products manufactured and supplied by it will fulfil the requirements stated in the standards and general and specific rules specified in the licence.

Persons representing the certification body will have unobstructed access without prior notification to the premises of the facility covered by the licence

The products for which the licence is granted will be manufactured to the same specifications as the sample that the certification body found by the initial testing to be in conformity with the standard.

c) **Surveillance**

The certification body carries out continuing surveillance of the licensee's conformity with the licensee's obligations, in accordance with the conditions stated in the general and specific rules for the scheme as specified in the licence.

Surveillance is carried out by the certification body personnel or by personnel of agencies on behalf of the certification body.

d) **Information on modifications in production**

The licensee to inform the certification body of any intended modification in the product, the production process or the management system and any organisational changes which could affect the licensee's ability to continue to produce the certified product.

e) **Complaints**

The licensee to keep records and report to the certification body any complaints regarding those aspects of the products covered by the licence.

f) **Publicity**

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