BRITISH STANDARD

BS EN
45011:1998

General requirements for bodies operating product certification systems

The European Standard EN 45011:1998 has the status of a British Standard

ICS 03.120.20

National foreword

This British Standard is identical with EN 45011, General requirements for bodies operating product certification systems. It is a revision of BS 7511:1989, which is withdrawn.

The EN 45000 series of standards will assist the process of mutual recognition between bodies engaged in conformity assessment, the development of national accreditation on a harmonized basis and the notification of such bodies by Governments to perform the relevant functions under European Community directives.

The UK participation in its preparation was entrusted to Technical Committee QS/3, Assessment, testing, certification and inspection, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 10, an inside back cover and a back cover.

This British Standard, having been prepared under the direction of the Management Systems Sector Board, was published under the authority of the Standards Board and comes into effect on 15 July 1998

ISBN 0 580 29415 3

Amendments issued since publication

Amd. No.	Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45011

February 1998

ICS 03.120.20

Supersedes EN 45011:1989

Descriptors: Testing laboratories, certification, approval organizations, specifications

English version

General requirements for bodies operating product certification systems

(ISO/IEC Guide 65:1996)

Exigences générales relatives aux organismes procédant à la certification de produits (Guide ISO/IEC 65:1996)

Allgemeine Anforderungen an Stellen, die Produktertifizierungssysteme betreiben (ISO/IEC Guide 65:1996)

This European Standard was approved by CEN/CENELEC on 8 August 1997.

CEN/CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN/CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN/CENELEC members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN/CENELEC

CEN Central Secrearіat
rue de Stassart 36, B-1050 Brussels

CENELEC Central Secretariat
rue de Stassart 35, B-1050 Brussels

Ref. No. EN 45011:1998 E

Foreword

The text of the ISO/IEC Guide 65:1996 of the Commitee on Conformity Assessment (CASCO) has been taken over as a European Standard by Technical Committee CEN/CLC/TC 1, Criteria for conformity assessment bodies, the secretariat of which is held by NSF, and approved by CEN and CENELEC.

This European Standard supersedes EN 45011:1989.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Contents

Introduction

Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. Some product certification systems may include initial testing of a product and assessment of its suppliers' quality systems, followed by surveillance that takes into account the factory quality system and the testing of samples from the factory and the open market. Other systems rely on initial testing and surveillance testing, while still others comprise type testing only.

This standard specifies requirements, the observance of which is intended to ensure that certification bodies operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and so furthering international trade.

The requirements contained in this standard are written, above all, to be considered as general criteria for organizations operating product certification systems; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account.

Assertion of conformity to the appropriate standards or other normative documents will be in the form of certificates or marks of conformity. Systems for certifying particular products or product groups to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this standard is concerned with third-parties providing product certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

The diversity in certification systems may at first seem unnecessary and even confuse newcomers in the field, clients and operators alike. The ISO/IEC publication Certification and related activities is available for background reading and will help to answer questions regarding the practices of the worldwide conformity assessment community.

1 Scope

1.1 This European Standard specifies general requirements that a third-party operating a product certification system shall meet if it is to be recognized as competent and reliable.

In this European Standard the term "certification body" is used to cover any body operating a product certification system. The word "product" is used in its widest sense and includes processes and services; the word "standard" is used to include other normative documents such as specifications or technical regulations.

1.2 The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both, as described in ISO/IEC Guide 53:

— type testing or examination;

— testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;

— testing or inspection of every product or of a particular product, whether new or already in use;

— batch testing or inspection;

— design appraisal.

NOTE 1 ISO/IEC Guide 28 may be consulted for a model of one form of a third-party product certification system.

2 References

ISO 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary.*

ISO/IEC Guide 7:1994, *Guidelines for drafting of standards suitable for use for conformity assessment.*

ISO/IEC Guide 23:1982, *Methods of indicating conformity with standards for third-party certification systems.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

ISO/IEC Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity.*

ISO/IEC Guide 28:1982, *General rules for a model third-party certification system for products.*

ISO/IEC Guide 39:1988, *General requirements for the acceptance of inspection bodies.*

ISO/IEC Guide 53:1988, *An approach to the utilization of a supplier's quality system in third-party product certification.*

ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems.*

3 Definitions

For the purposes of this standard, the relevant definitions given in ISO/IEC Guide 2 and ISO 8402 apply, together with the following definition.

3.1

supplier

the party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which the certification is based

4 Certification body

4.1 General provisions

4.1.1 The policies and procedures under which the certification body operates and their administration shall be non-discriminatory and shall be administered in a non-discriminatory manner. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this standard.

4.1.2 The certification body shall make its services accessible to all applicants whose activities fall within its declared field of operation. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification be conditional upon the number of certificates already issued.

4.1.3 The criteria against which the products of a supplier are evaluated shall be those outlined in specified standards. Requirements for standards suitable for this purpose are contained in ISO/IEC Guide 7. If explanation is required as to the application of these documents for a specific certification system, it shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence, and published by the certification body.

4.1.4 The certification body shall confine its requirements, evaluation and decision on certification to those matters specifically related to the scope of the certification being considered.

4.2 Organization

The structure of the certification body shall be such as to foster confidence in its certifications. In particular, the certification body shall:

a) be impartial;

b) be responsible for decisions relating to its granting, maintaining, extending, suspending and withdrawing of certification;

c) identify the management (committee, group or person) which shall have overall responsibility for all of the following:

1) performance of testing, inspection, evaluation and certification as defined in this standard;

2) formulation of policy matters relating to the operation of the certification body;

3) decisions on certification;

4) supervision of the implementation of its policies;

5) supervision of the finances of the body;

6) delegation of authority to committees or individuals as required to undertake defined activities on its behalf;

7) technical basis for granting certification;

d) have documents which demonstrate it is a legal entity;

e) have a documented structure which safeguards impartiality including provisions to ensure the impartiality of the operations of the certification body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system;

f) ensure that each decision on certification is taken by a person(s) different from those who carried out the evaluation;

g) have rights and responsibilities relevant to its certification activities;

h) have adequate arrangements to cover liabilities arising from its operations and/or activities;

i) have the financial stability and resources required for the operation of a certification system;

j) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for performing certification functions relating to the type, range and volume of work performed, under a responsible senior executive;

k) have a quality system giving confidence in its ability to operate a certification system for products;

l) have policies and procedures that distinguish between product certification and any other activities in which the certification body is engaged;

m) together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the certification process;

n) have formal rules and structures for the appointment and operation of any committees which are involved in the certification process; such committees shall be free from any commercial, financial and other pressures that might influence decisions; a structure where members are chosen to provide a balance of interests where no single interest predominates will be deemed to satisfy this provision;

o) ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications, and it shall not:

1) supply or design products of the type it certifies;

2) give advice or provide consultancy services to the applicant as to methods of dealing with matters which are barriers to the certification requested;

3) provide any other products or services which could compromise the confidentiality, objectivity or impartiality of its certification process and decisions;

p) have policies and procedures for the resolution of complaints, appeals and disputes received from suppliers or other parties about the handling of certification or any other related matters.

4.3 Operations

The certification body shall take all steps necessary to evaluate conformance with the relevant product standards according to the requirements of specific product certification system (see clause **3**). The certification body shall specify the relevant standards or parts thereof and any other requirements such as sampling, testing and inspection requirements which form the basis for the applicable certification system.

In conducting its certification operations, the certification body shall observe, as appropriate, the requirements for the suitability and competence of body(ies) or person(s) carrying out testing, inspection and certification/registration as specified in ISO/IEC Guides 25, 39 and 62.

4.4 Subcontracting

When a certification body decides to subcontract work related to certification (e.g. testing or inspection) to an external body or person, a properly documented agreement covering the arrangements including confidentiality and conflict of interest shall be drawn up. The certification body shall:

a) take full responsibility for such subcontracted work and maintain its responsibility for granting, maintaining, extending, suspending or withdrawing certification;

b) ensure that the subcontracted body or person is competent and complies with the applicable provisions of this standard and other standards and guides relevant to testing, inspection or other technical activities (see clause **2**), and is not involved either directly or through the person's employer with the design or production of the product in such a way that impartiality would be compromised;

c) obtain the applicant's consent.

NOTE 2 Where work related to certification has been undertaken prior to the application for certification, the body may take account of it, provided it can take responsibility as detailed in **4.4**a) and satisfy itself regarding the matters detailed in **4.4**b).

NOTE 3 The requirements given in **4.4**a) and b) are also relevant, by extension, when a certification body uses, for granting its own certification, work performed by another certification body with which it has signed an agreement.

4.5 Quality system

4.5.1 The management of the certification body having executive responsibility for quality shall define and document its policy for quality and its objectives for, and commitment to, quality. The management shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.5.2 The certification body shall operate an effective quality system in accordance with the relevant elements of this standard and appropriate for the type, range and volume of work performed. This quality system shall be documented and the documentation shall be available for use by the certification body staff. The certification body shall ensure effective implementation of the documented quality system, procedures and instructions. The certification body shall designate a person having direct access to its highest executive level who, irrespective of other responsibilities, shall have defined authority for:

a) ensuring that a quality system is established, implemented and maintained in accordance with this standard; and

b) reporting on the performance of the quality system to the body's management for review and as a basis for improvement of the quality system.

4.5.3 The quality system shall be documented in a quality manual and associated quality procedures, and the manual shall contain or refer to at least the following:

a) a quality policy statement;

b) a brief description of the legal status of the certification body, including the names of its owners and, if different, names of the persons who control it;

c) the names, qualifications, experience and terms of reference of the senior executive and other certification personnel, both internal and external;

d) an organization chart showing lines of authority, responsibility and allocation of functions stemming from the senior executive;

e) a description of the organization of the certification body, including details of the management (committee, group or person) identified in **4.2**c), its constitution, terms of reference and rules of procedure;

f) the policy and procedures for conducting management reviews;

g) administrative procedures including document control;

h) the operational and functional duties and services pertaining to quality, so that the extent and limits of each person's responsibility are known to all concerned;

i) the procedure for the recruitment, selection and training of certification body personnel and monitoring of their performance;

j) a list of its approved subcontractors and the procedures for assessing, recording and monitoring their competence;

k) its procedures for handling nonconformities and for assuring the effectiveness of any corrective and preventive actions taken;

l) the procedures for evaluating products and implementing the certification process, including:

1) the conditions for issue, retention and withdrawal of certification documents;

2) controls over the use and application of documents employed in the certification of products;

m) the policy and procedure for dealing with appeals, complaints and disputes;

n) its procedures for conducting internal audits, based on the provisions of ISO 10011-1.

4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification

4.6.1 The certification body shall specify the conditions for granting, maintaining and extending certification and the conditions under which certification may be suspended or withdrawn, partially or in total.

4.6.2 The certification body shall have procedures to:

a) grant, maintain, withdraw and, if applicable, suspend certification;

b) extend or reduce the scope of certification;

c) re-evaluate, in the event of changes significantly affecting the product's design or specification, or changes in the standards to which compliance of the product is certified, or changes in the ownership, structure or management of the supplier, if relevant, or in the case of any other information indicating that the product may no longer comply with the requirements of the certification system.

4.7 Internal audits and management reviews

4.7.1 The certification body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the quality system is implemented and is effective.

The certification body shall ensure that:

a) personnel responsible for the area audited are informed of the outcome of the audit;

b) corrective action is taken in a timely and appropriate manner; and

c) the results of the audit are documented.

4.7.2 The body's management with executive responsibility shall review its quality system at defined intervals which are sufficiently short to ensure its continuing suitability and effectiveness in satisfying the requirements of this standard and the stated quality policy and objectives. Records of such reviews shall be maintained.

4.8 Documentation

4.8.1 The certification body shall provide (through publications, electronic media or other means), update at regular intervals, and make available on request, the following:

a) information about the authority under which the certification body operates;

b) a documented statement of its product certification system, including its rules and procedures for granting, maintaining, extending, suspending and withdrawing certification;

c) information about the evaluation procedures and certification process related to each product certification system;

d) a description of the means by which the organization obtains financial support and general information on the fees charged to applicants and to suppliers of certified products;

e) a description of the rights and duties of applicants and suppliers of certified products, including requirements, restrictions or limitations on the use of the certification body's logo and on the ways of referring to the certification granted;

f) information about procedures for handling complaints, appeals and disputes;

g) a directory of certified products and their suppliers.

4.8.2 The certification body shall establish and maintain procedures to control all documents and data that relate to its certification functions. These documents shall be reviewed and approved for adequacy by appropriately authorized and competent personnel prior to issuing any documents following initial development or any subsequent amendment or change being made. A listing of all appropriate documents with the respective issue and/or amendment status identified shall be maintained. The distribution of all such documents shall be controlled to ensure that the appropriate documentation is made available to personnel of the certification body or suppliers when they are required to perform any function relating to the certification body's activities.

4.9 Records

4.9.1 The certification body shall maintain a record system to suit its particular circumstances and to comply with existing regulations. The records shall demonstrate that the certification procedures have been effectively fulfilled, particularly with respect to application forms, evaluation reports, surveillance activities and other documents relating to granting, maintaining, extending, suspending or withdrawing certification. The records shall be identified, managed and disposed of in such a way as to ensure the integrity of the process and the confidentiality of the information. The records shall be kept for a period of time so that continued confidence may be demonstrated for at least one full certification cycle, or as required by law.

4.9.2 The certification body shall have a policy and procedures for retaining records for a period consistent with its contractual, legal or other obligations. The certification body shall have a policy and procedures concerning access to these records consistent with **4.10.1**.

NOTE 4 The question of the length of time for retention of records requires specific attention in the light of legal circumstances and recognition arrangements.

4.10 Confidentiality

4.10.1 The certification body shall have adequate arrangements consistent with applicable laws to safeguard confidentiality of the information obtained in the course of its certification activities at all levels of its organization, including committees and external bodies or individuals acting on its behalf.

4.10.2 Except as required in this standard or by law, information gained in the course of certification activities about a particular product or supplier shall not be disclosed to a third-party without the written consent of the supplier. Where the law requires information to be disclosed to a third-party, the supplier shall be informed of the information provided as permitted by the law.

5 Certification body personnel

5.1 General

5.1.1 The personnel of the certification body shall be competent for the functions they perform, including making required technical judgements, framing policies and implementing them.

5.1.2 Clearly documented instructions shall be available to the personnel describing their duties and responsibilities. These instructions shall be maintained up to date.

5.2 Qualification criteria

5.2.1 In order to ensure that evaluation and certification are carried out effectively and uniformly, the minimum relevant criteria for the competence of personnel shall be defined by the certification body.

5.2.2 The certification body shall require its personnel involved in the certification process to sign a contract or other document by which they commit themselves:

a) to comply with the rules defined by the certification body, including those relating to confidentiality and independence from commercial and other interest; and

b) to declare any prior and/or present association on their own part, or on the part of their employer, with a supplier or designer of products to the evaluation or certification of which they are to be assigned.

The certification body shall ensure that, and document how, any contracted personnel for their own part, and on the part of their employer if any, satisfy all the requirements for personnel outlined in this standard.

5.2.3 Information on the relevant qualifications, training and experience of each member of the personnel involved in the certification process shall be maintained by the certification body. Records of training and experience shall be kept up to date, in particular the following:

a) name and address;

b) organization affiliation and position held;

c) educational qualification and professional status;

d) experience and training in each field of the certification body's competence;

e) date of most recent updating of records;

f) performance appraisal.

6 Changes in the certification requirements

The certification body shall give due notice of any changes it intends to make in its requirements for certification. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following decision on, and publication of, the changed requirements, it shall verify that each supplier makes any necessary adjustments within such time as, in the opinion of the certification body, is reasonable.

7 Appeals, complaints and disputes

7.1 Appeals, complaints and disputes brought before the certification body by suppliers or other parties shall be subject to the procedures of the certification body.

7.2 Each certification body shall:

a) keep a record of all appeals, complaints and disputes and remedial actions relative to certification;

b) take appropriate subsequent action;

c) document the action taken and its effectiveness.

8 Application for certification

8.1 Information on the procedure

8.1.1 The certification body shall provide to applicants an up-to-date detailed description of the evaluation and certification procedures, appropriate to each certification scheme, and the documents containing the requirements for certification, the applicants' rights and duties of suppliers which have certified products (including fees to be paid by applicants and suppliers of certified products).

8.1.2 The certification body shall require that a supplier:

a) always complies with the relevant provisions of the certification programme;

b) makes all necessary arrangements for the conduct of the evaluation, including provision for examining documentation and access to all areas, records (including internal audit reports) and personnel for the purposes of evaluation (e.g. testing, inspection, assessment, surveillance, reassessment) and resolution of complaints;

c) makes claims regarding certification only in respect of the scope for which certification has been granted;

d) does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification which the certification body may consider misleading or unauthorized;

e) upon suspension or cancellation of certification, discontinues its use of all advertising matter that contains any reference thereto and returns any certification documents as required by the certification body;

f) uses certification only to indicate that products are certified as being in conformity with specified standards;

g) endeavours to ensure that no certificate or report nor any part thereof is used in a misleading manner;

h) in making reference to its product certification in communication media such as documents, brochures or advertising, complies with the requirements of the certification body.

8.1.3 When the desired scope of certification is related to a specific system or type of system operated by the certification body, any explanation needed shall be provided to the applicant.

8.1.4 If requested, additional application information shall be provided to the applicant.

8.2 The application

8.2.1 The certification body shall require completion of an official application form, signed by a duly authorized representative of the applicant, in which or attached to which are the following:

a) the scope of the desired certification;

b) a statement that the applicant agrees to comply with the requirements for certification and to supply any information needed for evaluation of products to be certified.

8.2.2 The applicant, as a minimum, shall provide the following information:

a) corporate entity, name, address and legal status;

b) a definition of the products to be certified, the certification system, and the standards against which each product is to be certified if known to the applicant.

9 Preparation for evaluation

9.1 Before proceeding with the evaluation, the certification body shall conduct, and maintain records of, a review of the application for certification to ensure that:

a) the requirements for certification are clearly defined, documented and understood;

b) any difference in understanding between the certification body and the applicant is resolved; and

c) the certification body has the capability to perform the certification service with respect to the scope of the certification sought and, if applicable, the location of the applicant's operations and any special requirements such as the language used by the applicant.

9.2 The certification body shall prepare a plan for its evaluation activities to allow for the necessary arrangements to be managed.

9.3 The certification body shall assign personnel appropriately qualified to perform the tasks for the specific evaluation. Personnel shall not be assigned if they have been involved in, or been employed by a body involved in, the design, supply, installation or maintenance of such products in a manner and within a time period which could conflict with impartiality.

9.4 To ensure that a comprehensive and correct evaluation is carried out, the personnel involved shall be provided with the appropriate working documents.

10 Evaluation

The certification body shall evaluate the products of the applicant against the standards covered by the scope defined in its application against all certification criteria specified in the rules of the scheme.

11 Evaluation report

The certification body shall adopt reporting procedures that suit its needs but, as a minimum, these procedures shall ensure that:

a) personnel appointed to evaluate the conformance of the products shall provide the certification body with a report of findings as to the conformity with all the certification requirements;

b) a full report on the outcome of the evaluation is promptly brought to the applicant's notice by the certification body, identifying any nonconformities that have to be discharged in order to comply with all of the certification requirements and the extent of further evaluation or testing required. If the applicant can show that remedial action has been taken to meet all the requirements within a specified time limit, the certification body shall repeat only the necessary parts of the initial procedure.

12 Decision on certification

12.1 The decision as to whether or not to certify a product shall be taken by the certification body on the basis of the information gathered during the evaluation process and any other relevant information.

12.2 The certification body shall not delegate authority for granting, maintaining, extending, suspending or withdrawing certification to an outside person or body.

12.3 The certification body shall provide to each supplier offering certified products, formal certification documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal certification documents shall permit identification of the following:

a) the name and address of the supplier whose products are the subject of certification;

b) the scope of the certification granted, including, as appropriate:

1) the products certified, which may be identified by type or range of products;

2) the product standards or other normative documents to which each product or product type is certified;

3) the applicable certification system;

c) the effective date of certification, and the term of the certification if applicable.

12.4 In response to an application for amendment to the scope of a certificate already granted, the certification body shall decide what, if any, evaluation procedure is appropriate in order to determine whether or not the amendment should be made and shall act accordingly.

13 Surveillance

13.1 The certification body shall have documented procedures to enable surveillance to be carried out in accordance with the criteria applicable to the relevant certification system.

13.2 The certification body shall require the supplier to inform it about any of the changes cited in **4.6.2**c), such as intended modification to the product, manufacturing process or, if relevant, its quality system, which affect the conformity of the product. The certification body shall determine whether the announced changes require further investigations. If such is the case, the supplier shall not be allowed to release certified products resulting from such changes until the certification body has notified the supplier accordingly.

13.3 The certification body shall document its surveillance activities.

13.4 Where the certification body authorizes the continuing use of its mark on products of a type which have been evaluated, the certification body shall periodically evaluate the marked products to confirm that they continue to conform to the standards.

14 Use of licences, certificates and marks of conformity

14.1 The certification body shall exercise proper control over ownership, use and display of licences, certificates and marks of conformity.

14.2 Guidance on the use of certificates and marks permitted by the certification body may be obtained from ISO/IEC Guide 23.

14.3 Incorrect references to the certification system or misleading use of licences, certificates or marks, found in advertisements, catalogues, etc., shall be dealt with by suitable action.

NOTE Such actions are addressed in ISO/IEC Guide 27 and can include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

15 Complaints to suppliers

The certification body shall require the supplier of certified products to:

a) keep a record of all complaints made known to the supplier relating to a product's compliance with requirements of the relevant standard and to make these records available to the certification body when requested;

b) take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification;

c) document the actions taken.

Annex ZA (normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO/IEC Guide 2	1996	*Standardization and related activities — General vocabulary*	EN 45020	1998
ISO/IEC Guide 7	1994	*Guidelines for drafting of standards suitable for use for conformity assessment*	—	
ISO/IEC Guide 23	1982	*Methods of indicating conformity with standards for third-party certification systems*	—	
ISO/IEC Guide 25	1990	*General requirements for the competence of calibration and testing laboratories*	EN 45001	1989
ISO/IEC Guide 27	1983	*Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*	—	
ISO/IEC Guide 28	1982	*General rules for a model third-party certification system for products*	—	
ISO/IEC Guide 39	1988	*General requirements for the acceptance of inspection bodies*	EN 45004	1995
ISO/IEC Guide 53	1988	*An approach to the utilization of a supplier's quality system in third-party product certification*	—	
ISO/IEC Guide 62	1996	*General requirements for bodies operating assessment and certification/registration of quality systems*	EN 45012	1998
ISO 8402	1994	*Quality management and quality assurance — Vocabulary*	EN ISO 8402	1995
ISO 10011-1	1990	*Guidelines for auditing quality systems — Part 1: Auditing*	EN 30011-1	1993

blank

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: 020 8996 9000. Fax: 020 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: 020 8996 9001. Fax: 020 8996 7001.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre. Tel: 020 8996 7111. Fax: 020 8996 7048.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: 020 8996 7002. Fax: 020 8996 7001.

Copyright

BSI
389 Chiswick High Road
London
W4 4AL