STANDARD MOLDOVENESC

SM EN ISO/IEC 17000:2020

ICS 01.040.03
03.120.20

Adoptat la 23.09.2020

Evaluarea conformităţii. Vocabular şi principii generale

Оценка соответствия. Словарь и общие принципы

Conformity assessment. Vocabulary and general principles

Prezentul standard este identic cu standardul european
EN ISO/IEC 17000:2020

Prezentul standard înlocuieşte standardul SM EN ISO/IEC 17000:2017 care este anulat din data de 31.12.2020

EN

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NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2020

ICS 01.040.03; 03.120.20

Supersedes EN ISO/IEC 17000:2004

English version

Conformity assessment - Vocabulary and general principles (ISO/IEC 17000:2020)

Évaluation de la conformité - Vocabulaire et principes généraux (ISO/IEC 17000:2020)

Konformitätsbewertung - Begriffe und allgemeine Grundlagen (ISO/IEC 17000:2020)

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European foreword

This document (EN ISO/IEC 17000:2020) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/JTC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by December 2020, and conflicting national standards shall be withdrawn at the latest by December 2020.

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The text of ISO/IEC 17000:2020 has been approved by CEN as EN ISO/IEC 17000:2020 without any modification.

STANDARD 17000

Second edition
2020-05

Conformity assessment — Vocabulary and general principles

Évaluation de la conformité — Vocabulaire et principes généraux

Reference number
ISO/IEC 17000:2020(E)

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Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see http://patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO).

This second edition cancels and replaces the first edition (ISO/IEC 17000:2004), which has been technically revised.

The main changes compared to the previous edition are as follows:

— addition of new terms: "object of conformity assessment" (see 4.2), "owner" (see 4.13), "impartiality" (see 5.3), "independence" (see 5.4), "validation" (see 6.5), "verification" (see 6.6), "decision" (see 7.2), "expiry" (see 8.4) and "restoration" (see 8.5);

— change of concept of conformity assessment system;

— deletion of the definition of the term "product" from the body of the document and addition to Annex B;

— editorial revision of Annex A limited to changes in the terms and definitions in Clauses 4 to 9;

— extension of Annex B.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The ISO Committee on conformity assessment (CASCO) develops International Standards relating to conformity assessment activities such as testing, inspection and various forms of certification. For many years, ISO/IEC Guide 2 included a core vocabulary for conformity assessment, built up from a small number of terms and definitions first compiled to facilitate communication and understanding about product certification based on standards for traditional manufactured goods.

In 2000, CASCO decided to remove conformity assessment terminology from ISO/IEC Guide 2 and provide instead a self-contained vocabulary more readily applicable within the planned international standards on conformity assessment and in the drafting or revision of related documents. The first edition of this document was published in 2004, as a consistent framework within which more specific concepts could be defined appropriately and denoted by the most appropriate terms.

Additional concepts unique to particular activities such as accreditation, certification of persons and use of marks of conformity are not included in this document but are provided in International Standards related to those activities.

Terms and definitions related to trade and regulation are given in Clause 9. These are intended not only to standardize usage within the conformity assessment community, but also to help policy makers concerned with the facilitation of trade within regulatory and international treaty frameworks.

The terms and definitions specified in this document, particularly in Clauses 6 and 7, reflect the adoption by CASCO in November 2001 of the functional approach.

To provide a better understanding of the defined concepts, their grouping and their relationships, a description of the functional approach is included in Annex A for information.

The terms included in this document relate to concepts considered essential to define. General terms used to denote conformity assessment concepts for which common language usage is sufficient are not included in this document. Terms not common across all International Standards for conformity assessment and with definitions specific to a particular application are not included in this document but are included in the specific relevant standard.

Relevant terms defined in other documents are listed in Annex B:

— terms applicable to specific aspects of conformity assessment, as defined in other conformity assessment standards;

— terms generally applicable in conformity assessment contexts for which definitions are published outside conformity assessment standards.

Conformity assessment — Vocabulary and general principles

1 Scope

This document specifies general terms and definitions relating to conformity assessment (including the accreditation of conformity assessment bodies) and to the use of conformity assessment to facilitate trade.

The general principles of conformity assessment and a description of the functional approach to conformity assessment are provided in Annex A.

Conformity assessment interacts with other fields such as management systems, metrology, standardization and statistics. The boundaries of conformity assessment are not defined in this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Terms related to conformity assessment in general

4.1
conformity assessment
demonstration that *specified requirements* (5.1) are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in Annex A can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

Note 2 to entry: Conformity assessment includes activities defined elsewhere in this document, such as but not limited to *testing* (6.2), *inspection* (6.3), *validation* (6.5), *verification* (6.6), *certification* (7.6), and *accreditation* (7.7).

Note 3 to entry: Conformity assessment is explained in Annex A as a series of functions. Activities contributing to any of these functions can be described as conformity assessment activities.

Note 4 to entry: This document does not include a definition of "conformity". "Conformity" does not feature in the definition of "conformity assessment". Nor does this document address the concept of compliance.

4.2
object of conformity assessment
object
entity to which *specified requirements* (5.1) apply

EXAMPLE Product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof.

Note 1 to entry: The term "body" is used in this document to refer to *conformity assessment bodies* (4.6) and *accreditation bodies* (4.7). The term "organization" is used in its general meaning and may include bodies according to the context. The more specific ISO/IEC Guide 2 definition of an organization as a body based on membership is not applicable to the field of *conformity assessment* (4.1).

4.3
first-party conformity assessment activity
conformity assessment activity that is performed by the person or organization that provides or that is the *object of conformity assessment* (4.2)

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities in relation to a given object are not to be confused with the legal identification of the relevant parties to a contract.

EXAMPLE Activities performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object.

Note 2 to entry: If an activity is performed by an external body acting on behalf of and controlled by a person or organization that provides or is the object, the activity is still called a first-party conformity assessment activity (e.g. internal audits performed by a consultant who is not part of the organization).

4.4
second-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that has a user interest in the *object of conformity assessment* (4.2)

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities in relation to a given object are not to be confused with the legal identification of the relevant parties to a contract.

EXAMPLE Persons or organizations performing second-party conformity assessment activities include, for example, purchasers or users of products, or potential customers seeking to rely on a supplier's management system, or organizations representing those interests. Examples of organizations representing user interest include consumer advocacy organizations, regulators implementing legislation governing products and services for the protection of consumer and public interests, centralized government procurement organizations and private sector purchasing agents.

Note 2 to entry: If an activity is performed by an external body acting on behalf of and controlled by a person or organization with a user interest, the activity is still called a second-party conformity assessment activity (e.g. supply chain audits conducted by an external body on behalf of the purchaser).

4.5
third-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that is independent of the provider of the *object of conformity assessment* (4.2) and has no user interest in the object

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities in relation to a given object are not to be confused with the legal identification of the relevant parties to a contract.

4.6
conformity assessment body
body that performs conformity assessment activities, excluding *accreditation* (7.7)

4.7
accreditation body
authoritative body that performs *accreditation* (7.7)

Note 1 to entry: The authority of an accreditation body can be derived from government, public authorities, contracts, market acceptance or scheme owners.

4.8
conformity assessment system
set of rules and *procedures* (5.2) for the management of similar or related *conformity assessment schemes* (4.9)

Note 1 to entry: A conformity assessment system can be operated at an international, regional, national, sub-national, or industry sector level.

4.9
conformity assessment scheme
conformity assessment programme
set of rules and *procedures* (5.2) that describes the *objects of conformity assessment* (4.2), identifies the *specified requirements* (5.1) and provides the methodology for performing *conformity assessment* (4.1)

Note 1 to entry: A conformity assessment scheme can be managed within a *conformity assessment system* (4.8).

Note 2 to entry: A conformity assessment scheme can be operated at an international, regional, national sub-national, or industry sector level.

Note 3 to entry: A scheme can cover all or part of the conformity assessment functions explained in Annex A.

4.10
access
access to a scheme
opportunity for an applicant to obtain a *conformity assessment* (4.1) service from a body under a *conformity assessment scheme* (4.9)

4.11
participant
participant in a system
participant in a scheme
person or organization that implements or operates under the rules and *procedures* (5.2) of a *conformity assessment system* (4.8) or *scheme* (4.9) without being involved in their development, revision or approval

4.12
member
member of a system
member of a scheme
person or organization that is involved in the development, revision or approval of the rules and *procedures* (5.2) of a *conformity assessment system* (4.8) or *scheme* (4.9)

4.13
owner
owner of a system
owner of a scheme
system owner
scheme owner
person or organization responsible for the development and maintenance of a *conformity assessment system* (4.8) or *conformity assessment scheme* (4.9)

Note 1 to entry: A scheme owner does not necessarily operate the *scheme* (4.9).

Note 2 to entry: A system owner or a scheme owner can be a *conformity assessment body* (4.6) itself, a governmental authority, a trade association, a group of conformity assessment bodies or others.

5 Terms related to basic concepts

5.1
specified requirement
need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in normative documents such as regulations, standards and technical specifications.

Note 2 to entry: Specified requirements can be detailed or general.

5.2
procedure
specified way to carry out an activity or a process

Note 1 to entry: In this context, a process is defined as a set of interrelated or interacting activities that use inputs to deliver an intended result.

[SOURCE: ISO 9000:2015, 3.4.5, modified — The original Note to entry has been replaced with a new Note to entry.]

5.3
impartiality
objectivity with regard to the outcome of a conformity assessment activity

Note 1 to entry: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.

5.4
independence
freedom of a person or organization from the control or authority of another person or organization

EXAMPLE A *conformity assessment body* (4.6) can be independent from the person who is the *object of conformity assessment* (4.2) or from the organization providing the *object of conformity assessment* (4.2).

6 Terms relating to selection and determination

6.1
sampling
selection and/or collection of material or data regarding an *object of conformity assessment* (4.2)

Note 1 to entry: Selection can be on the basis of a procedure, an automated system, professional judgement etc.

Note 2 to entry: Selection and collection can be performed by the same or different persons or organizations.

6.2
testing
determination of one or more characteristics of an *object of conformity assessment* (4.2), according to a *procedure* (5.2)

Note 1 to entry: The procedure can be intended to control variables within testing as a contribution to the accuracy or reliability of the results.

Note 2 to entry: The results of testing can be expressed in terms of specified units or objective comparison with agreed references.

Note 3 to entry: The output of testing can include comments (e.g. opinions and interpretations) about the test results and fulfilment of specified requirements.

Note 4 to entry: Additional information on the concepts of *testing* (6.2) and *inspection* (6.3) is given in A.3.4.

6.3
inspection
examination of an *object of conformity assessment* (4.2) and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements

Note 1 to entry: Examination can include direct or indirect observations, which can include measurements or the output of instruments.

Note 2 to entry: *Conformity assessment schemes* (4.9) or contracts can specify inspection as examination only.

Note 3 to entry: Additional information on the concepts of *testing* (6.2) and *inspection* (6.3) is given in A.3.4.

6.4
audit
process for obtaining relevant information about an *object of conformity assessment* (4.2) and evaluating it objectively to determine the extent to which *specified requirements* (5.1) are fulfilled

Note 1 to entry: The specified requirements are defined prior to performing an audit so that the relevant information can be obtained.

Note 2 to entry: Examples of objects for an audit are management systems, processes, products and services.

Note 3 to entry: For accreditation purposes, the audit process is called "assessment".

6.5
validation
confirmation of plausibility for a specific intended use or application through the provision of objective evidence that *specified requirements* (5.1) have been fulfilled

Note 1 to entry: Validation can be applied to claims to confirm the information declared with the claim regarding an intended future use.

6.6
verification
confirmation of truthfulness through the provision of objective evidence that *specified requirements* (5.1) have been fulfilled

Note 1 to entry: Verification can be applied to claims to confirm the information declared with the claim regarding events that have already occurred or results that have already been obtained.

6.7
peer assessment
assessment of a body against *specified requirements* (5.1) by representatives of other bodies in, or candidates for, an *agreement group* (9.10)

Note 1 to entry: "Candidates" are included for the situation where a new group is being formed, at which time there would be no bodies in the group.

Note 2 to entry: The term "peer assessment" is sometimes referred to as "peer evaluation".

7 Terms relating to review, decision and attestation

7.1
review
consideration of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of *specified requirements* (5.1) by an *object of conformity assessment* (4.2)

7.2
decision
conclusion, based on the results of *review* (7.1), that fulfilment of *specified requirements* (5.1) has or has not been demonstrated

7.3
attestation
issue of a statement, based on a *decision* (7.2), that fulfilment of *specified requirements* (5.1) has been demonstrated

Note 1 to entry: The resulting statement, referred to in this document as a "statement of conformity", is intended to convey the assurance that the specified requirements have been fulfilled. Such an assurance does not, of itself, provide contractual or other legal guarantees.

Note 2 to entry: First-party attestation and third-party attestation are distinguished by the terms *declaration* (7.5), *certification* (7.6) and *accreditation* (7.7), but there is no corresponding term applicable to second-party attestation.

7.4
scope of attestation
range or characteristics of *objects of conformity assessment* (4.2) covered by *attestation* (7.3)

7.5
declaration
first-party *attestation* (7.3)

7.6
certification
third-party *attestation* (7.3) related to an *object of conformity assessment* (4.2), with the exception of *accreditation* (7.7)

7.7
accreditation
third-party *attestation* (7.3) related to a *conformity assessment body* (4.6), conveying formal demonstration of its competence, *impartiality* (5.3) and consistent operation in performing specific conformity assessment activities

8 Terms relating to surveillance

8.1
surveillance
systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

8.2
suspension
temporary restriction of the statement of conformity by the body that issued the statement, for all or part of the specified *scope of attestation* (7.4)

EXAMPLE 1 The issuing body suspends the statement of conformity because the *specified requirements* (5.1) are no longer fulfilled.

EXAMPLE 2 The client of the issuing body voluntarily requests suspension of the statement of conformity.

EXAMPLE 3 The issuing body suspends the statement of conformity because it temporarily ceases to perform that type of conformity assessment activity.

8.3
withdrawal
cancellation
revocation of the statement of conformity by the body that issued the statement

EXAMPLE 1 The issuing body withdraws the statement of conformity because the *specified requirements* (5.1) are no longer fulfilled.

EXAMPLE 2 The client of the issuing body voluntarily requests withdrawal of the statement of conformity.

EXAMPLE 3 The issuing body withdraws or transfers the statement of conformity because it ceases to perform that type of conformity assessment activity.

8.4
expiry
ending of the validity of the statement of conformity after a specified period

8.5
restoration
reinstatement of the full or partial statement of conformity

8.6
appeal
request by the person or organization that provides, or that is, the *object of conformity assessment* (4.2) to a *conformity assessment body* (4.6) or an *accreditation body* (4.7) for reconsideration by that body of a *decision* (7.2) it has made relating to that object

8.7
complaint
expression of dissatisfaction, other than *appeal* (8.6), by any person or organization to a *conformity assessment body* (4.6) or an *accreditation body* (4.7), relating to the activities of that body, where a response is expected

9 Terms relating to trade and regulation

9.1
approval
permission for a product, service or process to be marketed or used for stated purposes or under stated conditions

Note 1 to entry: Approval can be based on fulfilment of specified requirements or completion of specified procedures.

Note 2 to entry: Approval can be given in the context of a *conformity assessment scheme* (4.9).

9.2
designation
governmental authorization of a *conformity assessment body* (4.6) to perform specified conformity assessment activities

Note 1 to entry: Designation is sometimes referred to as "notification".

9.3
designating authority
organization established within government, or empowered by government, to designate *conformity assessment bodies* (4.6) and to suspend or withdraw their *designation* (9.2)

9.4
equivalence
equivalence of conformity assessment results
sufficiency of different conformity assessment results to provide the same level of assurance of conformity with regard to the same *specified requirements* (5.1)

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

9.5
recognition
recognition of a conformity assessment result
acknowledgement of the validity of a conformity assessment result provided by another person or organization

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

9.6
acceptance
acceptance of a conformity assessment result
use of a conformity assessment result provided by another person or organization

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

9.7
unilateral arrangement
arrangement whereby one party recognizes or accepts a conformity assessment result of another party

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

9.8
bilateral arrangement
arrangement whereby two parties recognize or accept each other's conformity assessment results

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

9.9
multilateral arrangement
arrangement whereby more than two parties recognize or accept each other's conformity assessment results

Note 1 to entry: The expression "conformity assessment result" signifies the output of any conformity assessment activity (e.g. a report or certificate) and can include a finding of nonconformity.

9.10
agreement group
bodies that are signatories to the agreement on which an arrangement is based

9.11
reciprocity
relationship between two parties, where both have the same rights and obligations towards each other

Note 1 to entry: Reciprocity can exist within a *multilateral arrangement* (9.9), comprising a network of bilateral reciprocal relationships.

Note 2 to entry: Although the rights and obligations of the parties are the same, opportunities emanating from them can differ. This can lead to unequal relationships between parties.

9.12
equal treatment
treatment accorded to products, services or processes from one supplier that is no less favourable than that accorded to like products, services or processes from any other supplier, in a comparable situation

9.13
national treatment
treatment accorded to products, services or processes originating in other countries that is no less favourable than that accorded to like products, services or processes of national origin, in a comparable situation

9.14
equal and national treatment
treatment accorded to products, services or processes originating in other countries that is no less favourable than that accorded to like products, services or processes of national origin, or originating in any other country, in a comparable situation

Annex A
(informative)

Principles of conformity assessment

A.1 Functional approach

A.1.1 Conformity assessment is a series of three functions that satisfy a need or demand for demonstration that specified requirements are fulfilled:

— selection;

— determination; and

— review, decision and attestation.

Such demonstration can add substance or credibility to claims that specified requirements are fulfilled, giving users greater confidence in such claims. Standards are often used as the specified requirements since they represent a broad consensus of what is wanted in a given situation. As a result, conformity assessment is often viewed as a standards-related activity.

A.1.2 Conformity assessment can be applied to products, processes, services, systems, installations, projects, data, designs, materials, claims, persons or organizations and also to those bodies that perform conformity assessment activities. For convenience within this document, the expression "object of conformity assessment" is used to refer collectively to any or all of these entities.

A.1.3 Each of the various kinds of users of conformity assessment has its own specific needs. As a result, there is much variety in the different types of conformity assessment activities performed. However, all types of conformity assessment follow the same functional approach, as shown in Figure A.1.

A.1.4 Shape A in Figure A.1 represents a conformity assessment function. The specific activities in each function can vary from one type of conformity assessment to another, based on the needs of users, the nature of the specified requirements and the object of conformity assessment involved.

A.1.5 Shape B in Figure A.1 represents output from a function and is also the input to the next function. The nature of the output varies, depending on the specific activities that have been undertaken.

A.1.6 Shape C in Figure A.1 represents a decision.

A.1.7 Conformity assessment activities can be characterized as "first-party" (see 4.3), "second-party" (see 4.4) or "third-party" (see 4.5). Generally, for each of these categories:

— the conformity assessment activities are under the control or direction of the type of person or organization stated in the relevant definition, and

— the critical decision on which attestation is based is made by the type of person or organization stated in the relevant definition.

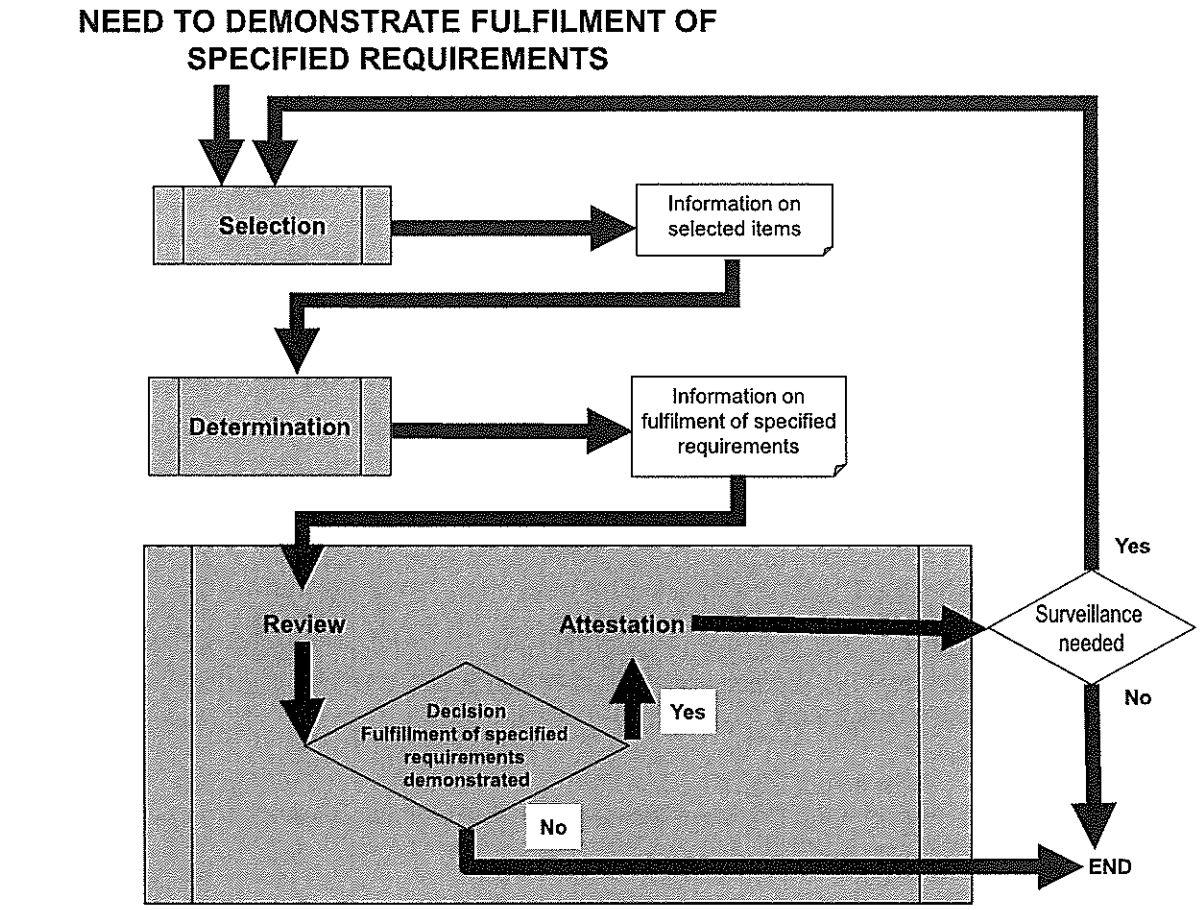

Figure A.1 — Functional approach to conformity assessment

A.2 Selection

A.2.1 Selection involves planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function. Selection activities vary widely in number and complexity. In some instances, very little selection activity can be necessary.

A.2.2 Some consideration can be necessary regarding the selection of the object of conformity assessment. Frequently, the object can be a large number of identical items, ongoing production, a continuous process or a system, or can involve numerous locations. In such cases, representative sampling can be necessary. For example, the sampling plan for river water related to a demonstration that pollution requirements are fulfilled would be an example of a sizeable and significant sampling activity. However, occasionally the object can be the whole population, for instance when a single, individual product is the object of conformity assessment. Even in such cases, sampling can be necessary to select a part of the entire object that is representative of the whole (e.g. selection of critical parts of a bridge for a determination of material fatigue).

A.2.3 It can also be necessary to consider the specified requirements. In many cases, a standard or other pre-existing requirements exist. However, care should be taken when applying the pre-existing requirements to the specific object of conformity assessment. For example, caution can be necessary when applying a standard written for polyethylene pipes to polypropylene pipes. In some cases, only a very general set of requirements exists which possibly needs to be expanded for assessment to be meaningful or acceptable to the users. For example, a government regulator can require that products pose no unacceptable safety risks (the general requirement) and expect a certification body to establish detailed requirements for individual certified products or types of products. Or, general management system requirements possibly need to be more focused when the management system addresses fulfilment of specific service requirements.

A.2.4 Selection can also include choice of the most appropriate procedures (for example, testing methods or inspection methods) to be used for determination activities. It is not uncommon that new or modified methods need to be developed to conduct determination activities. It can be necessary to select the proper locations and the proper conditions, or the individuals to perform the procedure.

A.2.5 Finally, additional information can be necessary to perform determination activities properly so that the demonstration that specified requirements are fulfilled will be effective. For example, the scope of testing to be covered by laboratory accreditation needs to be identified before appropriate determination activities can be performed. Or, a description of a service can be necessary before performing appropriate determination activities. Also, a determination activity can be a review of information alone, and that information needs to be identified and collected. For example, a copy of a product's instructions for use or warning markings can be necessary.

A.2.6 In Figure A.1, all the information, samples (if sampling is used), decisions and other output from the selection function are represented as "information on selected items".

A.3 Determination

A.3.1 Determination activities are undertaken to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample. Some types of determination activities are defined in A.3.2 and A.3.3.

A.3.2 The terms "testing" (see 6.2), "inspection" (see 6.3), "audit" (see 6.4), "validation" (see 6.5), "verification" (see 6.6) and "peer assessment" (see 6.7), which are defined as types of determination activities only, can be used with "scheme" to describe conformity assessment schemes that include the type of determination activity indicated. Thus, a "peer assessment scheme" is a conformity assessment scheme that includes peer assessment as the determination activity.

A.3.3 Various determination activities have no specific name or designation. An example is the examination or analysis of a design, or other descriptive information, in relation to specified requirements. Individual sub-fields of conformity assessment (e.g. testing, certification, accreditation) can have terms defined for determination activities that are unique to that sub-field. There is no generic term used in this document or in practice to represent all determination activities.

A.3.4 Care should be taken to understand clearly the determination activities characterized as "testing" and "inspection" (see 6.2 and 6.3). Because of the historical use of these terms, there is overlap between them. The same activity can be identified by some as "testing" and by others as "inspection". The viewpoint of the user of the activity as to either "testing" or "inspection" is important in determining which conformity assessment standard is applicable to the body performing the activity.

A.3.5 In Figure A.1, all the output from the determination function is represented as "information on fulfilment of specified requirements". The output is a combination of all the information created through the determination activity, as well as all the input to the determination function. The output is usually structured to facilitate review, decision and attestation activities.

A.4 Review, decision and attestation

A.4.1 "Review" (see 7.1) constitutes the final stage of checking before taking the important "decision" (see 7.2) as to whether or not the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements. "Attestation" (see 7.3) results in a "statement" in a form that most readily reaches all of the potential users. "Statement of conformity" is a generic expression used to include all means of communicating that fulfilment of specified requirements has been demonstrated.

A.4.2 If fulfilment of the specified requirements has not been demonstrated, the finding of non-conformity can be reported.

A.4.3 The terms "declaration" (see 7.5), "certification" (see 7.6) and "accreditation" (see 7.7), which are defined as types of attestation only, can be used with "scheme" to describe conformity assessment schemes that include the type of attestation activity indicated as the final step. Thus, a "certification scheme" is a conformity assessment scheme that includes selection, determination, review, decision and finally certification as the attestation activity.

A.5 Need for surveillance

A.5.1 Conformity assessment can end when attestation is performed. However, in some cases systematic iteration of the functions in Figure A.1 can be necessary to maintain the validity of the statement resulting from attestation. The needs of users drive such activities. For example, an object of conformity assessment can change over time, which can affect its continuing fulfilment of specified requirements. Or, users can demand ongoing demonstration that specified requirements are fulfilled, for example, when a product is produced continuously or when a service is provided on an ongoing basis.

A.5.2 The activities undertaken in surveillance are planned in order to satisfy the need to maintain the validity of an existing statement resulting from attestation. A complete repeat of the initial assessment is usually not necessary in every iteration of surveillance to satisfy this need. Thus, the activities in each function in Figure A.1 during surveillance can be reduced, or different from the activities undertaken in the initial assessment.

A.5.3 Selection activities take place in both the initial assessment and in surveillance. However, entirely different choices can be made in surveillance. For example, it is possible that a test for a product has been selected in the initial assessment. In surveillance, an inspection can be selected to determine that a sample of the product is the same as the sample originally tested. In fact, the choices in selection can change from time to time, based on information from previous iterations of surveillance and other inputs. Ongoing risk analysis or consideration of market feedback regarding actual fulfilment of specified requirements can be part of selection activities in surveillance.

A.5.4 Choices about the specified requirements can be different as well. For example, it is possible that only a subset of the specified requirements is selected in any given iteration of surveillance. Or, similarly, it is possible that only a portion of the object of conformity assessment is selected for determination activities in surveillance; for example, it is possible that only a portion of an accredited certification body is assessed during surveillance.

A.5.5 As noted above, the different choices in selection can lead to different determination activities for surveillance purposes. However, in both initial assessment and surveillance, the output from selection defines the determination activities and how they will be carried out.

A.5.6 The review, decision and attestation function is also used in both initial assessment and surveillance. In surveillance, a review of all the inputs and outputs in Figure A.1 leads to a decision whether the statement resulting from attestation continues to be valid. In many cases, no special action

is taken if the statement continues to be valid. In other cases, for example, if the scope of attestation has been extended, a new statement of conformity can be issued.

A.5.7 If the decision is that the statement of conformity is no longer valid, appropriate activities are necessary to advise users; for example, that the scope of attestation has been reduced or that the statement has been suspended or withdrawn.

Annex B
(informative)

Related terms defined in other standards

B.1 Related terms defined in other conformity assessment standards

ability	ISO/IEC TS 17027
accommodation of special needs	ISO/IEC TS 17027
accreditation activity	ISO/IEC 17011
accreditation body logo	ISO/IEC 17011
accreditation body personnel	ISO/IEC 17011
accreditation decision	ISO/IEC 17011
accreditation process	ISO/IEC 17011
accreditation scheme	ISO/IEC 17011
accreditation symbol	ISO/IEC 17011
adverse impact of examinations	ISO/IEC TS 17027
applicant	ISO/IEC 17024, ISO/IEC TS 17027, ISO/IEC 17040
approval of persons	ISO/IEC TS 17027
assessment	ISO/IEC 17024, ISO/IEC TS 17027, ISO/IEC 17011
assessment plan	ISO/IEC 17011
assessment programme	ISO/IEC 17011
assessment technique	ISO/IEC 17011
assessor	ISO/IEC 17011
assigned value	ISO/IEC 17043
attribute	ISO/IEC TS 17027
audit time	ISO/IEC 17021-1, ISO/IEC TS 17023
auditor	ISO/IEC 17021-1, ISO/IEC TS 17021-4
bias	ISO/IEC TS 17027
candidate	ISO/IEC 17024, ISO/IEC TS 17027
category of persons	ISO/IEC TS 17027
certificate	ISO/IEC 17024, ISO/IEC TS 17027

certificate holder	ISO/IEC TS 17027
certification audit	ISO/IEC 17021-1
certification body	ISO/IEC TS 17027, ISO/IEC 17065
certification mark	ISO/IEC TS 17027
certification process	ISO/IEC 17024, ISO/IEC TS 17027,
certification requirements	ISO/IEC TS 17027, ISO/IEC 17065
certification scheme	ISO/IEC 17021-1, ISO/IEC TS 17023, ISO/IEC 17024, ISO/IEC TS 17027
certification system	ISO/IEC 17065
certified client	ISO/IEC 17021-1
certified person	ISO/IEC TS 17027
client	ISO/IEC 17021-1, ISO/IEC 17043, ISO/IEC 17065
client organization	ISO/IEC TS 17023
competence	ISO/IEC 17021-1, ISO/IEC TS 17021-4, ISO/IEC 17024, ISO/IEC TS 17027
code of conduct	ISO/IEC TS 17027
code of practice	ISO/IEC TS 17027
continuing professional development/education	ISO/IEC TS 17027
conformity assessment activity	ISO/IEC 17011
consultancy	ISO/IEC 17011, ISO/IEC 17021-1, ISO/IEC 17065, ISO/IEC 17029
coordinator	ISO/IEC 17043
credential	ISO/IEC TS 17027
credentialing	ISO/IEC TS 17027
criterion-referenced pass mark	ISO/IEC TS 17027
criterion-referenced cut score	ISO/IEC TS 17027
customer	ISO/IEC TR 17028, ISO/IEC 17043
decision rule	ISO/IEC 17025
designation for persons	ISO/IEC TS 17027
diagnostic score report	ISO/IEC TS 17027
difficulty index	ISO/IEC TS 17027
duration of management system certification audits	ISO/IEC 17021-1, ISO/IEC TS 17023

e-assessment	ISO/IEC TS 17027
eligibility	ISO/IEC TS 17027
equating of examinations	ISO/IEC TS 17027
equivalence of certification results	ISO/IEC TS 17027
evaluation	ISO/IEC 17065
examination (computer-based examination, criterion-referenced examination, norm-referenced examination, standardized examination)	ISO/IEC 17024, ISO/IEC TS 17027
examination adaptation	ISO/IEC TS 17027
examination administration	ISO/IEC TS 17027
examination blueprint	ISO/IEC TS 17027
examination form	ISO/IEC TS 17027
examination modification	ISO/IEC TS 17027
examination security	ISO/IEC TS 17027
examiner	ISO/IEC 17024, ISO/IEC TS 17027
examiner reliability (inter-rater reliability, inter-rater agreement)	ISO/IEC TS 17027
extending accreditation	ISO/IEC 17011
fairness	ISO/IEC 17024, ISO/IEC TS 17027
flexible scope of accreditation	ISO/IEC 17011
granting accreditation	ISO/IEC 17011
guide	ISO/IEC 17021-1
inspection body	ISO/IEC 17020
inspection scheme	ISO/IEC 17020
inspection system	ISO/IEC 17020
interested party	ISO/IEC 17011, ISO/IEC TS 17021-4, ISO/IEC 17024
interlaboratory comparison	ISO/IEC 17025, ISO/IEC 17043
intralaboratory comparison	ISO/IEC 17025
invigilator	ISO/IEC 17024, ISO/IEC TS 17027
issuer of a third-party mark of conformity	ISO/IEC 17030
item	ISO/IEC TS 17027
job analysis	ISO/IEC TS 17027

knowledge	ISO/IEC TS 17027
laboratory	ISO/IEC 17025
learning outcomes	ISO/IEC TS 17027
licence/licensure	ISO/IEC TS 17027
maintaining accreditation	ISO/IEC 17011
major nonconformity	ISO/IEC 17021-1
management system consultancy	ISO/IEC 17021-1
minor nonconformity	ISO/IEC 17021-1
monitoring	ISO/IEC TS 17021-4, ISO/IEC TS 17027
nonconformity	ISO/IEC 17021-1
observer	ISO/IEC 17021-1
organization	ISO/IEC TS 17021-4
outlier	ISO/IEC 17043
owner of a third-party mark of conformity	ISO/IEC 17030
pass mark/cut score/passing score	ISO/IEC TS 17027
permanent site	ISO/IEC TS 17023
personnel	ISO/IEC 17024, ISO/IEC TS 17027
process	ISO/IEC 17065
product requirement	ISO/IEC 17065
production <of a reference material>	ISO Guide 30
proficiency test item	ISO/IEC 17043
proficiency testing	ISO/IEC 17025, ISO/IEC 17043
proficiency testing provider	ISO/IEC 17043
proficiency testing round	ISO/IEC 17043
proficiency testing scheme	ISO/IEC 17043
programme owner	ISO/IEC 17024, ISO/IEC 17029, ISO/IEC 17065
psychometrics	ISO/IEC TS 17027
qualification	ISO/IEC 17024, ISO/IEC TS 17027
reassessment	ISO/IEC 17011
recertification	ISO/IEC TS 17027
reducing accreditation	ISO/IEC 17011

register	ISO/IEC TS 17027
reference material	ISO 17034
reference material producer	ISO 17034
registration	ISO/IEC TS 17027
reliability	ISO/IEC 17024, ISO/IEC TS 17027
remote assessment	ISO/IEC 17011
robust statistical method	ISO/IEC 17043
scope of accreditation	ISO/IEC 17011
scope of certification	ISO/IEC TS 17027, ISO/IEC 17065
scope of certification scheme	ISO/IEC TS 17027
scope of validation	ISO/IEC 17029
scope of verification	ISO/IEC 17029
score report	ISO/IEC TS 17027
self-declaration	ISO/IEC TS 17027
self-evaluation/self-assessment	ISO/IEC TS 17027
skill	ISO/IEC TS 17027
standard deviation for proficiency assessment	ISO/IEC 17043
subcontractor	ISO/IEC 17043
supply chain	ISO/IEC TS 17021-4
suspending accreditation	ISO/IEC 17011
sustainable development	ISO/IEC TS 17021-4
team leader	ISO/IEC 17011
technical area	ISO/IEC 17021-1
technical expert	ISO/IEC 17011, ISO/IEC 17021-1
temporary site	ISO/IEC TS 17023
third-party mark of conformity	ISO/IEC 17030
training	ISO/IEC TS 17027
validation body	ISO/IEC 17029
validation statement	ISO/IEC 17029
validation programme	ISO/IEC 17029
validity	ISO/IEC TS 17027

verification body	ISO/IEC 17029
verification statement	ISO/IEC 17029
verification programme	ISO/IEC 17029
withdrawing of accreditation	ISO/IEC 17011
witnessing	ISO/IEC 17011

B.2 Related terms defined in standards other than conformity assessment standards

audit evidence	ISO 19011, ISO 9000
calibration	ISO/IEC Guide 99
capability	ISO 9000
characteristic	ISO 9000
compliance	ISO 19600
conformity	MSS core definition[1]
continual improvement	MSS core definition[1]
corrective action	MSS core definition[1]
document	ISO 9000
documented information	MSS core definition[1]
effectiveness	MSS core definition[1]
examination	ISO 15189
instrument	ISO/IEC Guide 99
information	ISO 9000
management system	MSS core definition[1]
measurement	ISO/IEC Guide 99
measurement uncertainty	ISO/IEC Guide 99
metrological standard	ISO/IEC Guide 99
metrological traceability	ISO/IEC Guide 99
normative document	ISO/IEC Guide 2
objective	MSS core definition[1]
organization	ISO 9000
performance	MSS core definition[1]

policy	MSS core definition[1]
process	ISO 9000
product	ISO 9000
risk	MSS core definition[1]
requirement	MSS core definition[1]
service	ISO 9000
specification	ISO 9000
standard (norm)	ISO/IEC Guide 2
supplier	ISO 9000
system	ISO 9000
top management	MSS core definition[1]
type A MSS	ISO/IEC Directives, Part 1
type B MSS	ISO/IEC Directives, Part 1

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ICS 01.040.03; 03.120.20

Price group A