# INTERNATIONAL STANDARD

# **ISO/IEC** 17000

Second edition 2020-05

Corrected version 2020-12

# Conformity assessment Vocabulary and general principles

Évaluation de la conformité — Vocabulaire et principes généraux de la conformité de la con



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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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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 <a href="https://patents.iec.ch">www.iso.org/patents</a>) or the IEC list of patent declarations received (see <a href="https://patents.iec.ch">http://patents.iec.ch</a>).

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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

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 <u>Annex B;</u>
- editorial revision of Annex A limited to changes in the terms and definitions in Clauses 4 to 9;
- extension of <u>Annex B</u>.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

This corrected version of ISO/IEC 17000:2020 corrects the price indication. The technical content remains unchanged.

# 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 <u>Clause 9</u>. 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 <u>Clauses 6</u> and <u>7</u>, 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 <u>Annex B</u>:

- 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.

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# Conformity assessment — Vocabulary and general principles

# 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. IDF of ISOILEC

# 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 attemption of the property of the propert
- IEC Electropedia: available at http://www.electropedia.org/

# Terms related to conformity assessment in general

# 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 <u>Annex A</u> 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

entity to which specified requirements (5.1) apply

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

# ISO/IEC 17000:2020(E)

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)

## 47

# 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.

# 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, subnational, 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 subnational, 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.

# 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* ( $\overline{7.1}$ ), that fulfilment of *specified requirements* ( $\overline{5.1}$ ) has or has not been demonstrated

## 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

### Terms relating to surveillance 8

# 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)

The issuing body suspends the statement of conformity because the *specified requirements* (5.1) **EXAMPLE 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.

# 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

# 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

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# Annex A

(informative)

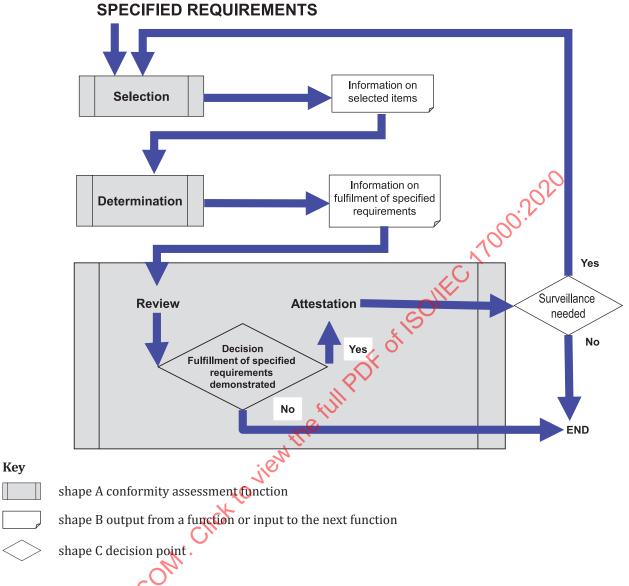
# Principles of conformity assessment

# 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 <u>Figure A.1</u>.
- **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 Cip Figure A.1 represents a decision.
- **A.1.7** Conformity assessment activities can be characterized as "first-party" (see <u>4.3</u>), "second-party" (see <u>4.4</u>) or "third-party" (see <u>4.5</u>). 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.



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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 <u>6.2</u> and <u>6.3</u>). 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 <u>7.1</u>) constitutes the final stage of checking before taking the important "decision" (see <u>7.2</u>) as to whether or not the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements. "Attestation" (see <u>7.3</u>) 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 <u>Figure A.1</u> leads to a decision whether the statement resulting from attestation continues to be valid. In many cases, no special action

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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.

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# 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

ISO/IEC 17011 accreditation decision

ISO/IEC 17011 accreditation process

ISO/IEC 17011 accreditation scheme

A. Click to view the ISO/IEC 17011 accreditation symbol

ISO/IEC TS 17027 adverse impact of examinations

ISO/IEC 17024, ISO/IEC TS 17027, ISO/IEC 17040 applicant

approval of persons ISO/IEC TS 17027

ISO/IEC 17024, ISO/IEC TS 17027, ISO/IEC 17011 assessment

ISO/IEC 17011 assessment plan

assessment programme ISO/IEC 17011

assessment technique ISO/IEC 17011

ISO/IEC 17011 assessor

assigned value ISO/IEC 17043

attribute ISO/IEC TS 17027

audit time ISO/IEC 17021-1, ISO/IEC TS 17023

ISO/IEC 17021-1, ISO/IEC TS 17021-4 auditor

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

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certificate holder ISO/IEC TS 17027

certification audit ISO/IEC 17021-1

ISO/IEC TS 17027, ISO/IEC 17065 certification body

ISO/IEC TS 17027 certification mark

ISO/IEC 17024, ISO/IEC TS 17027, certification process

ISO/IEC TS 17027, ISO/IEC 17065 certification requirements

ISO/IEC 17021-1, ISO/IEC TS 17023, ISO/IEC 17024, certification scheme

ISO/IEC TS 17027

certification system ISO/IEC 17065

certified client ISO/IEC 17021-1

certified person ISO/IEC TS 17027

ISO/IEC 17021-1, ISO/IEC 17043, ISO/IEC 17065 client

client organization ISO/IEC TS 17023

ISO/IEC 17021-1, ISO/IEC TS 17021-4, ISO/IEC competence

17024, ISOMEC TS 17027

ISO/IECTS 17027 code of conduct

ISO/IEC TS 17027 code of practice

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

M. Chick to credential ISO/IEC TS 17027

credentialing ISO/IEC TS 17027

criterion-referenced pass mark ISO/IEC TS 17027

ISO/IEC TS 17027 criterion-referenced cut score

ISO/IEC TR 17028, ISO/IEC 17043 customer

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

ISO/IEC TS 17027 equating of examinations

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

SO/IEC TS 17027

ISO/IEC TS 17027 examination adaptation

examination administration ISO/IEC TS 17027

ISO/IEC TS 17027 examination blueprint

**ISO/IEC TS 1702** examination form

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, in-

ter-rater agreement)

extending accreditation ISO/IEC 17011

fairness ISO/IEC 17024, ISO/IEC TS 17027

OM. Click to view the flexible scope of accreditation ISO/IEC 17011

granting accreditation ISO/IEC 17011

ISO/IEC 17021-1 guide

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

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knowledge ISO/IEC TS 17027

laboratory ISO/IEC 17025

ISO/IEC TS 17027 learning outcomes

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 TS 17021-4, ISO/IEC TS 17027
ISO/IEC 17021-1
ISO/IEC 17021-1
ISO/IEC TS 17021-4 monitoring

nonconformity

observer

organization

ISO/IEC 17043 outlier

ISO/IEC 17030 owner of a third-party mark of conformity

ISO/IEC TS 17023

ISO/IEC 17024, ISO/IEC TS 17027

ISO/IEC 17065

ISO/IEC 17065

ISO/IEC 17065

ISO/IEC 17065

ISO/IEC 17065

proficiency testing provider ISO/IEC 17043

proficiency testing round ISO/IEC 17043

ISO/IEC 17043 proficiency testing scheme

programme owner ISO/IEC 17024, ISO/IEC 17029, ISO/IEC 17065

psychometrics ISO/IEC TS 17027

ISO/IEC 17024, ISO/IEC TS 17027 qualification

reassessment ISO/IEC 17011

recertification ISO/IEC TS 17027

ISO/IEC 17011 reducing accreditation