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## Conformity Assessment — General principles and requirements for validation and verification bodies

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents 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](http://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 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](http://www.iso.org/patents)).

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

For an explanation on 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 the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

The committee responsible for this document is ISO Policy Committee on Conformity Assessment (ISO/CASCO).

This is the first edition of this document.

## Introduction

A growing need has been felt for providing validation and verification activities beyond their specific applications established in the greenhouse gas sector. The development of this document, specifying generic requirements for bodies performing validation or verification activities as conformity assessment in different sectors, i.e. beyond the established sectors, is therefore a response to this need.

Validation and verification as conformity assessment are understood to be a confirmation of reliability of information contained in claims. Other terms in use for the object of assessment by validation/verification are statement, declaration, assertion, prediction or report.

Both activities are distinguished according to the perspective of each assessment with regard to the timeline of the assessed claim. Validation is applied to claims regarding an intended use or projected effect (confirmation of plausibility), while verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

Assurance is provided and is serving as a confidence building element for stakeholders and parties interested in the claim. The operated programme can define varied levels of assurance, e.g. a reasonable or limited level of assurance.

The functional approach according to ISO/IEC 17000 to the demonstration that specified requirements are fulfilled specifies conformity assessment as a series of the three functions (1) selection, (2) determination and (3) review and attestation. According to this functional approach, validation and verification as conformity assessment include a decision on issuing a validation/verification statement. The validation/verification body issues the confirmation of the claim as a validation/verification statement that the claim conforms with the initially specified requirements, whether they are general or detailed and free from material misstatements operated programme can define additional steps within the validation/verification process.

When determining whether a claim made by the client can be confirmed, validation/verification activities have to gather information and develop complete understanding regarding fulfilment of the specified requirements. This can include an appropriate evaluation of data and plans, reviewing documentation, performing alternative calculations, visiting sites or interviewing people.

Since the requirements in this document are generic in nature, a programme for the particular validation/verification is to be operated. These programmes further specify definitions, principles, rules, processes, and requirements for validation/verification process steps as well as for the competence of validators/verifiers for a specific sector. Programmes can be legal frameworks, international, regional or national standards, global initiatives, sector applications as well as individual agreements with clients of the validation/verification body.

The requirements specified by this document are common to both activities, validation as well verification, wherever a requirement applies only to one activity it is identified.

Validation/verification bodies, as specified by this document, can be internal bodies of the organization that provides the claim (first party), bodies that have a user interest in the claim (second party) or bodies that are independent of the person or organization that provides the claim and have no user interests in that claim (third party).

The validation/verification bodies described in this document are primarily expected to be third party validation/verification bodies that have no user interest. The requirements specified in this standard may also be applied to bodies that have a user interest in the claim (second party) or bodies that are internal to the organization that provides the claim (first party).

By defining validation/verification as confirmation, these activities are differentiated from other CASCO tools as neither resulting in a characterisation (testing) nor providing examination (inspection) or an attestation of conformity for a defined period (certification). However, validation/verification activities are intended to match applications of the conformity assessment system. Just as test reports from a laboratory can be included for inspection purposes or as auditing the producer's management system can be used for product certification, validation/verification statements can be used for another

conformity assessment activity. Likewise, results of other conformity assessment activities can be used when performing validation/verification activities.

Statements of conformity themselves, issued as result of another conformity assessment activity, e.g. supplier's declaration of conformity regarding product specifications according to ISO/IEC 17050 or certificates or design examination and verification in the context of inspection activities according to ISO/IEC 17020, are not considered to be objects of validation/verification.

Furthermore, this document does not apply to situations where validation/verification activities are being undertaken within the process of testing (ISO/IEC 17025, ISO 15189), inspection (ISO/IEC 17020) or certification (ISO/IEC 17021-1, ISO/IEC 17065) and where specific requirements are to be applied for structuring and performing these processes. Examples are method validation as a step of a testing activity performed in accordance with ISO/IEC 17025 and design validation/verification in the context of implementing a management system according to ISO 9001.

Current examples for validation/verification as conformity assessment activities include greenhouse gas (GHG) emissions (e.g. according to ISO 14064-3), environmental labelling, declarations and footprints (e.g. according to ISO 14020 series, such as the environmental product declaration or EPD), sustainability or environmental reporting (e.g. according to ISO 14016). Potential new applications can include claims relating to construction technology, energy management, financial management, industrial automation systems, software and systems engineering, artificial intelligence, information technology, healthcare products and medical devices, machine safety, safety and design engineering, and social responsibility. However, in sector applications where validation/verification are not performed as conformity assessment activities as defined by this document, these activities are not within the scope of this document.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

For the purposes of research, users are encouraged to share their views on this document and their priorities for changes to future editions. Click on the link below to take part in the online survey:

(CASCO Secretariat to insert the link at a later stage.)





# Conformity Assessment — General principles and requirements for validation and verification bodies

## 1 Scope

**1.1** This document contains general principles and requirements for the competence, consistent operation and impartiality of bodies providing validation/verification as conformity assessment.

**1.2** Bodies operating according to this document can be first party, second party as well as third party bodies. Bodies can be validation bodies only, verification bodies only, or provide both activities.

**1.3** This document is applicable to validation/verification bodies in any sector, providing confirmation that claims are either plausible with regards to the intended purpose (validation) or correctly stated (verification). However, statements of conformity themselves, issued as result of another conformity assessment activity (e.g. testing, inspection and certification), are not considered to be subject to validation/verification according to this document.

**1.4** This document is applicable to any sector, in conjunction with sector specific programmes that contain requirements for validation or verification processes and procedures.

**1.5** This document can be used as a basis for accreditation by accreditation bodies, peer assessment within peer assessment groups, or other forms of recognition of validation/verification bodies by international or regional organizations, governments, regulatory authorities, programme owners, industry bodies, companies, clients or consumers.

**NOTE** This document contains generic requirements and is neutral with regard to the operated validation or verification programme. Requirements of the applicable programmes are additional to the requirements of this document.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

## 3 Terms and definitions

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

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

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

## 3.1 impartiality

presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence activities of the validation/verification body.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “openmindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, modified - [3.2](#), replacement of *certification body* by *validation/verification body*]

## 3.2 validation

confirmation of a claim ([3.11](#)), through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: Objective evidence can come from real or simulated sources.

Note 2 to entry: Validation is considered to be a process to evaluate the reasonableness of the assumptions, limitations, and methods that support a claim about the outcome of future activities.

Note 3 to entry: Validation is applied to claims regarding an intended future use based on projected information (confirmation of plausibility).

[SOURCE: ISO 9000:2015, 3.8.13, modified – “of a claim” added; notes 1-2 deleted, Note 3 “the use of conditions for validation can be” replaced with “objective evidence can come from”; new Notes 2 and 3 added]

## 3.3 validation body

body that performs validation

Note 1 to entry: A validation body can be an organization, or part of an organization.

## 3.4 validation programme

rules, procedures and management for carrying out validation activities in a specific sector or field

Note 1 to entry: Validation programmes may be operated at international, regional, national, sub-national or sector-specific level.

Note 2 to entry: A programme can also be called a “scheme”.

Note 3 to entry: A set of standards able to cover all the requirements of this document can serve as a programme.

[SOURCE: ISO/IEC 17000:2004, 2.8 *conformity assessment system*, modified to make validation specific.]

## 3.5 verification

confirmation of a claim ([3.11](#)), through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: Verification is considered to be a process for evaluating a claim based on historical data and information to determine whether the claim is materially correct, and conforms with specified requirements.

Note 2 to entry: Verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

[SOURCE: ISO 9000:2015, 3.8.12, modified - “of a claim” added, Notes 1-3 deleted and new Notes 1-2 added]

**3.6****verification body**

body that performs verification (3.5)

Note 1 to entry: A verification body can be an organization, or part of an organization.

**3.7****verification programme**

rules, procedures and management for carrying out verification activities in a specific sector or field

Note 1 to entry: Verification programmes may be operated at international, regional, national, sub-national or sector-specific level.

Note 2 to entry: A programme can also be called a “scheme”.

Note 3 to entry: A set of standards able to cover all the requirements of this document can serve as a programme.

[SOURCE: ISO/IEC 17000:2004, 2.8 *conformity assessment system*, modified to make verification specific.]

**3.8****consultancy**

participation in establishing the claim (3.11) that will be validated or verified

Note 1 to entry: The term “consultancy” is used in relation to activities of validation/verification bodies, their personnel and organizations related or linked to the validation/verification bodies.

Note 2 to entry: Arranging training and participating as a trainer is not considered consultancy, provided that, where the course relates to the claim being validated or verified, it is confined to the provision of generic information; i.e. the trainers should not provide client-specific solutions.

Note 3 to entry: The provision of generic information, but not client specific solutions for establishing the claim being validated or verified, is not considered to be consultancy. Such information may include:

- explaining the meaning and intention of validation/verification requirements;
- identifying improvement opportunities;
- explaining associated theories, methodologies, techniques, or tools;
- sharing non-confidential information on related best practices;
- other relevant aspects that are not covered.

**3.9****programme owner**

person or organization responsible for developing and maintaining a specific validation programme (3.4) or verification programme (3.7)

Note 1 to entry: The programme owner can be the validation/verification body itself, a governmental authority, a trade association, a group of validation/verification bodies, an external programme owner or others.

**3.10****scope of validation/verification**

identification of:

- the claim (3.11) to be the object of validation (3.2) or verification (3.5), including the boundaries of the object,
- the applicable validation/verification programme (3.4/3.7), and
- the standards and other normative documents, including their date of publication, to which the claim (3.11) is validated/verified

**3.11  
claim**

information declared by the client ([3.14](#))

Note 1 to entry: The claim is the object of conformity assessment by validation/verification.

Note 2 to entry: The claim could represent a situation at a point in time or could cover a period of time.

Note 3 to entry: The claim should be clearly identifiable and capable of consistent evaluation or measurement against specified requirements by a validation/verification body.

Note 4 to entry: The claim could be provided in the form of a report, a statement, a declaration, a project plan, or consolidated data.

**3.12  
validation statement**

declaration by the validation body ([3.3](#)) of the outcome of the validation process

Note 1 to entry: Validation statements can be referred to using specific programme relevant terminology, such as decisions, opinions or reports.

Note 2 to entry: The validation statement does not refer a period of validity. The validation statement reflects only the situation at the point in time it is issued.

Note 3 to entry: Validation statement can be positive or negative.

**3.13  
verification statement**

declaration by the verification body ([3.6](#)) of the outcome of the verification process

Note 1 to entry: Verification statements can be referred to using specific programme relevant terminology, such as decisions, opinions or reports.

Note 2 to entry: The verification statement does not refer a period of validity. The verification statement reflects only the situation at the point in time it is issued.

Note 3 to entry: Verification statement can be positive or negative.

**3.14  
client**

organization or person requesting validation or verification

**3.16  
level of assurance**

degree of confidence in the claim ([3.11](#))

Note 1 to entry: The level of assurance and/or the intended user of the claim is defined in the programme.

**3.17  
materiality**

concept that misstatements, individually or aggregated may influence the reliability of the claim ([3.11](#)) for the intended user

Note 1 to entry: The materiality can be qualitative or quantitative.

**3.18  
level of materiality**

quantitative threshold above which misstatements, individually or aggregated, are considered as influencing the reliability of the claim ([3.11](#)) for the intended users

Note 1 to entry: The level of materiality can be defined in the programme.

## 4 Principles

### 4.1 General

**4.1.1** The principles described in this clause provide the basis for the subsequent specific performance and descriptive requirements specified in this document. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.

**4.1.2** The overall aim of validation/verification should be to give confidence to all parties that a validated/verified claim fulfills the requirements. The value of validation/verification is the public confidence and trust that is established by an impartial and competent assessment by a validation/verification body. Parties that have an interest in validation/verification include, but are not limited to:

- a) the clients of the validation/verification bodies;
- b) the programme owners;
- c) the users of the validated/verified claims.

### 4.2 Impartiality

**4.2.1** Being impartial, and being perceived to be impartial, is necessary for a validation/verification body to deliver validation/verification that provides confidence. It is important that all internal and external personnel are aware of the need for impartiality.

**4.2.2** Threats to impartiality may include but are not limited to the following:

- a) Self-interest: threats that arise from a person or body acting in their own interest. A concern related to validation/verification, as a threat to impartiality, is financial self-interest.
- b) Self-review: threats that arise from a person or body reviewing the work done by themselves.
- c) Familiarity (or trust): threats that arise from a person or body being too familiar with or trusting of another person instead of seeking evidence for validation/verification.
- d) Intimidation: threats that arise from a person or body having a perception of being coerced openly or secretly, such as a threat to be replaced or reported to a supervisor.

### 4.3 Competence

**4.3.1** Personnel have the necessary knowledge, skills, experience, training, supporting infrastructure, and capacity to effectively complete validation/verification activities.

**4.3.2** The validation/verification body determines and accepts the competence of any organizations that:

- a) undertake outsourced activities; or
- b) provide evidence which is relied upon as a basis for validation/verification.

### 4.4 Evidence - based decision making

The validation/verification activities use rational methods for reaching reliable and reproducible validation/verification conclusions and are based on sufficient and appropriate facts and evidence.

## 4.5 Responsibility

**4.5.1** The client of the validation/verification body, and not the validation/verification body, has the responsibility for the claim made by it regarding the object of validation/verification and conformity with the validation/verification specific requirements.

**4.5.2** The validation/verification body has the responsibility to assess sufficient objective evidence upon which to base a validation/verification decision.

## 4.6 Openness

A validation/verification body needs to provide public access to, or disclosure of, appropriate information about its validation/verification process and upon request, timely information about the status of the validation/verification.

## 4.7 Confidentiality

To gain the privileged access to information and data that is needed for carrying out validation/verification activities adequately, it is essential that a validation/verification body does not disclose any confidential information. It should be ensured that the confidential information obtained or created during validation/verification activities is safeguarded and not inappropriately disclosed.

## 4.8 Responsiveness to complaints

Parties that have an interest in validation/verification have the opportunity to make complaints. These complaints are appropriately managed and concluded by the validation/verification body.

**NOTE** An appropriate balance between the principles of openness and confidentiality, including responsiveness to complaints, is necessary in order to demonstrate integrity and credibility to all users of validation/verification outcomes.

## 4.9 Risk-based approach

Validation/verification bodies need to take into account the risks associated with providing competent, consistent and impartial validation/verification. Risks may include, but are not limited to, those associated with:

- a) the objectives of the validation/verification and the programme requirements;
- b) the evidence-gathering used in the validation/verification process and the levels of assurance required to be achieved;
- c) real and perceived impartiality;
- d) legal, regulatory and liability issues;
- e) the client organization, where validation/verification is being carried out and its operating environment, geographic location, etc.;
- f) health and safety issues for the validation/verification teams;
- g) perception of interested parties;
- h) misleading claims by the client.

## 5 General requirements

### 5.1 Legal entity

The validation/verification body shall be a legal entity, or a defined part of a legal entity, that can be held legally responsible for all its validation/verification activities.

NOTE A governmental validation/verification body is a legal entity on the basis of its governmental status.

### 5.2 Responsibility for validation/verification statements

The validation/verification body shall be responsible for, and shall retain authority for, its validation/verification statements.

### 5.3 Management of impartiality

**5.3.1** Validation/verification activities shall be undertaken impartially.

**5.3.2** The validation/verification body shall be responsible for the impartiality of its validation/verification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

**5.3.3** The validation/verification body shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a body with a risk to impartiality.

NOTE 1 While the requirements for impartiality in this document are the same for first, second and third party bodies, the relevant inputs and outcome of the respective risk assessment can differ.

NOTE 2 A relationship that threatens the impartiality of the validation/verification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.

**5.3.4** If a risk to impartiality is identified, the validation/verification body shall be able to demonstrate how it eliminates or minimizes such risk.

**5.3.5** The validation/verification body shall have top management commitment to impartiality.

**5.3.6** The identification of risks to impartiality according to [5.3.3](#) shall include consultation with appropriate interested parties to advise on matters affecting impartiality including openness and public perception. The consultation with appropriate interested parties shall be balanced with no single interest predominating.

NOTE One way of fulfilling the consultation requirement of this clause is by the use of a committee of these interested parties.

**5.3.7** The validation/verification body shall not offer or provide both consultancy ([3.8](#)) and validation/verification ([3.2/3.5](#)) for the same claim from the same client, under the same validation/verification programme.

**5.3.8** Where the relationship between a body that provides consultancy ([3.8](#)) and the validation/verification body poses an unacceptable threat to the impartiality of the validation/verification body, the validation/verification body shall not provide validation/verification activities to clients, or potential clients the validation/verification body is pre-engaged with, who have received consultancy relating to the same claim.



**5.3.9** Review and decision on issuance of a validation/verification statement shall be made by personnel different from those who carried out the execution. When providing both, validation and verification activities to the same client, the validation/verification body shall consider the potential threat to impartiality (e.g. self-review and familiarity) and shall manage this risk accordingly. The validation/verification body's activities shall not be marketed or offered as linked with the activities of another organization that provides consultancy.

**5.3.10** When made aware of (e.g. via a complaint) inappropriate links or announcements by any consultancy organization stating or implying that validation/verification would be simpler, easier, faster or less expensive if the validation/verification body were used, the validation/verification body shall take action. A validation/verification body shall not state or imply that validation/verification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

**5.3.11** The validation/verification body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations. This includes the actions of those bodies to which validation/verification activities have been outsourced.

**5.3.12** The validation/verification body shall have a publicly available commitment that it understands the importance of impartiality in carrying out its validation/verification activities and manages conflicts of interest and ensures objectivity.

## **5.4 Liability**

The validation/verification body shall be able to demonstrate that it has evaluated the risks arising from its validation/verification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities in each validation/verification programme it operates, including the geographic areas.

## **6 Structural requirements**

### **6.1 Organizational structure and top management**

**6.1.1** The validation/verification body shall be organized and managed so as to enable it to maintain the capability to perform its validation/verification activities.

**6.1.2** Validation/verification activities shall be structured and managed so as to safeguard impartiality.

**6.1.3** The validation/verification body shall document its organizational structure, duties, responsibilities and authorities of management and other personnel involved in validation/verification and any committees. If the validation/verification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

**6.1.4** The validation/verification body shall identify the top management (board, group of persons, or person) having overall authority and responsibility for each of the following:

- a) development of policies and establishment of processes relating to its operations;
- b) supervision of the implementation of the policies and processes;
- c) ensuring impartiality;
- d) supervision of its finances;
- e) development of validation/verification activities and requirements;
- f) performance of validation/verification activities;



- g) decisions on issuance of validation/verification statements;
- h) delegation of authority to committees or individuals, as required, to undertake defined activities on its behalf;
- i) contractual arrangements;
- j) personnel competence requirements;
- k) responsiveness to complaints and appeals;
- l) management system of the validation/verification body;
- m) provision of adequate resources for validation/verification activities.

## 6.2 Operational control

**6.2.1** The validation/verification body shall have a process for the effective control of validation/verification activities delivered by branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location.

**6.2.2** The validation/verification body shall determine and establish the appropriate level and method of control of activities undertaken including its processes, sectors of validation/verification bodies' activities, competence of personnel, lines of management control, reporting and remote access to operations including records.

**6.2.3** The validation/verification body shall consider the risk that these activities pose to the competence, consistency and impartiality of the validation/verification body.

## 7 Resource requirements

### 7.1 General

The validation/verification body shall have access to personnel, facilities, equipment, systems and support services that are necessary and fit for purpose to perform its validation/verification activities.

NOTE Requirements for personnel, facilities, equipment, systems and support services can be contained in the validation/verification programme.

### 7.2 Personnel

**7.2.1** The validation/verification body shall employ, or have access to, a sufficient number of personnel to undertake its validation/verification activities.

NOTE Personnel include those persons that are employees, directors and committee members of the body, and any contracted, outsourced or other persons that are used by the body to undertake verification/validation activities.

**7.2.2** The validation/verification body shall require all personnel involved in validation/verification activities to enter into a legally enforceable agreement by which the personnel commit themselves to the following:

- a) to comply with the processes and instructions defined or adopted by the validation/verification body, including those relating to impartiality and confidentiality;
- b) to declare any prior and/or present association on their own part, or on the part of another person or organization with which they have a relationship (e.g. a family member or their employer), with a client of the validation/verification body; and

- c) to reveal any situation known to them that may present them or the validation/verification body with a perceived or actual conflict of interest.

**7.2.3** The validation/verification body shall use this information as input into identifying risks to impartiality raised by the activities of such personnel, or by the persons or organizations related to them (see [5.3.3](#)).

**7.2.4** All personnel of the validation/verification body, either internal or external, that could influence the validation/verification activities, shall act impartially.

**7.2.5** Within a period specified by the validation/verification body, personnel who have provided consultancy on the object of validation/verification shall not perform validation/verification activities in relation to their previous involvement. The period shall ensure that the risk to impartiality is minimized or eliminated.

**NOTE** The period can be specified in the programme or, if specified by the validation/verification body, it reflects a period that is long enough to ensure that the consultancy does not compromise impartiality.

**7.2.6** Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the validation/verification body's behalf, shall keep confidential all information obtained or created during the performance of the body's validation/verification activities, except as required by law or by the validation/verification programme.

**7.2.7** The validation/verification body shall communicate to personnel their duties, responsibilities and authorities.

### **7.3 Management process for the competence of personnel**

**7.3.1** The validation/verification body shall have processes for management of competence of personnel involved in the validation/verification process. The processes shall require the validation/verification body to:

- a) determine the criteria for the competence of personnel for each function in the validation/verification process, including at least:
- the ability to apply generic validation and verification concepts (e.g. level of assurance, risk, materiality, misstatements, evidence gathering);
  - knowledge about the type and typical content of the client's claims;
  - knowledge of the programme requirements (e.g. competence required for specific validation/verification process).
- b) identify training needs and provide, as necessary, training on validation/verification processes, requirements, methodologies, activities and other relevant validation/verification programme requirements;
- c) demonstrate that the personnel have the required competence for the duties and responsibilities they undertake;
- d) formally authorize personnel for functions in the validation/verification process;
- e) monitor the performance of the personnel.

**NOTE** Further requirements and competence for personnel may be contained in the validation/verification programme.

**7.3.2** The validation/verification body shall maintain personnel records to demonstrate fulfillment of the requirements in [7.3.1](#), including relevant qualifications, training, experience, affiliations, professional status and competence. This includes management and administrative personnel in addition to those performing validation/verification activities.

## 7.4 Outsourcing

In the absence of applicable programme prohibitions on outsourcing, the validation/verification body may outsource validation /verification activities and shall:

- a) retain full responsibility for the validation/verification;
- b) not outsource the engagement, the decision to issue the statement and the issuance of the statement;
- c) have a legally enforceable agreement, including confidentiality and management of impartiality provisions, with each body that provides outsourced activities;
- d) ensure that the body that provides outsourced activities conforms with the applicable requirements of this document, including competence, impartiality and confidentiality and to any applicable programme requirements; and
- e) obtain consent from the client to use the outsourced body.

NOTE Outsourcing refers to contract arrangements with another organization, including other validation/verification bodies, to provide validation/verification activities to the validation/verification body.

## 8 Validation/verification programme

The validation/verification body shall apply one or more validation/verification programme(s) that are consistent with the requirements of this document.

NOTE 1 A validation/verification programme is a set of rules, procedures and management for carrying out validation/verification activities in a specific sector or field containing the following elements:

- scope of validation/verification;
- specific competence criteria for the validation/verification team and body;
- process for validation/verification;
- evidence gathering activities of validation/verification;
- reporting of validation/verification.

NOTE 2 [Annex A](#) specifies the elements that can be included in a validation/verification programme.

## 9 Process requirements

### 9.1 General

The validation/verification body shall complete the following process steps in undertaking its validation/verification activities:

- pre-engagement ([9.2](#));
- engagement ([9.3](#));
- planning ([9.4](#));
- execution ([9.5](#));

- review (9.6);
- decision and issuance of the validation/verification statement (9.7).

## **9.2 Pre-engagement**

**9.2.1** The validation/verification body shall require the client to submit information sufficient to carry out a pre-engagement review, including at least the following:

- a) client name and the claim to be validated/verified;
- b) locations where the client's activities are undertaken;
- c) the validation/verification programme and associated specified requirements against which the claim will be validated/verified;
- d) the objectives and scope of the validation/verification;
- e) reports, data and any other relevant information and any other relevant parameters;
- f) where known at this stage and where applicable, the materiality and the level of assurance;
- g) any other information as required by the validation/verification programme.

**9.2.2** The validation/verification body shall conduct a pre-engagement review of the information received from the client to ensure that:

- a) an applicable programme exists or a programme to be applied is established;
- b) the claim is understood (e.g. content and complexity);
- c) the scope of the validation/verification has been agreed with the client;
- d) the specified requirements against which the claim will be validated/verified have been identified and are suitable;
- e) the materiality and level of assurance have been agreed;
- f) the process for validation/verification activities can be achieved (e.g. evidence gathering activities);
- g) the proposed validation/verification duration can be estimated;
- h) the validation/verification body has identified and has access to the resources and competencies that are required to undertake the validation/verification;
- i) the time frame for the planned validation/verification can be proposed.

## **9.3 Engagement**

**9.3.1** The validation/verification body shall have an agreement with each client for the provision of validation/verification activities in accordance with the relevant requirements of this document and the requirements specified in the relevant validation/verification programme:

- a) for third party validations/verifications, a legally enforceable agreement;
- b) for second and first party validations/verifications, an internal agreement such as service level agreement, internal contract, statement of work, or other enforceable internal agreement.

**9.3.2** The validation/verification body shall ensure its agreement requires that the client complies at least, with the following:

- a) validation/verification requirements;
- b) making all necessary arrangements for the conduct of the validation/verification, including provisions for examining documentation and access to all relevant processes, areas, records, and personnel; and
- c) making provisions, where applicable, to accommodate observers.

**9.3.3** The agreement shall confirm that the client engages the validation/verification body to undertake validation/verification activities, including the specification of:

- a) the items listed in [9.2](#);
- b) the specific requirements for the validation/verification activity, including any additional relevant requirements set by a programme or standard.

**9.3.4** The validation/verification body shall take responsibility for any inputs that it accepts to take into account as part of its validation/verification activities, including inputs that have been generated by the client or other external parties.

## 9.4 Planning

**9.4.1** The validation/verification body shall undertake the following planning activities taking into account the requirements specified in the applicable validation/verification programme before undertaking the validation/verification:

- a) assign competent resources to undertake the activities;
- b) determine the validation/verification activities based on the understanding of the claim;
- a) assess the risk of a material misstatement regarding the claim;
- b) confirm the timing and access arrangements with the client;
- c) determine evidence-gathering activities needed to complete the validation/verification in accordance with the specified requirements and consistent with the results of b) and c);
- d) prepare an evidence-gathering plan, taking into account c) and any measures that the client has in place to control sources of potential errors, omissions and misrepresentations; and
- e) prepare a validation/verification plan considering the evidence-gathering plan as an input.

NOTE 1 Preparation of an evidence-gathering plan and a validation/verification plan can be an iterative process.

NOTE 2 In some programmes, the evidence-gathering plan is called sampling plan.

NOTE 3 The level of assurance is used to determine the depth of detail that a validation or verification body designs into their validation or verification plan and evidence-gathering plan to determine if there are any material errors, omissions, or misrepresentations.

NOTE 4 Other parameters that can be specified by programmes to be considered during planning are: materiality, level of assurance.

**9.4.2** The validation/verification body shall develop a validation/verification plan that describes activities and schedules, and includes the following:

- a) scope and objectives;

- b) identification of the validation/verification team members and their roles and responsibilities in the team (e.g. team leader);
- c) time frame and duration of validation/verification activities; and
- d) specified requirements.

**9.4.3** The validation/verification body shall inform the client of the names of the team members with sufficient notice for any objection to the appointment of a team member to be made.

## **9.5 Execution**

**9.5.1** The validation/verification body shall perform the validation/verification activities in accordance with the validation/verification plan.

**9.5.2** The validation/verification plan shall be revised as necessary during the validation/verification execution.

**9.5.3** Any revisions to the validation/verification plan shall be internally documented, including the reasons, and communicated to the client.

**9.5.4** The body shall undertake the following activities:

- a) collection of objective evidence on original data/information, its traceability through the data/information management process, any further analysis and calculation;
- b) identification of misstatements and consideration of their materiality; and
- c) assessment of conformity with specified requirements, taking into account the validation/verification programme.

**9.5.5** The validation/verification body shall prepare the following:

- a) a conclusion on the outcome of the activities in [9.5.1](#);
- b) a draft validation/verification statement; and
- c) a report, if applicable.

**NOTE** The report can be a separate document or can be included in a document containing the draft validation/verification statement.

## **9.6 Review**

**9.6.1** The validation/verification body shall undertake the review activities as specified in the programme.

**9.6.2** The review shall be carried out by persons who have not been involved in the planning and execution steps of the validation/verification process.

**9.6.3** The review shall confirm that all validation/verification activities have been completed in accordance with the agreement and the programme and whether the claim is free from material misstatement.

**9.6.4** The review shall have available all records of the validation/verification activities as specified in [9.10](#).

## 9.7 Decision and issuance of the validation/verification statement

### 9.7.1 Decision

**9.7.1.1** The validation/verification body shall make the decision to issue the validation/verification statement upon completion of the validation/verification review.

**9.7.1.2** When the decision is not to issue a validation/verification statement, the validation/verification body shall inform the client.

**9.7.1.3** The person assigned by the validation/verification body to decide to issue the validation/verification statement shall not have been involved in the execution (9.5).

### 9.7.2 Issuance of the validation/verification statement

If the validation/verification body decides to issue a validation/verification statement to the client (9.7.1) the statement shall:

- a) identify whether it is a validation statement or a verification statement;
- b) include the name and address of the validation/verification body, other symbols (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous;
- c) include a reference to the validation/verification programme and associated specified requirements;
- d) include the status of the validation/verification body for the statement in question (i.e. first party, second party or third party);
- e) describe the objectives, scope and specified requirements of the validation/verification;
- f) describe whether the data and information supporting the claim were hypothetical, projected and/or historical in nature;
- g) state the client's name;
- h) refer to the claim, including date or period which the claim covers;
- i) include the conclusion reached about the claim, including the fulfillment of any programme related requirements (e.g. materiality or level of assurance);
- j) indicate the date of the statement.

## 9.8 Facts discovered after issuance of the validation/verification statement

**9.8.1** If new facts or information that could materially affect the validation/verification statement are discovered after this date, the validation/verification body shall:

- a) communicate the matter as soon as practicable to the client and, if required, the programme owner;
- b) take appropriate action including the following:
  1. discussing the matter with the client;
  2. consider if the validation/verification statement requires revision.

**9.8.2** If the validation/verification statement requires revision, the validation/verification body shall implement processes to issue a new statement including specification of the reasons for the revision.



**9.8.3** The validation/verification body may also communicate to other parties the fact that reliance of the original statement may now be compromised given the new facts or information.

## **9.9 Complaints and appeals**

**9.9.1** The validation/verification body shall have a documented process to receive, evaluate and make decisions on complaints and appeals.

**9.9.2** A description of the handling process for complaints and appeals shall be available to any interested party on request.

**9.9.3** Upon receipt of a complaint, the validation/verification body shall confirm whether the complaint relates to validation/verification activities that it is responsible for and, if so, shall deal with it.

**9.9.4** The validation/verification body shall be responsible for all decisions at all levels of the handling process for complaints and appeals.

**9.9.5** Investigation and decision on appeals shall not result in any discriminatory actions.

**9.9.6** The handling process for complaints and appeals shall include at least the following elements and methods:

- a) a description of the process for receiving, validating, investigating the complaint or appeal, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints and appeals, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken.

**9.9.7** The validation/verification body receiving the complaint or appeal shall be responsible for gathering and verifying (evaluating) all necessary information to validate (substantiate) the complaint or appeal.

**9.9.8** Whenever possible, the validation/verification body shall acknowledge receipt of the complaint or appeal, and provide the complainant or appellant with progress reports and the outcome.

**9.9.9** The decision to be communicated to the complainant or appellant shall be made by, or reviewed and approved by, individual(s) not involved in the original activities in question.

**9.9.10** Whenever possible, the validation/verification body shall give formal notice of the end of the complaint and appeal.

## **9.10 Validation/verification records**

**9.10.1** The validation/verification body shall maintain and manage records of its validation/verification activities including:

- a) application information and validation/verification scopes;
- b) justification for how validation/verification duration is determined;
- c) any revisions to the validation/verification planning activities;
- d) confirmation of the completion of validation/verification activities, including findings and information on material or non-material misstatements;



- e) records of evidence to support conclusions;
- f) validation/verification statements;
- g) records of complaints and appeals, and any subsequent correction or corrective actions.

**9.10.2** The validation/verification body shall maintain validation/verification records securely and confidentially, including during their transport, transmission, or transfer.

**9.10.3** The validation/verification body shall retain validation/verification records in accordance with the programme, contractual, legal, and other management system requirements.

NOTE ISO 15489-1 defines the concepts and principles from which approaches to the creation, capture and management of records are developed.

## 10 Information requirements

### 10.1 Publicly provided information

**10.1.1** Publicly provided information shall include:

- a) information about the validation/verification process;
- b) impartiality commitment;
- c) list of validation/verification activities the validation/verification body provides, including reference to applicable programmes;
- d) complaints and appeals procedure.

**10.1.2** The validation/verification body shall maintain and, upon request, provide clear, traceable, and accurate information about its activities and the sectors in which it operates.

**10.1.3** The validation/verification body shall provide, upon request, the status of a given validation/verification statement, including the name of the client, the programme requirements, and the object of validation/verification.

### 10.2 Other information to be available

The validation/verification body shall provide information and update clients on the following:

- a) the applicable validation/verification programmes and any changes;
- b) the fees for the validation/verification activity;
- c) the validation/verification body's requirements for the client to:
  1. comply with the validation/verification programme,
  2. make all necessary arrangements for the conduct of the validation/verification activities,
  3. make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation assessors or trainee validator/verifier);
- d) its policy governing any statement that the client is authorized to use when making reference to its validation/verification statement in communication of any kind in line with the requirements in [10.3](#).

### 10.3 Reference to validation/verification and use of marks

**10.3.1** A validation/verification body shall have rules governing any reference to validation/verification or use of its marks that it authorizes its clients to use.

**10.3.2** These rules shall ensure, among other things, traceability back to the validation/verification body and to the statement issued.

**10.3.3** This reference or marks shall be used only on the claim which has been validated/verified and shall not be misleading with regards to product certification.

### 10.4 Confidentiality

**10.4.1** The validation/verification body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of validation/verification activities.

**10.4.2** The validation/verification body shall inform the client, in advance, of the information it intends to place in the public domain.

**10.4.3** Except for information that the client makes publicly available, or when agreed between the validation/verification body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

**10.4.4** When the validation/verification body is required by law or authorized by contractual arrangements to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided.

**10.4.5** Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be confidential between the client and the validation/verification body. The provider (source) of this information shall be confidential to the body and shall not be shared with the client, unless agreed by the source.

## 11 Management system requirements

### 11.1 Options

#### 11.1.1 General

The validation/verification body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document. In addition to meeting the requirements of [Clauses 5-10](#) of this document the body shall implement a management system in accordance with either Option A or with Option B.

#### 11.1.2 Option A

As a minimum, the management system of the validation/verification body shall address the following:

- a) management system documentation ([11.2](#));
- b) control of management system documents ([11.3](#));
- c) control of records ([11.4](#));
- d) actions to address risks and opportunities ([11.5](#));

- e) improvement (see [11.6](#));
- f) corrective actions ([11.7](#));
- g) internal audits ([11.8](#)); and
- h) management review ([11.9](#)).

### 11.1.3 Option B

A validation/verification body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of this document, fulfils at least the management system requirements of this clause.

## 11.2 Management system documentation (Option A)

**11.2.1** The validation/verification body's management shall establish, document, and maintain policies and objectives for fulfilment of the purposes of this document.

**11.2.2** The validation/verification body's management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of this document.

**11.2.3** The validation/verification body's management shall ensure that its policies and objectives are understood, implemented and maintained at all organizational levels of the validation/verification body.

**11.2.4** All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this document shall be included, referenced, or linked to documentation of the management system.

**11.2.5** All personnel involved in validation/verification activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

## 11.3 Control of management system documents (Option A)

**11.3.1** The validation/verification body shall establish processes to control the documents (internal and external) that relate to the fulfilment of this document.

**11.3.2** The validation/verification body shall define the controls needed to:

- a) approve documents for adequacy prior to issue;
- b) review and update (as necessary) and re-approve documents;
- c) ensure that changes and the current revision status of documents are identified;
- d) ensure that relevant versions of applicable documents are available at points of use;
- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin are identified and their distribution controlled;
- g) prevent the unintended use of obsolete documents, and apply suitable identification to them if they are retained for any purpose.

NOTE Documentation can be in any form or type of medium, and includes proprietary and in-house developed software.

## 11.4 Control of records (Option A)

**11.4.1** The validation/verification body shall establish processes to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this document.

**11.4.2** The validation/verification body shall establish processes for retaining records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

## 11.5 Actions to address risks and opportunities (Option A)

**11.5.1** The validation/verification body shall consider the risks and opportunities associated with the validation/verification activities in order to:

- a) give assurance that the management system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the validation/verification body;
- c) prevent, or reduce, undesired impacts and potential failures in the validation/verification body's activities;
- d) achieve improvement.

**11.5.2** The validation/verification body shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
  - 1. integrate and implement these actions into its management system;
  - 2. evaluate the effectiveness of these actions.

**NOTE** Although this document specifies that the validation/verification body plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Validation/verification bodies can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

**11.5.3** Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of the validation/verification statement.

**NOTE 1** Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

**NOTE 2** Opportunities can lead to expanding the scope of the validation/verification body's activities, addressing new clients, using new technology and other possibilities to address clients' needs.

## 11.6 Improvement (Option A)

**11.6.1** The validation/verification body shall identify and select opportunities for improvement and implement any necessary actions.

**NOTE** Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data.

**11.6.2** The validation/verification body shall seek feedback, both positive and negative, from its clients. The feedback shall be analysed and used to improve the management system, validation/verification body's activities and service to its clients.

NOTE Examples of the types of feedback include clients' satisfaction surveys, communication records and review of reports with clients.

### **11.7 Corrective actions (Option A)**

The validation/verification body shall establish processes for identification and management of nonconformities in its activities. The validation/verification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The processes shall define requirements for:

- a) identifying nonconformities (e.g. from valid complaints and internal audits);
- b) determining the causes of nonconformity;
- c) correcting nonconformities;
- d) evaluating the need for actions to ensure that nonconformities do not recur;
- e) determining and implementing in a timely manner, the actions needed;
- f) recording the results of actions taken;
- g) reviewing the effectiveness of corrective actions.

### **11.8 Internal audit (Option A)**

**11.8.1** The validation/verification body shall conduct internal audits at planned intervals to provide information on whether the management system:

- a) conforms to:
  - the validation/verification body's own requirements for its management system, including the validation/verification activities;
  - the requirements of this document;
- b) is effectively implemented and maintained.

**11.8.2** The validation/verification body shall conduct internal audits at planned intervals to provide information on whether the management system:

- a) plans, establishes, implements and maintains an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the validation/verification body's activities concerned, changes affecting the validation/verification body and the results of previous audits;
- b) defines the audit criteria and scope for each audit;
- c) ensures that the results of the audits are reported to relevant management;
- d) implements appropriate correction and corrective actions without undue delay;
- e) retains records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

## 11.9 Management review (Option A)

**11.9.1** The validation/verification body's management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

**11.9.2** The inputs to management review shall be recorded and shall include information related to the following:

- a) changes in internal and external issues that are relevant to the validation/verification body;
- b) fulfilment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcome of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the work or in the range of validation/verification body's activities;
- i) client and personnel feedback;
- j) complaints and appeals;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) other relevant factors, such as monitoring activities and training.

**11.9.3** The outputs from the management review shall record all decisions and actions related to at least:

- a) the effectiveness of the management system and its processes;
- b) improvement of the validation/verification body's activities related to the fulfilment of the requirements of this document;
- c) provision of required resources;
- d) any need for change.

## Annex A (informative)

### Optional elements of validation / verification programmes

**A.1** The programme owner is responsible for defining the level of detail included in the validation/verification programme beyond the minimum requirements of this document.

**A.2** The following elements should be addressed in the programme, based on the requirements of this document.

**A.3** The validation/verification programme should specify:

- a. the wording used for validation/verification statements, since they may be using sector specific terminology ([3.12](#) and [3.13](#));
- b. the claim to be the object of validation/verification ([3.11](#)) should be clearly defined and the requirements against which the claim has to be assessed, have to be stated (8);
- c. the criteria for competence of personnel for the validation/verification team and body (8);
- d. the process steps to be undertaken as a minimum in conducting the validation/verification activities ([9.1](#)) to achieve the intended results;
- e. the review activities that the validation/verification body shall undertake including the confirmation that all activities have been completed in accordance with the programme requirements ([9.6.1](#));
- f. the reporting requirements (8);
- g. requirements regarding what records the validation/verification body should retain as an evidence of conducting of validation/verification (8; [9.10.3](#));
- h. the evidence gathering activities of validation/verification (8);
- i. the process for validation/verification (8);
- j. the way in which the results of the validation/verification are to be interpreted and what the consequences are of the results. This also means that it should be laid down which findings prevent the issuance of a validation/verification statement ([9.6.3](#));
- k. the level of assurance, if required, and the materiality ([9.2.2](#));
- l. the validation/verification statement ([9.7](#)) issued on the basis of the evaluation of the claim ([9.5](#)) in order to be in accordance with the validation/verification carried out.

**A.4** The following elements may be considered by the programme owner, when developing the programme:

- a. the necessity of an impartiality monitoring function ([5.3.6](#)) the period within which personnel who has provided consultancy on the object of validation/verification shall not perform validation/verification activities in relation to their previous involvement ([7.2.5](#));
- b. describe the training needs for personnel on validation/verification processes, requirements, methodologies, activities and other relevant validation/verification programme requirements. The programme owner might consider providing training programmes ([7.3.1](#) b);

- c. requirements for monitoring of personnel ([7.3.1](#));
- d. requirements on personnel, facilities, equipment, systems and support services ([7.1](#));
- e. if and under which conditions the validation/verification body may outsource validation/verification activities ([7.4](#));
- f. additional parameters for the pre-engagement phase, including but not limited to sampling, materiality criteria, quality parameters, timeframes, fees ([9.2](#));
- g. requirements for the validation/verification agreement ([9.3](#));
- h. the planning and preparation activities that the body shall undertake before undertaking the actual validation/verification activity ([9.4](#));
- i. arrangements to be made if there are facts discovered after attestation that could materially affect the validation/verification statement ([9.6.3](#));
- j. specific confidentiality requirements ([7.2.6](#));
- k. rules governing any reference to validation/verification, including the use of marks by the validation/verification body or its clients.



## Annex B (informative)

### Terminology of ISO/IEC 17029 related to generic CASCO terms

CASCO generic terms	ISO/IEC 17029
<b>Object of conformity assessment</b>	Claim
<b>Conformity Assessment Body</b>	Validation/Verification Body
<b>Conformity Assessment Scheme</b>	Validation/Verification programme
<b>Statement of conformity</b>	Validation/Verification statement
<b>Selection of conformity assessment</b>	Pre-engagement, engagement and planning
<b>Determination of conformity assessment</b>	Execution, including evidence-gathering
<b>Review of conformity assessment activities</b>	Review
<b>Attestation</b>	Issuance of the validation/verification statement
<b>Surveillance</b>	Not applicable

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- [17] ISO 9001:2015, *Quality management systems — Requirements*
- [18] ISO 19011, *Guidelines for auditing management systems*
- [19] Commission Regulation (EU) No 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council Text with EEA relevance