



# CASCO

*Competency or management system based standards?*

## **Frequently Asked Questions**



# Frequently Asked Questions: Competency based standards vs management system based standards

## **What is the intent of this document?**

In developing ISO deliverables (International Standards, Technical Specifications, etc.) ISO Technical Committees (ISO/TCs) are often required to choose between developing requirements for a management system for an organization's activities or developing requirements for the competence of an organization to carry out its activities. It is very important to ensure that TCs can make an informed decision on the type of standard they will develop. The aim of this publication is to provide assistance to ISO/TCs in understanding:

- the difference between the two types of standards
- the types of activities to which they can apply
- their outcomes when properly implemented



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# 1. Management system

## 1.1 What is a management system?

A management system is a set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives.

For example: a quality management system is a specific set of elements to direct and control an organization with regard to its quality; an environmental management system is used to develop and implement an organization's environmental policy; etc.



## 1.2 What is a management system standard?

A management system standard describes those interrelated or interacting elements that should be implemented for an effective management system. Management system standards may be generic if they are applicable to any organization. For example, ISO 9001 describes the requirements for a quality management system, ISO 14001 describes the requirements for an environmental management system standard. Sector specific standards specify requirements that are applicable to particular sectors such as food, medical devices or automotive industry. Examples are ISO 22000 for food safety management system or ISO 13485 for medical devices. Management system standards are applicable to all organizations, regardless of their type (public, private, not for profit...), their size and the product or service provided.



## 1.3 How do you check if management system requirements are implemented?

Auditing is the key activity to evaluate conformance with the requirements of the management systems standards.

Audits are a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which specified requirements are fulfilled. Audits are used to determine the extent to which the management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the management system and to identify opportunities for improvement.

## 1.4 Who can perform the audits?

Organizations that want to demonstrate that their management system meets the requirements of the relevant management system standard can choose between three approaches. The choice depends on factors such as the level of risk (e.g. health or environment), customer requirements, the level of independence required and regulatory requirements:

- Audits conducted by the organization itself and can form the basis for an organization's self-declaration of conformity (first-party)
- Audits conducted by customers of the organization or by regulatory authority or by other persons on behalf of the customer or regulatory authority (second-party)
- Audits conducted by external independent organizations (third-party). Such organizations, provide independent audits of conformity with requirements of management systems standards. Sometimes such audits will result in certification. Therefore certification is one of the possible options to demonstrate conformity



## 1.5 What are the outcomes of management system certification ?

Management system standards deal with a particular scope of an organization's output and not the organization as a whole. When an organization has applied for certification to one of the management system standard, such as ISO 9001, ISO 14001, etc., it is the management system of the organisation that would be certified and not the organization or its products and services themselves.

For example, for an organization, the certification to ISO 9001 is expected to provide confidence that the organization has a quality management system that conforms to the applicable requirements of ISO 9001 and :

- has established a quality management system that is suitable
- analyzes and understands customer needs and expectations
- ensures that product and service characteristics have been specified in order to meet customer and applicable statutory and regulatory requirements
- has determined and is managing the processes needed to achieve the expected outcomes
- has ensured the availability of resources necessary to support the operation and monitoring of these processes
- monitors and controls the defined product and service characteristics
- aims to prevent nonconformities
- has implemented an effective internal audit and management review process
- is monitoring, measuring and continually improving the effectiveness of its quality management system

## 2. Competency based standards

### 2.1 What are competency based standards?

They are standards that specify the requirements for a body (organization) or person to demonstrate its competence to perform specific activities. Most of these standards are currently for organizations performing conformity assessment activities such as testing, inspection and certification (called conformity assessment bodies). It is essential that conformity assessment bodies be competent to ensure that the outcome of their activities is reliable.



## 2.2 What do competency based standards contain?

These standards specify the requirements that must be implemented for a conformity assessment body to be able to demonstrate that it operates in a competent manner. See table below.

### **Content of a standard for conformity assessment body**

#### **General requirements**

- ▶ Legal and contractual matters
- ▶ Responsibility
- ▶ Management of impartiality
- ▶ Liability and financing

#### **Structural requirements**

- ▶ Organizational structure and top management

#### **Resource requirements**

- ▶ Competence of personnel
- ▶ Determination of competence criteria
- ▶ Evaluation processes

#### **Information requirements**

- ▶ Public information
- ▶ Confidentiality
- ▶ Information on the certification activity and requirements

#### **Process requirements.**

- ▶ Detailed requirements on how to conduct the conformity assessment activity – *audit* for certification bodies, *test* for laboratory and *inspection* for inspection bodies.

#### **Management system requirements**

## 2.3 Why do competency based standards also include management system requirements?

A management system is a system, i.e. a set of elements, that helps an organization to establish policies and objectives and their supporting processes with regard to its operation and, importantly, helps the achievement of those objectives.

The output of a conformity assessment body (e.g. test or inspection results or technical information, usually provided in the form of reports or certificates) must be consistently accurate and reliable for it to be useful. A properly functioning management system provides the enabling infrastructure for the delivery of the output of the conformity assessment body's activities.

## 2.4 Who uses competency based standards and what for?

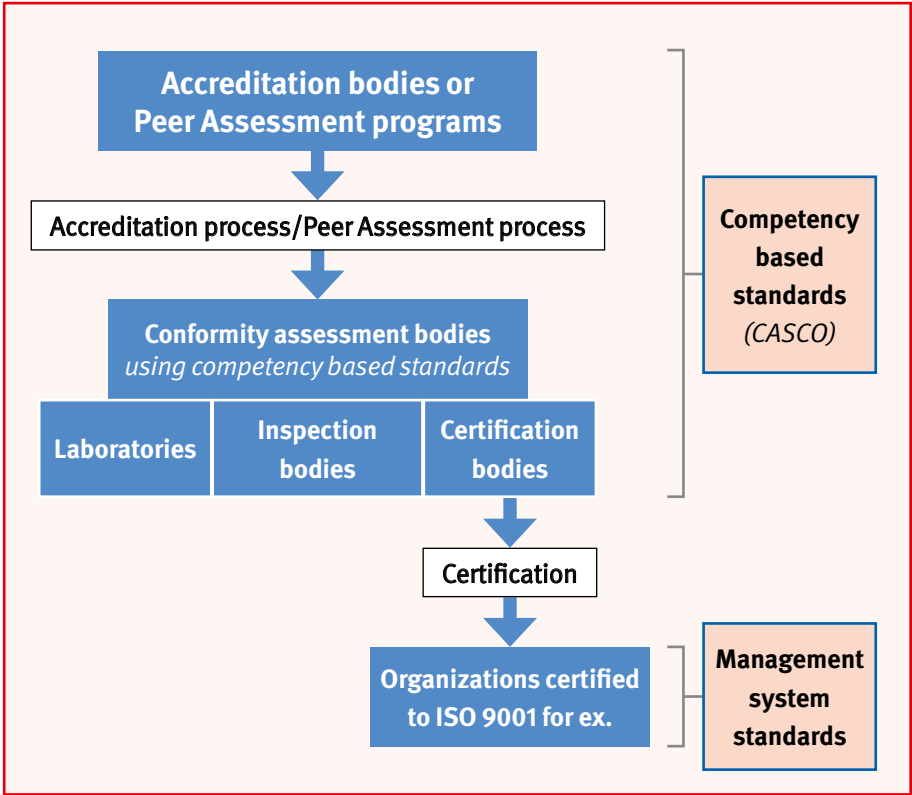
Competency based standards are written for use by conformity assessment bodies (such as laboratories, inspection bodies and certification bodies). They are also used as the basis for assessment criteria by accreditation bodies and in peer assessment programs.

Conformity assessment bodies choose to comply with competency based standards to demonstrate their competence to carry out specific conformity assessment tasks to their customers and to stakeholders such as Regulators.

Conformity assessment bodies can choose to have their conformance with the relevant standard assessed by accreditation bodies or through peer assessment programs.



The box below shows where competency based standards and management system standards apply in the system :



## 2.5 How do you determine that competency requirements are met?

This is achieved by an on-site assessment which has many elements of an audit but also includes a further dimension – a judgement on whether the conformity assessment body is competent to provide its services.

The process to assess the competence of a conformity assessment body is based on the particular standard relevant to the conformity assessment body (e.g. ISO/IEC 17025, ISO/IEC 17021-1, etc.). Assessing the competence of a conformity assessment body involves assessing all aspects of its operations necessary to deliver reliable testing, inspection or certification outcomes, including:

- the competence of the personnel
- the validity of the conformity assessment methodology and conformity assessment results
- the impartiality of the services offered
- the effectiveness of the management system

An assessment thus requires in depth knowledge of the technical and professional aspects of the service provided by the body and assessing these against the requirements provided by the competence based standards.

## 2.6 Who can perform the assessment?

Both accreditation bodies and organizations that provide schemes built on peer assessment undertake competency based assessments.

If the conformity assessment body chooses to be accredited, the assessments are conducted by accreditation bodies which are usually appointed or recognized by national governments and hold an important position in the conformity assessment hierarchy.

The criteria that must be met by accreditation bodies are specified in ISO/IEC 17011, which is also a competency based standard. Accreditation bodies from different economies have formed multilateral arrangements which underpin mutual recognition of the accreditation of conformity assessment bodies. Accreditation bodies that are signatories to these arrangements demonstrate their competence by a process of peer evaluation.

Where it is appropriate to its needs, a conformity assessment body can choose to participate in a sector-specific scheme that may require it to be recognized (qualified) by a peer assessment program.

Within these sector-specific schemes, peer assessment involves the assessment of competence of conformity assessment bodies by other members (i.e. peers) of the same peer assessment program. The basic requirements for peer assessment programs and the peer assessment process are contained in ISO/IEC 17040 (which is also a competency based standard).

Peer assessment programs often involve international conformity assessment schemes where qualification to the scheme requires not only competence (such as assessed by an accreditation process), but also knowledge and application of harmonized testing methodologies, harmonized interpretation of standards and harmonized operational procedures that are all defined in scheme rules.

Peer assessment of these extra dimensions ensures consistent results from all of the conformity assessment bodies, from across the world that participate in the scheme. Consistent results are at the core of multilateral recognition agreements which are often the main goal of international conformity assessment schemes.

## 2.7 What are the outcome and value of accreditation ?

Accreditation provides conformity assessment bodies, their clients and stakeholders with an independent attestation of their competence to perform specific activities. This may, or may not be for all the conformity assessment activities that the body performs. The activities for which accreditation is held are described in a publicly available scope of accreditation.

The scope of accreditation typically describes the type of activities performed, any applicable standards, codes or specifications that apply and where relevant, any limitations to the conformity assessment body's capability. Accreditation enhances the acceptance of the outputs of conformity assessment bodies by regulators, suppliers, purchasers, consumers and other interested parties. Accreditation also contributes to facilitate international trade in goods and services through the international recognition of the outputs from conformity assessment bodies accredited by signatories to international multilateral arrangements. This potentially eliminates the need for exported products to be re-tested, re-inspected or re-certified in the importing economy, thereby reducing costs for manufacturers and importers.





## 2.8 Does a conformity assessment body always need to be accredited?

The need for accreditation depends on many factors. Accreditation is an important risk mitigation tool and the use of accredited conformity assessment bodies is mandated in various sectors in many economies by regulators, specifiers and procurers, particularly in relation to high risk products and services.

Although it is the decision of the conformity assessment body whether it wants to be accredited, the driver is often the expectation of the conformity assessment body's customers.

## 2.9 What are the outcome and value of peer assessment?

Peer assessment is often a condition for membership to an international conformity assessment system or scheme. Achieving admission to such a scheme facilitates recognition of conformity assessment results by the conformity assessment body's peers (i.e. other scheme members) but also by regulators and industry groups in the economies that participate in the scheme, thereby facilitating trade.



## 2.10 Does a conformity assessment body always need to be peer assessed?

Where peer assessment according to ISO/IEC 17040 is a condition of membership to an international conformity assessment system or scheme, a successful peer assessment tells all the other conformity assessment bodies participating in the scheme that they can have confidence in, and recognize the results issued by that conformity assessment body.

This is because peer assessment (in the context of these international schemes) typically assesses the competence to perform specific activities, the knowledge and application of harmonized testing methodology, harmonized interpretation of standards and harmonized operational procedures that are all defined in the international scheme's rules. This ensures that all the conformity assessment bodies that participate in the international scheme perform their work in the same way and therefore achieve consistent results.

### 3. What are the rules for developing these two types of standards, and where to find them ?

The **ISO/IEC Directives Part 1, Annex SL** rules the development of ISO management system standards and contains the “ High level structure, identical core text, common terms and core definitions ” which has to be used.

Indeed, all management system standards shall, in principle, use consistent structure, common text and terminology so that they are easy to use and compatible with each other. More information on ISO management system standards can be seen on **ISO website**.

For the development of competency based standards, ISO/TCs are required by **ISO Directives, Part 2, Clause 33** to consult with the ISO committee on conformity assessment (CASCO). CASCO Secretariat can be reached through **casco@iso.org** and information about CASCO can be found on **ISO website**.

# About **ISO**

ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 163\* national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.

ISO has published more than 21 300\* International Standards and related documents covering almost every industry, from technology to food safety, to agriculture and healthcare.

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