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## **Conformity assessment — Use of management systems — Principles and requirements**

*Évaluation de la conformité — Utilisation des systèmes de  
management — Principes et exigences*



Reference number  
ISO/PAS 17005:2008(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/PAS 17005 was prepared by the ISO *Committee on conformity assessment* (CASCO).

## Introduction

In 2001, the ISO Council asked its policy committee on conformity assessment (CASCO) to study and prepare a group of common elements for application in future ISO documents on conformity assessment. Subsequent to this request, ISO/CASCO approved the formation of Working Group 23, *Common elements in ISO/IEC Standards for conformity assessment activities*, to undertake this task.

The working group has identified several common elements, including among others

- impartiality (ISO/PAS 17001),
- confidentiality (ISO/PAS 17002),
- complaints and appeals (ISO/PAS 17003),
- disclosure of information (ISO/PAS 17004), and
- management systems (ISO/PAS 17005).

This Publicly Available Specification addresses the “management systems” element that occurs in many of the ISO/IEC Guides and International Standards on conformity assessment.

This Publicly Available Specification covers the agreed principles on the inclusion of management system requirements, and also provides requirements clauses intended to be included in future International Standards on conformity assessment.

This Publicly Available Specification is intended to apply to the drafting of documents on conformity assessment by ISO/CASCO.

Clause 4 contains statements that are intended to orientate ISO/CASCO working groups in their task of creating requirements to address management systems in their documents.

The requirements to be inserted into future ISO/CASCO documents that cover the common element of “management systems” are detailed in Clause 5. ISO/CASCO has adopted a common structure for presentation of requirements. Requirements should be grouped under one or more of the following headings:

- a) General requirements;
- b) Structural requirements;
- c) Resource requirements;
- d) Process requirements;
- e) Management system requirements.

As such, each of the common elements will have requirements related to it grouped under one or more of the headings given in a) to e).

This Publicly Available Specification is not intended to become a future International Standard. At the end of three years after the date of publication, it is expected this Publicly Available Specification will be withdrawn and its contents incorporated as appropriate in relevant ISO/CASCO normative and guidance documents.

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# Conformity assessment — Use of management systems — Principles and requirements

## 1 Scope

This Publicly Available Specification specifies principles and requirements for the element of management systems as it relates to standards for conformity assessment.

It is an internal tool for use in the ISO standards development process by ISO/CASCO working groups when considering the element of management systems in preparation of their documents.

This Publicly Available Specification is not intended to be used directly in conformity assessment activities.

## 2 Normative references

The following referenced documents are indispensable for the application 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 apply.

**NOTE** The use of the term “body” in this Publicly Available Specification means either an accreditation body or a conformity assessment body as defined in ISO/IEC 17000.

## 4 Background and principles for writing management system requirements in CASCO documents

### 4.1 General

**4.1.1** Management systems are a recognized tool to support the consistent fulfilment of requirements for bodies and their activities.

**4.1.2** It is recognized that “management system” is a broad term, and can be characterized as being a system to establish policy and objectives and to achieve those objectives (as defined in ISO 9000). A management system can be orientated to cover different needs that are not limited to quality.

**4.1.3** Within CASCO documents, management system requirements may cover any of these needs depending on the scope of the document being developed.

**4.1.4** However, when drafting such requirements, CASCO working groups shall apply the ISO/IEC Directives and the contents of this Publicly Available Specification.

**4.1.5** It is recognized that in some fields specific management system requirements already exist, such as ISO 9001 for quality management systems and ISO 14001 for environmental management systems. CASCO working groups shall not write management system requirements that contradict these established requirements where they exist.

**4.1.6** Within conformity assessment activities, the management system is an internal mechanism to ensure consistent fulfilment of requirements by bodies and their activities. It is generally understood that management systems are integral tools in achieving this fulfilment of requirements. Therefore, CASCO documents may include requirements for management systems as part of their overall requirements related to conformity assessment.

**4.1.7** Assessment of whether a body or activity conforms to requirements may in some cases include assessment of the fulfilment of management system requirements. This occurs when the CASCO requirements include management system requirements.

**4.1.8** Unless fulfilment of all the requirements of a specific management system standard is explicitly included within a set of CASCO requirements, fulfilment of those CASCO requirements shall not be presented as fulfilment of a specific management system standard.

## **4.2 Quality management system requirements in CASCO documents**

**4.2.1** As a basis for writing management system requirements in CASCO documents, it is recognized that an International Standard on quality management systems already exists, i.e. ISO 9001.

**4.2.2** It is possible through definition of applicability provisions within the scope of a quality management system, as allowed for in ISO 9001:2000, Clause 7, for the quality management system to be utilized to ensure the consistent fulfilment of conformity assessment requirements.

**4.2.3** Thus a quality management system that includes such a statement in the scope and fulfils the requirements of ISO 9001 may be used by bodies to ensure that they consistently fulfil conformity assessment requirements (see Annex A for further information).

**4.2.4** Bodies that choose to have a quality management system that fulfils all of the requirements of ISO 9001 shall gain benefit from this fulfilment and be able to use that same quality management system, unless otherwise explicitly specified by the CASCO document, to meet any conformity assessment requirements that cover quality management systems.

## **4.3 Principles for writing management system requirements in CASCO documents**

Taking into consideration the background information specified in 4.1 and 4.2 above, the following principles apply to CASCO working groups when drafting management system requirements in CASCO documents:

- a) wherever a management system is deemed necessary, CASCO documents should include management system requirements;
- b) CASCO documents may recommend the fulfilment of requirements in ISO 9001 for the quality management system, with more detail where needed;
- c) management system requirements in CASCO documents are not intended to conflict with the related requirements in ISO 9001 for quality management systems;
- d) a CASCO document should not state that fulfilment of the requirements of the CASCO document implies the management system requirements of another standard are also fulfilled;
- e) CASCO working groups should not draft requirements that lead to duplicate management systems or induce duplicate management system assessments.



## 5 Requirements for management systems

### 5.1 General

In developing this Publicly Available Specification it was recognized that there are varying degrees of specificity that ISO/CASCO working groups should consider. As a result, the requirements in this clause are categorized into three levels of specificity, as outlined below.

- a) **Obligatory:** these are specific requirements that shall be used by ISO/CASCO working groups where the element shall be addressed, without modification, except for substitution of more specific terms.

**EXAMPLE** The phrase “Conformity assessment activities shall be undertaken impartially” can be replaced with the more specific phrase “Management system certification activities shall be undertaken impartially”.

Justification is required from ISO/CASCO working groups that do not use these requirements when dealing with the relevant common element.

- b) **Recommended:** these are requirements that working groups should use if they wish to have a greater degree of specification. Modification is permissible.
- c) **Suggested:** these are considerations that could be taken into account in the drafting of documents by the ISO/CASCO working groups.

By providing for these different levels of specificity, this Publicly Available Specification achieves the ISO/CASCO intent to have an agreed statement on elements that are common to all conformity assessment activities, and at the same time maintains some flexibility for specific wording by individual ISO/CASCO working groups.

As an aid to CASCO working groups, in 5.2 below, the text contained in boxes indicates the text that they shall either use (obligatory requirements) or otherwise incorporate (recommended requirements) in future International Standards; the rest of the text is explanatory in nature.

### 5.2 Obligatory requirements

**5.2.1** The 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 <insert correct description; e.g. International Standard>. In addition to meeting the requirements of clauses <insert the relevant clauses of the International Standard in question> the body shall implement a management system in accordance with 5.2.4 (option A) or with 5.2.5 (option B).

**5.2.2** The ISO/CASCO working groups shall elaborate clauses covering the aspects listed below.

The body shall

- a) identify the processes needed for the management system and their application throughout the body,
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the body in accordance with the requirements of this <insert correct description; e.g. International Standard>.

NOTE Processes needed for the management system referred to above can include processes for management activities, provision of resources and other conformity assessment processes.

**5.2.3** Where a body chooses to outsource any process that affects conformity with requirements, the body shall ensure control over such processes. Control of such outsourced processes shall be identified within the management system.

**5.2.4 (Option A)** As a minimum, the management system of the body shall address the following:

- management system manual, including policies and responsibilities;
- control of documents;
- control of records;
- management review;
- internal audits;
- corrective actions;
- preventive actions;
- complaints and appeals (ISO/PAS 17003).

**5.2.5 (Option B)** A 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 <insert correct description, e.g. International Standard>, fulfils at least the management system section requirements.

NOTE 1 CASCO working groups can add an informative annex showing the correspondence between ISO 9001 and this <insert correct description, e.g. International Standard> by stating:

- a) which clauses of ISO 9001 apply directly;
- b) which clauses of ISO 9001 are amplified by clauses of this <insert correct description, e.g. International Standard>;
- c) which clauses of ISO 9001 are met by clauses of this <insert correct description, e.g. International Standard>.

NOTE 2 Annex A of this Publicly Available Specification can assist in formulating such an informative annex.

### **5.3 Recommended requirements**

Any individual clause of ISO 9001 (see Annex A).

## Annex A (informative)

### Applying ISO 9001 requirements as management system requirements to ensure ongoing fulfilment of ISO/CASCO standards by accreditation bodies and conformity assessment bodies

Conformity assessment bodies and accreditation bodies may establish quality management systems in accordance with ISO 9001. ISO 9001 has been widely utilized as an effective set of requirements for quality management systems. The use of ISO 9001 as a source of requirements for a management system to systematically ensure ongoing fulfilment of ISO/CASCO requirements may provide significant benefits, such as

- lower costs for bodies that have already implemented ISO 9001 quality management systems, and
- proven effectiveness to systematically ensure ongoing fulfilment of ISO/CASCO requirements.

The requirements of ISO 9001 were not written for the specialized situation of a management system to ensure ongoing fulfilment of ISO/CASCO standards. Special considerations are needed when applying ISO 9001 requirements in this situation. ISO/CASCO Working Groups are advised that the meaning of ISO 9001 text in this specialized situation is not always clear and additional detail may be needed. In addition, there can be requirements in ISO/CASCO standards that directly fulfil ISO 9001 requirements for this specialized situation.

Table A.2 provides guidance for ISO/CASCO Working Groups on recommending ISO 9001 as a management system to ensure the ongoing fulfilment of ISO/CASCO requirements. Clauses not listed in Table A.2 can be directly applied to management systems to ensure ongoing fulfilment of ISO/CASCO standards. Clauses that are listed can be understood to apply in the way explained in the corresponding ISO/CASCO requirement column. Conformity assessment bodies and accreditation bodies may choose, in addition to applying the explanations provided in the ISO/CASCO requirement column, to apply the ISO 9001 clauses directly. Furthermore, conformity assessment bodies and accreditation bodies may choose to use its management system to consistently achieve other objectives in addition to meeting the ISO/CASCO requirements. There is no expectation that two or more management systems need to be maintained by the conformity assessment body or accreditation body.

The extensive nature of Table A.2 shows the significant difference between a quality management system and a management system in ensuring ongoing fulfilment of ISO/CASCO standards, and hence also shows the significant difference between certification of a quality management system and accreditation (or other form of recognition) based on an ISO/CASCO standard. However, a single management system can be developed to address both quality and the ongoing fulfilment of ISO/CASCO requirements. Special care should be taken when applying ISO 9001 as a source of requirements to ensure ongoing fulfilment of ISO/CASCO requirements.

Table A.1 describes the special aspects of ISO/CASCO requirements, for which ongoing fulfilment needs to be ensured, compared to “customer and applicable regulatory requirements” (see ISO 9001:2000, 1.1).

Table A.1

ISO 9001 customer requirements	ISO/CASCO requirements
Subject to legal requirements, organizations have the freedom to design their management system in order to best serve their own and their customer's needs.	In addition to legal requirements, bodies must design their management system to conform to the requirements within the ISO/CASCO documents.
Customers and regulatory authorities by definition have expertise regarding requirements for products (requirements are their stated or implied needs/expectations).	Expertise regarding ISO/CASCO documents does not necessarily exist within those entities who expect fulfilment of requirements therein.
Requirements are for "products" (the results of a process). The organization decides what processes and organizational structures, resources and characteristics are needed to produce the product.	Requirements are primarily for conformity assessment processes and the body that performs the process. These requirements are set by ISO/CASCO documents, not the body. There are only a few requirements in CASCO documents for the product (the output of the conformity assessment process – the attestation, see ISO/IEC 17000).

As a result of the above differences, the additional information given in Table A.2 is provided regarding specific clauses within ISO 9001:2000 when they are applied as requirements to ensure ongoing fulfilment of ISO/CASCO requirements for accreditation bodies and conformity assessment bodies. ISO 9001 clauses not mentioned are assumed to apply directly.

Table A.2

ISO 9001:2000		Comment on application of the ISO 9001 (sub)clause for use as part of the management system requirements in ISO/CASCO documents
(sub)clause	heading	
1.1, bullet a)	Scope	The scope is to consistently fulfil ISO/CASCO requirements, whether customers and regulatory authorities demand this or not.
1.1, bullet b)		The aim is to fulfil ISO/CASCO requirements regardless of the extent to which this enhances the satisfaction of any external entity.
1.2	Application	The notes in this table provide guidance on the application of exclusions for ISO 9001:2000 requirements in this specialized situation.
2	Normative references	Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement – the Normative references (ISO/IEC 17000 in particular) within ISO/CASCO documents take precedence and shall be used.
3	Terms and definitions	Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement – ISO/IEC 17000 provides terms and definitions for ISO/CASCO documents. Throughout, the term "organization" means the accreditation body or conformity assessment body.
4	Quality management system	Throughout all of ISO 9001:2000, all references to "quality management system" mean "management system to ensure ongoing fulfilment of ISO/CASCO requirements".

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Table A.2 (continued)

ISO 9001:2000		Comment on application of the ISO 9001 (sub)clause for use as part of the management system requirements in ISO/CASCO documents
(sub)clause	heading	
4.1, para. 2, bullet a)	General requirements	Throughout all of ISO 9001:2000, only those processes impacted by ISO/CASCO requirements are included. Any ISO/CASCO requirements for processes shall be fulfilled. Bodies cannot deviate from those processes specified in ISO/CASCO requirements, however the body may use its management system to consistently achieve other objectives in addition to meeting the ISO/CASCO requirements.
4.1, para. 2, bullet b)		Any ISO/CASCO requirements for sequence and interactions of processes shall be fulfilled – bodies cannot identify sequence and interactions of processes different from those in ISO/CASCO requirements.
4.1, para. 2, bullet c)		Bodies shall also determine how the management system fulfils organizational and other ISO/CASCO requirements not related to processes. The management system's fulfilment of such requirements shall also be controlled and effective.
4.1, para. 2, bullet e)		Measurement of processes required by ISO/CASCO documents is assumed to mean measurement of the inputs or outputs of processes. However, inputs and outputs of such processes within accreditation bodies and conformity assessment bodies may not be measurable. In these cases, however, they can be monitored and analyzed in a general way.
4.1, para. 2, bullet f)		The actions necessary are those for the achievement and ongoing fulfilment of ISO/CASCO requirements.
4.1, para. 2, bullet f)		Continual improvement means reducing the severity or frequency of failures to fulfil ISO/CASCO requirements.
4.1, para. 3		This table shall also be considered as well as any specific requirements in an ISO/CASCO document.
4.1, para. 4		ISO/CASCO documents frequently set more specific requirements for managing the “outsourcing” of processes. Only processes impacted by ISO/CASCO requirements need be considered.
4.2.1, bullet a)	Documentation requirements	The quality policy and objectives needed relate to fulfilment of ISO/CASCO requirements. Objectives may or may not be measurable.
4.2.1, bullet b)		A manual is required for the management system to ensure ongoing fulfilment of the ISO/CASCO requirements.
4.2.1, bullet c)		Also, any documented procedures required by ISO/CASCO requirements.
4.2.1, bullet d)		Also, any documents needed regarding fulfilment of organizational and other ISO/CASCO requirements not related to processes.
4.2.1, bullet e)		Only records associated with ISO/CASCO requirements. Also, any records required by ISO/CASCO requirements.
4.2.2	Quality manual	Throughout all of ISO 9001:2000, replace the concept of “quality” with the concept of “fulfilment of ISO/CASCO requirements”.
4.2.2, bullet a)		The scope of the quality manual is the fulfilment of ISO/CASCO requirements.
4.2.2, bullet b)		Includes any documented procedures specifically required by ISO/CASCO requirements.
4.2.2, bullet c)		Any ISO/CASCO requirements for interactions of processes shall be fulfilled – bodies cannot identify interactions of processes different from those in ISO/CASCO requirements.
4.2.4	Control of records	Records are only those related to providing evidence of fulfilment of all ISO/CASCO requirements.

Table A.2 (continued)

ISO 9001:2000		Comment on application of the ISO 9001 (sub)clause for use as part of the management system requirements in ISO/CASCO documents
(sub)clause	heading	
5.1	Management responsibility — Management commitment	The commitment of top management is required to the ongoing fulfilment of ISO/CASCO requirements.
5.1, bullet a)		The required communication shall address the importance of fulfilment of ISO/CASCO requirements.
5.1, bullet b)		The required policy is for fulfilment of ISO/CASCO requirements.
5.2	Customer focus	Top management shall ensure fulfilment of ISO/CASCO requirements regardless of the extent to which this enhances the satisfaction of any external entity.
5.3, bullet a)	Quality policy	The purpose should include the fulfilment of ISO/CASCO requirements.
5.3, bullet b)		Commitment is to ongoing fulfilment of ISO/CASCO requirements.
5.4.1	Planning — Quality objectives	Some objectives (for fulfilment of ISO/CASCO requirements) may not be measurable based on the nature of conformity assessment.
5.5.2, bullet a)	Responsibility, authority and communication — Management representative	Also, ensuring that the fulfilment of organizational and other ISO/CASCO requirements not related to processes is established, implemented and maintained.
5.5.2, bullet c)		The requirement is ensuring promotion and awareness of ISO/CASCO requirements.
5.6.2, bullet b)	Management review input	Any external feedback related to ISO/CASCO requirements shall be considered.
5.6.2, bullet c)		Process performance and fulfilment of ISO/CASCO requirements.
5.6.3, bullet a)	Management review output	“Improvement” means improvement of the ability to identify and resolve problems with fulfilment of ISO/CASCO requirements.
5.6.3, bullet b)		“Improvement” is not applicable – it can be assumed to mean ongoing improvement in fulfilment of ISO/CASCO requirements.
6.1	Resource management — Provision of resources	Any ISO/CASCO resource requirements shall be fulfilled.
6.1, bullet b)		Resources are needed for the fulfilment of ISO/CASCO requirements regardless of the extent to which this enhances the satisfaction of any external entity.
6.2	Human resources	Human resources are those related to activities impacted by ISO/CASCO requirements. Any ISO/CASCO requirements for human resources shall be fulfilled. ISO/CASCO standards commonly provide requirements for human resources.
6.3	Infrastructure	Infrastructure shall support fulfilment of ISO/CASCO requirements. Any ISO/CASCO infrastructure requirements shall be fulfilled.
6.4	Work environment	Work environment shall support fulfilment of ISO/CASCO requirements.
7	Product realization	In this section, “product realization” means the design of conformity assessment activities (or changes to those designs) that fulfil ISO/CASCO requirements. These requirements are not applicable when another entity designs the conformity assessment activities (e.g. when the conformity assessment body operates a conformity assessment system or scheme controlled by an external entity).

Table A.2 (continued)

ISO 9001:2000		Comment on application of the ISO 9001 (sub)clause for use as part of the management system requirements in ISO/CASCO documents
(sub)clause	heading	
7.1, bullet a)	Planning of product realization	The "requirements for the product" are ISO/CASCO requirements.
7.1, bullet b)		The "product" is replaced with fulfilment of ISO/CASCO requirements.
7.1, bullet c)		Bodies cannot deviate from those processes specified in ISO/CASCO requirements. However, if not included in the ISO/CASCO requirement document, the body may determine their own.
7.1, bullet d)		Records that the design meets the ISO/CASCO requirements are the documents required for the conformity assessment activity.
7.1, para. 3		The body shall meet any ISO/CASCO requirements for documents related to the conformity assessment activity.
7.2.1	Customer-related processes — Determination of requirements related to the product	Only ISO/CASCO requirements are relevant. Therefore, no specific activities are needed to identify requirements.
7.2.2, paras. 1 to 3	Review of requirements related to the product	The body shall review ISO/CASCO requirements. Evidence of this review are the processes, documents, organizational characteristics and other evidence of fulfilment of ISO/CASCO requirements. In other words, evidence of fulfilment of ISO/CASCO requirements is <i>prima facie</i> evidence that ISO/CASCO requirements were reviewed.
7.2.2, para. 4		"Product requirements" are ISO/CASCO requirements.
7.2.3	Customer communication	ISO/CASCO standards commonly require interaction with stakeholders to protect the impartiality of designs of conformity assessment activities.
7.2.3, para. 1, bullets a), b)		Customer communication is only required with those parties who express an interest in the fulfilment of ISO/CASCO requirements and only to an extent commensurate with the level of that external interest.
7.2.3, bullet c)		Only applies to feedback/complaints related to ISO/CASCO requirements. ISO/CASCO standards commonly include requirements for complaints and appeals which shall be fulfilled.
7.3	Design and development	Design and development means the design of a conformity assessment activity that fulfils ISO/CASCO requirements. Requirements in 7.3.1 to 7.3.6 are not applicable if the conformity assessment activity to which the ISO/CASCO requirements are being applied has already been designed.
7.3.2	Design and development inputs	ISO/CASCO requirements are the only relevant design inputs.
7.3.3	Design and development outputs	Design outputs are the processes, documents, organizational characteristics and other evidence of fulfilment of ISO/CASCO requirements.
7.3.5	Design and development verification	ISO/CASCO requirements are the only relevant design inputs.
7.3.6	Design and development validation	The design verification from 7.3.5 is also the design validation.
7.3.7	Control of design and development changes	There is no need for "evaluation of the effect of the changes on ..... product already delivered" in the context of conformity assessment activities.

Table A.2 (continued)

ISO 9001:2000		Comment on application of the ISO 9001 (sub)clause for use as part of the management system requirements in ISO/CASCO documents
(sub)clause	heading	
7.4	Purchasing	Requirements apply only to purchased products that can have an impact on the fulfilment of ISO/CASCO requirements.
7.5.1, bullet a)	Control of production and service provision	Only information related to performance of conformity assessment activities as required by ISO/CASCO requirements.
7.5.1, bullet f)		ISO/CASCO standards commonly provide these requirements directly. There is no "post delivery service" in the context of conformity assessment activities.
7.5.1, bullet f)		The review and attestation function activities and any surveillance activities (see ISO/IEC 17000).
7.5.2	Validation of processes for production and service provision	Many conformity assessment processes cannot be measured and, thus, shall be validated. The phrase "..... the ability of these processes to achieve planned results" means fulfilment of ISO/CASCO requirements.
7.5.2, bullets a) to e)		ISO/CASCO standards commonly set these requirements that are the arrangements that processes shall meet. Bodies cannot establish requirements different from those in ISO/CASCO documents.
7.5.3	Identification and traceability	Only ISO/CASCO requirements are relevant. "Where appropriate" means when established by ISO/CASCO requirements. Product means each instance of use of the conformity assessment system/scheme for an object of conformity.
7.5.4	Customer property	Only applicable if related ISO/CASCO requirements exist. In many forms of conformity assessment, physical product samples are routinely damaged and destroyed.
7.5.5	Preservation of product	Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement. ISO/CASCO standards will define any requirements for preserving fulfilment of ISO/CASCO requirements during any instance of a conformity assessment system/scheme for an object of conformity.
7.6	Control of monitoring and measuring devices	Only requirements for monitoring and measuring the performance of conformity assessment set by ISO/CASCO requirements (for the review and attestation function) are relevant. ISO/CASCO documents, not the body (nor ISO 9001:2000), determine processes and actions to be undertaken.
8.1	Measurement, analysis and improvement	Measurement of fulfilment of ISO/CASCO requirements is usually not possible. However, fulfilment of ISO/CASCO requirements can be monitored and analyzed. "Improvement" is not applicable – it can be assumed to mean ongoing fulfilment of ISO/CASCO requirements.
8.1, bullet a)		"Conformity of the product" means fulfilment of ISO/CASCO requirements.
8.1, bullet c)		"Improvement" means improvement of the ability to identify and resolve problems with fulfilment of ISO/CASCO requirements.
8.2.1	Monitoring and measurement — Customer satisfaction	Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement – ISO/CASCO requirements are independent of external entities. Only ISO/CASCO requirements for feedback from external entities are relevant.
8.2.2, bullet a)	Internal audit	Compliance with ISO 9001:2000 as further clarified by this table and the ISO/CASCO standard.
8.2.2, para. 2		Internal audits address only ISO/CASCO requirements. The "status and importance" of what to audit will be determined by the importance of the related ISO/CASCO requirements.



Table A.2 (continued)

ISO 9001:2000		Comment on application of the ISO 9001 (sub)clause for use as part of the management system requirements in ISO/CASCO documents
(sub)clause	heading	
8.2.3	Monitoring and measurement of processes	ISO/CASCO requirements, not the body, will commonly establish the methods for "monitoring and, where applicable, measurement of the quality management system processes".
8.2.4, para. 1	Monitoring and measurement of product	ISO/CASCO requirements, not the body, shall commonly establish the means to "monitor and measure the characteristics" of the conformity assessment activities for fulfilment of ISO/CASCO requirements.
8.2.4, para. 2		"Acceptance criteria" are ISO/CASCO requirements. ISO/CASCO requirements, not the body, shall establish requirements for "authorizing release of the" attestation (see ISO/IEC 17000).
8.2.4, para. 3		Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement. Only ISO/CASCO requirements are relevant.
8.3	Control of nonconforming product	Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement. ISO/CASCO documents commonly set requirements for bodies when conformity assessment activities have not met ISO/CASCO requirements, including situations where attestation as been made but fulfilment of requirements has not been adequately demonstrated.
8.4	Analysis of data	Data may not be available as the fulfilment of ISO/CASCO requirements is usually not quantifiable. However, qualitative information can be gathered. "Improvement" means improvement of the ability to identify and resolve problems with fulfilment of ISO/CASCO requirements.
8.4, bullet a)		Fulfilment of this ISO 9001 requirement shall be achieved through fulfilment of the specific ISO/CASCO requirement. Information about the fulfilment of ISO/CASCO requirements provides no information about customer satisfaction.
8.4, bullet b)		This means fulfilment of ISO/CASCO requirements.
8.4, bullet c)		"Products and processes" means processes, organizational characteristics and other elements of bodies impacted by ISO/CASCO requirements.
8.4, bullet d)		Only those suppliers who provide goods and services impacting fulfilment of ISO/CASCO requirements.
8.5.1	Continual improvement	Throughout, "improve the effectiveness of the quality management system" means improvement of the ability to identify and resolve problems with fulfilment of ISO/CASCO requirements.
8.5.2	Corrective action	"Nonconformities" mean lack of fulfilment of ISO/CASCO requirements.
8.5.2, bullet a)		Only complaints related to ISO/CASCO requirements are relevant.
8.5.3	Preventive action	"Nonconformities" mean lack of fulfilment of ISO/CASCO requirements.

## Bibliography

- [1] ISO 9000, *Quality management systems — Fundamentals and vocabulary*
- [2] ISO 9001:2000, *Quality management systems — Requirements*
- [3] ISO 14001, *Environmental management systems — Requirements with guidance for use*
- [4] ISO/PAS 17001, *Conformity assessment — Impartiality — Principles and requirements*
- [5] ISO/PAS 17002, *Conformity assessment — Confidentiality — Principles and requirements*
- [6] ISO/PAS 17003, *Conformity assessment — Complaints and appeals — Principles and requirements*
- [7] ISO/PAS 17004, *Conformity assessment — Disclosure of information — Principles and requirements*

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