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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

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Contents

Page

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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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.

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).

