Quality management systems — Guidance and criteria for the development of documents to meet needs of specific product and industry/economic sectors

1 Introduction

This ISO/TC 176 document provides guidance on the implementation of the ISO/IEC policy for the development of quality management system requirements documents and related guidance documents, for specific product and industry/economic sectors. It also provides guidance on the development of sector-specific documents based on ISO 9004:2000, Quality management systems — Guidelines for performance improvements.

The objective of the policy and this guidance is as follows:

a) to ensure that an ISO, ISO/IEC or IEC committee’s approach to sector quality management system documents continues to facilitate trade by contributing to the elimination of non-tariff barriers;

b) to maintain the integrity of the “generic” ISO 9000 standards and to encourage greater use of the ISO 9001 standard as the basis for all quality management system requirements;

c) to provide a mechanism for ISO to respond effectively to sector needs;

d) to establish a fair and common sector approach which builds on the ISO 9000 standards;

e) to minimize the proliferation of quality management system standards within industry;

f) to facilitate further harmonization of sector quality management system documents;

g) to increase customer and supplier confidence in the implementation of quality management systems;

h) to promote greater integrity and consistency in the conformity assessment of quality management systems.

This document provides criteria to enable the determination of the need for sector-specific quality management system documents based on the ISO 9000 family of standards. It also provides guidance on the preferred methodology for the development of sector documents.

The sector policy and guidance is intended to be consistent with, and complementary to, the relevant ISO/IEC Directives and related Guides. This guidance document will be updated subject to further adjustments of such documents, in particular draft ISO Guide 72, Guidelines for the justification and development of management systems standards.

2 Normative references

ISO 704:1987, Principles and methods of terminology

ISO 9000:2000, Quality management systems — Fundamentals and vocabulary
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ISO 9001:2000, *Quality management systems — Requirements*


3 Definitions

To be developed if needed.

4 Applicability

This guidance document is primarily intended for use by ISO, ISO/IEC and IEC committees and their established liaison organizations. It may also be used by non-ISO and non-IEC organizations to assist in rationalizing the need for sector documents which contain requirements or guidance for quality management systems.

ISO/TC 176 recommends strongly that ISO, ISO/IEC and IEC committees, and non-ISO and non-IEC organizations, considering the preparation of documents containing requirements or guidance for quality management systems, establish liaison status with ISO/TC 176. The establishment of liaison status will permit ISO/TC 176 to provide advice and guidance during document development and endorsement (if appropriate) of the published document.

ISO 9001:2000 and ISO 9004:2000 are the normative documents for requirements and guidance respectively in the field of quality management systems. In this sector document it is assumed that sector-specific documents will be based on these standards.


5 Sector policy

The sector policy is as follows. This text is reproduced in the ISO/IEC Directives, Part 2, 2001, 6.8.1.

When an ISO or IEC committee wishes to develop quality management system requirements or guidance for a particular product or industry/economic sector it shall respect the following rules.

a) Normative reference shall be made to ISO 9001:2000 in its entirety or, subject to the “applicability” provisions detailed in the scope of ISO 9001:2000, to its clauses or subclauses. Alternatively, subject to the “applicability” provisions detailed in the scope of ISO 9001:2000, the clauses or subclauses may be reproduced verbatim.

b) If text from ISO 9001:2000 is reproduced in the sector document, it shall be distinguished from the other elements of the sector document [see d)].

c) Terms and definitions specified in ISO 9000:2000 shall be referred to in a normative manner or reproduced verbatim.

d) The guidance and criteria provided in *Quality management systems — Guidance and criteria for the development of documents to meet needs of specific product and industry/economic sectors*, approved by ISO/TC 176, shall be considered not only when determining the need for a sector-specific requirements or guidance document but also in the document development process.

6 Sector document development process

6.1 Establishing the need

ISO 9001:2000, Quality management systems — Requirements, has been specifically developed to be applicable to any type of generic product (hardware, software, services and processed material), to be applied by any size of organization and to be suitable for implementation by any industry/economic sector.

ISO 9004:2000 also has general applicability as guidance for performance improvement.

One of the ISO/TC 176 key strategies concerns minimizing the proliferation of standards in the field of quality management:

“supporting where needed, the development of supplementary standardization-related products that are compatible with, and do not detract from, dilute, or modify the requirements of the generic ISO/TC 176 standards”

This key strategy recognizes that some product or industry/economic sectors may need particular additional quality management system requirements or guidance specific to the sector, e.g.

1. specific management system requirements to meet regulations or laws, such as public safety, and
2. more explicit requirements or guidance based on sector-established best practice or documented Codes of Practice.

In order to determine whether a sector document is needed which adds particular requirements or provides sector-specific guidance to the generic ISO 9001:2000 and ISO 9004:2000 standards, the sector group should consider the following.

1. Are there sector-specific statutory requirements relevant to quality management (e.g. personnel or public safety) which must be referenced or included?
2. Does the sector have a particular terminology\(^2\) which must be used to facilitate understanding of the generic ISO 9001 and ISO 9004 standards?
3. Is there an established sector best practice or Code of Practice that needs to be reflected for effective implementation of the generic ISO 9001 and ISO 9004 standards?
4. If the proposed sector-particular requirements or guidance document results in suppliers in the sector establishing and implementing multiple quality management systems, is this consequence unavoidable?

\(^2\) “particular terminology” means specific terms in common use in the sector. It does not include sector preferences for a different form of wording from that used in the generic standards.
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5. If the proposed sector-particular requirements or guidance document results in the need to develop
   • new quality management system certification schemes or
   • schemes or criteria for accreditation of certification bodies or
   • quality management system auditor training and qualification requirements
   are such consequences unavoidable?

If the answer to one or more of these questions is affirmative, the need to develop a sector-specific document is established in principle. Committees wishing to produce a sector-specific quality management system document should proceed to develop a proposal as described in 6.2.

6.2 Procedure for development of a sector document

In addition to the requirements of the ISO/IEC Directives, Part 1, 2001, Annex C, Justification of proposals for the establishment of standards, and relevant ISO guidance, a proposal to develop a sector document, including (when required), a New Work Item Proposal for a quality management system sector document should also address the following:

a) indication of how the sector stakeholders would be adequately represented during working level development of the sector quality management system document;

b) provision of details concerning any intellectual property arrangement between ISO or IEC, their member bodies and the associated sector organization(s) for the resulting sector document;

c) indication of the relationship of the sector with ISO/CASCO and the International Accreditation Forum (IAF) during both the sector document’s development and implementation;

d) where necessary, inclusion of details concerning sector plans for any certification or accreditation requirements or schemes that supplement the guidance in ISO/IEC Guide 61 and ISO/IEC Guide 62;

e) provision of information concerning sector plans for any auditor training or qualification requirements.

Prior to the development of a proposal, the applicant should consult with ISO/TC 176 on the need and rationale for a sector document. ISO/TC 176 will consider the proposals and examine the possibility of other sectors with similar needs (e.g., production of harmonized documents that could meet the needs of more than one sector). ISO/TC 176 will advise the sector group of its conclusions.

The sector group should establish clear channels of communication and liaison between all stakeholders, including ISO/TC 176 and others as appropriate, such as ISO/CASCO and the International Accreditation Forum (IAF).

ISO/TC 176 should be included in the process of commenting on drafts of sector documents. It is recommended that members of the sector group be involved in language translations and interpretations of the final sector document.

6.3 of this sector policy provides a guide to sector groups in the drafting process of sector documents.

6.3 Drafting

6.3.1 Drafting may include expert assistance from ISO/TC 176.
6.3.2 Sector-particular requirements documents should be explicit and unambiguous, realistically achievable and not dependent on further guidance documents for a proper understanding of the sector expectations.

6.3.3 In accordance with this sector policy, sector-specific requirements documents based on ISO 9001 must reference the clauses or subclauses of ISO 9001 (see, for example, ISO 13485) or reproduce the requirements clauses or subclauses fully, except where not applicable as allowed by the “applicability” provisions detailed in the scope of ISO 9001:2000. Note that ISO copyright considerations need be taken into account for non-ISO groups. Additional particular requirements or guidance to the ISO 9001 text should be identified clearly (see, for example, ISO/TS 16949).

6.3.4 The terminology specified in ISO 9000:2000 shall be referenced for generic concepts. Sector-specific terminology should be derived from generic concepts (wherever practicable) in accordance with ISO/TC 37 guidance standards such as ISO 704.

6.3.5 If sector-specific particular requirements or guidance detract from or dilute the generic requirements of ISO 9001:2000, e.g. a requirement is not needed or is necessarily different to meet a regulatory application, the sector-specific document should show clearly that conformity with ISO 9001 cannot be claimed by a user of the sector document.

6.3.6 Sector-specific guidance should not to be written in a form such that it could be used by second or third parties to measure conformity with requirements. For example, avoid using the term “shall”.

6.3.7 Quality management system documents should not include specifications of requirements for products or processes.

7 Examples of sector text conforming to this sector policy


4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 1 Guidance on quality manuals is given in ISO 10013.

NOTE 2 All the quality system documents should be controlled. See Figure 2.
4.2.3 Quality planning

The requirements given in 4.2.3 of ISO 9001:1994 apply.

Particular requirement for all medical devices:

The supplier shall establish and maintain a file containing documents defining product specifications and quality system requirements (process and quality assurance) for:

- complete manufacturing, and
- installation and servicing, if appropriate,

for each type/model of medical device, or referring to the location(s) of this information (see 4.5.2 and 4.16).