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Secretariat of ISO/TC 176/SC 2

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ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2008

In conjunction with the publication of the International Standard ISO 9001:2008, ISO/TC 176/SC 2 has published a number of guidance modules:

- Guidance on ISO 9001:2008 Sub-clause 1.2 'Application'
- Guidance on the Documentation requirements of ISO 9001:2008
- Guidance on the Terminology used in ISO 9001 and ISO 9004
- Guidance on the Concept and Use of the Process Approach for management systems
- Guidance on 'Outsourced Processes'

Together these are being made available as the ISO/TC 176/SC 2 "ISO 9000 Introduction and Support Package".

Feedback from users of the standards will be used to determine whether additional modules should be developed, or if these published modules should be revised.

The modules, and further information on the ISO 9001:2008 standard, may be downloaded from the following web sites:

www.iso.org
www.iso.org/tc176/sc2

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ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2008

1 Introduction

Two of the most important objectives in the revision of the ISO 9000 series of standards have been

- a) to develop a simplified set of standards that will be equally applicable to small as well as medium and large organizations, and
- b) for the amount and detail of documentation required to be more relevant to the desired results of the organization's process activities.

ISO 9001:2008 *Quality management systems – Requirements* has achieved these objectives, and the purpose of this additional guidance is to explain the intent of the new standard with specific regard to documentation.

ISO 9001:2008 allows an organization flexibility in the way it chooses to document its quality management system (QMS). This enables each individual organization to develop the minimum amount of documentation needed in order to demonstrate the effective planning, operation and control of its processes and the implementation and continual improvement of the effectiveness of its QMS.

It is stressed that ISO 9001 requires (and always *has* required) a “*Documented quality management system*”, and not a “*system of documents*”.

2 What is a “document”? - Definitions and references

The following are some of the main objectives of an organization's documentation, independent of whether or not it has implemented a formal QMS;

- a) Communication of Information
 - as a tool for information transmission and communication. The type and extent of the documentation will depend on the nature of the organization's products and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.
- b) Evidence of conformity
 - provision of evidence that what was planned, has actually been done.
- c) Knowledge sharing
 - to disseminate and preserve the organization's experiences. A typical example would be a technical specification, which can be used as a base for design and development of a new product.

A list of commonly used terms relating to documentation is presented in Annex A (taken from ISO 9000:2005). It must be stressed that, according to ISO 9001:2008 clause 4.2 *Documentation requirements* documents may be in any form or type of medium, and the definition of “document” in ISO 9000:2005 clause 3.7.2 gives the following examples:

- paper
- magnetic
- electronic or optical computer disc
- photograph
- master sample

Users are also referred to ISO/TR 10013 *Guidelines for quality management systems documentation* for further guidance.

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3 ISO 9001:2008 Documentation Requirements

ISO 9001:2008 clause 4.1 *General requirements* requires an organization to “establish, *document*, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard”

Clause 4.2.1 *General* explains that the quality management system documentation *shall* include:

- a) documented statements of a quality policy and quality objectives;
- b) a quality manual
- c) documented procedures required by this International Standard
- d) documents needed *by the organization* to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard;

The notes after Clause 4.2 make it clear that where the standard specifically requires a “documented procedure”, the procedure has to be established, documented, implemented and maintained. It also emphasizes that the extent of the QMS documentation may differ from one organization to another due to:

- the size of organization and type of activities;
- the complexity of processes and their interactions, and
- the competence of personnel.

All the documents that form part of the QMS have to be controlled in accordance with clause 4.2.3 of ISO 9001:2008, or, for the particular case of records, according to clause 4.2.4.

4 Guidance on Clause 4.2 of ISO 9001:2008

The following comments are intended to assist users of ISO 9001:2008 in understanding the intent of the general documentation requirements of the International Standard.

- a) Documented statements of a quality policy and objectives:
 - Requirements for the quality policy are defined in clause 5.3 of ISO 9001:2008. The documented quality policy has to be controlled according to the requirements of clause 4.2.3.
Note Organizations that are revising their quality policy for the first time, or in order to meet the amended requirements in ISO 9001:2008, should pay particular attention to clause 4.2.3 (c), (d) and (g).
 - Requirements for quality objectives are defined in clause 5.4.1 of ISO 9001:2008. These documented quality objectives are also subject to the document control requirements of clause 4.2.3.
- b) Quality Manual:
 - Clause 4.2.2 of ISO 9001:2008 specifies the minimum content for a quality manual. The format and structure of the manual is a decision for each organization, and will depend on the organization’s size, culture and complexity. Some organizations may choose to use the quality manual for other purposes besides that of simply documenting the QMS
 - A small organization may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by the standard.
 - Large, multi-national organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.
 - The quality manual is a document that has to be controlled in accordance with the requirements of clause 4.2.3.
- c) Documented procedures:
 - ISO 9001:2008 specifically requires the organization to have “documented procedures” for the following six activities:

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- 4.2.3 Control of documents
 - 4.2.4 Control of records
 - 8.2.2 Internal audit
 - 8.3 Control of nonconforming product
 - 8.5.2 Corrective action
 - 8.5.3 Preventive action
- These documented procedures have to be controlled in accordance with the requirements of clause 4.2.3
 - Some organizations may find it convenient to combine the procedure for several activities into a single documented procedure (for example, corrective action and preventive action). Others may choose to document a given activity by using more than one documented procedure (for example, internal audits). Both are acceptable.
 - Some organizations (particularly larger organizations, or those with more complex processes) may require additional documented procedures (particularly those relating to product realization processes) to implement an effective QMS.
 - Other organizations may require additional procedures, but the size and/or culture of the organization could enable these to be effectively implemented without *necessarily* being documented. However, in order to demonstrate compliance with ISO 9001:2008, the organization has to be able to provide objective evidence (not necessarily documented) that its QMS has been effectively implemented.
- d) Documents needed *by the organization* to ensure the effective planning, operation and control of its processes:
- In order for an organization to demonstrate the effective implementation of its QMS, it may be necessary to develop documents other than documented procedures. However, the only documents specifically mentioned in ISO 9001:2008 are:
 - Quality policy (clause 4.2.1.a)
 - Quality objectives (clause 4.2.1.a)
 - Quality manual (clause 4.2.1.b)
 - There are several requirements of ISO 9001:2008 where an organization *could* add value to its QMS and demonstrate conformity by the preparation of other documents, even though the standard does not specifically require them. Examples may include:
 - Process maps, process flow charts and/or process descriptions
 - Organization charts
 - Specifications
 - Work and/or test instructions
 - Documents containing internal communications
 - Production schedules
 - Approved supplier lists
 - Test and inspection plans
 - Quality plans
 - All such documents have to be controlled in accordance with the requirements of clause 4.2.3 and/or 4.2.4, as applicable
- e) Records:
- Examples of records specifically required by ISO 9001:2008 are presented in Annex B.
 - Organizations are free to develop other records that may be needed to demonstrate conformity of their processes, products and quality management system.
 - Requirements for the control of records are different from those for other documents, and all records have to be controlled according to those of clause 4.2.4 of ISO 9001:2008.

5 Organizations preparing to implement a QMS

For organizations that are in the process of implementing a QMS, and wish to meet the requirements of ISO 9001:2008, the following comments may be useful.

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- For organizations that are in the process of implementing or have yet to implement a QMS, ISO 9001:2008 emphasizes a process approach. This includes:
 - Identifying the processes necessary for the effective implementation of the quality management system
 - understanding the interactions between these processes.
 - *documenting* the processes to the extent necessary to assure their effective operation and control. (It may be appropriate to document the processes using process maps. It is emphasized, however, that documented process maps are *not* a requirement of ISO 9001:2008.)
- These processes include the management, resource, product realization and measurement processes that are relevant to the effective operation of the QMS.
- Analysis of the processes should be the driving force for defining the amount of documentation needed for the quality management system, taking into account the requirements of ISO 9001:2008. It should *not* be the documentation that drives the processes.

6 Organizations wishing to adapt an existing QMS

For organizations that currently have a QMS the following comments are intended to assist in understanding the changes to documentation that may be required or facilitated by the transition to ISO 9001:2008

- An organization with an existing QMS should not need to rewrite all of its documentation in order to meet the requirements of ISO 9001:2008. This is particularly true if an organization has structured its QMS based on the way it effectively operates, using a process approach. In this case, the existing documentation may be adequate and can be simply referenced in the revised quality manual.
- An organization that has not used a process approach in the past will need to pay particular attention to the definition of its processes, their sequence and interaction.
- An organization may be able to carry out some simplification and/or consolidation of existing documents, in order to simplify its QMS.

7 Demonstrating conformity with ISO 9001:2008

For organizations wishing to demonstrate conformity with the requirements of ISO 9001:2008, for the purposes of certification/registration, contractual, or other reasons, it is important to remember the need to provide evidence of the effective implementation of the QMS.

- Organizations may be able to demonstrate conformity without the need for extensive documentation.
- To claim conformity with ISO 9001:2008, the organization has to be able to provide objective evidence of the *effectiveness* of its processes and its quality management system. Clause 3.8.1 of ISO 9000:2005 defines “objective evidence” as “*data supporting the existence or variety of something*” and notes that “*objective evidence may be obtained through observation, measurement, test, or other means.*”
- Objective evidence does not necessarily depend on the existence of documented procedures, records or other documents, except where specifically mentioned in ISO 9001:2008. In some cases, (for example, in clause 7.1(d) *Planning of product realization*, and clause 8.2.4 *Monitoring and measurement of product*), it is up to the organization to determine what records are necessary in order to provide this objective evidence.
- Where the organization has no specific internal procedure for a particular activity, and this is not required by the standard, (for example, clause 5.6 *Management Review*), it is acceptable for this activity to be conducted using as a basis the relevant clause of ISO 9001:2008. In these situations, both internal and external audits may use the text of ISO 9001:2008 for conformity assessment purposes.

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Annex A

Terms and Definitions relating to Documents

The following terms and definitions are taken from ISO 9000:2005:

Term	ISO 9000:2005 Clause	Definition
Document	3.7.2	information and its supporting medium
Procedure	3.4.5	specified way to carry out an activity or a process (Note: Procedures can be documented or not)
Quality Manual	3.7.4	document specifying the quality management system of an organization
Quality Plan	3.7.5	document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract
Record	3.7.6	document stating results achieved or providing evidence of activities performed
Specification	3.7.3	document stating requirements

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Annex B

Records required by ISO 9001:2008

Clause	Record required
5.6.1	Management reviews
6.2.2 e)	Education, training, skills and experience
7.1 d)	Evidence that the realization processes and resulting product fulfil requirements
7.2.2	Results of the review of requirements related to the product and actions arising from the review
7.3.2	Design and development inputs relating to product requirements
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and any necessary actions arising from the evaluations
7.5.2 d)	As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
7.5.3	The unique identification of the product, where traceability is a requirement
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use
7.6 a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6	Validity of the previous measuring results when the measuring equipment is found not to conform to requirements
7.6	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results and follow-up actions
8.2.4	Indication of the person(s) authorizing release of product.
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
8.5.2 e)	Results of corrective action
8.5.3 d)	Results of preventive action