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Guidance on the requirements for Documented Information of ISO 9001:2015

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 9001:2015 *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 documented information.

ISO 9001:2015 allows organization flexibility in the way it chooses to document its quality management system (QMS). This enables each individual organization to determine the correct amount of documented information 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 documented information? - Definitions and references

The term Documented information was introduced as part of the common High Level Structure (HLS) and common terms for Management System Standards (MSS).

The definition of documented information can be found in ISO 9000 clause 3.8.

Documented information can be used to communicate a message, provide evidence of what was planned has actually been done, or knowledge sharing.

The following are some of the main objectives of an organization's documented information 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 documented information 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
- d) 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 or service.

A list of commonly used terms and definitions relating to documented information is presented in ISO 9001:2015 Annex A.

It must be stressed that, according to ISO 9001:2015 clause 7.5.3 *Control of documented information requirements*, documents may be in any form or type of medium, and the definition of "document" in ISO 9000:2015 clause 3.8.5 gives the following examples:

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

3 ISO 9001:2015 Documentation Requirements

ISO 9001:2015 clause 4.4 *Quality management systems and its processes* requires an organization to "maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confident that the processes are being carried out as planned."

Clause 7.5.1 *General* explains that the quality management system documentation *shall* include:

- a) documented information required by this International standard;
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system

The note after this Clause make it clear that the extent of the QMS documented information can differ from one organization to another due to the:

- a) size of organization and its type of activities, processes, products and services;
- b) complexity of processes and their interactions,
- c) competence of persons.

All the documented information that forms part of the QMS has to be controlled in accordance with clause 7.5 *Documented information*.

4 Guidance on Clause 7.5 of ISO 9001:2015

The following comments are intended to assist users of ISO 9001:2015 in understanding the intent of the general documented information requirements of the International Standard. Documented information can refer to:

a) Documented information needed to be *maintained* by the organization for the purposes of establishing a QMS (high level transversal *documents*). These include:

- The scope of the quality management system (clause 4.3).
- Documented information necessary to support the operation of processes (clause 4.4).
- The quality policy (clause 5.).
- The quality objectives (clause 6.2).
- This documented information is subject to the requirements of clause 7.5.

b) Documented information *maintained* by the organization for the purpose of communicating the information necessary for the organization to operate (low level, specific *documents*). See 4.4. Although ISO 9001:2015 does not specifically require any of them, examples of documents that can add value to a QMS may include:

- Organization charts
- Process maps, process flow charts and/or process descriptions
- Procedures
- Work and/or test instructions
- Specifications
- Documents containing internal communications
- Production schedules
- Approved supplier lists
- Test and inspection plans
- Quality plans
- Quality manuals
- Strategic plans
- Forms

Where it exists, all such documented information, is also subject to the requirements clause 7.5.

c) Documented information needed to be *retained* by the organization for the purpose of providing evidence of result achieved (records). These include:

- Documented information to the extent necessary to have confidence that the processes are being carried out as planned (clause 4.4).
- Evidence of fitness for purpose of monitoring and measuring resources (clause 7.1.5.1).
- Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist) (clause 7.1.5.2).
- Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS (clause 7.2).
- Results of the review and new requirements for the products and services (clause 8.2.3).
- Records needed to demonstrate that design and development requirements have been met (clause 8.3.2)
- Records on design and development inputs (clause 8.3.3).
- Records of the activities of design and development controls (clause 8.3.4).
- Records of design and development outputs (clause 8.3.5).
- Design and development changes, including the results of the review and the authorization of the changes and necessary actions (clause 8.3.6).
- Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities (clause 8.4.1)

- Evidence of the unique identification of the outputs when traceability is a requirement (clause 8.5.2).
- Records of property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner (clause 8.5.3).
- Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken (clause 8.5.6).
- Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s) (clause 8.6).
- Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity (clause 8.7).
- Results of the evaluation of the performance and the effectiveness of the QMS (clause 9.1.1).
- Evidence of the implementation of the audit programme and the audit results (clause 9.2.2).
- Evidence of the results of management reviews (clause 9.3.3).
- Evidence of the nature of the nonconformities and any subsequent actions taken (clause 10.2.2).;
- Results of any corrective action (clause 10.2.2).

Organizations are free to develop other records that may be needed to demonstrate conformity of their processes, products and services and quality management system. Where it exists, all such records are also subject to the requirements clause 7.5.

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 9001:2015, the following comments may be useful.

- For organizations that are in the process of implementing or have yet to implement a QMS, ISO 9001:2015 emphasizes a process approach. This includes:
 - determining the processes necessary for the effective implementation of the quality management system
 - determining 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 mapping tools. It is emphasized, however, that documented process mapping tools are *not* a requirement of ISO 9001:2015).
- Analysis of the processes should be the driving force for defining the amount of documented information needed for the quality management system, taking into account the requirements of ISO 9001:2015. It should *not* be the documented information 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 documented information that may be required or facilitated by the transition to ISO 9001:2015:

- An organization with an existing QMS should not need to rewrite all of its documented information in order to meet the requirements of ISO 9001:2015. This is particularly true if an organization has structured its QMS based on the way it effectively operates, using a process approach.
- An organization may be able to carry out some simplification and/or consolidation of existing documented information in order to simplify its QMS.

7 Demonstrating conformity with ISO 9001:2015

For organizations wishing to demonstrate conformity with the requirements of ISO 9001:2015, 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 documented information
- To claim conformity with ISO 9001:2015, the organization has to be able to provide objective evidence of the *effectiveness* of its processes and its quality management system. Clause 3.8.3 of ISO 9000:2015 defines “objective evidence” as “*data supporting the existence or verity 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 information, except where specifically mentioned in ISO 9001:2015. In some cases, (for example, in clause 8.1 (e) *Operational planning and control*, it is up to the organization to determine what documented information is necessary in order to provide this objective evidence.
- Where the organization has no specific documented information for a particular activity, and this is not required by the standard, it is acceptable for this activity to be conducted using as a basis the relevant clause of ISO 9001:2015. In these situations, both internal and external audits may use the text of ISO 9001:2015 for conformity assessment purposes.