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ISO 9001:2015 TRANSITIONS

7.5 - Documented Information

DOCUMENTED INFORMATION

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What is “Documented Information”?

- 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.

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What is “Documented Information”?

- 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:
  - 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.
  - Evidence of Conformity
    - Provision of evidence that what was planned has actually been done.
  - 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 or service.

Types

- 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

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“Maintained” by the Organization

- 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.

“Maintained” by the Organization

- Although ISO 9001:2015 does not specifically require any of them, examples of documents that can add value to a QMS may include (mid-low level, *specific* documents):
  - 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

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“Retained” by the Organization

- 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).

“Retained” by the Organization

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

Adapting to ISO 9001:2015

- 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.

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