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From documented procedure to documented information: the new approach of ISO 9001:2015

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Abstract. ISO standards are normally reviewed and revised every 5-10 years. In September 2015, after extensive review, ISO 9001:2015 standard was published. At the same time also new revision of ISO 14001 standard was published, by harmonizing their layout to the 9001 one.
This paper focuses on the documents necessary for the implementation of a Quality Management System (QMS). The renewed standard defines documented information as relevant data that are required to be controlled and maintained by the organization to support the operation and to be confident that the processes are being carried out as planned. QMS needs to include documented information required by the standard as well as documented information determined by the organization necessary for the effectiveness of the system. According to ISO 9001:2008 it is possible to classified the specifically required documentation in a 3 levels pyramid: top tier included descriptive documentation (e.g. Quality Manual), tier 2 the set of procedures and work instructions (prescriptive documentation), tier 3 consisted of records. In the new standard, a new pyramid model is necessary to classify required documents: top tier concerns high level transversal documents (for the purposes of establishing a QMS), tier 2 contains specific documents (for the purpose of communicating the information necessary for the organization to operate), tier 3 remains of records (for the purpose of providing evidence of results achieved). An organization with an existing QMS should not need to rewrite all of its documented information in order to meet the requirements of the renewed standard, and it may be able to carry out some reduction and/or consolidation of existing documents, in order to simplify its QMS.

Keywords*: standards, quality management, certification, information*

Introduction

ISO standards are periodically reviewed and revised and in September 2015, after extensive review, a new ISO 9001standard was published. At the same time also the new revision of ISO 14001 standard was published, by harmonizing their layout to the 9001 one. Two of the most important goals in the revision of the two main management ISO standards deal with developing a simplified set of requirements that will be applicable to small, as well as medium and large organizations, without disparities, and allowing organizations the flexibility in handling 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.

This paper focuses on the documents necessary for the implementation of a QMS. The new standard defines documented information as relevant data that are required to be controlled and maintained by the organization to support the operation of processes and to have confidence that the processes have been carried out as planned (clause 4.4).

Material and methods

Making a comparison between the requirements of ISO 9001 version 2008 and 2015 one, the aim of this paper is to outline the correspondence between required documents in order to demonstrate that an organization with an existing QMS should not need to rewrite all of its documented information and it may be able to carry out some simplification and/or consolidation of existing documents, simplifying its system.

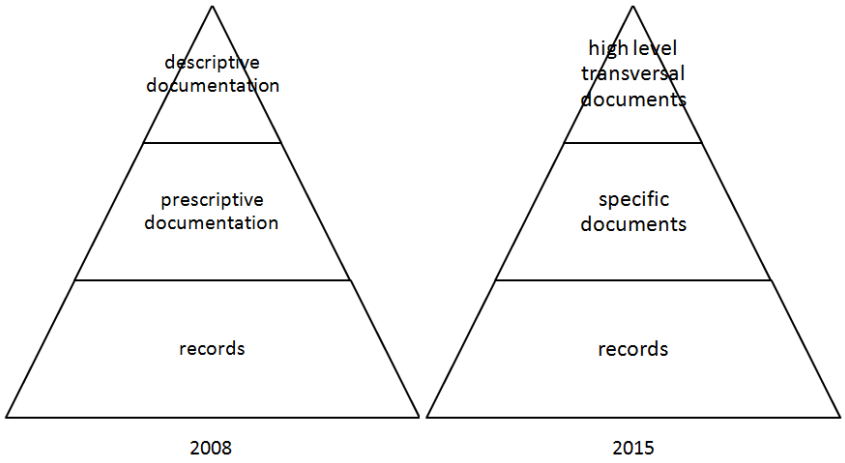
Results and discussion

The Quality Management System (QMS) needs to include documented information required by the standard as well as necessary documented information determined by the organization for the effectiveness of the system. ISO 9001:2008 outlined in clause 4.2.1 that the documentation could differ among the organizations, depending on their size, activities, competence of personnel, complexity of processes and their interactions. The documentation could be in any form or type of medium. ISO 9001:2015 clause 4.4 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 confidence that the processes have been carried out as planned. In 2008 standard is required for an organization to establish, document, implement and maintain a QMS and continually improve its effectiveness, in accordance with the requirements of the standard. In 2015 standard, the term "documented information" replaces the previously used terms "documented procedures" and "records" and, consequently, it is used for all required documents.

According to ISO 9001:2008, it is possible to classified the document requirements in a 3 levels pyramid (see figure 1): top tier included descriptive documentation (e.g. Quality Manual), tier 2 the set of procedures and work instructions (prescriptive documentation), tier 3 consisted of records. In the new standard, a new pyramid model classifies required documents: top tier concerns high level transversal documents (for establishing the QMS), tier 2 contains specific documents (for communicating among the organization the information necessary to operate), tier 3 are records (for providing evidence of the achieved results).

Figure 1.



Source: Authors' elaboration

The documented information (d.i.) to be maintained by the organization, compared with the previously document requirements, includes (see table 1):

Table 1.

"Documented information required by ISO 9001:2008 and 2015"

ISO 9001:2008 **Descriptive documentation**	**ISO 9001:2015** **High level transversal documents**
No document required	4.3 scope of the quality management system
4.2.1.a Documented statements of a quality policy and quality objectives	5.5.2 quality policy
	6.2.1 quality objectives
4.2.1.b Quality manual	*Not required*
4.2.1.c Records required 4.2.1.d Documents and records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.	7.5 a d.i. required by the Standard 7.5 b d.i. determined by the organization as being necessary for the effectiveness of the QMS 7.5.2 creating and updating d.i. 7.5.3 control of d.i.

Source: Authors' elaboration

While ISO 9001:2008 expressly required documented procedure, 2015 version does not specifically requires any of them as d.i. (see table 2). However, among specific documents, are included procedures and any other document maintained by the organization for the purpose of communicating the information necessary to operate. It is a choice of the organization to arrange them in a documented mode for the effectiveness of its processes (clause 4.4.2).

Table 2.

"Documented information required by ISO 9001:2008 and 2015"

ISO 9001:2008 **Prescriptive documentation**	**ISO 9001:2015** **Specific documents**
4.2.3 Procedure of control of documents	*Not expressly required*
4.2.4 Procedure of control of record	*Not expressly required*
8.2.2 Procedure of internal audit	*Not expressly required*
8.3 Procedure of control of nonconforming products	*Not expressly required*
8.5.2 Procedure of corrective actions	*Not expressly required*
8.5.3 Procedure of preventive actions	*Not expressly required*

Source: Authors' elaboration

Records provide evidence of the achieved result (see table 3 for those expressly required by the standards). The organizations are free to develop other records (also subject to the requirements clause 7.5) that may be needed to demonstrate conformity of their processes, products and services and QMS.

Table 3.

"Documented information required by ISO 9001:2008 and 2015"

ISO 9001:2008 Records	**ISO 9001:2015 Records**
4.2.1.c Records required 4.2.1.d Documents and records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.	4.4.2 a d.i. to support the operation of its processes 4.4.2 b d.i. to have confidence that the processes are being carried out as planning
5.6.1 Management review - general	*Not required*
6.2.2.e Competence, training and awareness – maintain appropriate records of education, training, skills and experience	7.2 d.i. as evidence of competence
7.1.d Planning of product realization – records needed to provide evidence that the realization processes and resulting product meet requirements	8.2.3.2 a d.i. on the results of the review of requirements related to products and services
7.2.2 Review of requirements related to the product	8.2.3.2 b d.i. on any new requirements for products and services 8.3.2 d.i. needed to demonstrate that design and development requirements have been met
7.3.2 Design and development inputs	8.3.3 design and development inputs
7.3.4 Design and development review	8.3.4 design and development controls
7.3.5 Design and development verification	
7.3.6 Design and development validation	
Not required	8.3.5 design and development outputs
7.3.7 Control of design and development changes	8.3.6 design and development changes
	8.4.1 records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities
7.4.1 Purchasing process	8.5.1 control of production and service provision

7.5.3 Production and service provision – Identification and traceability	8.5.2 identification and traceability
7.5.4 Production and service provision – Customer property	8.5.3 property belonging to customers or external providers
	8.5.6 results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken
	8.6 release of products and services
7.6 Control of monitoring and measuring equipment	9.1 monitoring, measurement, analysis and evaluation
8.2.2 Monitoring and measurement – Internal audit	9.2.2 evidence of the implementation of the audit program 9.3.3 management review outputs
8.2.4 Monitoring and measurement – Monitoring and measurement of product	7.1.5.1 d.i. as evidence of fitness for purpose of the monitoring and measurement resources 7.1.5.2 evidence of the basis used for calibration of the monitoring and measurement resources
8.5.2 Corrective actions 8.5.3 Preventive actions	8.7.2 nonconformity, actions taken, concessions obtained, authority deciding the action in respect of the nonconformity
	10.2.2 nonconformity and corrective actions

Source: Authors' elaboration

Conclusion

The ISO 9001:2015 approach for the quality management system emphasizes the needing of a more appropriate use of the documented information. With the update of its certified QMS to the 2015 standard, an organization should not need to rewrite all of its documented information in order to meet the requirements of the new standard. The organization may be able to carry out some simplification and/or consolidation of existing documents in order to simplify its QMS, without compromising the control over their processes and in a logic of effectiveness and continuous improvement.

References

1. EN ISO 9001:2015 Quality Management Systems – Requirements
2. EN ISO 9001:2008 Quality Management Systems – Requirements