ISO 9001:2008 to ISO 9001:2015 QMS Upgrade Instructions / Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from the ISO 9001:2008 version to the ISO 9001:2015 version for Quality management systems used in all types of industries.

The above Quality Management Systems are compatible with each other and have common requirements.

In ISO 9001:2015, the requirements are described in:

- Clause 4 Context of the organization
- Clause 5 Leadership
- Clause 6 Planning for the quality management system
- Clause 7 Support
- Clause 8 Operation
- Clause 9 Performance evaluation
- Clause 10 Improvement

Previously in ISO 9001:2008, the requirements were described in:

- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product realization
- Clause 8 Measurement, analysis and improvement

You have the 2008 version in place and now have the objective of upgrading the system to the 2015 version. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

Essentially, the documentation package for the management system will contain:

- One condensed Manual to introduce the documented information required for ISO 9001:2015.
- A group of procedure/system documents in your QMS with updates to reflect a document numbering system related to the new clause numbers and to incorporate the upgrades for ISO 9001:2015 requirements,
- A group of forms and attachments needed for the documented information and systems.

The documentation will need to be reviewed, upgraded and implemented. The first step is to assign a person responsible for the QMS, such as with a Management Representative to become familiar with the changes for 2015 version of the ISO 9001:2015 standard. Visit http://the9000store.com/ for training materials, resources and information on quality management systems requirements.

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The following table with detailed instructions focuses on the areas of the documentation required for the ISO 9001:2015 quality management system. As you undertake the task of upgrading your quality management system from the 2008 version to the 2015 version, note that in the left hand column of the instructions, the ISO 9001:2015 clauses shown in **bold numbers** have key changes from 2008 to 2015. The intent of the main clauses is shown in blue font and the text in *italics* indicates where requirements were included in previous ISO 9001:2008.

Use a copy of the ISO 9001:2015 standard along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

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ISO 9001: 2015 Clause	Changes to the existing ISO 9001:2008 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The international standard ISO 9001:2015 is restructured and contains 10 sections or clauses 1 through 10.	ISO 9001:2015	The requirement clauses of the new standard are the Clause 4 through Clause 10. Your company needs to become familiar with the new structure and the changes and subsequently upgrade the Quality Management System (QMS).		
All	While the specific requirement for a quality manual is not in ISO 9001:2015, the standard requires that Documented Information be maintained for the QMS.	Manual	Replace / rework your existing Quality Manual with a condensed version that will introduce the quality system.		
---	*In ISO 9001:2008, the requirement for a Quality Manual was included in clause 4.2.2.*	Manual	In the manual include sections for: • Scope of the Quality Management System (QMS) • Distribution Control List, • Revision Status, • Quality Policy and Objective, Strategic Direction, • Organization Chart, • Company Background - Products and Services, • Process Flow Diagram, • List of Documented Information, • Records Documentation Matrix.		
---	The specific requirement for documented procedures is not in ISO 9001:2015; however documented information is required to plan, establish, implement, and maintain the QMS processes.	Documented information	The QMS documented information may be presented in any suitable format such as in a method, an instruction, a system, a process, a procedure, etc. You will need to add / replace / rework your QMS procedures to incorporate the ISO 9001:2015 requirements.		

	In ISO 9001:2008, the requirement for control of documents was included in 4.2.3, and the requirement for control of records was in 4.2.4.		An early consideration is the development of a process for the control of documented information. Replace / rework the documented procedures for Control of Documents and Control of Records with a procedure, P-750 for Documented Information and include it in section 7.5.		
4	This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the QMS. In addition the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.				
4	Clause 4, Context of the Organization is a new requirement in ISO 9001:2015.	Documented information	Your company will have to determine the issues and requirements that can impact on the planning of the QMS and that can affect the ability to achieve the intended results f the QMS.		
4.1	Documented information for the QMS sets the stage for an understanding of the requirements and of the international standard as a whole.	Procedure	Document the information (in a document P-400, Organizational Context) to outline the process to understand and determine the internal and external issues that are relevant to the QMS.		
4.2	A stakeholder approach provides for an understanding of the requirements of interested parties.		Include (in a document P-400) the process to understand and determine the needs and expectations of interested parties.		
4.3	*In ISO 9001:2008, the scope of the QMS was required to be included in a Quality manual per par 4.2.2.*		Include (in a document P-400) the process to determine the scope of the QMS.		
4.3	*In ISO 9001:2008, the application and exclusion of requirements were included in par 1.2.*		Include justifications for requirements of the standard that do not apply to the scope of the QMS. Note that conformity to ISO 9001:2015 can only be claimed if the requirements determined to be not applicable do not affect your ability or responsibility to meet product and service requirements and enhance customer satisfaction.		
4.4	*In ISO 9001:2008, the requirement for the QMS and its processes was in 4.1.*		Your company will have to establish, implement, maintain and continually improve the QMS.		
4.4.1	*In ISO 9001:2008, the requirement for the QMS and its processes was in 4.1.*		Provide an outline (in a document P-400) of the process to determine the application and interaction of the processes needed for the QMS.		
4.4.2	In ISO 9001:2015, documented information that supports the processes is required to be maintained and retained. *In ISO 9001:2008, the requirement for the*		See clause 7.5. Document the information (in a document P-750) to outline the process for the control of documented information.		