

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

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.		
---	<i>In ISO 9001:2008, the requirement for a Quality Manual was included in clause 4.2.2.</i>	Manual	In the manual include sections for: <ul style="list-style-type: none"> • 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. 		
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	<i>records was in 4.2.4.</i>		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 of 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	<i>In ISO 9001:2008, the scope of the QMS was required to be included in a Quality manual per par 4.2.2.</i>		Include (in a document P-400) the process to determine the scope of the QMS.		
4.3	<i>In ISO 9001:2008, the application and exclusion of requirements were included in par 1.2.</i>		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	<i>In ISO 9001:2008, the requirement for the QMS and its processes was in 4.1.</i>		Your company will have to establish, implement, maintain and continually improve the QMS.		
4.4.1	<i>In ISO 9001:2008, the requirement for the QMS and its processes was in 4.1.</i>		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. <i>In ISO 9001:2008, the requirement for the documentation was in par 4.2.</i>		See clause 7.5. Document the information (in a document P-750) to outline the process for the control of documented information.		