ISO 9001:2015 to IATF 16949:2016 - QMS Transition Checklist

IATF 16949:2016 Clause	Changes to the existing ISO 9001:2015 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The International Automotive Standard IATF 16949:2016 is restructured and contains 10 sections or clauses numbered 1 through 10. It is important to note that the standard is revised to incorporate the new clause structure and content of ISO 9001:2015. Also, new automotive industry requirements, definitions, and notes are included.	IATF 16949:2016	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). Your company now has an opportunity to review the exiting ISO 9001:2015 QMS and improve the system while incorporating the IATF 16949:2016 requirements.		
All	While the specific requirement for a quality manual is not in ISO 9001:2015, the new standard requires a Quality Manual as part of the Documented Information be maintained for the QMS.	Manual	For an existing quality manual, review / rework / update your document into a condensed version that will introduce the new quality system or if a manual is not available, prepare a new Quality Manual.		
---	The format and structure of the quality manual is at your discretion and will depend on the size, culture, and complexity of your company, see also clause 7.5.1.1.	Manual	In the condensed manual include sections for: • Scope of the Quality Management System (QMS) • Distribution Control List, • Revision Status, • Quality Policy and Objective, Strategic Direction, Corporate Policies • Organization Chart, • Company Background - Products and Services, • Process Flow Diagram, • List of Documented Information, • Records Documentation Matrix.		
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			procedures to incorporate the IATF requirements. 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, (such as P-750) for Documented Information and include it in section 7.5.		
4	For ISO 9001:2015, 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. For IATF 16949:2016, sections are introduced to supplement requirements for the scope of the QMS, customer specific requirements, conformance of products and processes, and product safety.				
4	Clause 4, Context of the Organization is a requirement in IATF 16949:2016.	Documented information	Your company must 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. For typical guidance, see procedure P-400 for Organizational context and worksheet, F-440-002 to identify issues and requirements.		
4.1	Documented information for the QMS sets the stage for an understanding of the requirements and of the international standard.	Procedure	Review and document the information (in a document P-400, Organizational Context) that outlines 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	Clause 4.3 covers the requirement for the scope of the QMS.		Include P-400, the process to determine the scope of the QMS. Refer to 4.3 a) thru c) and consider the internal and external issues, the requirements of interested parties, and your products and services.		
	For IATF 16949, the requirements for		Include in the scope of the QMS, the supporting on-		

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4.3.1	determining the scope of the QMS are supplemented.		site or off-site functions, such as design centers, corporate headquarters, and distribution centers.		
4.3.1	For IATF 16949, an exclusion is only permitted for clause 8.3, design and development of products.		If your company does not design and develop products or services, include justification for the exclusion of clause 8.3. Note that conformity to IATF 16949 can only be claimed if the exclusion does not affect your ability or responsibility to meet product and service requirements and enhance customer satisfaction.		
4.3.2	For IATF 16949, customer specific requirements are included in the scope of the QMS.		Evaluate customer-specific requirements and include them in the scope of the QMS.		
4.4	Clause 4.4 covers the requirements for the QMS and its processes.		Your company must establish, implement, maintain, and continually improve the QMS.		
4.4.1	Clause 4.4.1 covers the requirements for the QMS and its processes.		Provide an outline (in a document P-400) of the process to determine the application and interaction of the processes needed for the QMS. As you proceed through the upgrade of the QMS, consider the use of the QMS process identification worksheet F-440-001 to determine the inputs required and the outputs expected from processes. Address risks and opportunities and plan to implement actions to address them. See clause 6.1.		
4.4.1.1	For IATF 16949, conformance of products and processes is assured.		In P-400, provide an outline of the process to ensure conformance of all products and processes, including service parts, outsourced parts, customer, statutory, and regulatory requirements.		
4.4.1.2	For IATF 16949, a documented process to manage product safety is required.		In P-400, include the process to manage product safety related products and processes. In product safety worksheet, F-440-003 consider items 4.4.1.2 a) thru m).		
4.4.2	Documented information that supports the processes are maintained and retained.		Document (in a P-400) the process to establish and maintain the documented information to support the operation of the processes and retained to provide		

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			the confidence that the processes are carried out as planned. See Documented information, clause 7.5. Outline (in a document P-750) the process for the control of documented information.		
5	**For ISO 9001:2015**, this clause requires that your top management demonstrates leadership and commitment with respect to the QMS and to customer focus. This section also asks top management to establish, implement and maintain a quality policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood. **For IATF 16949:2016**, sections are introduced to supplement requirements for corporate responsibility, process effectiveness and efficiency, process owners, organizational roles, responsibilities & authorities, and responsibility and authority for product requirements and corrective actions.				
5	Clause 5, Leadership is a requirement in IATF 16949:2016.	Procedure	Review and re-write your existing document (such as P-500) to incorporate the revised requirements for leadership and commitment.		
5.1	Clause 5.1 covers the requirements for leadership and commitment.		Include the actions to demonstrate the leadership and commitment to the QMS. Refer to specific requirements in clause 5.1.1 and include the requirements for a) thru j)		
5.1.1.1	For IATF 16949, corporate responsibility policies are defined and implemented.		In P-500, define the corporate responsibility policies, for anti-bribery policy, employee code of conduct, and whistle-blowing policy to be implemented.		
5.1.1.2	For IATF 16949, product realization processes are reviewed and evaluated for effectiveness.		In P-500, include the review and evaluation of processes to improve their effectiveness and efficiency.		
5.1.1.3	For IATF 16949, process owners are identified.		In P-500, identify the process owners who are responsible for managing the processes and related outputs.		
5.1.2	Clause 5.1.2 covers the requirements for customer focus.		Include the actions to demonstrate the leadership and commitment to customer focus. Refer to 5.1.2 a) thru c) requirements dealing with meeting customer and regulatory requirements, addressing risks and opportunities, and customer satisfaction.		
5.2	Clause 5.2 covers the quality policy.		Include the process for developing a quality policy that is appropriate to the purpose and context of your company and communicating this quality policy.		