

**IATF 16949:2016 Automotive Quality Management Systems - The Basic Gap Analysis Checklist**

This gap analysis checklist is prepared for use in evaluating a Quality Management System (QMS) against the requirements of the new Automotive standard. The IATF 16949:2016 standard includes the requirements of ISO 9001:2015 and specifies additional automotive industry requirements.

In the checklist, each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. Because the automotive standard refers to ISO 9001:2015 for many of the requirements, you will need to have copies of the IATF 16949:2016 and ISO 9001:2015 standards to use along with this checklist so that, if required, you can refer to the requirements.

The intent of the main clauses of the new standard is summarized in **blue font**, and additional information is provided for the IATF 16949:2016 to supplement the intent of ISO 9001:2015.

**Blue font summarizes the new standard**

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed.

In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also, note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to comply with the IATF 16949:2016 standard.

---	QUALITY MANAGEMENT SYSTEM	Currently in Place	Compliant Yes / No	If No - % Completed	Items Needed
4	<b>CONTEXT OF THE ORGANIZATION</b>				
<p><b>For ISO 9001:2015</b>, 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.</p> <p><b>For IATF 16949:2016</b>, sections are introduced to supplement requirements for the scope of the QMS, customer specific requirements, conformance of products and processes, and product safety.</p>					

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	<p>them?</p> <ul style="list-style-type: none"> <li>• Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results?</li> <li>• Opportunities for improvement of the processes and the QMS?</li> </ul>				
<b>4.4.1.1</b>	<b>Conformance of products and processes</b>				
	How does your company ensure conformance to all customer, statutory & regulatory requirements for all products and processes, including service parts and those that are outsourced?				
<b>4.4.1.2</b>	<b>Product safety</b>				
	What processes are documented for the management of product safety related products and manufacturing processes?				
	<p>Do the processes include, as applicable:</p> <ul style="list-style-type: none"> <li>• Your identification of the statutory and regulatory product safety requirements?</li> <li>• Customer notification of above product safety requirements?</li> <li>• Special approvals, typically by the customer, for design FMEA?</li> <li>• Identification of product safety related characteristics?</li> <li>• Identification and controls of safety related characteristics of product and at the point of</li> </ul>				

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	<p>Is the quality policy appropriate to the purpose and context of the organization and supports the strategic direction?</p> <p>Does the quality policy provide for a framework for setting and reviewing quality objectives?</p> <p>Does the policy include a commitment to satisfy applicable requirements?</p> <p>Does it include a commitment to continual improvement of the QMS?</p>				
<b>5.2.2</b>	<b>Communicating the quality policy</b>				
	<p>How do you ensure that your quality policy is:</p> <ul style="list-style-type: none"> <li>• Communicated, understood, and applied within your company?</li> <li>• Available as documented information?</li> <li>• Available to relevant interested parties?</li> </ul>				
<b>5.3</b>	<b>Organizational roles, responsibilities, and authorities</b>				
	<p>Has top management ensured that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the company?</p> <p>Has the top management assigned the responsibility and authority for:</p> <ul style="list-style-type: none"> <li>• Ensuring that the QMS conforms to the requirements of ISO 9001:2015 standard?</li> <li>• Ensuring that the processes are delivering their intended outputs?</li> </ul>				