

INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 into IATF 16949:2016 Quality Management Systems - The Internal Audit Checklist

This checklist is based on the information provided in the Oct 1, 2016 1st edition of the IATF 16949:2016 International Automotive Standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard as you transition from ISO 9001:2015. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

Both the versions of the IATF and ISO standards deal with Quality Management Systems and line up when comparing the contents, the new requirements and / or new terminology. The additions for ISO 9001 into IATF 16949 are highlighted **in yellow**. The auditors are expected to keep in mind that the standard does not require mandatory procedures for the various QMS processes; however, the auditors will expect documented information to be available because in the clauses of the standard, the phrase such as 'documented procedures' is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and titles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right-hand column a:

Yes - for Acceptable Condition or **No** - for Deficient Condition

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4	CONTEXT OF THE ORGANIZATION		
4.1	Understanding the organization and its context		
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction? Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)? How do you monitor and review the information		

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	related to the external and internal issues?		
	Additional Questions		
4.2	Understanding the organization and its context		
	<p>With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, have you determined:</p> <ul style="list-style-type: none"> • The interested parties relevant to the QMS? • The requirements of these interested parties that are relevant to the QMS? <p>How do you monitor and review the information about the interested parties and their relevant requirements?</p>		
	Additional Questions		
4.3	Determining the scope of the quality management system		
	<p>To establish the scope of the QMS, has your company determined the boundaries and applicability of the QMS?</p> <p>When determining the scope of the QMS, have you considered the:</p> <ul style="list-style-type: none"> • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 		

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	<p>4.2)?</p> <ul style="list-style-type: none"> • Products and services covered by the QMS? 		
	<p>When a requirement of ISO 9001:2015 can be applied, has your company applied it (see also clause 4.3.1 below)?</p> <p>When requirements cannot be applied, and to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?</p> <p>Has your company provided justification for any instance where a requirement of the standard cannot be applied?</p> <p>Is the scope of the QMS available and maintained as documented information?</p>		
	Additional Questions		
4.3.1	Determining the scope of the quality management system - supplemental		
	<p>When determining the scope of the QMS, are the supporting on-site or off-site functions, such as design centers, corporate headquarters, and distribution centers, included in the QMS scope?</p>		
	<ul style="list-style-type: none"> • In determining the scope of the QMS, have you considered product design and development (per clause 8.3) as the only permitted exclusion? • If applicable, is this exclusion justified and maintained as documented information? • Do you recognize that permitted exclusions do not 		