INSERT COMPANY NAME/LOGO HERE

ISO/TS 16949:2009 to IATF 16949:2016 QMS - The Transition 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 as you transition from ISO/TS 16949:2009. The IATF 16949:2016 standard includes the requirements of ISO 9001:2015 and specifies additional automotive industry requirements.

Each requirement is expressed as a question that the user (auditor / assessor) can ask to evaluate your QMS capabilities. You will need to have copies of the ISO 9001:2015 and ISO 9001:2008 standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the standard do not line up when comparing the requirements:

- New requirements and / or new terminology are highlighted in yellow.
- The intent of the main clauses of the new standard is shown in blue font.
- The 3rd left-hand column in green shade is intended to provide reference to the previous clauses and requirements of ISO/TS 16949:2009.

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	ISO/TS 16949 Clause / Requirement	Currently in Place	Compliant Yes / No	If No - % Completed	Items Needed
4	CONTEXT OF THE ORGANIZATION					
---		4 Quality management system				
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 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.						
4.1	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 related to the external and internal issues?					
4.2	Understanding the needs and expectations of interested parties					
	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:					

	• The interested parties relevant to the QMS? • The requirements of these interested parties that are relevant to the QMS? How do you monitor and review the information about the interested parties and their relevant requirements?					
4.3	**Determining the scope of the quality management system**					
	To establish the scope of the QMS, has your company determined the boundaries & applicability of the QMS? When determining the scope of the QMS, have you considered the: • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 4.2)? • Products and services covered by the QMS?					
	When a requirement of ISO 9001:2015 can be applied, has your company applied it (see also clause 4.3.1 below)? 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? Has your company provided justification for any instance where a requirement of the standard cannot be applied?					

	Is the scope of the QMS available and maintained as documented information?	4.2.2 a) Scope of QMS included in a quality manual				
4.3.1	**Determining the scope of the quality management system - supplemental**					
	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?					
	• 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 include manufacturing process design?	1.2 Clause 7.3, Design and development is the only permitted exclusion 4.2.2 a) Include in a quality manual, details of and justification for exclusions				
4.3.2	**Customer-specific requirements**					
	Has your company evaluated and included customer specific requirements in the scope of the QMS?					
4.4	**Quality management system and its processes**					
4.4.1	Has your company obtained the current versions of the ISO 9001:2015 and IATF 16949:2016 international standards? As required by the standard, have you	4.1 Processes managed per the international standard 4.1 Document, implement, maintain a QMS and				

	established, documented implemented, maintained, and continually improved the QMS? Have you determined the processes needed for the QMS, their interactions and applications throughout your company?	continually improve it 4.1 a) Determine the processes and their applications				
	For the QMS processes have you determined: • Inputs required and the outputs expected from the processes? • Sequence and interaction of the processes? • Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes? • Resources needed and ensure their availability? • Assignment of the responsibilities and authorities for these processes? • Risks and opportunities (per 6.1), and plans to implement the actions to address them? • Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results? Opportunities for improvement of the processes and the QMS?	4.1 b) Sequence and interaction 4.1 c) Criteria and methods 4.1 d) Resources available to support operations 4.1 e) Monitor and measure 4.1 f) Implement actions to improve				

