INSERT COMPANY NAME/LOGO HERE

AS 9100 Rev D Quality Management Systems - The 2009-to-2016 Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of AS 9100 Rev D as you transition from AS 9100 C to AS 9100 D. 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 AS 9100 D and AS 9100 C standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the AS 9100 standards do not line up when comparing the requirements:

- New requirements and / or new terminology and new clause numbers are highlighted in yellow.
- The intent of the main clauses of the new standard is shown in blue font.
- The right hand column in green shade is intended to provide reference / comparison / similarities to the AS 9100 Rev C requirements, and to identify and locate where in the new clauses, the former requirements are relevant.
- Comments highlighted in red font indicate removed / missing requirements.

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 main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with AS 9100 Rev D.

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QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If NO - % Complete	Items Needed	AS 9100 Rev C Requirements
4 CONTEXT OF THE ORGANIZATION					**4.0 Quality management system**
This first 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 Quality Management System (QMS). In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.					----
4.1 Understanding the organization and its context					----
Does your company determine the external and internal issues that are relevant to your purpose and strategic direction?					
Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?					
Does your company 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, do you determine:					

• Opportunities for improvement of the processes and the QMS?					4.1 f) Implement actions to achieve planned results and continually improve processes
Does your company maintain the necessary documented information to support the operation of processes?					4.2.1 QMS documentation includes a) Documented statements for the quality policy and quality objectives b) Quality manual c) Documented procedures and record d) Documents and records required as necessary 4.2.1 Ensure that personnel have access to and are aware of relevant QMS documentation and changes
	A quality manual is not included as a requirement from clause 7.5.1 of AS 9100 D; however, the note in 4.4.2 suggests that a quality manual can be used to compile into a single source the documented information for the QMS.				
	Throughout AS 9100 D, documents and records are replaced with the term documented information.				
4.4.2 Does your company maintain and retain the necessary documented information to provide the confidence that the processes are being carried out as planned?					4.2.4 Records to provide evidence of conformity are controlled

• Where no such standards exist, do you retain documented information for the basis used for calibration or verification?					7.6 a) Where no such standards exist, the basis used for calibration or verification is recorded
• Identified in order to determine their calibration status?					7.6 c) Identification to determine calibration status
• Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?					7.6 d) Safeguarded from adjustments that invalidate results
Have you established, implemented, and maintained a process for the recall of monitoring and measuring equipment requiring calibration or verification?					7.6 Establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification
Is a register of the monitoring and measuring equipment maintained?					7.6 Maintain a register of monitoring and measuring equipment
Does the register include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria?					7.6 Define the process used for the calibration/verification and details of type unique identification, location, frequency of checks, check methods and acceptance criteria
Is calibration or verification of monitoring and measuring equipment carried out under suitable environmental conditions?					7.6 Ensure that environmental conditions are suitable for the calibration, inspection, testing and measurement being carried out

