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AS 9100 Rev D with ISO 13485:2016 Quality Management Systems - The Internal Audit Checklist

This checklist is based on the information provided in the 2016-09 revision of the AS 9100 Rev D, SAE standard and in the 2016 third edition of ISO 13485:2016 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standards as you include the requirements of ISO 13485:2016. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

While both the AS 9100 and ISO 13485 standards deal with Quality Management Systems, the structures of the AS and ISO standards do not exactly line up when comparing the contents, the new requirements and/or new terminology. The AS 9100 Rev D standard includes the requirements of ISO 9001:2015 and additional aviation, space, and defense (ASD) industry requirements. The AS requirements over 9001 are highlighted in yellow. The additions for ISO 13485 over AS 9100 are highlighted in green and the relevant ISO 13485:2016 clause number appears with the audit question. The auditors are expected to keep in mind that the AS 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**		
	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?		
	Additional Questions		
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:		
	• The interested parties that are relevant to the QMS?		
	• The requirements of these interested parties that are relevant to the QMS?		
	Does your company monitor and review the information about these interested parties and their relevant requirements?		
	Additional Questions		

4.3	Determining the scope of the quality management system		
	To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?		
	4.2.2 a) Is the scope of the QMS included in a quality manual?		
	When determining the scope of the QMS, do you consider the:		
	• External and internal issues (per above clause 4.1)?		
	• Requirements of relevant interested parties (per above clause 4.2)?		
	• The products and services of your company?		
	When a requirement of AS 9100 D can be applied, is the requirement applied by your company?		
	When requirements cannot be applied, and to claim conformity to AS 9100 D, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?		
	Is the scope of the QMS available and maintained as documented information?		
	Does the scope state the products and services covered by the QMS?		
	Does your company provide justification for any instance where a requirement of the standard cannot		

	be applied?		
	4.2.2 a) Are any justifications for exclusions in clauses 6, 7, or 8 included in the quality manual?	AS9100D requirements over 13485 are highlighted in green.	
	Additional Questions		
4.4	**Quality management system and its processes**		
4.4.1	As required by the standard, do you establish, document, implement, maintain and continually improve the QMS?		
	Does the QMS also address customer and applicable statutory and regulatory quality management system requirements?	The ISO 13485:2016 requirements over ISO 9001:2015 are highlighted in yellow	
	4.1.1 Do you establish, implement, and document a QMS and maintain its effectiveness per ISO 13485:2016 standard and regulatory requirements?		
	4.1.1 Have you documented the roles undertaken by your company under the regulatory requirements?		
	Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?		
	That is, for the QMS processes do you determine the:		
	• 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 they are available?		
	• Assignment of the responsibilities and authorities for these processes?		
	• Risks and opportunities (per 6.1), and plans to implement the appropriate 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?		
	4.1.4 Are changes to QMS processes evaluated for impact on the QMS, impact on medical devices? 4.1.4 Are changes to QMS processes controlled?		
	Does your company maintain the necessary documented information to support the operation of processes?		
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?		

	4.1.3 e) Have you established and maintained records to demonstrate conformance and compliance to requirements? 4.2.1 Does the QMS documentation include: • Documented statements for the quality policy and quality objectives? • Quality manual? • Documented procedures and records? • Required documents and records? • Documents specified by regulatory requirements.?		
	Does the documented information include:		
	• General description of relevant interested parties (see above clause 4.2 a)?		
	• Scope of the QMS, including boundaries and applicability (see above clause 4.3)?		
	• Description of the processes needed for the QMS and their application throughout the organization?		
	• Sequence and interaction of the processes?		
	• Assignment of the responsibilities and authorities for these processes?		
	Note: The above description of the QMS can be compiled in a single source of documented information and referred to as a quality manual.		