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Quality Manual

QM-9100-D

AS 9100 D

Quality Management Systems

Quality Manual / Documented Information

Document No. QM-9100-D

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AS 9100 Rev D - Quality Management Systems – The Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating a Quality Management System (QMS) against the requirements of the new Aerospace standard. The AS 9100 Rev D standard includes the requirements of ISO 9001:2015 and specifies additional aviation, space, and defense (ASD) industry requirements.

In the checklist, each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. You will need to have copies of the AS 9100 D and ISO 9001:2015 standards to use along with this checklist so that, if required, you can refer to the requirements and the clarification sections of Annex A.

While the structure of the AS and ISO standards are the same when comparing the contents, the additional ASD requirements are highlighted in yellow in the relevant sections of the checklist and the intent of the main clauses of the new standard is shown in blue font.

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.

---	QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If No - % Completed	Items Needed
4	CONTEXT OF THE ORGANIZATION				
Intend of clause	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.				

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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?				
	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:				
	<ul style="list-style-type: none"> • Inputs required and the outputs expected from the processes? 				
	<ul style="list-style-type: none"> • Sequence and interaction of the processes? 				
	<ul style="list-style-type: none"> • Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes? 				
	<ul style="list-style-type: none"> • Resources needed and ensure they are available? 				
	<ul style="list-style-type: none"> • Assignment of the responsibilities and authorities for these processes? 				
	<ul style="list-style-type: none"> • Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them? See also Operational risk management (per 8.1.1) 				

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AS 9100 Rev D Quality Management Systems - The Internal Audit Checklist

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?		
	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 in order 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?		

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5.2	Policy		
5.2.1	Developing the quality policy		
	Has your top management established, implemented and maintained a quality policy that:		
	<ul style="list-style-type: none"> • Is appropriate to the purpose and context of the organization? 		
	<ul style="list-style-type: none"> • Provides a framework for setting and reviewing quality objectives? 		
	<ul style="list-style-type: none"> • Includes a commitment to satisfy applicable requirements? 		
	<ul style="list-style-type: none"> • Includes a commitment to continual improvement of the QMS? 		
5.2.2	Communicating the quality policy		
	Is your quality policy:		
	<ul style="list-style-type: none"> • Communicated, understood and applied within your company? 		
	<ul style="list-style-type: none"> • Available as documented information? 		
	<ul style="list-style-type: none"> • Available to relevant interested parties? 		
	Additional Questions		

1.0 Purpose/Scope

- 1.1 This procedure describes the process for performing Internal Audits at **Your Company**.
- 1.2 The procedure applies to the audit of the QMS where performance is evaluated.

2.0 Responsibilities and Authorities

- 2.1 The **President** has the prime responsibility and approval authority for this procedure.
- 2.2 In support of the **President**, the **Quality team / AS steering committee** is responsible to ensure that internal audits are conducted at planned intervals.
- 2.3 Additional responsibilities for the **Quality team leader / Management representative / audit coordinator, lead auditor, auditors, management staff, employees, and the corrective action coordinator** are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 Reference

- 3.1.1 This document relates to clause 9.2 of the AS 9100 D standard, Internal audit.

3.2 Definition


- 3.2.1 Audit Team: May be one or more auditors, including the lead auditor.

4.0 Resources

- 4.1 None

5.0 Instructions

- 5.1 In support of the procedure P-910 for Monitoring, measuring, analysis and evaluation, this procedure addresses the internal audits of the QMS.
- 5.1.1 Internal audits are conducted to ensure that the QMS conforms to **Your Company's** own requirements and to those of the AS 9100 D standard, is effectively implemented and maintained, and continues to be suitable, adequate and effective.
- **The company's own requirements include customer and applicable statutory and regulatory quality management system requirements.**
- 5.1.2 The **President / Quality team / AS steering committee** ensure that internal audits are conducted at planned intervals **at a minimum of two times per year**.
- At the call of the **President**, internal audits may be conducted more frequently based on performance and results observed during previous audits.
 - **Performance indicators can be evaluated to determine whether the**



Recommendations for customization are included in blue type.

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AS 9100 Rev D Quality Management Systems - The Internal Audit Checklist

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

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 '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

---	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS / COMMENTS	STATUS
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)?		



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We are excited to present this training course to help familiarize you with AS9100 Rev D.

You will be presented with information, and then have a chance to test your knowledge with quizzes at the end of the sections.

At the end of the training you will have the opportunity to print a *Certificate of Completion* for your records.

