AS 9100 C to AS 9100 D - QMS Upgrade Instructions / Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the upgrade from the AS 9100 C version to the AS 9100 D revision for Quality management systems used in the aviation, space, and defense industries.

The above Quality Management Systems are compatible with each other and have common requirements.

In the SAE Aerospace Standard **AS 9100D**, the requirements are described in: • Clause 4 Context of the organization • Clause 5 Leadership • Clause 6 Planning • Clause 7 Support • Clause 8 Operation • Clause 9 Performance evaluation • Clause 10 Improvement	Previously in **AS 9100C**, the requirements were described in: • Clause 4 Quality management system • Clause 5 Management responsibility • Clause 6 Resource management • Clause 7 Product realization • Clause 8 Measurement, analysis and improvement

You have the 2009 Rev C version in place and now have the objective of upgrading the system to the 2016 Rev D revision. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

Essentially, the documentation package for the management system will contain:

- One condensed Manual to introduce the documented information required for AS 9100 D.
- A group of procedure/system documents in your QMS with updates to reflect a document numbering system related to the new clause numbers and to incorporate the upgrades for AS 9100 D requirements,
- A group of forms and attachments needed for the documented information and systems.

The documentation will need to be reviewed, upgraded and implemented. The first step is to assign a person responsible for the QMS, such as with a Management Representative to become familiar with the changes for the 2016 version of the AS 9100 D standard. Visit AS9100store.com for training materials, resources and information on quality management systems requirements.

The following table with detailed instructions focuses on the areas of the documentation required for the AS 9100 D quality management system. As you undertake the task of upgrading your quality management system from the 2009 version to the 2016 version, note that the intent of the main clauses is shown in blue font, and in the 2nd left hand column of the instructions, the text in *italics* indicates where requirements were included in previous AS 9100 C.
Use a copy of the AS 9100 D standard along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

AS 9100 C to AS 9100 D - QMS Upgrade Instructions / Checklist

AS 9100 Rev D Clause	Changes to the existing AS 9100 Rev C Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The SAE international Aerospace standard AS 9100 Rev D is restructured and contains 10 sections or clauses numbered 1 through 10. The standard is revised to incorporate the new clause structure and content of ISO 9001:2015. In addition, aviation, space, and defense(ASD) industry requirements, definitions, and notes are included.	AS 9100 D	The requirement clauses of the new standard are the Clause 4 through Clause 10. Your company needs to become familiar with the new structure and the changes and subsequently upgrade the Quality Management System (QMS).		
All	While the specific requirement for a quality manual is not in AS 9100 D, the standard requires that Documented Information be maintained for the QMS.	Manual	Replace / rework your existing Quality Manual with a condensed version that will introduce the quality system. A quality manual is not included as a requirement in 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.		
---	*In AS 9100 C, the requirement for a Quality Manual was in clause 4.2.2.*	Manual	In the condensed manual include sections for: • Scope of the Quality Management System (QMS) • Distribution Control List, • Revision Status, • Quality Policy and Objective, Strategic Direction, • Organization Chart, • Company Background - Products and Services, • Process Flow Diagram, • List of Documented Information, • Records Documentation Matrix.		
---	The specific requirement for documented procedures is not in AS 9100 D; however documented information is required to plan, establish, implement, and maintain the QMS processes. *In AS 9100 C, the requirement for control of documents was included in 4.2.3, and the requirement for control of records was*	Documented information	The QMS documented information may be presented in any suitable format such as in a method, an instruction, a system, a process, a procedure, a manual, etc. You will need to add / replace / rework your QMS procedures to incorporate the AS 9100 D requirements. An early consideration is the development of a process for the control of documented information. Replace / rework the documented procedures for		

	in 4.2.4.		Control of Documents and Control of Records with a procedure, (such as P-750) for Documented Information and include it in section 7.5.		
4	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	Clause 4, Context of the Organization is a new requirement in AS 9100 D.	Documented information	Your company will have to determine the issues and requirements that can impact on the planning of the QMS and that can affect the ability to achieve the intended results of the QMS. For typical guidance, see procedure P-400 for Organizational context and worksheet, F-440-002 to identify issues and requirements.		
4.1	Documented information for the QMS sets the stage for an understanding of the requirements and of the international standard as a whole.	Procedure	Document the information (in a document P-400, Organizational Context) to outline the process to understand and determine the internal and external issues that are relevant to the QMS.		
4.2	A stakeholder approach provides for an understanding of the requirements of interested parties.		Include (in a document P-400) the process to understand and determine the needs and expectations of interested parties.		
4.3	*In AS 9100 C, the scope of the QMS was required to be included in a quality manual per par 4.2.2.*		Include (in a document P-400) the process to determine the scope of the QMS. Refer to 4.3 a) thru c) and consider the internal and external issues, the requirements of interested parties, and your products and services.		
4.3	*In AS 9100 C, the application and exclusion of requirements were included in par 1.2 and only permitted in clause 7.*		Include justifications for requirements of the standard that do not apply to the scope of the QMS. Note that conformity to AS 9100 D can only be claimed if the requirements determined to be not applicable do not affect your ability or responsibility to meet product and service requirements and enhance customer satisfaction.		
4.4	*In AS 9100 C, the requirement for the QMS and its processes was in 4.1.*		Your company will have to establish, implement, maintain and continually improve the QMS.		
4.4.1	*In AS 9100 C, the requirement for the QMS and its processes was in 4.1.*		Provide an outline (in a document P-400) of the process to determine the application and interaction of the processes needed for the QMS. As you proceed through the upgrade of the QMS, consider the use of the QMS process identification worksheet F-440-001 to determine the inputs required and the outputs expected from the		

1.0 Purpose/Scope

1.1 The purpose of this procedure is to provide a method to assist assigned individuals in performing consistent, complete, satisfactory root cause analysis.

2.0 Responsibilities and Authorities

2.1 The Management Representative is responsible for determining whether or not a Root Cause Analysis is appropriate for the situation.

2.2 The Management Representative is responsible for ensuring that all completed Root Cause Analysis documentation is filed and stored appropriately.

2.3 The Management Representative is responsible for the overall coordination of the Root Cause Analysis process including closure after satisfactory results have been obtained.

2.4 The Management Representative is responsible for the coordination of root cause analysis training with procedure P-720 for Competence and awareness.

3.0 References and Definitions

3.1 References

3.1.1 This document relates to clause 9.1.3, Analysis and evaluation and clause 10.2, Nonconformity and corrective action, of AS 9100 D standard.

3.2 Definitions

3.2.1 Cause: An event or condition that results in an effect. Anything that shapes or influences the outcome.

3.2.2 Event: A real-time occurrence describing one action, typically an error, failure, or malfunction or unwanted condition.

3.2.3 Condition: Any found state, whether or not resulting from an event, that may have safety, health, quality, security, operational, or environmental implications.

3.2.4 Barrier: A physical device or an administrative control used to reduce risk of the undesired outcome to an acceptable level. Barriers can provide physical intervention or procedural separation in time and space.

3.2.5 Contributing Factor: An event or condition that may have contributed to the occurrence of an undesired outcome but, if eliminated or modified, would not by itself have prevented the occurrence.

3.2.6 Organizational Factors: Any operational or management structural entity that exerts control over the system at any stage in its life cycle, including but not limited to the system's concept, development, design, fabrication, test, maintenance, operation, and disposal.

3.2.7 Root Cause Analysis (RCA) a structured evaluation method that identifies the root causes for an undesired outcome and the actions adequate to prevent recurrence. Root cause analysis should continue until organizational factors have been identified, or until data has been exhausted.

3.2.8 Root Cause(s): One or more factors that contributed to or created the proximate cause and subsequent undesired outcome and, if eliminated,

INSERT YOUR COMPANY NAME/LOGO HERE

F-815-001-A
Key Characteristic – Critical Item Identification

Instructions: Use the following table to record the identification and justification for the designation of a characteristic as a key characteristic.
Delete the blue, italicized type as you start to complete the form.

Key Characteristic Identification				
Document Number:		Description:		
Engineer:		Date:		
Characteristic Selected	Relevancy	Analysis Performed	Summary of Analysis Results	Justification for Designation as a key characteristic
Enter selected key characteristic.	• *Product fit* • *Form* • *Function* • *Performance* • *Service life* • *Producibility*	*Describe the various types of analysis performed.*	*Enter the summary of all analysis performed.*	*Enter the justification / need for designating this particular characteristic as a key characteristic.*

Attach all data, reports and summaries referenced in the above table that support the key characteristics selected above.

INSERT COMPANY NAME/LOGO HERE

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 tittles 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)?		

	Does the management representative have the organizational freedom and unrestricted access to top management to resolve quality management issues? NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.		
	Additional Questions		
6	**PLANNING**		
6.1	**Actions to address risks and opportunities**		
6.1.1	When planning for the QMS, does your company consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed?		
	Is this performed to:		
	• Give assurance that the QMS can achieve its intended results?		
	• Enhance desirable effects?		
	• Prevent, or reduce undesired effects?		
	• Achieve improvement?		

AS 9100 Rev D: Introduction to the Requirements

Requirements of AS 9100 D

Section 4: Context of the Organization
Section 5: Leadership
Section 6: Planning
Section 7: Support
Section 8: Operation – continued.
Section 9: Performance Evaluation
Section 10: Improvement

Section 8: Operation

This clause has the most requirements and this is the third newsletter to explain its contents. In previous newsletters, we talked about some nine requirements. This newsletter deals with the remaining sections of clause 8.

Control of production and service provision is the next requirement and deals with the implementation of the controlled conditions for our production operations. These conditions include a wide range of controls from having documented information on the specifications for the products, to control of tools and software, to validation and verification of processes, to how the process is carried out, to the final release for delivery and to post-delivery. Changes needed for production activities are reviewed and controlled to ensure that requirements continue to be met.

Products and services are verified at different stages of production and the release for shipment to customers takes place only after all inspection and test are completed and requirements met.

Property belonging to customers or external providers for use or inclusion in our products and services is identified, protected and treated with care to ensure that requirements are maintained. Post-delivery activities apply to our products where warranty obligations, maintenance services and final disposition assistance are needed.

Identification and traceability are requirements where products and services are identified to make sure that we know whether or not a product is accepted or rejected. When required by the customer or by our own specs, traceability means that we need to serialize and be able to trace where products are delivered. This is very important in the event of product recall.

Preservation of process outputs involves the protection of our products throughout the production operations to ensure that requirements are maintained.

Control of nonconforming outputs ensures that products that do not met requirements are identified and controlled to prevent the unintended use.

Operation Procedures listed below provide the remaining details on how our company plans and manages Clause 8.

P-851, Control of production and service provision,

P-852, Identification and traceability,

P 854, Preservation of products,

P-870, Control of nonconforming outputs.

Watch for our next newsletter for more introduction to AS 9100 D, what it will mean to you and your coworkers.