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:			Previously in AS 9100C, the requirements were described in:			
•	Clause 4	Context of the organization	٠	Clause 4	Quality management system	
•	Clause 5	Leadership	•	Clause 5	Management responsibility Resource management	
	Clause 6	Planning	•	Clause 6		
•	Clause 7	Support Operation	•	Clause 7	Product realization	
•	Clause 8			Clause 8	Measurement, analysis and improvement	
•	Clause 9	Performance evaluation				
•	Clause 10	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 <u>AS9100store.com</u> 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.

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AS 9100	Changes to the existing AS 9100 Rev C	Reference	Changes in existing documentation	Upgrade Checklist	
Rev D Clause	Quality System	document		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.	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		

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	in 4.2.4.		Control of Documents and Control of Records with a				
			procedure, (such as P-750) for Documented	1			
			Information and include it in section 7.5.				
	This first clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (
4	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.						
	Clause 4, Context of the Organization is a		Your company will have to determine the issues and				
4	new requirement in AS 9100 D.	Documented	requirements that can impact on the planning of the				
		information	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.				
	Documented information for the QMS sets		Document the information (in a document P-400,				
4.1	the stage for an understanding of the	Procedure	Organizational Context) to outline the process to	1			
	requirements and of the international		understand and determine the internal and external				
	standard as a whole.		issues that are relevant to the QMS.				
	A stakeholder approach provides for an		Include (in a document P-400) the process to				
4.2	understanding of the requirements of		understand and determine the needs and				
	interested parties.		expectations of interested parties.				
	In AS 9100 C, the scope of the QMS was		Include (in a document P-400) the process to				
4.3	required to be included in a quality		determine the scope of the QMS. Refer to 4.3 a) thru				
	manual per par 4.2.2.		c) and consider the internal and external issues, the				
			requirements of interested parties, and your products				
			and services.				
	In AS 9100 C, the application and		Include justifications for requirements of the standard				
4.3	exclusion of requirements were included		that do not apply to the scope of the QMS.	1			
	in par 1.2 and only permitted in clause 7.		Note that conformity to AS 9100 D can only be				
			claimed if the requirements determined to be not	1			
			applicable do not affect your ability or responsibility				
			to meet product and service requirements and				
			enhance customer satisfaction.	<u> </u>			
	In AS 9100 C, the requirement for the		Your company will have to establish, implement,	1			
4.4	QMS and its processes was in 4.1.		maintain and continually improve the QMS.				
	In AS 9100 C, the requirement for the		Provide an outline (in a document P-400) of the	1			
4.4.1	QMS and its processes was in 4.1.		process to determine the application and interaction				
			of the processes needed for the QMS.	1			
			As you proceed through the upgrade of the QMS,				
			consider the use of the QMS process identification				
			worksheet <u>F-440-001</u> to determine the inputs	1			
			required and the outputs expected from the	1			

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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,

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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.