ISO 9001:2015 to AS9100D - QMS Upgrade Instructions / Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from ISO 9001:2015 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 AS 9100 D and ISO 9001:2015 standards 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

You have the ISO 9001:2015 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 the9100store.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 ISO 9001:2015 version to the 2016 version, note that the intent of the main clauses is shown in blue font, and in the first left hand column of the instructions, the clause numbers highlighted in green indicates where specific AS 9100 D additions are made to ISO 9001:2015. Keep in mind that while you need to focus on the new requirements of AS 9100 D, your company now has an opportunity to review the exiting ISO 9001:2015 QMS and improve the system while incorporating the AS 9100 D requirements.

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.

			• Achieve improvement.		
6.1.2	This sub-clause focuses on the planning of actions to be taken to address risks and opportunities.	Procedures	In P-600, review / upgrade how you plan the actions to address risks and opportunities, how you integrate and implement them in the QMS, and how you evaluate the effectiveness of the actions taken. See procedure P-612 and related forms F-612-001, F-612-002, and F-610-001 & F-810-002 for more information on the risk management process.		
6.2	Quality objectives and the planning to achieve them applies to both standards where objectives at relevant functions, levels, and processes are included.		Review / upgrade your system for establishing quality objectives at the relevant functions, levels and processes and the planning to achieve them. Refer to specific requirements in clause 6.2.1 a) thru g) and clause 6.2.2 a) thru e)		
6.3	Planning for changes applies to both standards where needed QMS changes are determined and carried out in a planned manner.		Include the process for the planning of changes to the QMS and for carrying them out in a planned and systematic way. Refer to specific requirements in clause 6.3 s a) thru d) dealing with the purpose of change, QMS integrity, resources, and responsibility.		
7	This clause requires that your company determine and provide the resources needed to establish, implement, maintain, and continually improve the QMS. This section covers the resources that support the QMS and include people, infrastructure, environment for the operation of processes, monitoring and measuring resources, and organizational knowledge. In addition, competence, awareness of the human resources / personnel and methods for communication among the personnel along with systems for documented information need to be determined.				
7	Clause 7, Support is a requirement in both AS 9100 D and ISO 9001:2015.	Documented information	Review your existing system for the management of resources.		
7.1		Procedure	Review / upgrade the information (in a document P-710) that outlines the process for managing the resources of infrastructure and environment for the operation of the processes.		
7.1.1			Review your statement indicating that when determining and providing resources, consideration is given to capabilities, constraints, and external provision.		
7.1.2			Review the methods required to provide the persons needed for an effective QMS and for the operation and control of the processes. (See also 7.2 competence and 7.3 awareness).		
7.1.3			Review the system required to determine and provide the infrastructure for the operation of the processes.		
			Review the methods required to determine and		

			organizational knowledge (7.1.6) in this document.		
7.2	In AS 9100 D, the periodic review of the necessary competence of people is required to be considered.		In P-720, consider the periodic review of the necessary competence of the people.		
7.3			Refer to clause 7.3 and in P-720 review the awareness requirements a) thru d).		
7.3	In AS 9100 D, new awareness items e) through h) are required for persons doing work for the company.		In P-720 include the new requirements for: • relevant QMS documented information, and changes thereto, • their contribution to product or service conformity, • their contribution to product safety, • the importance of ethical behavior.		
7.4		Procedure	Review / upgrade the information (in a document P-740) that outlines the process for both internal and external communications of quality matters. Refer to 7.4 a) thru e) and include the information on what, when, with whom, how, who will be communicating.		
7.4	In AS 9100 D, communication includes internal and external feedback		Ensure that your communication system includes internal and external feedback relevant to the QMS.		
7.5	In AS 9100 D and ISO 9001:2015, 'Documented Information' replaces documented procedure and record. Documented procedure is now expressed as a requirement to maintain documented information. Record is now expressed as a requirement to retain documented information.	Procedure	Review /upgrade the information (in a document P-750) that outlines the process for the control of documented information. Incorporate a document numbering system related to the clause numbers. Ensure that documented procedures for Control of Documents and Control of Records are included in P-750, Control of documented information.		
7.5.2	In AS 9100 D, a note clarifies approval implications.		In P-750, clarify that approval implies authorized persons and approval methods are identified for the relevant types of necessary documented information.		
7.5.3.1			In P-750 include the method to adequately protect documented information from loss of confidentiality, improper use, or loss of integrity.		
7.5.3.2			Refer to clause 7.5.3.2 and in P-750 review the requirements a) thru d).		
7.5.3.2	In AS 9100 D, a requirement for control of unintended use of obsolete documents is included at item e).		In P-750 include the new requirement for a system to prevent the unintended use of obsolete documented information by removal or by suitable identification or controls if retained for any purpose.		
7.5.3.2	In AS 9100 D, electronically managed documented information is addressed.		In P-750 and when documented information is managed electronically, data protection processes		

1.0   Purpose/Scope

1.1   This procedure describes the process used to determine and control the selection of key characteristics and critical items of assemblies, components, materials and processes and the usage of same.

2.0   Responsibilities and Authorities

2.1   The product / process engineer is responsible for the selection of all necessary key characteristics and critical items and determining the appropriate data to be collected and evaluated.

3.0   References and Definitions

3.1   Reference

3.1.1   This document addresses clause 8.1 g of the AS 9100 D standard, covering key characteristics and critical items.

3.2   Definitions

3.2.1   Key Characteristic - The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or producibility.

3.2.2   Critical Items - Those items such as functions, parts, software, characteristics, processes having significant effect on the provision and use of the products and services. including safety, performance, form, fit, function, producibility, or service life.

3.2.3   Risk Analysis – To determine the importance of, or value of a situation or condition. Broadly defined to include risk assessment, risk characterization, risk communication, risk management, and policy relating to risk.

3.2.4   Pareto Analysis - A formal technique for identifying the changes that will provide the greatest benefits. A Pareto analysis is a sorted histogram with two features. First is the cumulative distribution curve. Second, the vital few are identified. The histogram is sorted with the greatest occurrences to the left and descending occurrences moving to the right.

3.2.5   Failure Mode Effects Critically Analysis (FMECA) – A disciplined review technique that focuses on the development of products, materials and processes based upon prioritized actions and in depth analysis to reduce the risk of product failures, and the associated documentation of those actions and review process.

3.2.6   Flowdown – Technique for identifying key characteristics and critical items for a product or assembly down to subassemblies, details or processes believed to have a variation effect on upper level key characteristics and critical items.

4.0   Resources

4.1   Is there any special equipment or software required? (i.e.; special analysis

Planning Project Type					
Quality Plan		**Quality Objective**		**Risk & Opportunity**	

Project Name: _____ Date:_____

Project objective:

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Estimated time frame: _____

Estimated start date: _____

Project manager: _____

Team members: _____

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Project completion date:
Were objectives met?
Project status: Operational   Terminated   On-hold

Management approval: