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

INSERT YOUR COMPANY LOGO/NAME HERE

F-810-002
Project Planning Worksheet

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

Project Name: _____ Date: _____

Project objective:

_____

_____

_____

_____

_____

_____

_____

_____

Estimated time frame: _____

Estimated start date: _____

Project manager: _____

Team members: _____

_____

_____

Project completion date:

Were objectives met?

Project status: Operational Terminated On-hold

Management approval:

Every version of the AS 9100 standard has advocated risk avoidance and risk management. The new AS 9100 Rev D standard continues to expect organizations to identify and address risks affecting compliance of products and services, resulting in improved customer satisfaction.

Besides identifying the risks, organizations should address opportunities for improvements and corrective actions based on the risk analysis.

Note that while nonconformity and corrective action are requirements of AS 9100 Rev D, the concept of preventive action can be addressed through a risk-based approach where risks are determined and actions to address risks and opportunities are taken.

This risk analysis exercise is intended to outline several approaches / options for the management of risk at your company.

To prepare for the change, it is time to begin understanding Risk-Based Thinking and begin looking at your processes in terms of risks.

Risk is defined as the combination of the probability of occurrence of harm and the severity of that harm.

When evaluating risk, it is helpful to address it using two (2) metrics or parameters:

1. Severity (if harm happens, how serious is the event)
2. Likelihood (what is the probability of a harmful event occurring)

Because this topic is so important, it will have an impact on your QMS.

Risk-Based Thinking

INSERT COMPANY NAME/LOGO HERE

AS 9100 Rev D - Quality Management Systems – from ISO 9001:2015 - 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.				

INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 to AS 9100 Rev D 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 international aerospace standard and in the 2015-09 revision of ISO 9001:2015 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard as you transition from ISO 9001:2015. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

Both the versions of the AS 9100 and ISO 9001 standards deal with Quality Management Systems and line up when comparing the contents, the new requirements and / or new terminology. The additions for AS 9100 over ISO 9001 are highlighted in yellow. The auditors are expected to keep in mind that the standard does not requires 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 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?		

	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?		
	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?		
	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?		

