ISO 9001:2015 to AS 9120 B - QMS Transition 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 9120 B revision for Quality management systems used in the aviation, space, and defense distribution industries.

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

In the AS 9120 B 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 AS 9120 Rev B 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 9120 B.
- 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 9120 B 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 9120 B standard. Visit the 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 9120 B quality management system. As you undertake the task of upgrading your quality management system from the ISO version to the AS version, note that the intent of the main clauses is shown in **blue font**. In the first left hand column of the instructions, the clause numbers highlighted in green indicate where specific AS 9120 B additions are made to ISO 9001:2015, and the clause numbers highlighted in yellow indicate where ISO 9001 requirements are carried over for AS 9120 B.
Keep in mind that while you need to focus on the new requirements of AS 9120 B, your company now has an opportunity to review the carry-over ISO 9001 QMS and improve the system while incorporating the AS 9120 B requirements.

Use a copy of the AS standard along with this instruction, to pinpoint for your company, 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.

ISO 9001:2015 to AS 9120 B - QMS Transition Instructions/Checklist

AS 9120 Rev B Clause	Changes to the existing ISO 9001:2015 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The SAE international Aerospace standard AS 9120 Rev B 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 9120 B	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). Your company now has an opportunity to review the exiting ISO 9001:2015 QMS and improve the system while incorporating the AS 9120 B requirements.		
All	While the specific requirement for a quality manual is not in AS 9120 B and ISO 9001:2015, 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 QMS. A quality manual is not included as a requirement in clause 7.5.1 of AS 9120 B; 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.		
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---	The specific requirement for documented procedures is not in AS 9120 B and ISO 9001:2015; 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 9120 B requirements.		

			An early consideration is the development of a process for the control of documented information. Replace / rework the documented procedures for 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 both AS 9120 B and ISO 9001:2015.	Documented information	Your company must 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.	Procedure	Review the information (in a document P-400, Organizational Context) that outlines 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.		Review the process to understand and determine the needs and expectations of interested parties.		
4.3	In AS 9120 B, determining the scope of the QMS is in clause 4.3.		Review 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 9120 B, the scope of the QMS considers justification for requirements that do not apply.		Review any justifications for requirements of the standard that do not apply to the scope of the QMS. Note that conformity to AS 9120 B 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 9120 B, clause 4.4 outlines the requirements for the QMS and its processes.		Review your system to establish, implement, maintain, and continually improve the QMS.		
4.4.1	The AS 9120 B QMS must also address customer and applicable statutory and		Provide an outline (in a document P-400) of the process to determine the application and interaction		

1.0 Purpose/Scope

1.1 This procedure describes and defines the techniques utilized in statistical analysis used to monitor and measure the QMS and related sub-systems.

2.0 Responsibilities and Authorities

2.1 The Management Representative is responsible for maintaining this procedure and all related statistical techniques, work instructions and forms.

2.2 The Management Representative is responsible for the coordination of statistical techniques training with procedure P-720 for Competence and awareness.

3.0 References and Definitions

3.1 Reference: This document relates to clause 9.1.3, Analysis and evaluation, and clause 10.2, Nonconformity and corrective action, of AS 9120 B standard.

3.2 Definitions

3.2.1 Process Capability: A statistical technique used to evaluate the ability of a process to satisfy the needs of its customers.

3.2.2 Statistical Process Control (SPC): The use of statistical methods for collection, analysis, and display of process, product, or service variation data. This information is used to assist in data based decision-making for the continuous quality improvement process.

3.2.3 Specifications: The prescribed requirements to which a product or service must conform.

3.2.4 Variability: The variation or inconsistency of a measurement.

4.0 Resources

4.1 List any software programs used to collect, correlate, analyze and report data and the resulting summaries.

5.0 Instructions

5.1 In support of the planning procedure P-910 for Monitoring, measurement, analysis and evaluation, the Management Representative ensures that appropriate statistical techniques are implemented and applied at strategic points within the QMS such as customer complaint analysis, process measurement and control, analysis of non-conformances, etc.

5.2 Identification of Need for Statistics Gathering

5.2.1 The individual responsible for submitting statistical data and information for management review will identify the need for using statistical techniques in their departments and in other activities for which they are responsible.

5.2.2 Additional sources of expertise may be called upon to assist other departments in selecting and documenting specific statistical techniques.

5.2.3 Top Management may require that the performance of certain processes

INSERT YOUR COMPANY LOGO/NAME HERE

F-610-001
Risk and Opportunity Worksheet

Risks and Opportunities Guidelines

- The risks and opportunities are determined and addressed in order to ensure that the QMS can achieve its intended result(s), prevent, or reduce, undesired effects, and achieve continual improvement.
- Options to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.
- Actions to address the risks and opportunities are planned in order to integrate and implement them into the processes and to evaluate the effectiveness of these actions.
- Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.
- With inputs from the Quality team / ISO steering committee, this risk and opportunity worksheet is prepared by the Quality team leader / ISO management representative.
- The Quality team / ISO steering committee is responsible to set priorities for projects where risks and opportunities need to be addressed and to assign risk or opportunity project responsibilities.

The following instructions are used to assess the risks associated with the planning of the QMS processes and to assign priorities for the actions needed to address the risks and opportunities.

To determine the risks and opportunities that need to be addressed:

- In table below identify the activities/processes that are risk and opportunity candidates.
- Assign a value for each assessment category.
- R-values of 1 and 2 represent Risks/Threats, and O-values of 3 and 4 represent Opportunities.
- The project planning worksheet F-810-002 is used to plan high priority projects.

Customer Impact: How much does the customer care?
1 = Low customer priority
4 = Very important to the customer

Changeability Index: Can you fix it?
1 = Very Difficult / Expensive to fix
4 = Relatively easy / cheap to fix

Performance Status: How broken is it?
1 = Only a few problems in the past
4 = Always seems to be causing problems

Business Impact: How important is it to the business?
1 = Has little impact on the business
4 = Is very important to the business

Work Impact: What resources are available?
1 = People who have capability to work on this activity are scarce
4 = People who have capability to work on this activity can be available