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

AS 9120	Changes to the existing ISO 9001:2015	Reference	Changes in existing documentation	Upgrade Checklist	
Rev B Clause	Quality System	document		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.		
		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 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.		

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	In AS 9120 B, clause 5.2.1 outlines the		Review the process for developing a quality policy		
<mark>5.2.1</mark>	requirements for the quality policy.		that is appropriate to the purpose and context of your		
			company and communicating this quality policy.		
	In AS 9120 B, clause 5.2.2 outlines the		Review the new requirements that the quality policy		
<mark>5.2.2</mark>	requirements for the availability of the		is available as documented information and available		
	quality policy.		to interested parties.		
	In AS 9120 B, clause 5.3 covers		Review the system for ensuring that the		
<mark>5.3</mark>	organizational roles, responsibilities, and	Organization	responsibilities and authorities for relevant roles are		
	authorities.	chart	assigned and communicated.		
	In AS 9120 B, clause 5.3 requires the		Top management is required to appoint a specific		
<mark>5.3</mark>	appointment of a management		member of the team as the management		
	representative.		representative who has the responsibility and		
	In ISO 9001:2015, a specific management		authority to oversee the QMS and ensure that it		
	representative was not required to be		conforms to the requirements of the AS standard.		
	appointed.		This person must have unrestricted access to top		
			management and organizational freedom to deal		
			with quality management issues.		
			Note that the responsibility of the management		
			representative can include liaison with external		
			parties regarding QMS matters.		
6	determine the risks and opportunities that n	eed to be addres to plans to achie	ur company needs to consider the issues referred to in 4 ssed. In addition, this section covers the quality objective ve them determined. You will also need to carry out cha QMS is required.	es that will need to	be
	In AS 9120 B, clause 6 focuses on the		Review the information (in a document P-600) that		
6	planning for the quality management	Procedure	outlines the process for planning for the QMS.		
_	system and is a requirement in both AS				
	9120 B and ISO 9001:2015.				
	The 'Risk-Based-Thinking' approach is		Review the actions needed to address the risks and		
<mark>6.1</mark>	new in AS 9120 B where a key purpose of		opportunities associated with the internal and		
	the QMS is to act as a preventive tool.		external issues that are relevant to the QMS.		
	In AS 9120 B, clause 6.1.1 focuses on the		As applicable to your company, make use of your		
<mark>6.1.1</mark>	planning for the QMS and on determining		organizational knowledge, lessons learned and		
	the actions needed to address risks and		experience with the activities in every procedure to		
	opportunities.		determine the opportunities and risk that need to be		
			addressed and that can:		
			Give assurance that the procedure can achieve its		
			intended results		
			Enhance desirable effects		
			 Prevent or reduce undesired effects 		

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			Achieve improvement				
	In AS 9120 B, clause 6.1.2 focuses on the	_	In P-600, review and describe how you plan the				
<mark>6.1.2</mark>	planning of actions to be taken to address	Procedures	actions to address risks and opportunities, how you				
	risks and opportunities.		integrate and implement them in the QMS, and how				
			you evaluate the effectiveness of the actions taken.				
			See procedure <u>P-612</u> and related forms <u>F-612-001</u> ,				
			F-612-002, and F-610-001 & F-810-002 for more				
			information on the risk management process.				
<mark></mark>	In AS 9120 B, clause 6.2 focuses on		Review the system for establishing quality objectives				
<mark>6.2</mark>	quality objectives and the planning to		at the relevant functions, levels and processes and				
	achieve them.		the planning to achieve them.				
0.0.4	In AS 9120 B, clause 6.2.1 outlines the		Refer to specific requirements in clause 6.2.1 a) thru				
<mark>6.2.1</mark>	requirements for quality objectives.		g) and include the items ranging from a) consistent				
			with the quality policy to g) update as required.				
<mark>6.2.2</mark>	In AS 9120 B, clause 6.2.2 outlines		Refer to specific requirements in clause 6.2.2 a) thru				
<mark>0.2.2</mark>	additional requirements for quality		e) and include the items ranging from a) what will be				
	objectives. In AS 9120 B, the requirement for		done to e) how the results will be evaluated.				
<mark>6.3</mark>			Review the process for the planning of changes to the QMS and for carrying them out in a planned and				
0.3	planning of changes is in clause 6.3.		systematic way.				
			Refer to specific requirements in clause 6.3 and				
			include items ranging from a) purpose of changes, to				
			d) allocation of responsibilities.				
			a) allocation of responsibilities.				
	This clause requires that your company det	ermine and prov	ide the resources needed to establish, implement, main	tain, and continua	lly improve the		
7	QMS. This section covers the resources that support the QMS and include people, infrastructure, environment for the operation of processes,						
			owledge. In addition, competence, awareness of the hur				
			th systems for documented information need to be deter				
	In AS 9120 B, clause 7, Support is a		Review your existing system for the management of				
7	requirement in both AS 9120 B and ISO	Documented	resources.				
	9001:2015.	information					
	In AS 9120 B, clause 7.1 outlines the		Document the information (in a document P-710) to				
<mark>7.1</mark>	requirements for the management of	Procedure	outline the process for managing the resources of				
	resources.		infrastructure and environment for the operation of				
			the processes.				
	The requirements to consider the		Review a statement to indicate that when				
<mark>7.1.1</mark>	capabilities and the constraints on		determining and providing resources, consideration				
	existing resources and what is required to		is given to capabilities, constraints, and external				
	be obtained from external providers are		provision.				
	included in clause 7.1.1.						
	In AS 9120 B, clause 7.1.2 focuses on		Review the methods required to provide the persons				

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AS 9120 Rev B - Quality Management Systems – The Internal Audit Checklist

	• 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? 	
4.4.2	Does your company maintain the necessary documented information to support the operation of processes?	
	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, per section 4.2 a? 	
	 Scope of the QMS, including boundaries and applicability, per section 4.3? 	
	 Description of the processes needed for the QMS and their application throughout the organization? 	
	 Sequence and interaction of the processes? 	

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ISO 9001:2015 into AS 9120 Rev B - Quality Management Systems -- 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 9120 Rev B 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 9120 B 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 vellow 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 focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to comply with the AS 9120 Rev B standard.

	QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	lf 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.				
4.1	Understanding the organization and its context				

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P-400-A

Organizational Context

1.0 Purpose/Scope

- 1.1 The purpose of this procedure is to ensure that the context of Your Company and the needs and expectations of interested parties are understood.
- 1.2 The procedure applies to the external and internal issues that can affect the Quality Management System (QMS).

2.0 Responsibilities and Authorities

- 2.1 The President has the prime responsibility and approval authority for this procedure.
- 2.2 **Top management** is responsible to determine the relevant external and internal issues that affect the ability to achieve the intended result(s) of the QMS and that can impact on the planning of the QMS.

3.0 References and Definitions

- 3.1 Reference: This document addresses clause 4 of the AS 9120 B standard covering, Context of the organization.
- 3.2 Definitions
 - 3.2.1 Top management: Person or group of people who directs and controls an organization at the highest level.
 - 3.2.2 Context of the organization: Combination of internal and external factors and conditions that can have an effect on an organization.

4.0 Resources

4.1 As outlined in the procedure P-710 for Resource management.

5.0 Instructions

- 5.1 To fully understand the organization and its context, Your Company determines the external and internal issues that are relevant and that affect its ability to achieve the intended outcomes of the QMS.
 - 5.1.1 The external and internal issues include production and service conditions capable of affecting or being affected by the company.
 - 5.1.2 Relevant internal and external Issues may include the:
 - Business and quality management conditions related to the areas of leadership, customer focus, engagement of people, process approach, improvement, evidence-based decision making and relationship management that can either affect the company's purpose, or be affected by its decisions.
 - External cultural, social, political, legal, regulatory, financial, technological, economic, natural, and competitive context, whether international, national, regional, or local.

Organizational context		Page 1 of 6
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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

AS9120Store

Course Materials

The supplies you will need are:

- PowerPoint: Guide to Internal Audits (included).
- PowerPoint: <u>Requirements of AS 9120 REV B</u> (included).
 A complete version with Speaker Notes is in this Trainer's Guide
- PowerPoint: Steps of Internal Audit (included).
 - A complete version with Speaker Notes is in this Trainer's Guide
- Student Manual (included).
 - Print one copy for each student
 - > You may wish to have extra copies of the CAR form
 - It includes reduced versions of all the PowerPoints.
- AeroSource Company Documented Information (included).
 - > Print one copy for **each team** of two or three students.
 - See next page for list of contents.
 - Note that for this training, it is not possible to bring all documents from a fictitious company in the classroom.
 - However, documents relevant to the audit and non-conformances observed are included. In the list of documented information, the relevant manual and procedures are highlighted in brown font.
- The AS 9120 REV B Standard (NOT Included*)
 - > You will need one copy for every 2-3 students.
 - Standards are available electronically from <u>http://www.techstreet.com/products</u>

The AS 9120 REV B Standard is a copyrighted document and we are unable to include it.

Provided in Microsoft Word Easy to customize with your company name!

Welcome to AS 9120 Rev B

Our Company is working on becoming AS 9120 B registered. This international standard provides for a (QMS), Quality Management System that outlines some basic good business practices that we need to have in place for our distribution business.

By implementing a Quality Management System (QMS) that complies with AS 9120 B we will be able to make our company run more efficiently, increase customer satisfaction, and communicate to potential customers that we have good quality processes in place.

Surveyed AS 9120 Registered Companies state that they have:

- Higher customer satisfaction
- Increased profitability because of efficiencies
- Market advantages
- Improved communications
- Higher job satisfaction

What will employees need to do for the AS 9120 B Quality Management System?

First Management will be determining both the internal and external issues that are relevant to the QMS and will identify our "Key Processes".

Those are the processes that affect the quality of our product and our services. Then they will determine how we will control these processes to make sure that we are all doing them the same way, and the best way our organization has identified.

Controlling the process means having documented information for the quality management system, and training employees or finding other or best ways to make sure that the process is done consistently no matter who is doing it. This means that employees may be required to have certain training, or to follow specific work instructions.

Employees will also need to be aware of how their job affects the quality of our products and customer satisfaction.

AS 9120 Highlights: Things that you will be hearing about as we proceed with this project....

Our Quality Policy

We will identify our Quality Policy, and will be communicating it to all employees. It is important that all of us are aware of what this statement says about our company's vision is for quality and for meeting customers' expectations.

Registration Audit

To become AS 9120 B registered, an independent Registrar will audit our quality system. This Registration Audit will be done after we have set up processes to meet all the requirements of AS 9120 B.

The Registrar will send an auditor or audit team to come in to our facilities and evaluate the processes we have in place.

They will check to see if the processes meet the requirements of the standard, and to see if we are following the processes. If everything looks good, we will be recommended for registration and be recognized globally!



Watch for our next newsletter for more introduction to AS 9120 B, what it will mean to you and your coworkers.

