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 <a href="AS9100store.com">AS9100store.com</a> 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.

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:			
	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.			

5.2.1	In AS 9120 B, clause 5.2.1 outlines the requirements for the quality policy.		Review the process for developing a quality policy that is appropriate to the purpose and context of your		
5.2.2	In AS 9120 B, clause 5.2.2 outlines the requirements for the availability of the quality policy.		company and communicating this quality policy.  Review the new requirements that the quality policy is available as documented information and available to interested parties.		
5.3	In AS 9120 B, clause 5.3 covers organizational roles, responsibilities, and authorities.	Organization chart	Review the system for ensuring that the responsibilities and authorities for relevant roles are assigned and communicated.		
5.3	In AS 9120 B, clause 5.3 requires the appointment of a management representative. In ISO 9001:2015, a specific management representative was not required to be appointed.		Top management is required to appoint a specific member of the team as the management representative who has the responsibility and authority to oversee the QMS and ensure that it conforms to the requirements of the AS standard. 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 no	eed to be addressee 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 t	o be
6	In AS 9120 B, clause 6 focuses on the planning for the quality management system and is a requirement in both AS 9120 B and ISO 9001:2015.	Procedure	Review the information (in a document P-600) that outlines the process for planning for the QMS.		
<mark>6.1</mark>	The 'Risk-Based-Thinking' approach is new in AS 9120 B where a key purpose of the QMS is to act as a preventive tool.		Review the actions needed to address the risks and opportunities associated with the internal and external issues that are relevant to the QMS.		
<b>6.1.1</b>	In AS 9120 B, clause 6.1.1 focuses on the planning for the QMS and on determining the actions needed to address risks and opportunities.		As applicable to your company, make use of your organizational knowledge, lessons learned and experience with the activities in every procedure to 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		

			Achieve improvement		
6.1.2	In AS 9120 B, clause 6.1.2 focuses on the planning of actions to be taken to address risks and opportunities.	Procedures	In P-600, review and describe 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		
6.2	In AS 9120 B, clause 6.2 focuses on quality objectives and the planning to achieve them.		information on the risk management process.  Review the system for establishing quality objectives at the relevant functions, levels and processes and the planning to achieve them.		
<mark>6.2.1</mark>	In AS 9120 B, clause 6.2.1 outlines the requirements for quality objectives.		Refer to specific requirements in clause 6.2.1 a) thru g) and include the items ranging from a) consistent with the quality policy to g) update as required.		
6.2.2	In AS 9120 B, clause 6.2.2 outlines additional requirements for quality objectives.		Refer to specific requirements in clause 6.2.2 a) thru e) and include the items ranging from a) what will be done to e) how the results will be evaluated.		
6.3	In AS 9120 B, the requirement for planning of changes is in clause 6.3.		Review 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 and include items ranging from a) purpose of changes, to d) allocation of responsibilities.		
7	QMS. This section covers the resources that monitoring and measuring resources, and o	it support the QI rganizational kn	I ide the resources needed to establish, implement, main MS and include people, infrastructure, environment for the owledge. In addition, competence, awareness of the huith the systems for documented information need to be deter	ne operation of pr man resources / p	ocesses,
<mark>7</mark>	In AS 9120 B, clause 7, Support is a requirement in both AS 9120 B and ISO 9001:2015.	Documented information	Review your existing system for the management of resources.		
<b>7.1</b>	In AS 9120 B, clause 7.1 outlines the requirements for the management of resources.	Procedure	Document the information (in a document P-710) to outline the process for managing the resources of infrastructure and environment for the operation of the processes.		
7.1.1	The requirements to consider the capabilities and the constraints on existing resources and what is required to be obtained from external providers are included in clause 7.1.1.  In AS 9120 B, clause 7.1.2 focuses on		Review a statement to indicate that when determining and providing resources, consideration is given to capabilities, constraints, and external provision.  Review the methods required to provide the persons		

## **INSERT COMPANY NAME/LOGO HERE**

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

This checklist is based on the information provided in the Nov 2016 version of the AS 9120 Rev B International Aerospace 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 and ISO standards deal with Quality Management Systems and line up when comparing the contents, the new requirements and / or new terminology. The additions for ISO 9001 to AS 9120 B are highlighted in yellow. The auditors are expected to keep in mind that the standard does not require 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 SYSTEMS	OBSERVATIONS / COMMENTS	STATUS OK Yes / No			
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?					

AQG-Nov-2016 - Audit conducted by:	Date:	to	Copyright © AS9120Store	Page 1 of

69

### **INSERT COMPANY NAME/LOGO HERE**

# 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 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 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?	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.					
4.1	Understanding the organization and its context					

AQG-Nov-2016 - Audit conducted by:	Date: _	to	Copyright © AS9120Store	Page 1 of 63

## **INSERT YOUR COMPANY LOGO/NAME HERE**

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

- 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.

#### **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