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AS 9120 Rev B

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QM-9120-B

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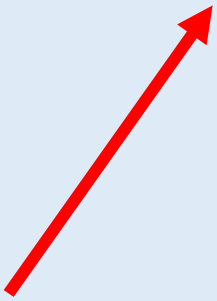

Blue text throughout the manual highlight areas for customization

Table of Contents – (this page)

Any text may be edited.

Blue text provides examples of what you may want ot use.

Black text describes the QMS.

Section A Scope or the Quality Management System **Provides general purpose and description of Quality Manual**

General

To determine and establish the scope of the QMS, Your Company determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company. The scope is available and maintained as documented information stating the products and services covered by the QMS.
Your Company applies all the requirements of AS 9120 Rev B when they are applicable within the determined scope of the QMS.
As developed with procedure P-400 for Organizational context, include the scope of your QMS here:

Blue text gives guidance for customization.

_____

_____

For example, if you are a distributor of landing gear tires, the scope of the Quality Management System includes the major product and service categories associated with the distribution of landing gear tires from the Main Street warehouse location to regional, national, and international aviation, space, and defense customers.

Conformity to the standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.
In the event that any requirement is not applicable at Your Company, justification for any instance where a requirement cannot be applied is documented.
Your Company has determined that the following requirement(s) is/are not applicable to the operations at this site:

_____.

As determined with procedure P-400, identify the requirement(s) that do not apply and document the justification here:

Related documents are referenced.

_____

_____Fo

r example, if you are a distributor of aircraft tires, a requirement that does not apply:

Clause 8.3 for design and development does not apply to the company. The product is designed and developed and meets requirements through the designer and provider of landing gear tires.

Section B References

a. Normative reference
9100:2016 Quality Management Systems – Requirements for aviation, space, and defense organizations,
ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary.
ISO 9001:2015 Quality Management Systems – Requirements

b. Definitions Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.

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INSERT YOUR COMPANY LOGO/NAME HERE

1.0 Purpose/Scope

1.1 To outline the requirements for control of measuring and monitoring equipment at Your Company.

1.2 The procedure applies to equipment where monitoring or measuring is used for evidence of conformity of products and services

2.0 Responsibilities and Authorities

2.1 The Quality assurance manager / Management representative has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality assurance manager and where monitoring or measuring is used for evidence of conformity of products and services, the Quality team / AS steering committee is responsible for determining the resources needed to ensure valid and reliable monitoring and measuring results.

2.3 The Quality team / AS steering committee is responsible to designate the Equipment coordinator, and to assign responsibility for calibration and maintenance of the equipment.

3.0 References and Definitions

3.1 Reference:This document addresses clause 7.1.5 of the AS 9120 B standard, covering monitoring and measuring resources.

3.2 No definitions

4.0 Resources

4.1 None, (unless an electronic equipment calibration tracking system is used).

5.0 Instructions

5.1 The Quality team / AS steering committee determines and provides the resources needed to ensure valid and reliable results when monitoring and measuring is used to verify conformity to requirements.

5.1.1 With procedures P-810 for Operational planning and control, P-851 for Control of production and service provision, and P-910 for Monitoring, measurement, analysis and evaluation, consideration is given to monitoring and measuring resources to ensure that they are:

- Suitable for the specific type of monitoring and measuring activities undertaken,
- Maintained to ensure their continuing fitness for their purpose and documented information maintained as evidence of fitness for purpose.
- Calibrated or verified in suitable environmental conditions.

5.2 The Quality team / AS steering committee ensures that measuring instruments are calibrated when measurement traceability is considered to be an essential part of providing confidence in valid measurement results, or is a statutory or regulatory requirement, or is customer or interested party expectations.

You can search and replace "your company" with your own company name.

INSERT COMPANY NAME/LOGO HERE

GUIDELINES – Evaluation and Selection of External Providers	Date Approved _____	Data Form A-840-001

Providers are evaluated and selected by one of the following methods:

Review methods listed below at par 1.1 to 1.6 and select one or more that are appropriate for your company.

If you have goods or services that vary in its impact on quality you may want to set up categories, the higher the impact the more comprehensive the method. You may need to combine more than one method, for example an audit and samples for inspection and test.

Blue text throughout the manual highlight areas for customization

1.1 The provider is, at a minimum, registered to ISO 9001:2015.

- Purchasing department staff reviews and maintains a copy of their certificate and quality manual on file.
- Purchasing / Quality management staff performs quality system development with the objective of provider conformance to ISO 9001:2015 and leading to AS 9120 B.

1.2 The provider provides graded or classed material, and provides certificate of analysis with the material or item.

1.3 Samples of the materials or items are provided for inspection and test, with satisfactory results.

- The person requesting the purchase documents the sample size required and the inspection and test to be performed on the purchasing documents.
- Completed inspection and test records show the criteria for acceptance and the actual results. If they are acceptable, the requisitioner sends them to purchasing to be kept in the provider's file.

1.4 An audit of the provider confirms that required elements of a quality system are in place and results documented in the provider assessment report F-840-001.

- The Quality manager assigns an individual or team to perform the audit.
- The Quality manager reviews the completed audit checklist, and determines if the supplier meets requirements.
- If the provider meets requirements, the purchasing manager indicates acceptance on the provider assessment report and keeps the audit checklist in the provider's file.
- The approved provider is added to the List of acceptable sources, form F-840-002.

1.5 The provider is specified by the customer contract. The use of customer designated providers does not relieve Your Company of the responsibility to ensure quality.

1.6 The Purchasing department places a trial order.

- Purchasing department orders the material or item, and the requisitioner uses the material, and measures the results.
- If the results are not acceptable, the product that it was used for is controlled according to the control of nonconforming product procedure, P-870.
- If the results are acceptable, they are documented and kept in the provider's file.

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INSERT YOUR COMPANY LOGO/NAME HERE

EQUIPMENT PROBLEM REPORT

EQUIPMENT DESCRIPTION:_____

LAST TASK PERFORMED:_____

JOB NUMBER:_____

DATE:_____ TIME:_____

OPERATOR:_____

REPORTED BY:_____

DESCRIPTION OF PROBLEM:

ACTION TAKEN

PROBLEM INVESTIGATED BY:_____

PROBLEM RESOLUTION DATE:_____

INSERT COMPANY NAME/LOGO HERE

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

This internal audit checklist is based on the information provided in the Nov 2016 revision of the AS 9120 Rev B, SAE 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. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

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 '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?		
	Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?		

INSERT COMPANY NAME/LOGO HERE

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 AS 9120 Rev B. Each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. You will need to have a copy of the AS 9120 B standard to use along with this checklist so that you can refer to the requirements and the clarification sections of Annex A. 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**				
	Does your company determine the external and internal issues that are relevant to your purpose and strategic direction?				

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Risk Management

Every version of the AS 9120 standard has advocated risk avoidance and risk management. The new AS 9120 Rev B 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 9120 Rev B, 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

Example: What can go wrong with a Process?

- Purchasing Process
  - Single Source supplier is wiped out by Tsunami
- What is the impact?
  - You are shut down
- What is the likelihood it will happen?
  - Unlikely (But it happens)
- How do you mitigate the risk?
  - Find another supplier
  - Revise design to allow other options