

AS9100 Rev B



AS9100 Store
QUALITY FOR AEROSPACE

Requirements of AS 9100 Rev B

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In the following slides, the AS9100 Standard is paraphrased for instructional purposes. Refer to the standard for the actual text.

Questions we will cover today:

- **What is AS9100?**
- **What are the steps for Registration?**
- **AS9100 Rev B: Clause by Clause Review**
- **What are the next steps?**
- **Appendix: Summary of Key AS9100 Requirements**

What is AS 9100?

- **Representatives from IAQG (International Aerospace Quality Group) designed AS 9100 as a common Quality System for Aerospace**
- **The standard outlines the basic elements of a good quality management system, which are good business practice**
- **It is 100% inclusive of ISO 9001, with over 100 additional requirements specific to Aerospace**
- **There are also two other standards:**
 - AS9110 – for Maintenance and Repair Organizations
 - AS9120 – for Stock List Distribution Organizations

Each member country has representatives that make up a Technical Advisory Group (TAG). These groups draft the standard, then members comment and vote on the standard. The document then becomes a standard.

These standards are not regulations. They are a method of getting a standard set of criteria for quality management systems. An outside agency, the registrar, will then audit to see if you have all the required elements in place. If you do, you will get AS 9100 registration. This registration tells others all over the world that you have this quality system in place.

As we go through the training, and cover the requirements you will see that these requirements are basically just good business practice.

The Process Model

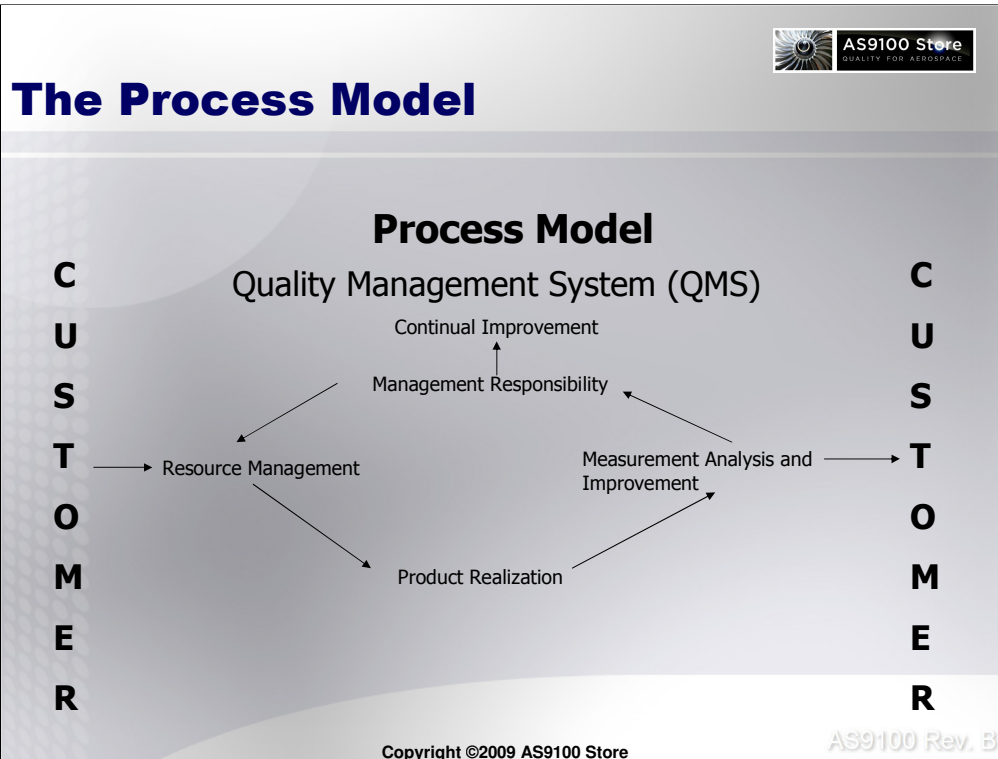
- **The AS9100 Standard is a design for a Quality Management System based on ISO's Process Model**
 - An organization is a system of interlinked processes
 - The standard is geared at managing and improving those processes
 - Key processes – those that lead to products and services- must be identified
 - Methods to measure and control these processes must now be included

The standard is based on a process model approach.

But what is a process model?

See slide bullets

lets look at the process model....



This example of the process model is included in the standard.

The five clauses are all found on the process model.

Management Responsibility, Measurement Analysis and Improvement, Product Realization and Resource Management make a cycle.

The most important input to this cycle is customer requirements.

The output of the cycle is customer satisfaction and continual improvement of the quality system.

The standard has been organized around this model.

Key Clauses for Process Approach

3 Key "Process Model" Clauses

- **4.1 QMS: General Requirements**
- **7.1 Product Realization: Planning of Realization Processes**
- **8.1 Measurement, Analysis and Improvement: Planning**

There are three key paragraphs in the standard that outline the requirements for identifying, measuring, controlling and improving your processes....the first step to move to the process approach.

Three Key Clauses of AS AS9100

The three clauses that contain the requirements that take the organization to a "Process Model" approach are 4.1, 7.1 and 8.1. These clauses ask us to take ownership of our quality management system; it is our responsibility to decide what processes will make up our system, and how they will be monitored, measured and continually improved.

4.1 Quality Management System: General Requirements

(summarize or read text from standard or student manual)

7.1 Product Realization: Planning of Realization Processes

(summarize or read text from standard or student manual)

8.1 Measurement, Analysis and Improvement: Planning

(summarize or read text from standard or student manual)

AS 9100 Rev B Requirements

- **What does AS 9100 Require?**
- **What are key points of clauses?**
- **What should Auditors look for?**

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Let's review the requirements.....

4.2 Documentation Requirements

▪ Control of Documents

- You must have a system in place to control your documents- your quality manual, procedures and work instructions
- Establish a process to approve documents, control the revision and distribution of the documents, and control changes to the documents
- You must make sure that people are working from the current, correct document.

Most companies will use a “Master List” to list the current revision and location of each document. Online systems work very well for document control if electronic files are protected from change.

Recording the distribution of documents is important; if a document is revised all previous revisions of the document must be replaced. This is only possible if you know where all those copies are.

Documents must be reviewed on a regular basis to make sure they are up to date.

Some organizations may choose to review all documents on a regular basis. For example, annually. However, there is not a requirement to do it on a regular basis, but “as necessary”.

This could be with regular use, and during internal audits. If employees are using the documents they should be watching for documents that need updating, and submitting document change requests. The internal audit program measures compliance with documentation requirements (along with other requirements) and should identify required revisions.

Document changes must be coordinated with customers and regulatory authorities whenever required by the contract or by regulatory requirements.

4.2 Documentation Requirements

- **Control of Quality Records**
 - Quality records must be controlled and protected, quality records are your evidence of complying with your quality system
 - Have a process in place that identifies what quality records you have, where they are kept, how long they are kept, how they are protected from damage
 - Include records created by or retained by suppliers.

A table works well for listing all your quality records, where they are generated and stored, how long they are stored and who is responsible for them. Include a requirement in your procedure that says quality records must be legible.

The procedure must address storage, retention times and disposition. If you archive records either on-site or off-site include your process in your procedure.

There is no specific requirements in the standard that detail how long you have to keep your records, but remember that the auditor will want to see six months to a year worth of records.

Coordination of changes with customers and or regulatory authorities, [in accordance with contract or regulatory requirements](#).

- Records created and/or retained by suppliers
- Access to Quality Records
- [Highlighted requirement is recurring throughout AS9100. Clause is referenced 8 different places.](#)

Configuration Management

- **Your organization must have a configuration management process**
 - Document the plan
 - Make the plan appropriate to your product
 - This is specific to AS9100 – above ISO 9000

Requirement to establish, document and maintain a configuration management process, [appropriate to the product](#).

Guidance is provided in ISO 10007 which is available here:
(www.as9100store.com/BuyStandards.aspx#ISO10007)

Many organizations fail the audit because they do not understanding Configuration Management or its application to the product.

7.3 Design and Development

- **Your procedure must outline your system including:**
 - 7.3.1 Design and Development planning
 - 7.3.2 Design and Development inputs
 - 7.3.3 Design and Development outputs
 - 7.3.4 Design and Development review
 - 7.3.5 Design and Development verification
 - 7.3.6 Design and Development validation
 - 7.3.7 Control of Design and Development changes

Your procedure will have a section for each of the items listed on the slide. You will need to state what your process is for each of these sections, and what your records are.

Design and development stages are based on organization, task sequence, mandatory steps, significant stages and method of configuration control

- For design - it is good to establish a process where the plan becomes the outline for the project. It will identify responsibilities, what the inputs are, what the timeline is, who needs to be involved in design review, guidelines for when to hold design review meetings, how the verification and validation will take place.
- Verification - checking to see if the design output meets design input.
- Validation - checking to see if the design performs what it was intended to. Guidance note provides guidance on the performance of design validation.

AS9100 Requires identification of:

- [Key characteristics, when applicable or in accordance with design or contract requirements](#)
- Pertinent data to allow the product to be manufactured, inspected, used and maintained

Examples:

Designing...

7.3.6 Design & Development Validation

- Only occurs after a successful design verification.
- Normally performed under defined operating conditions.
- Normally performed on the final product, but may be necessary at earlier stages prior to product completion.
- Multiple validations may be performed.

7.3.6.1 Documentation of Design & Development Verification & Validation



- **Sub-clause for documenting design verification and validation**
- **Requires all reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions**

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A form of configuration management

7.3.6.2 Design & Development Verification and Validation Testing



- **New sub-clause defines requirements where test are necessary for verification and validation**

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Test must be planned, controlled reviewed and documented to prove:

- test plans or specifications identify the product being tested
- test procedures identify the method of operation, performance of the test and recording of results
- the correct configuration is submitted for test*
- the requirements of the test plan and the test procedures are observed
- the acceptance criteria are met

7.3.7 Control of Design & Development Changes



- One additional requirement
- The organization's change control process shall provide for *customer and/or regulatory authority* approval of changes, *when required by contract or regulatory requirement*

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Consistent theme of contract/regulatory requirements.

8.2.4.1 Inspection Documentation

- Additional requirement addresses inspection documentation, which may be part of production, but shall include
- Criteria for acceptance and/or rejection
- Where in the sequence inspections are performed
- **A record of the measurement results**
- Type of instruments used and instructions associated with their use

8.2.4.1 Inspection Documentation

- Test records shall show actual test results data when required by specification or acceptance test plan.
- When applicable, this clause requires the documentation of actual data, where the previous slide requires a result (pass/fail, etc.)
- Addresses product qualification records

8.2.4.2 First Article Inspection

- Organization's system shall provide a process for inspection, verification and documentation of a representative item for the first production run of a new part
- Or following any subsequent change that invalidates the previous first article
- **Guidance Note: AS9102**

You can purchase a copy of AS9102 here:
<http://www.as9100store.com/BuyStandards.aspx#AS9102>

Appendix –AS9100 Key Requirements

- **Verification of Purchased Product (7.4.3) “P”**
 - Does the organization ensure test reports used to verify purchased product are acceptable per applicable specifications
 - Does the organization periodically validate test reports for raw material
 - How are the requirements for delegations defined, and
 - Is there a register of delegations

Appendix –AS9100 Key Requirements

- **Control of Production & Service Provision (7.5.1) “P”**
 - Does planning consider, as applicable
 - Establishment of process controls and control plans where key characteristics have been identified
 - Identification of in-process verification points
 - Variable measurement of key characteristics
 - Control of special processes

- **Controlled Conditions (7.5.1) “P”**
 - Ensure accountability of product
 - Ensure completion of all manufacturing & inspection operations have been completed as planned
 - Review the FOD program and audit on shop floor

Appendix –AS9100 Key Requirements

- **Production Documentation (7.5.1.1) “P”**
 - Take a sample of all shop floor documentation (routers, drawings, inspection plans, tool list and programs), and
 - Verify approval

- **Controlled of Production Process Changes (7.5.1.2) “P & M ”**
 - Show me a list of persons authorized to make changes
 - How are changes documented
 - What procedure controls the implementation of changes
 - Do changes require customer approval
 - Did the change require a new first article inspection