AS 9110 B to AS 9110 C - QMS Upgrade Instructions

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from the AS 9110 B version to the AS 9110 C revision for Quality management systems used by aviation, space, and defense maintenance providers.

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

In the SAE Aerospace standard, AS 9110 C, 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

Previously in AS 9110 B, the requirements were described in:

- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product realization
- Clause 8 Measurement, analysis, and improvement

You have the April-2012 Rev B version in place and now have the objective of upgrading the system to the Nov-2016 Rev C. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

The documentation will need to be reviewed, upgraded, and implemented. The first step is to assign a person responsible for the QMS, such as a Management Representative to become familiar with the changes for the AS 9110 C standard. Visit the AS9110store.com for forms, procedures, 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 9110 C quality management system. As you undertake the task of upgrading your quality management system, note that the intent of the main clauses is shown in **blue font,** and in the 2nd left hand column of the instructions, the text in ***italics*** indicates where requirements were included in previous AS 9110 B.
Use a copy of the AS 9110 C standard along with this instruction to pinpoint for your organization 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 9110 B to AS 9110 C - QMS Upgrade Instructions

AS 9110 Rev C Clause	Changes to the existing AS 9110 Rev B Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The SAE international Aerospace standard AS 9110 Rev C 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, requirements, definitions, and notes for aviation maintenance organizations are included.	AS 9110 C	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).		
All	While the specific requirement for a quality manual is not in AS 9110 C, 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 9110 C.		
---	*In AS 9110 B, the requirement for a Quality Manual was in clause 4.2.2.*	Manual	In the condensed manual include sections for: • Scope of the Quality Management System (QMS) • Distribution Control List, • Revision Status, • Quality/Safety 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 9110 C; however documented information is required to plan, establish, implement, and maintain the QMS processes. *In AS 9110 B, the requirement for control of documents was included in 4.2.3, and the requirement for control of records was in clause 4.2.4.*	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 quality plan, a manual, etc. You will need to add / replace / rework your QMS procedures to incorporate AS 9110 C 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 AS 9110 C, and replaces clause 4 Quality management system in AS 9110 B.	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. You may want to develop an organizational context worksheet 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	Document the information (in a document P-400, Organizational Context) to outline 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.		Include (in a document P-400) the process to understand and determine the needs and expectations of interested parties.		
4.3	In AS 9110 C, clause 4.3 requires the determination of the scope of the QMS. *In AS 9110 B, the scope of the QMS was required to be included in a quality manual per clause 4.2.2 a.*		Include (in a document P-400) 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 9110 B, the application and exclusion of requirements were included in clause 1.2.* *Exclusions were permitted in clause 7 when they did not affect the ability or responsibility to meet customer and regulatory & statutory requirements.*		Include justifications for requirements of the standard that do not apply to the scope of the QMS. Note that conformity to AS 9110 C 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 9110 C, clause 4.4covers the QMS and its processes. *In AS 9110 B, the requirement for the QMS and its processes was in 4.1.*		Your company must establish, implement, maintain, and continually improve the QMS.		
4.4.1	*In AS 9110 B, the requirement for the QMS and its processes was in 4.1.*		Provide an outline (in a document P-400) of the process to determine the application and interaction of the processes needed for the QMS. Address risks and opportunities and plan to implement actions to address them. See clause 6.1.		
4.4.2	In AS 9110 C, documented information that supports the processes is required to		Document (in P-400) the process to establish and maintain documented information. Refer to 4.4.2 a)		

	be maintained and retained.		thru c) and include the new requirements for: • General description of relevant interested parties, • Scope of the quality management system, including boundaries and applicability, • Description of the processes needed for the quality management system and their application throughout the organization, • The sequence and interaction of these processes • Assignment of the responsibilities and authorities for these processes.		
4.4.2	*In AS 9110 B, the requirements for the documentation were in clauses 4.2 and 4.2.1.*		See Documented information, clause 7.5. Outline (in a document P-750) the process for the control of documented information.		
5	This clause requires that your top management demonstrates leadership and commitment with respect to the QMS. In addition, top management is required to demonstrate leadership and commitment with respect to customer focus. This section also asks top management to establish, implement and maintain both a quality policy and a safety policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood. In addition, top management needs to identify responsible persons as the Management Representative, the Accountable Manager, the Quality Manager, and other Appointed Managers as required for operational activities.				
5	In AS 9110 C, clause 5, Leadership replaces clause 5, Management responsibility in AS 9110 B.	Documented information	Review and re-write your existing document for management responsibility and incorporate the requirements for leadership and commitment.		
5.1.1	In AS 9110 C, the general clause 5.1.1 outlines the requirements for leadership and commitment. *In AS 9110 B, the requirement for management commitment was in 5.1.*	Procedure	In a procedure such as P-500, include the actions to demonstrate the leadership and commitment to the QMS. Refer to the requirements in clause 5.1.1 a) thru l) and include the items ranging from a) accountability for an effective QMS, thru l) ensuring that corrective actions are promptly implemented.		
5.1.2	In AS 9110 C, clause 5.1.1 focuses on the customer. *In AS 9110 B, the requirement for customer focus was included in clause 5.2.*		Include the actions to demonstrate the leadership and commitment to customer focus. Refer to 5.1.2 a) thru d) requirements dealing with meeting customer and regulatory requirements, addressing risks and opportunities, customer satisfaction, product and service conformity and on-time delivery performance.		
5.2	In AS 9110 C, clause 5.2 outlines the requirements for the quality policy to be established and communicated. *In AS 9110 B, the requirement for quality*		Include the process for developing a quality policy that is appropriate to the purpose and context of your company and communicating this quality policy.		

	policy was included in clause 5.3.				
5.2.1	*In AS 9110 B, the requirement for establishing the quality policy was in clause 5.3.*		Include the requirements that the quality policy is available as documented information and available to interested parties.		
5.2.2	*In AS 9110 B, the requirement for communicating the quality policy was included in clause 5.3 d.*		Include the requirements that the quality policy is communicated, understood, and applied in the company.		
5.2.3	In AS 9110 C, the clause 5.2.3 requires a documented safety policy. *In AS 9110 B, the requirements for safety policy were in clause 5.7 and safety objectives were in clause 5.4.3.*		Include the new requirements that the safety policy is established and communicated. Refer to 5.2.3 a) thru c) and include the items for the: • Framework for setting safety objectives, • Safety reporting, • Continual improvement.		
5.3	In AS 9110 C, the clause 5.3 covers organizational roles, responsibilities, and authorities. *In AS 9110 B, the requirements for responsibility, authority, and communication were in 5.5 and 5.5.1.*	Organization chart	Include the system for ensuring that responsibilities and authorities for relevant roles are assigned and communicated. Refer to 5.3 a) thru e) and include items ranging from a) ensuring conformance to the AS standard, to e) ensuring integrity of the QMS when changes are made.		
5.3	*In AS 9110 B, the requirement for QMS planning was included in clause 5.4.2.*		Delete the requirements for QMS planning and include it in actions to address risk and opportunities in section 6.1.		
5.3	*In AS 9110 B, the requirements for the quality objectives were included in clauses 5.4 and 5.4.1.*		Delete the requirements for quality objectives and include them in quality objectives and planning to achieve them in section 6.2.		
5.3	In AS 9110 C, a management representative is required to be appointed per clause 5.3. *In AS 9110 B, the requirement for a management representative was included in clause 5.5.2.*		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.		
5.3.1	In AS 9110 C, the requirements for an accountable manger is in clause 5.3.1. *In AS 9110 B, the requirement for the accountable manager was in 5.5.1.1.*		Ensure that the Accountable Manager is the top executive with overall financial and corporate responsibility for the scope of approval. This manager ensures that all required continuing airworthiness activities, including maintenance activities, can be financed, and carried out to the applicable standards.		
5.3.2	In AS 9110 C, the new requirements for a quality manger is in clause 5.3.2.		Ensure that a person responsible for monitoring the quality management system is appointed and is		

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AS 9110 Rev B to AS 9110 Rev C - Quality Management Systems – Transition Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of AS 9110 Rev C as you transition from AS 9110 B to AS 9110 C. Each requirement is expressed as a question that the user (auditor / assessor) can ask to evaluate your QMS capabilities. You will need to have copies of the AS 9110 B and AS 9110 C standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the AS 9110 standards do not line up when comparing the requirements:

- New requirements and / or new terminology and new clause numbers are highlighted in yellow.
- The intent of the main clauses of the new standard is shown in blue font.
- The right-hand column in green shade is intended to provide reference / comparison / similarities to the AS 9110 Rev B requirements, and to identify and locate where in the new clauses, the former requirements are relevant.
- Comments highlighted in red font indicate removed / missing requirements.

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 main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with AS 9110 Rev C.

INSERT COMPANY NAME/LOGO HERE

AS 9110 Rev B to AS 9110 Rev C - Quality Management Systems – Transition Gap Analysis Checklist

AS 9110 Rev C QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If NO - % Complete	Items Needed	AS 9110 Rev B Requirements
4 CONTEXT OF THE ORGANIZATION					**4.0 Quality management system**
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?					
Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?					
Does your company monitor and review the information related to the external and internal issues?					
4.2 Understanding the needs and expectations of interested parties					----
With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, do you determine:					

• The interested parties that are relevant to the QMS?					
• The requirements of these interested parties that are relevant to the QMS?					
Does your company monitor and review the information about these interested parties and their relevant requirements?					
4.3 Determining the scope of the quality management system					**4.1 General requirements**
To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?					4.2.2 a) The scope of the QMS is required in a quality manual
When determining the scope of the QMS, do you consider the:					
• External and internal issues (per 4.1)?					
• Requirements of relevant interested parties (per 4.2)?					
• The products and services of your company?					
When a requirement of AS 9110 C can be applied, do you apply the requirement?					
When requirements cannot be applied, and to claim conformity to AS 9110 C, how do you determine if your ability or responsibility to ensure conformity of products and					4.2.2 a) Justifications for exclusions are required to be included in the quality manual

services are not affected?					
Is the scope of the QMS available and maintained as documented information?					
Does the scope state the products and services covered by the QMS?					
Does your company provide justification for any instance where a requirement of the standard cannot be applied?					1.2 Application - Exclusions permitted with justifications for clause 7 only in AS 9110 B
4.4 Quality management system and its processes			----		
4.4.1 As required by the AS 9110 C standard, do you establish, document, implement, maintain, and continually improve the QMS?					4.1 Establish, document, implement & maintain a QMS and continually improve its effectiveness per the requirements of AS 9110 B
Does the QMS also address customer and applicable statutory and regulatory quality management system requirements?					4.1 The QMS addresses customer and applicable statutory and authority QMS requirements
Are approvals, certificates, ratings, capability list, and licenses also addressed in the QMS?					4.1 Maintenance organizations obtain and maintain QMS approvals, certificates, ratings, licenses, and permits required by statutory & regulatory requirements
Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?					4.1 a) Determine the processes needed for the QMS and their application throughout the organization

INSERT YOUR COMPANY NAME HERE

AS 9110 Rev C – from ISO 9001:2015 – Quality Management Systems - Internal Audit Checklist

This checklist is based on the information provided in the Nov 2016 version of the AS 9110 Rev C 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 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 titles 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

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---	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS / COMMENTS	STATUS
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?		

4.4	Quality management system and its processes		
4.4.1	As required by the standard, do you establish, document, implement, maintain, and continually improve the QMS?		
	Does the QMS also address customer and applicable statutory and regulatory quality management system requirements?		
	Are approvals, certificates, ratings, capability list, and licenses also addressed in the QMS?		
	Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?		
	That is, for the QMS processes do you determine the:		
	• Inputs required and the outputs expected from the processes?		
	• Sequence and interaction of the processes?		
	• Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes?		
	• Resources needed and ensure they are available?		
	• Assignment of the responsibilities and authorities for these processes?		

	• Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them? See also Operational risk management (per 8.1.1).		
	• 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 your company establish and maintain documented information, as required by the competent authority?		
	Does the documented information include:		
	• General description of relevant interested parties, per see 4.2 a?		
	• Scope of the QMS, including boundaries and applicability, per see 4.3?		

	• Description of the processes needed for the QMS and their application throughout the organization?		
	• Sequence and interaction of the processes?		
	• Assignment of the responsibilities and authorities for these processes?		
	• Details of the system used to maintain and retain documented information of the work performed for each article or product?		
	Additional Questions		
5	**LEADERSHIP**		
5.1	**Leadership and commitment**		
5.1.1	**General**		
	Does top management demonstrate leadership and commitment with respect to the QMS by:		
	• Taking accountability for the effectiveness of the QMS?		
	• Ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization?		

1.0 Purpose

1.1 This procedure describes the process for controlling quality system documents.

2.0 Responsibilities

2.1 *Management* is responsible to ensure that personnel have access to and are aware of relevant quality management system (QMS) documentation and changes.

2.2 *Management* is responsible for assigning authors for documents.

2.3 The author is responsible for writing the document, creating related forms, getting a document number and submitting the document to the department manager for review.

2.4 *Department managers* are responsible for approving documents for their area of responsibility and ensure that they are legible, identifiable and available where needed.

2.5 *The document control coordinator* is responsible for assigning document numbers, maintaining the master list, posting new and revised documents on the network, distributing hard copies of documents and revising documents.

2.6 All employees are responsible for reviewing the documents as they use them and submitting document change requests to update documents as necessary.

2.7 *The network administrator* is responsible for backing up the network daily.

2.8 *Engineers are responsible for maintaining programs that control equipment. (If you have programs, controllers with programs or other software controlling your processes, the programs must be controlled.)*

3.0 Definitions

3.1 **Procedure**: Document outlining specific work processes and how the requirements of the AS9110B standard are being met.

3.2 **Work Instructions**: Step by step directions on how a task should be done.

3.3 **Attachments**: Documents used to further clarify or show examples of information described in the procedures and work instructions.

3.4 **Forms**: Documents used to make a record of completing all or part of the process described in procedures and work instructions.

3.5 **Records**: Completed forms or information generated as a result of the process described in a document and retained as indicated in the Control of Quality Records Procedure.

3.6 **References**: external documents or sources used in preparing documentation and completing work.

3.7 **Related Documents**: Other documents that may need to be altered if the current

3.8 P-720 Customer Related Processes

4.0 References

4.1 None

5.0 Revisions

Revision	Date	Section	Paragraph	Summary of change	Authorized by
A				**Initial issue**	

Risk-Based-Thinking

in

AS 9110 Rev C

Risk Management / Analysis of Risk

Risk Management

Every version of the AS 9110 standard has advocated risk avoidance and risk management. The new AS 9110 Rev C 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 9110 Rev C, 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

The main risk management requirements of AS 9110 C are outlined in two clauses.

- Clause 6.1, Actions to address risks and opportunities.
  This clause addresses the risks and opportunities when planning for the quality management system
- Clause 8.1.1, Operational risk management.
  This clause addresses the risks associated with the operational processes needed for the provision of products and services.

The new AS 9110 REV C introduces Risk-Based Thinking in section 0.3.3 and mentions risk in other clauses of the standard; for example, in clause 5.1.2 dealing with customer requirements and satisfaction, clause 8.1.3 on product safety, clause 8.2.2 dealing with customer requirements and clause 8.4.1 on external provider-purchasing activities.

The objective of the emphasis on risk is to have the organization, through its QMS, address uncertainty in processes that will affect the quality of the delivered goods or services to customers.

When addressing risk in your Quality Management System, be sure that you look beyond determining the "chance" that something happens to "the effect of an uncertainty" on your business objectives.

There are five (5) attributes to enhance risk management:

1. An organization should accept accountability for their risks and develop comprehensive controls and risk abatement strategies.

2. Risk management should be a part of an organization's continual improvement strategy. Organizations should set performance goals and then review and modify processes as required. An organization should review and modify its systems, resources, and capability / skills to ensure continual improvement.

3. Identify and train individuals with accountability for risk management. These individuals should have appropriate skills, have adequate resources to check and improve controls, monitor risks, and have the ability to communicate effectively with all the interested parties / stakeholders.

4. Decision making within the organization should include consideration of risks and the application of the risk management process where appropriate.

5. Maintain consistent and periodic reporting to all interested parties of the organization’s risk management performance.

INSERT YOUR COMPANY LOGO/NAME HERE

Risk and Opportunity Worksheet

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

Process / Activity	Customer Impact	Changeability Index	Performance Status	Business Impact	Work Impact	Rank	
						R	O

Review and Approval	
Prepared by: Quality team leader	Date:
Reviewed by: Quality team	Date:
Approved by: President	Date:

248 page Training Guide Included

AS 9110 Rev C
Internal Auditor Training

Trainer's Guide

Overview

These course materials are meant to train people to conduct internal quality audits within your organization, which are necessary to meet the internal audit requirements of the AS 9110 REV C standard.

The course is divided into two sections:

1. The first section will familiarize the students with the AS 9110 REV C requirements for quality management system.
    - Allow 4 hours for this section.
2. The second section is devoted to the auditing process. The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting a mock audit of a fictitious company.
    - Allow 8 hours for this section.

We recommend that you print this guide as you'll need the PowerPoint speaker notes to lead the class. This guide contains everything the instructor needs to lead the class.

Notes:

- It is assumed that the instructor has certified Lead Auditor credentials or equivalent experience. This is not meant as a self study course.

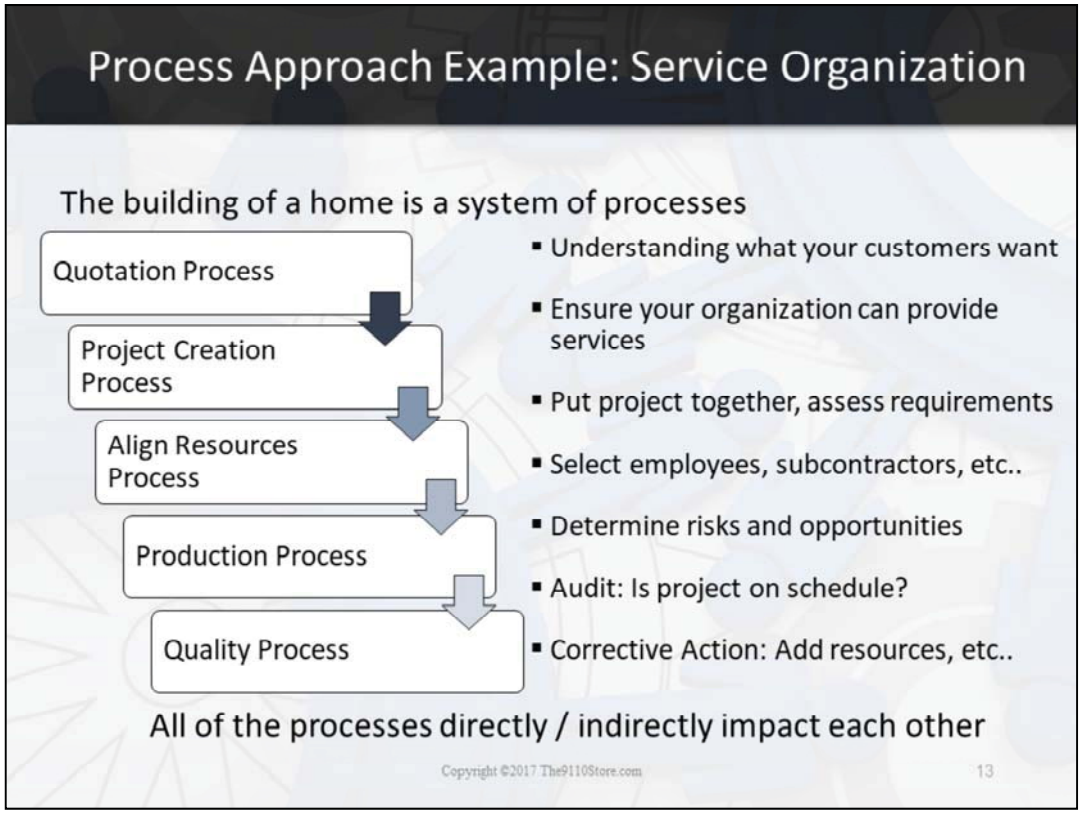
- It is recommended that the first audit the student is involved with be under the leadership of a lead auditor who has audit experience.

AeroFix Co Documented Information

AeroFix Co Documented Information – Contents

Qty	Documents and Records	No. of Pages
1	QM-9110-C Quality Manual	9
1	F-750-001 List of Documented Information	2
1	Internal Audit Master Schedule	1
1	P-500 Leadership Procedure	2
1	A-520-001 Quality Policy, Strategic Direction, and Safety Policy	1
1	P-810 Operational Planning and Control Procedure	2
1	F-610-001 Risk and Opportunity Worksheet	1
2	F-810-001 Project Planning Worksheet	3
1	P-820 Customer Related Processes Procedure	3
1	F-820-001 Client Assessment Report	1
2	F-820-010 AFC Quotation / Proposal	2
1	P-840 Control of External Providers Procedure	3
1	F-840-002 List of Approved Sources	1
3	F-840-005 AFC Purchase Order / Amended Purchase Order	3
1	F-840-010 External provider Problem Log Form	1
1	P-1020 Nonconformity and Corrective Action Procedure	2
1	F-912-001 Customer satisfaction survey	1
1	R-1020 Register of Improvement Action Reports - NCR-CAR	1
1	F-1020-001 Corrective Action Request Form (CAR)	1
1	NCR – Section 1 Corrective Action Requests	1
1	CAR – Section 2 Corrective Action Requests	1
1	P-930 Management Review Procedure	2
1	F-930-001 Management Review Meeting Agenda	1
1	F-930-002 Minutes of Management Review	2

Includes speaker's notes



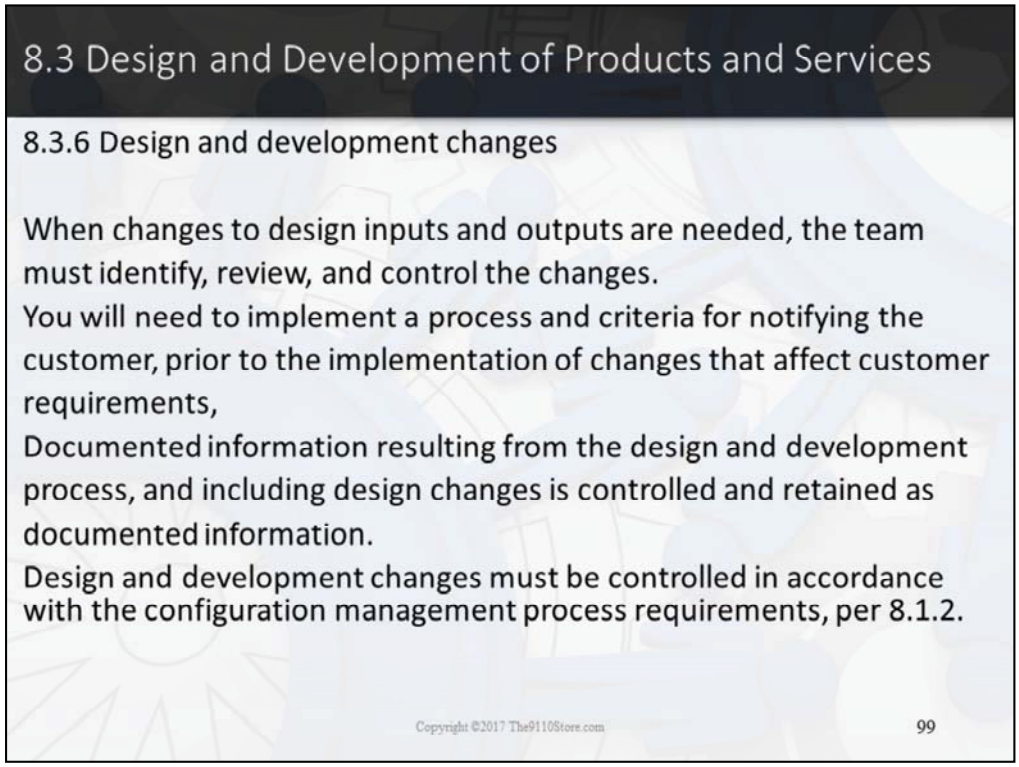
A process approach allows an organization to systematically evaluate each part of their business.

You are then able to look at each portion and measure the results against the desired objective.

In this example we've used a bakery to demonstrate how an organization is actually a system of processes.

The output of one process (purchasing) impacts the input of another process (production).

If the purchasing people only buy the least expensive ingredients, it may negatively impact the quality of the bread.



When changes to design inputs and outputs are needed, the team identifies, reviews, and controls the changes.

Documented information resulting from the design and development process, and including design changes are controlled and retained with procedure P-750 Control of documented information.

Have you implemented a process and criteria for notifying the customer, prior to the implementation of changes that affect customer requirements?

Are design and development changes controlled in accordance with the configuration management process requirements, per 8.1.2?

The project manager documents the proposed change and the reason for the change on a design change request.

When a design change is made, the project goes through verification and validation before being released to ensure there is no adverse impact on the conformity to requirements.

A design change is verified and validated as necessary before approval.

The change is approved by the original approvers of the project plan.

AS 9110 Rev C: Introduction to the Requirements

Requirements of AS 9110 C

Section 4: Context of the Organization
Section 5: Leadership
Section 6: Planning
Section 7: Support
Section 8: Operation
Section 9: Performance Evaluation
Section 10: Improvement

Section 9: Performance Evaluation

This clause requires that our company plan, implement and control the monitoring, measurement, analysis, and evaluation processes. Performance evaluation includes systems for the evaluation of customer satisfaction, analysis and evaluation of data, internal audits, and management review, all aimed at improved quality performance and an effective QMS.

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Monitoring, measurement, analysis, and evaluation.

For our maintenance services, we determine what needs to be monitored and measured, identify, and implement the methods for valid results, specify when the monitoring and measuring is to be performed, and when the results are analyzed and evaluated. Methods will include the use of statistical techniques and root cause analysis.

Customer satisfaction.

To determine how satisfied or dissatisfied our customers are, management monitors information relative to the customer perceptions of how well their needs and expectations are met.

Internal audit.

Our company conducts internal audits on a regular basis to ensure that the QMS conforms to requirements, is effectively implemented, and maintained, and continues to be suitable and adequate. This means that a team of our employees will be trained to evaluate processes in the different areas of the company. They will look at the planned, documented processes and see if the work is being done accordingly. They will see if the documented process is consistently leading to quality maintenance services, and meeting customer requirements.

Management review.

Our top management will also be holding regular meetings to evaluate how the QMS is working. When the QMS is complete, processes will be monitored, progress towards quality goals will be measured, and management will hold review meetings to see how the QMS is working and how it can be improved. During the meetings, top management will look at items such as:

- Data on how processes are working
- Action items for improvement
- Follow-up on action items from previous management reviews
- Changes that could affect the QMS
- The Quality Policy

Performance Evaluation Procedures listed below provide Clause 9 details.

P-910, Monitoring, measurement, analysis, and evaluation,
P-912, Customer satisfaction,
P-913, Statistical techniques,
P-914, Root cause analysis,
P-920, Internal audit,
P-930, Management review.

Watch for our next newsletter for more introduction to AS 9110 C, what it will mean to you and your coworkers.