ISO 9001:2015 to AS 9110 C - QMS Transition Instructions/Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from ISO 9001:2015 version to the AS 9110 C 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 9110 C 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 9110 Rev C 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 9110 C.
- 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 9110 C 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 9110 C standard. Visit the9110store.com 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 9110 C 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 9110 C additions are made to ISO 9001:2015, and the clause numbers highlighted in yellow indicate where ISO 9001 requirements are carried over for AS 9110 C.
Keep in mind that while you need to focus on the new requirements of IAQG, your company now has an opportunity to review the carry-over ISO 9001 QMS and improve the system while incorporating the AS 9110 C 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.

ISO 9001:2015 to AS 9110 C - QMS Transition Instructions/Checklist

AS 9110 Rev C Clause	Changes to the existing ISO 9001:2015 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, aviation, space, and defense(ASD) industry requirements, definitions, and notes 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). Your company now has an opportunity to review the exiting ISO 9001:2015 QMS and improve the system while incorporating the AS 9110 C requirements.		
All	While the specific requirement for a quality manual is not in AS 9110 C 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 9110 C; however, documented information is required to be maintained 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 9110 C 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 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 both AS 9110 C and ISO 9001:2015.	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	Review the information (in a document P-400, Organizational Context) that outlines 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.		Review the process to understand and determine the needs and expectations of interested parties.		
4.3	In AS 9110 C, determining the scope of the QMS is in clause 4.3.		Review 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 C, the scope of the QMS considers justification for requirements that do not apply.		Review any 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 4.4 outlines the requirements for the QMS and its processes and their interaction.		Review your system to establish, implement, maintain, and continually improve the QMS. Provide an outline (in a document P-400) of the process to determine the application and interaction of the processes needed for the QMS.		
4.4.1	The AS 9110 C QMS must also address customer and applicable statutory and		Document (in P-400) the process to address customer requirements, applicable statutory and		

	regulatory QMS requirements.		regulatory QMS requirements including any required approvals, certificates, ratings, capability list, or licenses. Determine the inputs required and the outputs expected from the processes and address risks and opportunities and plan to implement actions to address them. See clause 6.1.		
4.4.2	In AS 9110 C, clause 4.4.2 c) requires that documented information as required by the competent authority.		For the QMS, refer to 4.4.2 a) thru c) and add the new requirement to establish and maintain documented information as required by the competent authority.		
4.4.2	In AS 9110 C, clause 4.4.2 specifies new requirements for documented information.		Document (in a P-400) the process to establish and maintain the documented information 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, • Details of the system used to maintain and retain documented information for work done for each article or product. See Documented information, clause 7.5. Outline (in a document P-750) the process for the control of documented information.		
5 **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 appropria+te 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	Clause 5, leadership is a requirement in both AS 9110 C and ISO 9001:2015.	Procedure	Review your existing document (such as P-500) to incorporate the requirements for leadership and commitment.		
5.1.1	In AS 9110 C, clause 5.1.1 a) thru j) outlines the carry-over requirements to		Review the actions to demonstrate the leadership and commitment to the QMS.		

	demonstrate leadership and commitment.		Refer to the requirements in clause 5.1.1 a) thru j) dealing with a) accountability for the QMS, to j) support for relevant management roles.		
5.1.1	In AS 9110 C, clause 5.1.1 k) and l) outlines the new requirements to demonstrate leadership and commitment.		In P-500, include the new requirements dealing with k) ensuring that the safety policy and safety objectives are established, and l) ensuring that corrective actions, especially from the audits, are promptly implemented.		
5.1.2	In AS 9110 C, clause 5.1.2 a) thru c) covers the carry-over requirements for customer focus.		Review the actions to demonstrate the leadership and commitment to customer focus. Refer to 5.1.2 a) thru c) requirements dealing with meeting customer and regulatory requirements, addressing risks and opportunities, and customer satisfaction, product conformity, on-time delivery performance, and action taken if planned results are not or will not be met.		
5.1.2	In AS 9110 C, clause 5.1.2 d), covers a new requirement for product and service conformity and on-time delivery performance.		In P-500, include the requirements for customer focus 5.1.2 d) dealing with product conformity, on-time delivery performance, and action taken if planned results are not or will not be met.		
5.2.1	In AS 9110 C, clause 5.2.1outlines the requirements for the quality policy.		Review the process for developing a quality policy that is appropriate to the purpose and context of your company and communicating this quality policy.		
5.2.2	In AS 9110 C, clause 5.2.2 outlines the requirements for the availability of the quality policy.		Review the new requirements that the quality policy is communicated, is available as documented information and is available to interested parties.		
5.2.3	In AS 9110 C, clause 5.2.3 outlines the requirements for establishing and communicating the safety policy.		Include (in document P-500) the process for establishing and communicating a safety policy. Refer to 5.2.3 a) thru c.) dealing with requirements for the safety policy and safety objectives.		
5.3	In AS 9110 C, 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 9110 C, 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		

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**	

INSERT YOUR COMPANY LOGO/NAME HERE

F-610-001
Risk and Opportunity Worksheet

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

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F-610-001
Risk and Opportunity Worksheet

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

Review and Approval	
Prepared by: Quality team leader / SO management rep.	Date:
Reviewed by: Quality team / ISO steering committee	Date:
Approved by: President	Date:

The worksheet form F-610-001 provides for options / methods for risk analysis. Choose the option that is best suited for you – refer next page.

Example of completed worksheet

This worksheet is used to identify the processes required for the Quality Management System. It is designed to ensure that all the requirements of the AS 9110 C standard are addressed and documented information available. In addition, the worksheet can be used as a training tool to help interested parties, such as employees, customers, auditors, and registrar understand your QMS.

PROCESS INPUTS - AS 9110 C for Aviation Maintenance Organizations	PROCESS OUTPUTS Key Processes	DOCUMENTED INFORMATION for Processes	RESPONSIBILITY for Processes	REMARKS
Quality management systems - Requirements 1 Scope 2 Normative references 3 Terms and definitions	QMS-Manual	QM-9110-C Manual p.5 Manual p.6	President	
4 Context of the organization	Context of the organization	QMS-Section D	-----	
4.1 Understanding the organization and its context	**Organizational context**	P-400	President	
	Context	P-400 par 5.1		
	Context of the organization worksheet	F-440-002	AS committee	
4.2 Understanding the needs and expectations of interested parties	Needs and expectations	P-400 par 5.2		
4.3 Determining the scope of the quality management system	Scope of the QMS	P-400 par 5.4		
4.4 Quality management system and its processes	Process interactions	P-400 par 5.5		
	Flow diagram	FD-440-001		
	QMS Process Identification	F-440-001	Management representative	This Form
4.4.1 The organization … 4.4.2 To the extent …	Process support, confidence, and documented information	P-400, par 5.6 – 5.7		

5 Leadership	Leadership	QMS-Section D	-----	
5.1 Leadership and commitment	**Leadership**	P-500	President	
5.1.1 General	Leadership and commitment	P-500, par 5.1		
	Business process map	FD-510-001	AS Committee	
5.1.2 Customer focus	Customer focus	P-500, par 5.2		
5.2 Policy	Quality policy	P-500, par 5.3	AS Committee	
5.2.1 Establishing the quality policy	Quality policy – attachment	A-520-001		
5.2.2 Communicating the quality policy	Communication	P-500, par 5.3.5		
5.2.3 Establishing and communicating the safety policy	Safety policy	P-500 par 5.4	AS Committee	
	Safety policy - attachment	A-520-002		
5.3 Organizational roles, responsibilities, and authorities	Roles, responsibility, and authority	P-500 par 5.5		
	Management representative	P-500 par 5.5.2		
5.3.1 Accountable manager	Accountable manager	P-500 par 5.5.3		
5.3.2 Quality manager	Quality manager	P-500 par 5.5.4		
5.3.3 Other appointed managers	Other managers	P-500 par 5.5.5		
	Organization chart	A-530-001	H R manager	
6 Planning	Planning for the QMS	QMS-Section-D	-----	
6.1 Actions to address risks and opportunities	**Planning for the QMS**	P-600	Management rep	
6.1.1 When planning for the QMS…	Planning the QMS	P-600, par 5.1		
6.1.2 The organization shall plan …	Risk management- QMS Planning	P-600, par. 5.3		

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.

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 9100 D.

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.

INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 to AS 9110 Rev C - 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 9110 Rev C 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 9110 C 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 AS9110 Rev C 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?				
	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**				
	To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?				

	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, is the requirement applied by your company?				
	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 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?				
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				

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?		

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: