



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: