Risk-Based Thinking

in

ISO 9001:2015

Risk Management / Analysis of Risk

Risk Management

Every version of the ISO 9001 standard has advocated risk management and risk avoidance, but it has been implicit.

The new ISO 9001:2015 standard explicitly expects organizations to identify and address risks affecting compliance of products and services, resulting in improved customer satisfaction.

Besides identifying the risks, the new ISO standard expects organizations to address opportunities for improvements and corrective actions based on the risk analysis.

Note that while corrective action is a requirement of ISO 9001:2015, the concept of preventive action is expressed through a risk-based approach where risks are determined and actions to address risks and opportunities are taken.

The standard does not require you to create a formal risk management system. However, 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 the possibility of an event or activity negatively impacting the operational or strategic objectives of an organization.

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)

Because this topic is so important, it will have an impact on your QMS.

Risk-Based Thinking

The new ISO 9001:2015 covers Risk in a number of sections (e.g. 4.4, 6.1, 6.1.1, 6.1.2). 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 and QMS 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.

Instructions:

Conduct Risk Analysis for product realization steps required for your products. Consider the production steps and the activities / steps for all functions in your organization.

- Prepare process flow diagrams to describe the activities / steps.

- Make use of the Risk Management Worksheet to systematically conduct a risk analysis for each of the steps identified in each process flow diagram.

- Refer to worksheet.

Column 1 Transfer from the flow diagrams, the steps required for the process.

Column 2 Identify what may be present or could be introduced as a risk.

Column 3 Describe the risks that may exist or could be introduced.

Column 4 Assess the significance of the described risk.

Indicate in sub-column 1, the severity of the risk as **L for low, M for medium**, and **H for high**.

Indicate in sub-column 2, the likelihood of occurrence as **Low, Medium or High**.

When both the **Severity and Likelihood are High**, the **Significance in sub-column 3 is high**, the process step is at risk, it requires attention and corrective action is required and indicated in the last column.

When one or both severity and likelihood are indicated as medium, additional reviews are required and resulting actions justified (with inputs in columns 5 & 6).

Column 5 For Low, Medium, and High significance risks, indicate if the risk can be eliminated or reduced in a next step in the process.

Column 6 For all risks, describe what controls are in place to reduce or eliminate the risk.

Column 7 The Quality Team considers the inputs from columns 1 through 6 and indicates with a NO or a YES whether or not the process step is a risk.

Column 8 With a NO decision, a corrective action request (CAR) is not needed and N/A is indicated in this column.

With a YES conclusion, the Management Representative enters a CAR # in the last column and prepares and issues a Corrective Action Request to the individual responsible for the process step.

Notes:

1. *It is important to make sure that if you do not have sufficient experience in your company to make the above determinations you involve outside expertise or use external sources of information to make the decisions.*

2. *Additional risk assessment methods are provided in this risk analysis exercise to outline several approaches and offer options for the management of risk at your company.*

Draw the Process Flow Diagram(s) for your operations