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Risk-Based Thinking

in

ISO 9001:2015

Risk Management / Analysis of Risk

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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.

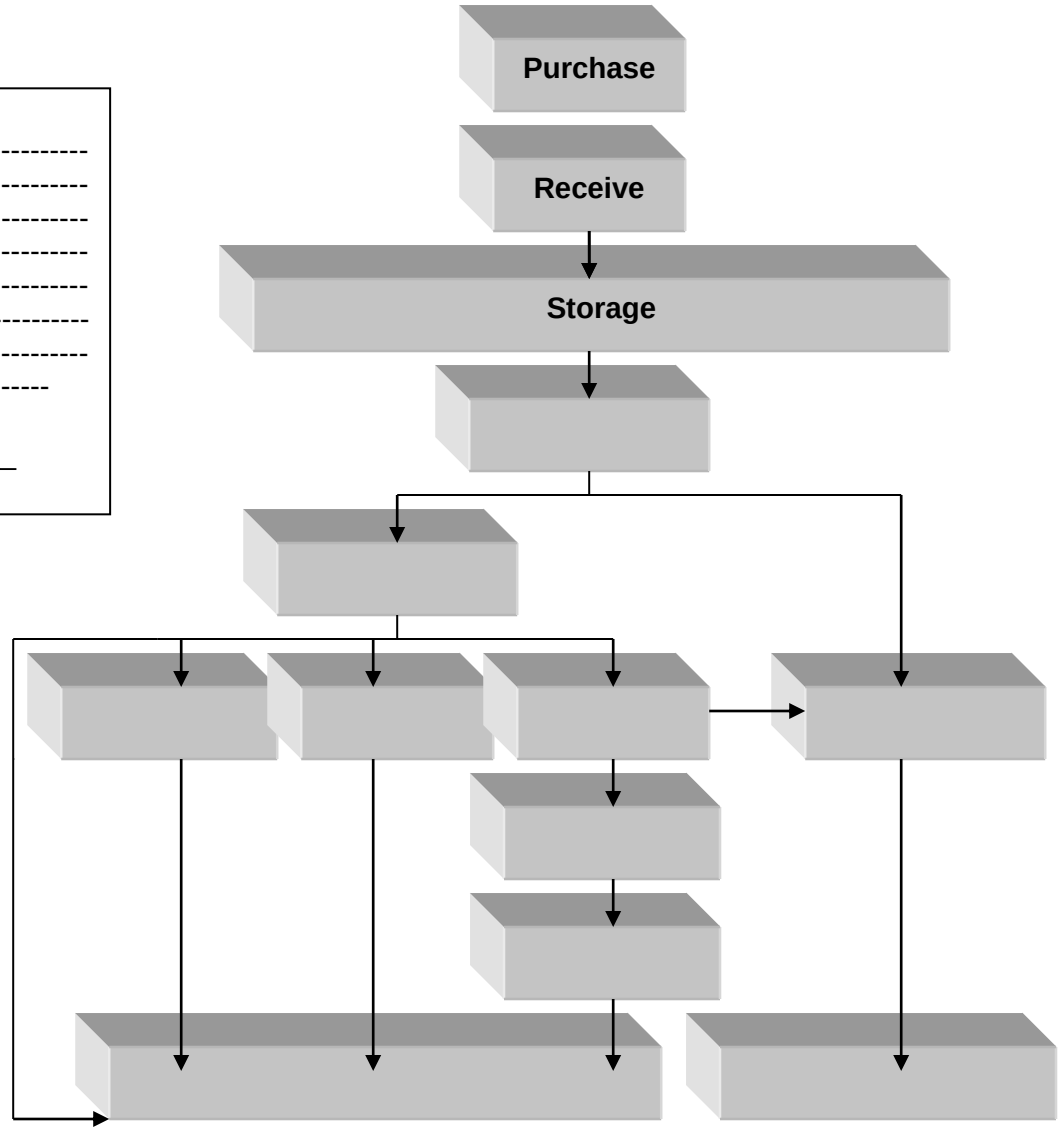
Risk is the possibility of an event or activity negatively impacting the operational or strategic objectives of an organization.

When evaluating risk, it is helpful to address it using two (2) metrics or parameters:

Draw the Process Flow Diagram(s) for your operations

Comments:

Prepared by; _____
Date: _____



Exercise - Conduct Risk Analysis - Risk Management Worksheet – Basic Method

The first 6 columns of this form are used to list the Potential Risks and Assess the Significance of the Risks

The last 2 columns of this form are used to indicate whether or not the Process Step is at risk and requires attention.

*** Refer to the process flow diagram(s).**

**** Where both the Severity and the Likelihood are high, the risk is significant and the Process Step requires corrective action.**

* Step	What is present or could be introduced as a risk?	Description of Risk	Significance 1 = Severity 2 = Likelihood 3 = Significance **			Does a next step in process eliminate the risk?	What controls exist to address the risk?	Is the Process Step at risk? Yes / No	** If YES, Issue the Corrective Action Request
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Compiled by Management representative: _____, Date: _____

Quality Steering Team review: 1_____, Date: _____, 2_____, Date: _____

Process Flow Diagrams can describe not only process steps in a production environment, but also sequential steps for administration and other management activities such as purchasing. This risk management worksheet can be used to analyze the risks associated with those activities.

Exercise – Action 2 - Conduct Risk Analysis - Risk Management Worksheet

ACTION 1	ACTION 2	ACTION 3	ACTION 4			ACTION 5	ACTION 6	ACTION 7	ACTION 8
* Step	Inputs	Description of Risk	Significance 1 = Severity 2 = Likelihood 3 = Significance **			Does a next step in process eliminate the risk?	What controls exist to address the risk?	Is the Process Step at risk? Yes / No	** If YES, Issue the Corrective Action Request
---	---	----	1	2	3	Justifications			CAR #