

**Risk-Based Thinking
In
Laboratory Quality Management Systems**

ISO/IEC 17025:2017

Risk Management / Analysis of Risk

SAMPLE

Risk Management

Earlier versions of standards for Laboratory Management Systems have advocated risk management and risk avoidance, but it has been implicit.

The new ISO/IEC 17025:2017 standard explicitly expects organizations to consider and identify actions to address risks and opportunities associated with their laboratory operations, processes, and activities, aimed at and resulting in improved performance.

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

Note that while corrective action is an ISO/IEC 17025:2017 requirement, 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 for your laboratory.

To prepare for the change, it is important to understand Risk Based Thinking and begin to look at your operations, processes, and activities in terms of risks and opportunities.

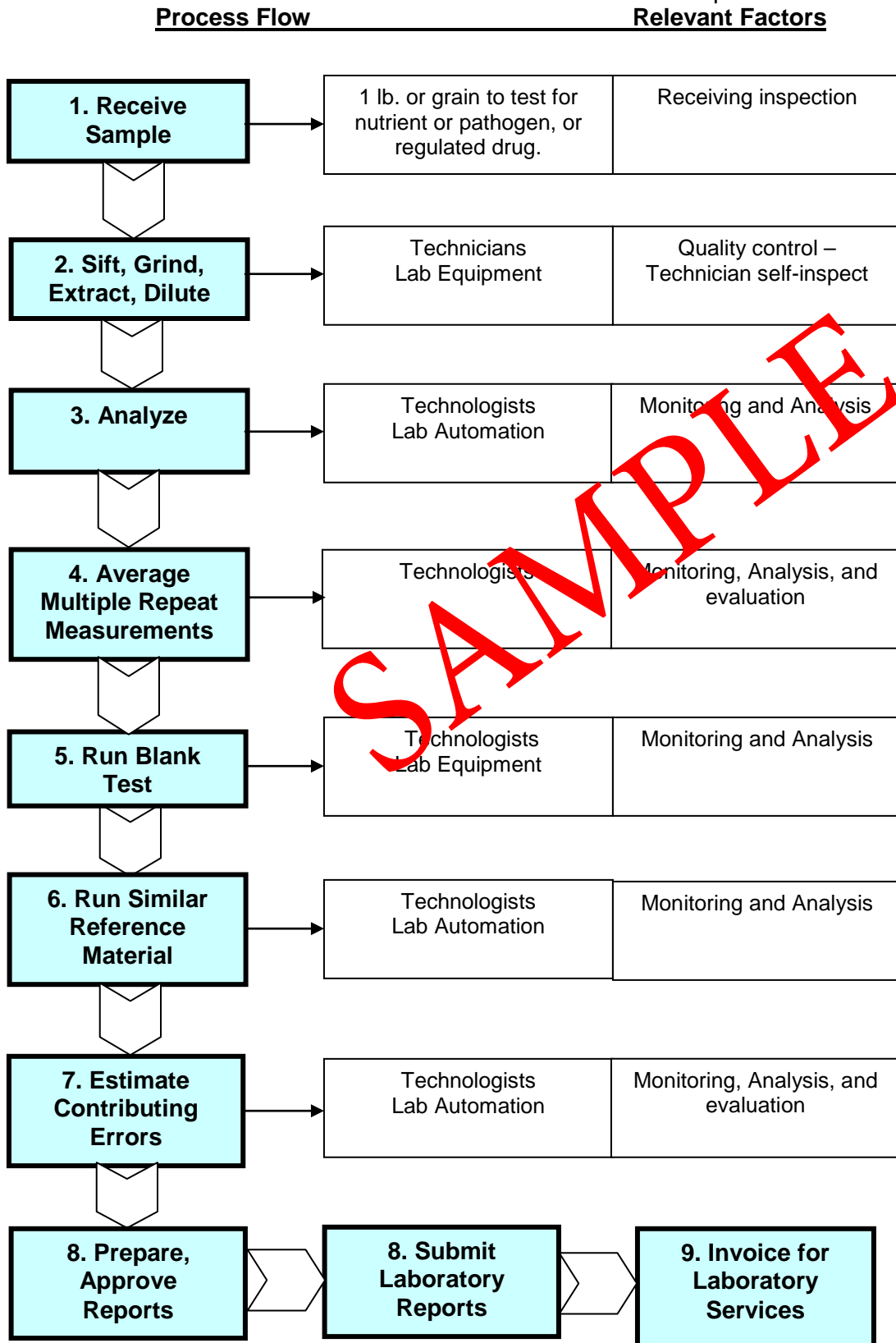
Risk is the possibility of an event or activity negatively impacting the operational or strategic objectives of an organization.

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).

Prepare Test Protocol Flow Diagram

The Process Flow Diagram for **Accredited Work** represents each step in a test protocol and includes other relevant factors associated with the steps.



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 Item / activity / process are at risk and require attention.

* Refer to the Test Protocol Flow Diagram.

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

Item Needing Attention	What is present or could be introduced as a risk?	Description of Risk	Risk Assessment 1 = Severity 2 = Likelihood 3 = Significance			Does a next step in process eliminate the risk?	What controls exist to address the risk?	Is the Item / process step at risk? Yes / No	If YES, Initiate Remedial Action
*	Aspect	---	*** Impact			---		Threat	Opportunity
---	---	----	1	2	3	Justifications		----	

SAMPLE

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LMS Team review: 1 _____, Date: _____, 2 _____, Date: _____

Exercise - Action 1 - Conduct Risk Analysis - Risk Management Worksheet

ACTION 1	ACTION 2	ACTION 3	ACTION 4			ACTION 5	ACTION 6	ACTION 7	ACTION 8
Item Needing Attention	Input	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 Item / process step at risk? Yes / No	If YES, Issue the Corrective Action Request
---	---	----	1	2	3	Justifications			

ACTION 1 *Item number and name*

Each Item identified on the 'Test Protocol Flow Diagram' as needing attention needs to be transferred to this worksheet and numbered and named in the same sequence as in the flow diagram. This is to ensure that all aspects of the process are visible and controlled, not just the items that are at risk.

Reviews can describe problem areas not only in a laboratory setting, 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 - Conduct Risk Analysis - Risk Management Worksheet – RPN 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 Item / process step is at risk and requires attention.

* Refer to the flow diagrams where the processes are identified, described and the item / process steps detailed.

** Refer to Frequency, Severity, and Detection Guidelines. *** Refer to Risk Category Guidelines in previous pages.

* Step *	What is present or could be introduced as a risk?	Description of Risk	** Analysis **			Risk Potential Number F x S x D	*** Risk *** 51 + = A 50 to 26 = B 25 to 16 = C 15 to 10 = D 9 to 1 = E	Item / process step at risk		If YES, Issue the Corrective Action Request
			F = Frequency	S = Severity	D = Detection			Yes = A, B, C D, E = No	NO	
---	---	----	F	S	D	R.P.N.	CATEGORY	YES	NO	CAR #

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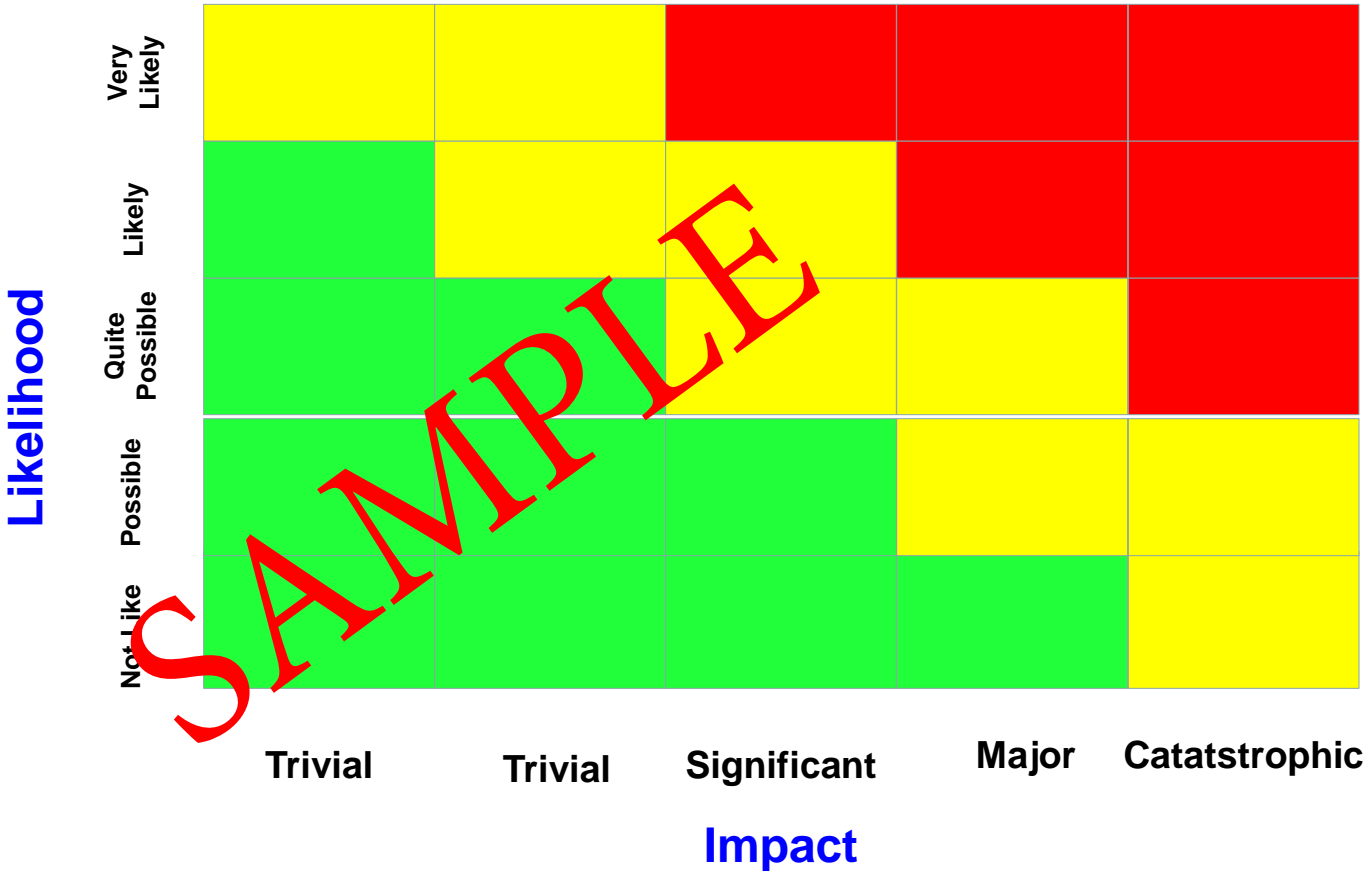
Risk Management / Risk Analysis in ISO/IEC 17025:2017

Includes Risk Power Point

**Committed to
Accurate and Valid
Laboratory Results**

Risk-Based Thinking

An informal risk management system aimed at improvement



Risk-Based Thinking

Example: What can go wrong with a Process?

- Purchasing Process
 - Single Source supplier is shut down by the onset of a devastating earthquake
- What is the impact?
 - You are shut down
- What is the likelihood it will happen?
 - Unlikely (But it can happen)
- How do you mitigate the risk?
 - Find another supplier
 - Revise design to allow other options

Action 3 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 #

ACTION 3 What type of risk is presented by the introduction of these inputs?

Describe the risks when non-complying laboratory issues result in areas such as:

- Lack of training
- Facility not maintained
- Equipment not verified
- Measuring equipment out of calibration
- Others

Risk Management Worksheet

Conduct Risk Analysis - Risk Management Worksheet

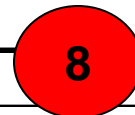
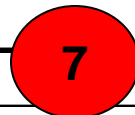
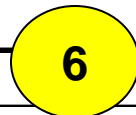
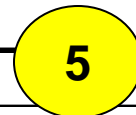
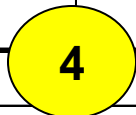
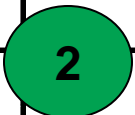
The first 6 columns of this form are used to list the Potential Risks and Assess the Significance of the Risks

The last 2 column 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			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 = Severity	2 = Likelihood	3 = Significance				
---	---	----	1	2	3				



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