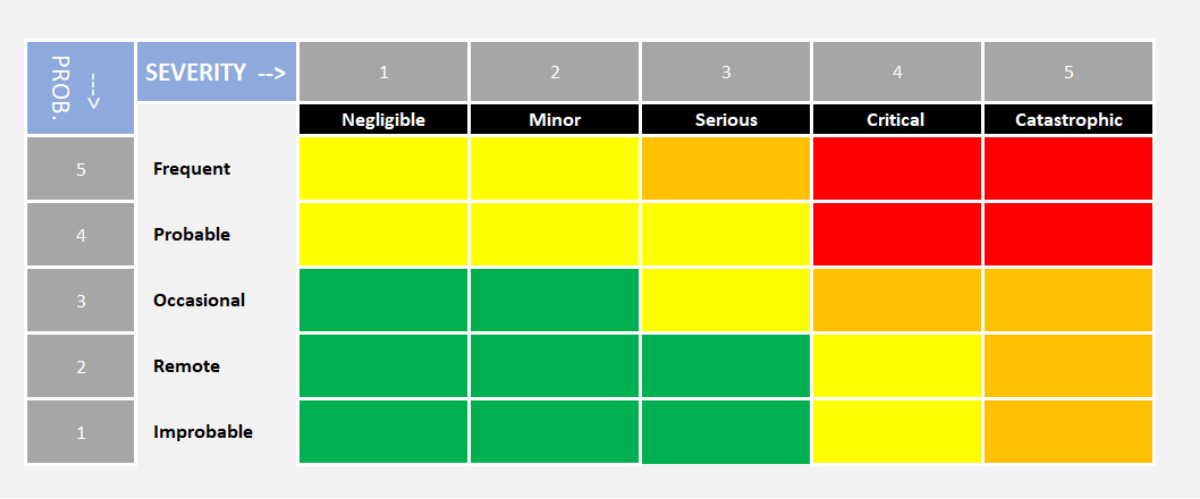
Background

Risk Management: What is it?

A risk is a *potential harm*, including the downstream effects on patient care and laboratory operations.

- *Potential* can be expressed in terms of *probability*.
- *Harm* can be expressed in terms of *severity*.

These two dimensions of risk can be plotted in a matrix of probability and severity, referred to as a "heat map," as shown below.



A risk matrix of probability and severity

Risk management is the systematic identification, evaluation, control, and monitoring of risks.

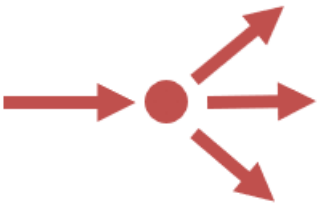
To be more specific:

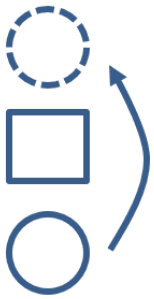
- We identify potential harms, eg:
  - Only one source of a key reagent, which may cause a shortage and inability to do testing.
- We evaluate those potential harms, in terms of probability and severity, which helps us prioritize them.
- We control risk by modifying work processes, including planning for contingencies.
- We monitor or track ongoing risks or the results of our control efforts.

Without risk management, two unfavorable things can happen:

- Foreseeable and preventable harms occur.
- The organization makes poor choices about which improvement projects to undertake, without first prioritizing them based on risk.

Risk management takes different forms. It may be:

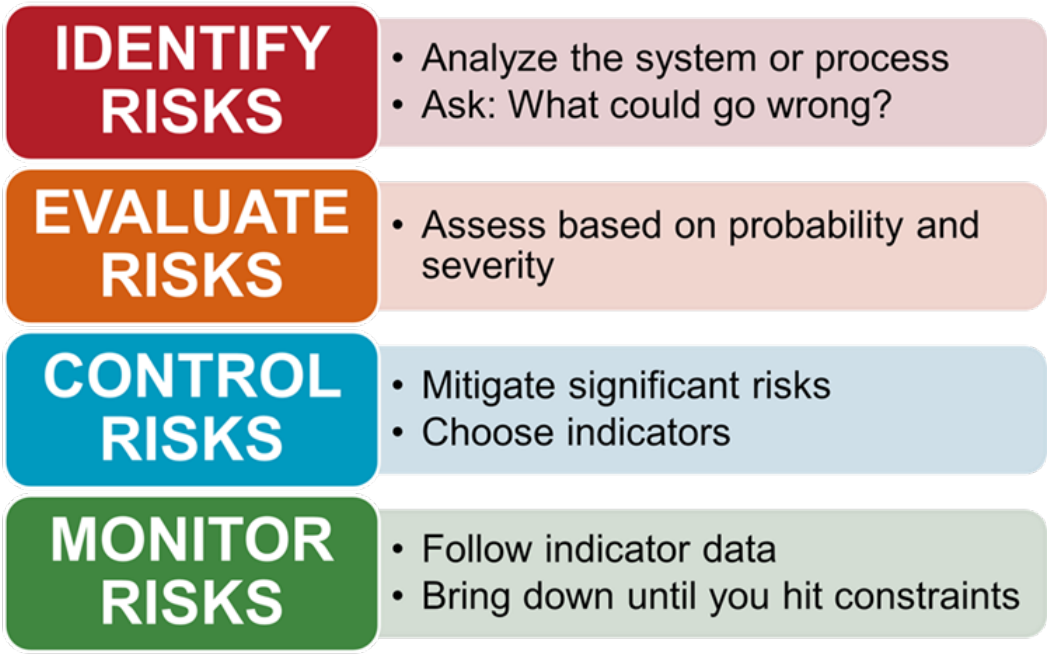
Periodic 	An annual internal audit that seeks to find risks, opportunities for improvement, and deviations from documented processes.
Reactive 	A project triggered by an occurrence or audit finding – eg, receiving a customer complaint about rejected specimens and starting a project to study the magnitude of the problem, what is happening at the collection site, and what can be done to improve things.
Continuous 	A continuous assessment based on daily events and observation of what is happening in the laboratory – eg, a section manager may conduct a daily huddle, conclude that one of the sections is facing a critical staffing shortage, and escalate the problem to the laboratory-wide huddle.

Proactive 	A project to evaluate potential weaknesses in a new, revised, or complex process – perhaps a new test method or instrument, or a new preanalytic process.

Risk management is both a process and a continual mindset. Laboratories need to create a culture of risk awareness. Staff need to be constantly alert to risk; they need to be willing to communicate it and act on it.

The Risk Management Process

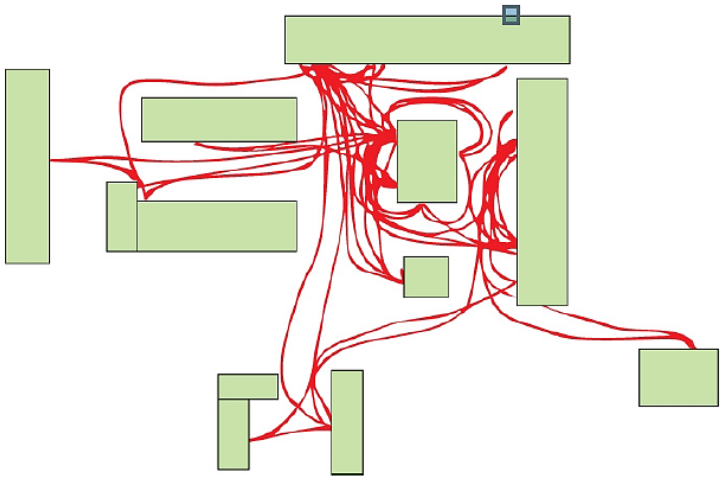
As mentioned above, the risk management process typically involves four key stages.



Summary of risk management stages

Here is an explanation of each stage:

1. **Identify risks.** Analyze the process or the system, understand it, and identify risks. For a specific process, this usually means performing process mapping.



Analyzing the flow of materials and people through the laboratory can reveal risk

2. **Evaluate risks.** Assess risks based on probability and severity/impact. Typically, this takes the form of a matrix, and assigning a value to the risk.

   Here is an example of a risk matrix:

PROB. -->	SEVERITY -->	1	2	3	4	5
		Negligible	Minor	Serious	Critical	Catastrophic
5	Frequent					
4	Probable					
3	Occasional					
2	Remote					
1	Improbable					

A risk matrix of probability and severity – aka, a "heat map"

Note: Many laboratories find it helpful to adopt or develop a scale of the increments of probability and severity.

Probability and Severity Continuum

3. **Control risks.** This involves the following steps:
    - Determine how to mitigate significant risks by changing the process – eg, by using mistake-proofing techniques – or by developing contingency plans.
    - Choose indicators that show whether the risk mitigation actions are working (eg, corrected reports, customer complaints, or TAT).

    Once the laboratory has taken these steps, it will need to revisit them. For example, the initial control measures/process changes may not produce the desired effect. New measures may be necessary.

    It is important to continually monitor whether the laboratory is measuring the right thing (ie, choosing the right indicator).

    Here is a summary of the possible responses to risk:
    - Ideally, the laboratory will be able to *terminate or avoid* the risk.
    - The next best thing is to *reduce or mitigate* the risk.
    - In some cases, it may be reasonable to *transfer* the risk – eg, outsource part of an operation, such as IT, or kit building, to a third party that is better positioned to handle the risk.
    - Finally, it is sometimes necessary to *accept* the risk.

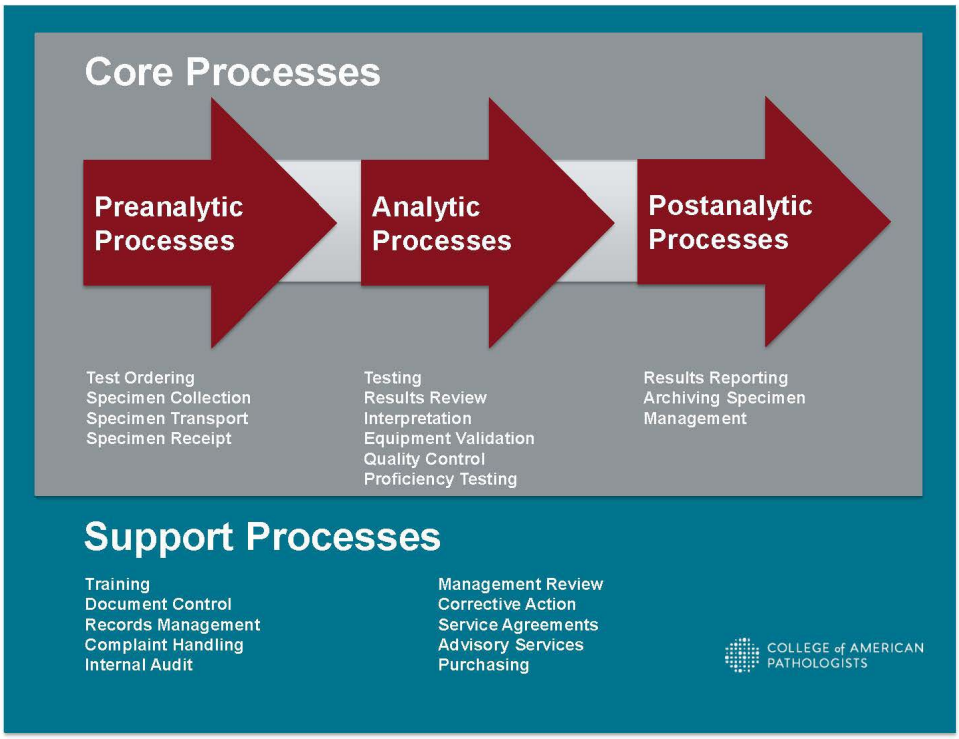
4. **Monitor risks.** Follow the data until you see a pattern of resolution based on the indicators chosen in step 3 above. Bring the risk down to the point where there are constraints (based on available technology or budget) that prevent you from reasonably bringing it down any further. There will always be some residual risk.

Jeremy Hart on managing joint venture risk

Scope of Risk Management

Risk management targets all processes in the laboratory, not just core testing areas.

It includes processes from the preanalytical and postanalytical phases, as well as support processes such as purchasing and training/onboarding.



Risk management addresses all laboratory processes – core and support

Micro and Macro Level

Risk management takes place on both a micro and macro level.

Micro Level

Risk management can be applied to individual processes, mistakes, and projects.

At this level, it identifies risk points, makes judgements of probability and severity, prioritizes risks, and responds with recommendations for countermeasures.

Here is a typical form used for risk assessment of a process.

Main Process Steps (List)	Hazard Identified = Step(s) in process with no human readable PPID	Risk Assessment Matrix Score	Priority Ranking
Accessioning	Consult block labels	2	1
Extraction - Maxwell	Extraction Cartridges	2	1
Extraction - Manual	Extraction column 2mL Collection tubes	2	1
Fragment Analysis (BRAF, CS & ID, JAK2CALR, MSI, MYD88, FLT3/NPM1)	0.2mL strip tubes PCR 96 well plate 3500 run	2	1
THR and HFE	0.2mL strip tubes PCR 0.2mL strip tubes enzyme digest 0.2mL strip tubes QIAXCEL	2	1
B and T Cell	96 well plate PCR (robot)	2	1

Process-level risk assessment form

Micro-level risk assessment is essential. However, medical laboratories are complex. There are many simultaneous and interacting processes, projects, and changes. So, micro-level risk assessment is not sufficient.

Macro Level

This means drawing information from throughout the quality management system (QMS), and from many individual risk assessments, and developing a “big picture” view of the risks for your laboratory/enterprise.

At the macro level, risk management means stepping back from specific areas and all the identified risks, and asking:

- What is the story that all the individual data points are telling us?
- What areas of our QMS are weak? For example:
    - Are our internal audits not finding critical problems?
    - Are our documents not giving people the information they need? Are they difficult to find or interpret?
    - Do we have a lack of standardization of processes?
    - Do we have a lack of clear assignment of roles?
    - Are we doing a good job with contingency planning?
- Where should we be allocating our time and attention?
- What is our most urgent project?
- What are our overall strengths, weaknesses, opportunities, and threats? (See more on SWOT analysis below.)

The ideal time to do this higher-level analysis is during your management reviews.

A tool commonly used for tracking macro-level risks is a risk register.

Condition Causing Risk	Impact Description	Probability	Severity	Risk level
Inadequate calibration protocols	Delays, repeat QC, TAT problems, lost insurance reimbursement	4	3	
Inadequate technical training	Delays in testing because people have to find someone to ask	3	4	
	People cannot access instrument controls; temperature issues	4	3	
SOPs don't contain adequate instructions; functional areas not involved	Inaccurate tests Low morale, turnover	4	4	

Example risk register

The Role of a QMS

A quality management system is a set of interacting parts, functions, and activities designed to ensure quality in an organization's goods and services. It typically includes:

- A well-planned set of processes for providing goods or services
- A system for monitoring the processes (eg, metrics, internal inspections, complaint handling systems)
- A system for improving the processes (eg, root cause analysis, corrective action, preventive action, risk assessment, change management)
- Infrastructure (eg, quality manager, management review committee, internal auditors) and ongoing activities to support quality within processes

The activities of the QMS are useful in revealing and controlling risks.

A QMS based on ISO 15189 is designed to constantly find, escalate, and manage risks.

Consider the four steps in the risk management process, and the associated QMS activities.

Step	QMS Activities That Reveal and Control Risk
IDENTIFY RISKS	• **Internal audits:** Appraising work processes, looking for issues and risks • **Occurrence management:** Following up on occurrences, tracking, and trending occurrences • **Root cause analysis:** Finding root cause, and looking for similar risks with the same cause and potentially the same solution • **Process development:** Planning out processes, their interactions, the handoffs, and identifying risk points • **PT review:** Looking for patterns or trends in PT data that indicate weaknesses and risks • **QC review:** Looking for trends that indicate a problem and risks • **Communication:** Setting up channels to detect and escalate risks (eg, huddles or daily management meetings)
EVALUATE RISKS	• **Management review meetings:** Looking at internal audit reports; looking at data to decide on priorities for improvement projects based on comparative risk • **Metrics/data analysis:** Tracking, analyzing, and trending data can reveal patterns (eg, if the percentage of inadequate specimens is continuing to rise, the laboratory may decide this risk merits action) • **Communication/huddles/daily management meetings:** Having discussions about probability and severity of risks, and choosing to escalate issues; escalating issues could include triggering an improvement project
CONTROL RISKS	• **Document control:** Using documents to standardize processes, reduce risk, and provide contingency plans • **Process development:** Setting up projects to address issues that have been identified; revising a process to address root causes; building mistake proofing into processes
MONITOR RISKS	• **Management review meetings:** Reviewing data over time to monitor risk and determine if the implemented strategies are succeeding