

Risk Assessment		
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Risk Assessment

1 Overview & Definitions

- 1.1 Decisions, actions and occurrences concerning laboratory operations can have a positive or negative impact on work product. A negative impact is considered a risk, while a positive impact is seen as an opportunity or benefit.
- 1.1.1 These risks and opportunities should be carefully evaluated and discussed to assess their overall potential impact on the laboratory and its operations.
- 1.1.2 Additionally, the laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel.
- 1.2 Risk assessment is the systematic process used to analyze potential actions, evaluate the likelihood and severity of outcomes, and determine appropriate measures to mitigate negative impacts.
- 1.2.1 The goal is to support informed decision-making while maintaining the integrity and efficiency of the laboratory functions.
- 1.2.2 Risk assessment is essential in laboratory environments to uphold the quality, accuracy, and impartiality of testing and calibration activities.
- 1.3 Risk assessments should be conducted prior to the implementation of any action or decision that may impact work product as well as any after any unexpected occurrences to ensure any potential consequences are identified and managed proactively.
- 1.4 The outcome of a risk assessment should be used to help determine whether or not an action or decision is implemented and if an unexpected occurrence has had an impact on the laboratory or its work product.
- 1.5 A risk assessment may be performed during, but is not limited to, the following scenarios:
- Major workflow changes/implementation
 - Implementation of a new method or technology
 - Changes to interpretation procedures
 - During Management System Reviews
 - Unexpected production system occurrences
 - Evaluating Non-Conforming Work, Preventive Actions, Corrective Actions, and/or Quality Incident Reviews

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- 1.6 Not all actions require following this formal Risk Assessment procedure. In some cases, other quality processes may be more appropriate, depending on the nature and timing of the concern. Those quality processes may themselves incorporate a risk assessment. The following subsections outline when alternative procedures apply:
- 1.6.1 If there are concerns regarding existing policies or procedures that may result in a potential non-conformity, these concerns should be addressed through the [Preventive Action process](#), located in the Quality Assurance Manual.
- 1.6.2 If an action has already occurred and is found to be non-compliant with current policies or procedures, it is handled as non-conforming work or through a Quality Incident Review. Guidance can be found in the [Control of Non-Conforming Work](#) and [Quality Incident Review Procedures](#).
- 1.6.3 Deviations from the standard casework process, although involving a form of risk assessment, do not follow this formal Risk Assessment procedure. These deviations are reviewed by the Technical Leader(s), who evaluate the scientific justification for the proposed deviation. Deviations are documented in the relevant case record(s).

2 Risk Assessment Process

- 2.1 Risk Assessments are documented using the [Risk Assessment Form](#) and are typically initiated by management when an action or activity may cause potential risk to the laboratory or its work product, as outlined in section 1.5.
- 2.1.1 A manager may assign any laboratory staff member to lead the risk assessment. This individual becomes the Lead Investigator.
- 2.1.2 Any staff member may bring concerns to their manager, the Quality Assurance Manager, the Technical Leader, the Deputy Director or Director, who will then help to determine if a formal Risk Assessment or other action is appropriate.
- 2.2 The Lead Investigator will gather relevant information and may consult with other staff to assess potential risks and opportunities associated with the proposed decision, action or occurrence.
- 2.2.1 This may involve speaking with analysts, managers, supervisors, training staff, QA personnel, and/or others affected by or knowledgeable about the matter. A small working group may be formed to assist with the assessment.
- 2.2.2 Supporting materials, such as manuals, standards, casefiles, test batches, and other relevant documents should be gathered and reviewed as part of the evaluation.
- 2.2.3 All individuals consulted and documents reviewed must be recorded on the [Risk Assessment Form](#). Additional materials may be attached as needed.

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- 2.3 The lead investigator, along with the risk assessment working group (if formed), will evaluate the gathered materials and identify both positive and negative potential outcomes.
- 2.3.1.1 Potential risks and benefits to consider may include, but are not limited to, impacts on:
- Impartiality
 - Financial resources
 - Physical resources (e.g., equipment, facilities, or infrastructure)
 - Staffing levels or availability
 - Existing policies and procedures
 - Compliance with relevant standards
 - Accuracy or reliability of results
- 2.3.2 A Risk Scale (see Section 3) may be used to help quantify and support the Risk Assessment Conclusions.
- 2.4 The following points must be documented on the Risk Assessment Form:
- 2.4.1 Decision/Activity/Occurrence Assessed
- 2.4.2 Assessment Performed By
- 2.4.3 Personnel Consulted in Assessment
- 2.4.4 List of Documents/Data Reviewed
- 2.4.5 Discussion Points
- 2.4.5.1 All potential negative outcomes (risks) and positive outcomes (opportunities) associated with the proposed decision, action or occurrence must be listed in the Discussion Points section of the Risk Assessment Form.
- 2.4.5.2 For each negative outcome, document any proposed actions that may help eliminate or minimize the associated risk, if applicable.
- 2.4.6 Assessment Conclusion
- 2.4.7 Further Actions Suggested
- 2.5 Findings and conclusions are presented to the initiating manager and any other relevant staff, such as the Technical Leader(s), Quality Assurance Manager, and/or Forensic Biology Management Team.
- 2.6 Management may request additional testing or information to support the risk assessment.

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- 2.7 Once all necessary information is gathered, management will determine the overall risk level and decide whether to proceed with the proposed decision or action or whether the occurrence has had a significant impact on laboratory operations. This conclusion must be documented on the Risk Assessment Form.
- 2.8 Upon completion of the assessment, the Risk Assessment Form must be signed by the Lead Investigator and a Reviewer. The reviewer may be the Quality Assurance manager or their designee.
- 2.9 Completed Risk Assessment Forms will be stored in the Management Folder in Qualtrax.
- 2.10 While routine Quality Assurance monitoring should identify any negative impacts from an implemented decision or action, each Risk Assessment should be reviewed and discussed during the next Management System Review. This helps ensure that no additional or unforeseen risks have arisen as a result of the decisions or actions taken.

3 Risk Scale

- 3.1 A Risk Scale is a visual and numerical tool used to evaluate the potential impact and likelihood of both negative risks and positive opportunities related to a proposed decision, action or occurrence. The Scale may be used to help guide what actions need to be taken or implemented.
- 3.2 For each negative outcome or concern, you may assign a numerical risk score based on the chance of occurrence and severity to laboratory operations.

Risk				
		Severity		
		High	Medium	Low
Chance of Occurrence	High	10	8	6
	Medium	8	6	4
	Low	6	4	2

- Low: Minimal risk; generally acceptable with little to no mitigation.
- Medium: Moderate risk; should be mitigated or closely monitored.
- High: Significant risk; requires strong justification and mitigation; may prevent implementation.

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- 3.3 Add all individual risk scores together to get the Overall Risk Score.
- 3.4 For each positive outcome or opportunity, assign a numerical opportunity score based on the chance of occurrence and level of benefit to laboratory operations.

Opportunity				
Chance of Occurrence	Level of Benefit			
		High	Medium	Low
	High	10	8	6
	Medium	8	6	4
	Low	6	4	2

- Low: Limited benefit; may not justify risk.
 - Medium: Notable improvement; worth consideration.
 - High: Strong benefit; may justify taking moderate or even high risks.
- 3.5 Add all individual opportunity scores together to get the Overall Opportunity Score.
- 3.6 Use the total scores from both categories to help guide the decisions or actions to be taken. These scores should be listed on the Risk Assessment Form.
- 3.6.1 If the Overall Risk score is higher than the Opportunity Score, or if risks cannot be effectively mitigated, the decision or action should not be implemented without further revision or safeguards.
- 3.6.2 If the scores are relatively equal, further discussion and judgment by management is required.
- 3.6.3 If the Opportunity score is higher than the Risk Score, the action may be justified, especially if risks are manageable.