

Guideline for Quality Issue Investigations



ANZPAA
Australia New Zealand
Policing Advisory Agency



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Introduction

About this Document

The purpose of this guideline is to provide information and a framework for investigating quality issues that may impact the reliability of forensic science outcomes.

It is crucial that the community, police, and justice system stakeholders have trust in forensic science. To achieve this, forensic service providers need to demonstrate that their scientific methodologies are sound and that there are effective processes in place to identify and resolve quality issues. Effective identification and resolution of quality issues enhance credibility and transparency, improve operational efficiency, prevent recurrence of nonconformities, and ensure compliance with legislative and accreditation requirements.

This document supports continuous improvement in forensic science by providing guidance on a structured, risk-based methodology for identifying and resolving quality issues. The guidance is designed to complement jurisdictional policies and procedures, and standards related to quality issue investigations.

This flexible and adaptable guideline can be applied across diverse jurisdictional environments. Forensic service providers can evaluate their current policies and procedures to determine the relevance and applicability of the information herein.

What is a Quality Issue?

For the purposes of this document, a quality issue is an event that has adversely impacted or could adversely impact the performance or reliability of the forensic service provider's product or service.

Quality issues may arise from a range of sources including process changes, workflow disruptions, nonconforming equipment and supplies, and human factors. The human decision-making component in a forensic method or process can lead to errors such as misclassifications or incorrect interpretation. These errors may arise from sources such as inadequate training, cognitive biases, fatigue, or miscommunication. Quality issues can stem from broader organisational or environmental factors, such as ineffective management of ongoing and sustained laboratory pressures, where the operational impact may not be adequately quantified, as well as ineffective quality control measures.

Quality issues also include near misses, which are events that could compromise the reliability of the results, impact customers, or negatively affect service delivery. Therefore, it is essential that they are considered as part of the quality issue investigation process.

Quality issues may be identified through mechanisms such as internal and external audit findings, quality assurance programs or customer complaints. While complaints serve as a form of feedback that may indicate a quality issue, they do not always reflect the underlying problem.

Identifying, assessing and understanding quality issues involves employing a systems approach, which evaluates the entire process rather than focusing on individual factors in isolation. When the entire system is analysed to identify the cause of errors, from communication to training, cognitive bias and organisational culture, these errors can be better addressed.¹

Although quality issues may introduce other types of risks, including financial and reputational risks, the primary focus in this document are the risks related to producing reliable and reproducible results and services.

FOOTNOTES

1 Taylor, M., et al. (2024). *Forensic DNA Interpretation and Human Factors: Improving the Practice Through a Systems Approach*.

Continuous improvement lies at the centre of investigating and managing quality issues. Investigating and resolving quality issues provides valuable opportunities to enhance and refine processes and practices, ultimately strengthening the quality management system.

Document Components

This document is organised into the following three sections with five appendices to guide the reader through the information.

Section 1

The Foundation

This section summarises the foundational elements that underpin an effective quality issue investigation process, as well as the key factors influencing successful implementation across forensic service providers.

Section 2

The Framework

This section provides an overview of the Quality Issue Investigation Framework ('the Framework'), with detailed guidance on methodology and operational considerations for each process stage.

Section 3

Case Studies

This section presents three case studies that demonstrate the practical application of the Framework and provide deeper insights into its implementation.

Appendices

Appendix A

Outlines the key terms and definitions.

Appendix B

Summarises general roles and responsibilities that support the quality issue investigation process.

Appendix C

Provides an overview of a three-tiered risk-based approach for quality issue investigation and management.

Appendix D

Includes risk assessment matrix examples, including information on calculating a risk rating.

Appendix E

Provides an implementation worksheet template to assist forensic service providers with comparing their policies and procedures against the Framework.

Selenium	mg/l
Sodium	mg/l
Zinc	mg/l
Chlorides	mg NO ₃ -l
Cyanide	mg SO ₄ -l
Fluorides	mg H ₂ S-l
Nitrates	ug/l
Nitrites	ug/l
Sulphates	mg/l
Sulphides	mg/l
TOTAL "drins"	mg/l
TOTAL "ddt"	mg/l
Hydrocarbons	
Anionic Detergents	
colloidal solids	



Section 1: **The Foundation**

Section 1: The Foundation

This section presents foundational concepts that underpin an effective quality issue investigation process and inform the investigation and management of quality issues.

Culture

An effective quality issue investigation process relies on a culture that values the reporting of quality issues, where individuals feel empowered to raise quality issues out of genuine commitment to quality and continuous improvement. This requires forensic service providers to uphold the principle of procedural fairness and to foster fair and objective decision-making in quality issue investigations. By ensuring personnel have a voice, forensic service providers can create an environment that encourages dialogue and trust. Culture can be strengthened when forensic service providers allocate time and resources to identify root causes and implement effective mitigation strategies.

Additionally, fostering a culture of risk awareness among personnel is fundamental to risk management. When employees understand the organisation's risk appetite and are equipped to manage risks effectively, it creates an environment where potential quality issues are proactively identified and addressed.²

The ANZPAA NIFS Quality Specialist Advisory Group developed Principles of Authentic Quality Culture in Forensic Science Service Provision. These principles detail the organisational values and practices supporting quality outcomes. The document can be downloaded from the ANZPAA NIFS website (<https://www.anzpaa.org.au/nifs/forensic-science>).

Governance

Investigating and managing quality issues involves a diverse set of roles, skills, and levels of responsibility. An interdisciplinary team with expertise in quality and relevant laboratory procedures is typically involved. **Table 2 (Appendix B)** provides general guidance on the roles and responsibilities required to support the investigations of quality issues.

Clearly defined policies and procedures covering the following roles, responsibilities, and authorities will support accountability and efficiency in the quality issue investigation and management process:

- who is responsible for coordinating and executing specific tasks
- who has authority over policies, practices and procedures, ensuring alignment with laboratory quality standards
- who will determine whether to seek support from subject matter experts
- who is accountable for progress reporting, authorising investigation closures, decision-making, and
- who has authority to issue instructions to halt or resume work activities.

The forensic service provider management holds ultimate responsibility for the laboratory, which includes the quality issue investigation and management process and associated policies and procedures.³

Stakeholder Collaboration

For the purposes of this document, the primary stakeholders include internal staff, industry partners (e.g. suppliers), customers (e.g. police investigators and coroners), members of the judiciary, and accreditation bodies. A collaborative stakeholder approach strengthens the quality issue investigation process by enabling more thorough assessments and informed decisions. By engaging with the relevant internal and external stakeholders throughout the process, particularly when conducting root cause analysis (RCA) and risk assessments, forensic service providers can leverage expertise and perspectives, leading to more comprehensive solutions and corrective actions. Stakeholder collaboration reduces the risk of bias and helps manage subjectivity at critical points. It also fosters a culture of transparency, aligned expectations, and shared accountability, ultimately strengthening quality issue investigations and management.

Section 2 highlights stakeholder communication at most stages of the quality issue investigation process. When performing a risk assessment for a quality issue, part of the process involves considering which stakeholders might be affected and determining who needs to be involved in the investigation, as well as who needs to be notified of outcomes. The information shared may relate to the nature of the quality issue, consequences of the quality issue, existing quality measures in place, corrective and preventative actions implemented to address the quality issue,⁴ and whether the evaluation of risk has been updated following mitigation strategies.

While stakeholder communication can occur at any stage, clear policies and procedures can assist in guiding how and when information is shared about investigation and corrective action outcomes, particularly where stakeholder impacts are involved.

Competency and Training

Forensic service providers are encouraged to provide formal training for relevant personnel, with a focus on good practice such as adhering to accreditation requirements that follow international standards, applying quality and risk management methods and tools, analysing data effectively, and evaluating the significance of risks associated with quality issues. This training may provide clarity on tasks and procedures, support the correct application of quality tools, and build capability to develop fit-for-purposes processes for wider application.

As elements of the quality issue investigation process involve subjective analysis, forensic service providers should ensure

FOOTNOTES

2 Taylor, M., et al. (2024). Forensic DNA Interpretation and Human Factors: Improving the Practice Through a Systems Approach.

3 Australian Standard International Organization for Standardization/International Electrotechnical Commission (2018). *AS ISO/IEC 17025:2018: General requirements for the competence of testing and calibration laboratories.*

4 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *ICH Harmonised Guideline: Quality Risk Management Q9 (R1).*

relevant personnel are trained to minimise subjectivity to support a robust quality issue investigation process.⁵ Given quality issues may be assessed and rated differently by different personnel, subjectivity can directly influence decision-making and the actions taken in response.

The effective management of subjectivity in quality issue investigation activities requires training in bias-minimisation strategies, appropriate application of quality tools, and evaluation against critical parameters or established criteria. Refer to *ICH Harmonised Guideline: Quality Risk Management Q9 (R1)*, 2023⁶ for further guidance on minimising subjectivity.

Where existing policies and procedures are limited, forensic service providers may strengthen training initiatives to ensure that quality issues are addressed consistently.

Training for operational staff in the following areas is also encouraged:

- problem identification, investigation, and RCA
- risk management and the forensic service provider's risk management framework, encompassing risk assessment and management processes and procedures, and the use of relevant quality tools
- accreditation requirements, covering relevant international standards, and
- quality management system requirements.

Forensic service provider personnel may find the online training material developed by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) relevant to their current responsibilities. The training material developed by ICH can be accessed from the training library on the ICH Website (<https://ich.org/page/training-library>). When considering this training material, forensic service providers should assess the suitability to determine its relevance and applicability as a complement to existing internal training.

Policies and Procedures

Forensic service providers have responsibilities to ensure policies, procedures and methods relating to quality issue investigation and management comply with relevant standards, align with good practice guidelines, and are effectively communicated to and understood by all personnel.

Forensic service providers should ensure policies and procedures clearly outline requirements for the investigation and resolution of quality issues. This may include notification and escalation pathways, documentation and reporting requirements, as well as timeframes for resolving low, moderate, high and extreme risk rated quality issues, to reduce subjectivity and ensure consistent and timely application of the process. Policies and procedures should clearly define the system for monitoring quality issues and related processes to

ensure ongoing quality assurance. Forensic service providers should consider incorporating regular data trend analyses in policies and procedures, as it provides an opportunity to proactively monitor for broader and ongoing trends, identify systemic or emerging quality issues, and develop effective mitigation strategies. Forensic service providers should consider the establishment of templates for risk assessment processes and root cause analysis to support procedures and ensure consistency and clarity for personnel undertaking these tasks.

To ensure policies and procedures related to quality issues remain appropriate and aligned to good practice, forensic service providers should undertake regular, comprehensive reviews that evaluate objectives, identify potential sources of bias, consider emerging guidelines and standards, and incorporate opportunities for innovation. These reviews should assess performance indicators such as stakeholder feedback, trend analysis, internal and external review findings, proficiency test results, validation and research outcomes, rather than being conducted in isolation.⁷

Policy Alignment

Aligning the forensic service provider's quality issue investigation framework with the organisation's enterprise risk management framework will ensure interoperability. If there is no organisational enterprise risk management framework, or if the existing framework is considered unsuitable for this purpose, the forensic service provider can develop a policy or procedure for identifying, assessing and evaluating risks relating to quality issues. This approach supports consistent risk management practices for both scientific and non-scientific related issues. Considerations for developing the framework include:

- the risk consequence rating
- the frequency of risk occurrence
- points within the process where a risk assessment may be required, for example:
 - when the quality incident occurs, and
 - after implementation of preventative and corrective actions
- the personnel involved in the risk assessment process, including individuals with relevant technical expertise and quality staff where appropriate (refer to **Table 2**), and
- the outcome of the risk assessment, which informs the control strategy and downstream components of the investigation process, such as escalation triggers, pathways and timeframes for action.

The risk classification for similar events may vary across forensic service providers due to different enterprise risk management frameworks and objectives contributing to jurisdictional strategic goals.

FOOTNOTES

5 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *ICH Harmonised Guideline: Quality Risk Management Q9 (R1)*.

6 Ibid.

7 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (2008). *ICH Harmonised Tripartite Guideline: Pharmaceutical Quality System Q10*.

A photograph of a laboratory or cleanroom environment. The scene is dominated by white cabinetry and shelving. On the shelves, numerous clear glass bottles of various sizes are neatly arranged. Below the shelves is a white countertop workbench. On the workbench, there are several more glass bottles, some with black caps, and a small piece of laboratory equipment. A black office chair with a five-point base is positioned at the workbench. In the background, another workbench area is visible, featuring a microscope and other lab equipment. The ceiling has recessed lighting fixtures. The overall atmosphere is clean and professional.

Section 2: The Framework

Section 2: The Framework

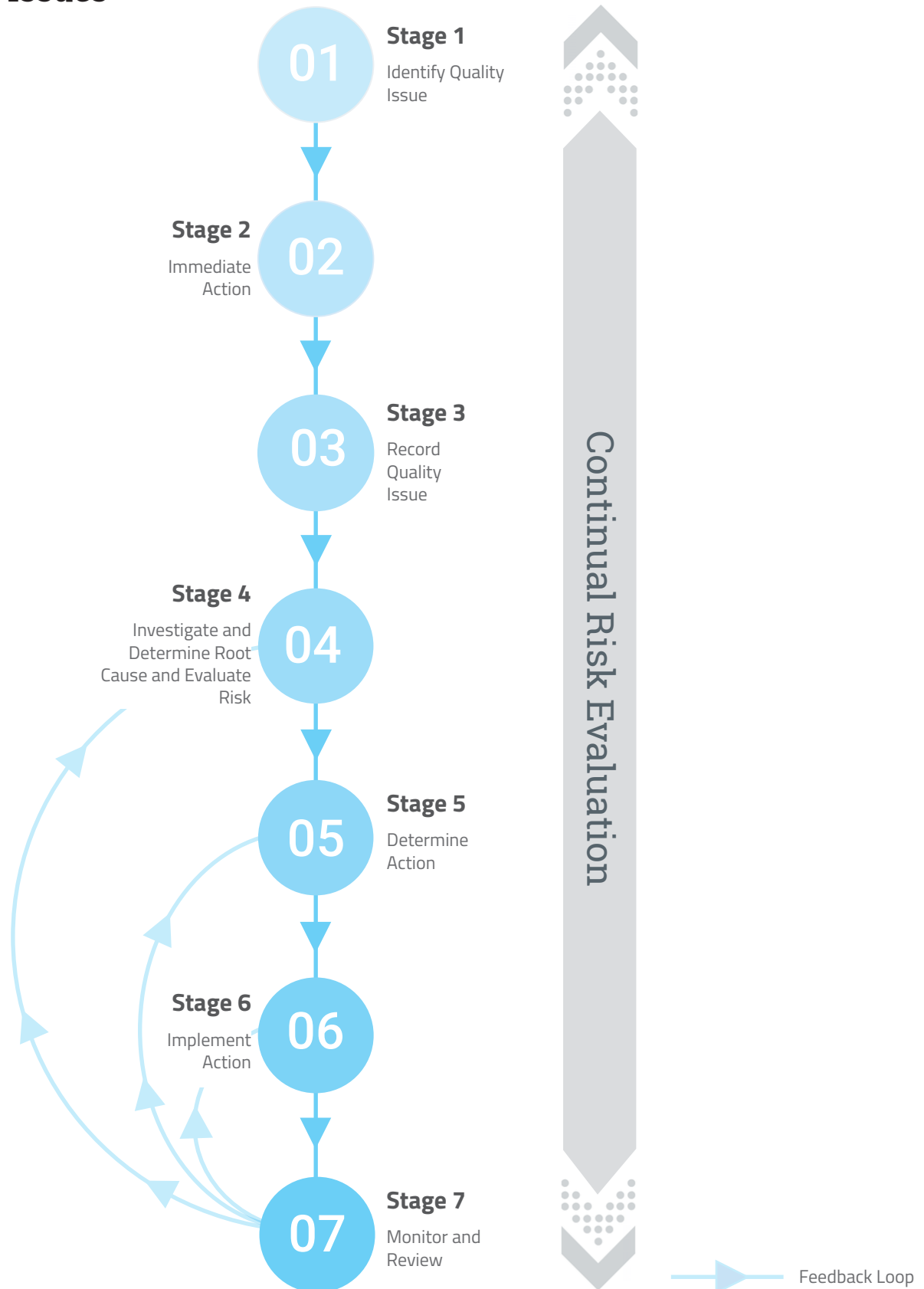
This section introduces the Framework for investigating quality issues, outlining objectives, methodologies and considerations for each stage to support consistent and effective application of the process. **Figure 1** provides a visual representation of the Framework, with the double-headed arrow, “Continual Risk Evaluation”, highlighting the importance of re-evaluating risk throughout the entire process.

The feedback loop illustrated in **Figure 1** shows that outcomes identified at **Stage 7** (Monitor and Review) inform whether the process returns to earlier stages for further investigation, reassessment and reimplementation of actions.

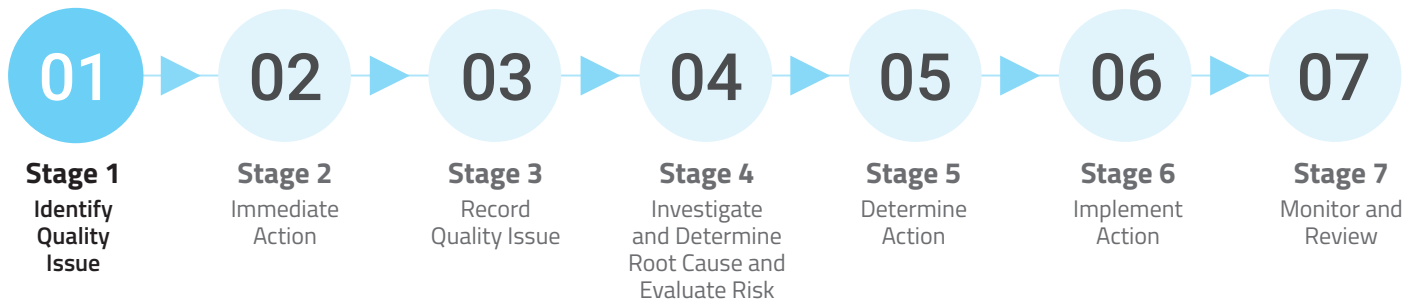
Identifying and categorising the quality issue in **Stage 1**, enables forensic service providers to plan their response based on an initial assessment of complexity and risk. By categorising quality issues into tiered risk-based levels, this approach enables consistent determination of the required oversight, documentation, resourcing, and urgency for each event. This ensures that resources are allocated efficiently and proportionately, allowing for timely resolution and effective management of quality issues.

For further guidance on applying a tiered, risk-based approach, refer to the example provided in **Appendix C**.

Figure 1. Framework for the Investigation and Management of Quality Issues



Stage 1: Identify Quality Issue



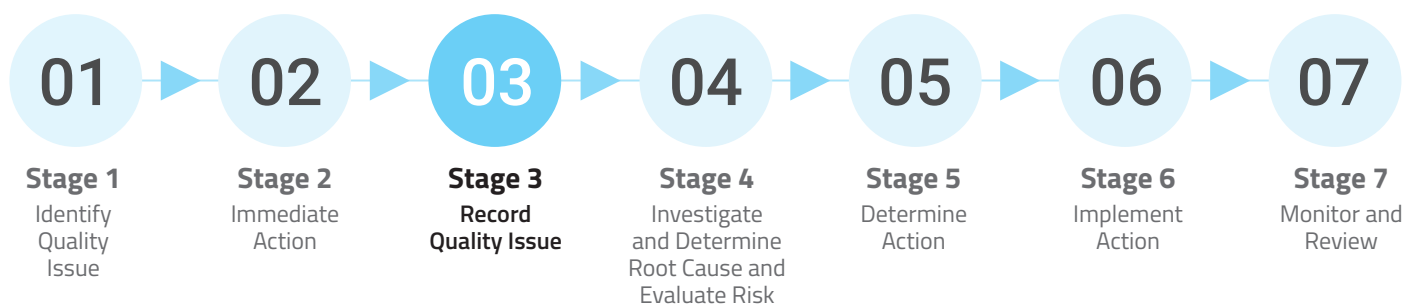
Objective	Method	Considerations
To identify a quality issue or potential quality issue.	<ul style="list-style-type: none"> Identify quality issues through a range of methods, including staff reporting, internal and external audits, quality control measures, and analysis of quality data and trends. Define the quality issue by determining the gap between the desired state (conformance or expected outcome or desired outcome) and the observed or potentially observed state (non-conformance or unexpected outcome or undesired outcome). 	<ul style="list-style-type: none"> Quality issues may be identified by internal and external stakeholders, including staff reporting and automated systems. It may be beneficial to categorise the quality issue based on an initial assessment of its complexity and associated risks to determine the level of resources required for the investigation. Refer to Appendix C for an example of a three-tiered, risk-based, quality issue categorising system.

Stage 2: Immediate Action



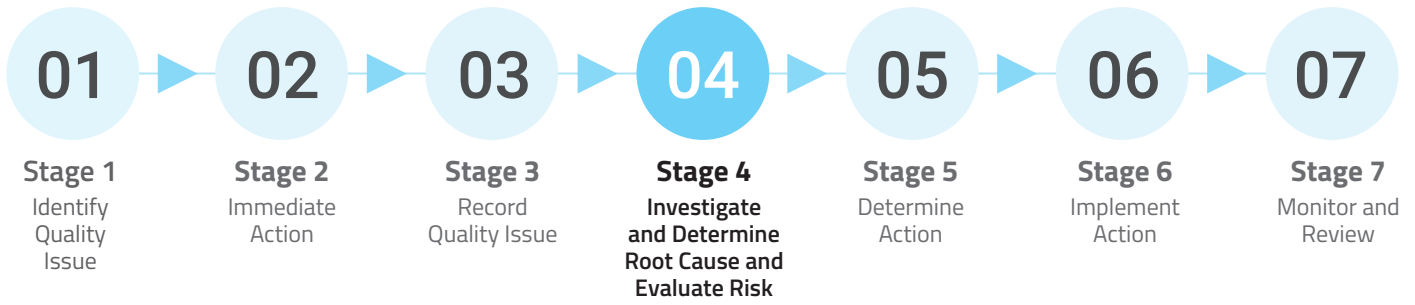
Objective	Method	Considerations
To immediately contain and manage the quality issue, mitigating risks and preventing further escalation.	<ul style="list-style-type: none"> Identify the immediate risk by assessing the extent and significance of likely impacts and take prompt action to contain the quality issue to prevent continuation or escalation. 	<ul style="list-style-type: none"> Immediate risks may include reduced quality or reliability of the work product or result, delays, errors, sample contamination or degradation, customer dissatisfaction, or unmet expectations. Immediate actions may serve as a corrective measure; however, they are not necessarily a complete or permanent solution to the issue. RCA (refer to Stage 4) may identify additional corrective or preventative actions to eliminate the root cause, including contributing factors, to correct the system that caused the quality issue. Forensic service providers should consider who can issue instructions to halt and resume work. This may include department heads, quality managers or safety representatives.

Stage 3: Record Quality Issue



Objective	Method	Considerations
To document quality issues and escalate through appropriate systems.	<ul style="list-style-type: none"> Record and escalate the quality issue in the appropriate local management system, capturing information such as the nature of the quality issue, its location, the personnel involved, the initial action taken, and any supporting evidence available at the time of reporting. Comply with local policies and procedures with requirements on record-keeping and collection of associated evidence and data. 	<ul style="list-style-type: none"> Personnel should have access to documentation relating to quality issues. Determine how these records will be made available during internal and external audits.

Stage 4: Identify Root Cause and Assess Risk



Objective	Method	Considerations
<p>Undertake a preliminary risk evaluation to inform decisions on whether to proceed to a formal investigation and corrective action.</p> <p>Determine the root cause to inform corrective actions.</p> <p>Evaluate the level of risk by considering the significance, frequency, and extent of the quality issue.</p>	<ul style="list-style-type: none"> Gather background information to support the risk evaluation. This may include reviewing previous quality issues, consulting with relevant stakeholders, observing processes, and collecting documents and data. Perform RCA and a risk assessment using the forensic service provider’s risk framework and quality tools to identify contributing factors and determine the risk level. Consider quality tools⁸ to be used, such as 5 Whys, flowcharts, check sheets, process mapping, cause and effect diagrams (e.g. Ishikawa diagram or Fishbone diagram), or a risk matrix. Record the RCA and risk assessment outcomes with the quality issue record, including the rationale for decisions, to ensure it is available for future reference and review (refer to Stage 3). Communicate risk and RCA information at key stages to relevant stakeholders, including decision-makers, personnel, quality, and senior management. This may include details on root causes and risk identification, analysis and evaluation. 	<ul style="list-style-type: none"> When performing RCA and assessing risk, forensic service providers should consider a systems approach to ensure that all possible causes are considered. Examine how work environments, systems, machines, materials, processes, methods, workloads, and cultural issues may have contributed to the quality issue, rather than attributing the problem only to personnel. A risk assessment may entail a formal assessment or risk-based judgement. It may not always be appropriate or necessary to use a formal risk management process when performing a risk assessment. A risk assessment may be conducted by quality or laboratory personnel, with quality oversight as required based on the scale of the quality issue.⁹ Risk assessment and RCA findings should be supported by evidence, which should be retained for future reference. When performing RCA and risk assessments, consideration should be given to information from method validations, multi-factor analysis, informed professional judgment, and stakeholder expectations. Forensic service providers should use quality tools for investigations, RCA, and risk assessments related to quality issues. Various quality tool templates, along with application information, are available online. Refer to Appendix D for an example of a risk assessment matrix tool. Forensic service providers are encouraged to evaluate existing tools and select those deemed suitable. Internal tools may also be acceptable.

FOOTNOTES

⁸ https://asq.org/quality-resources/quality-tools_

⁹ All personnel should receive training and follow established procedures to effectively assess quality issues and the right course of actions to follow. Once the quality issue has been rated for risk, the assessment may escalate to a quality staff member or the Quality Manager to verify the risk assessment before action is taken.

Stage 4: Identify Root Cause and Assess Risk

Objective	Method	Considerations
	<ul style="list-style-type: none"> Review risk assessment and RCA to determine the scope of work required and whether action or further action is needed (refer to Stage 5). Review local management system records, considering the additional information obtained from the risk management process. 	<ul style="list-style-type: none"> Manage and minimise subjectivity in risk management activities to support scientifically sound, risk-based decision-making, especially when assessing the complexity, likelihood and consequences of the quality issue. Effective control measures may include ensuring relevant stakeholder parties are represented when conducting RCA or risk analysis, using appropriate quality tools, evaluating results against critical parameters or specifications, maintaining raw data and records, using relevant information sources¹⁰, and seeking independent analysis. High-risk rated quality issues may require a separate escalation process to executive management for prompt action, and an integrated approach that involves quality, various stakeholders, as well as consultation across multiple disciplines. Low-risk rated quality issues may not demand immediate action and may be managed by laboratory personnel.

Quick Reference:

Root Cause Analysis and Risk Assessment Tools and Information

- A range of quality tools can be found on the American Society for Quality website: Quality Tools & Templates - List of Quality Tools | ASQ (<https://asq.org/quality-resources/quality-tools>), including templates and application information on check sheets, brainstorming, Ishikawa diagram, and Failure Mode Effects Analysis (FMEA).
- Refer to **Appendix D** for risk assessment matrix examples.
- Refer to Australian/New Zealand Standard International Electrotechnical Commission. (2020). *AS/NZS IEC 31010:2020 Risk management – Risk assessment techniques*.

FOOTNOTES

10 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *ICH Harmonised Guideline: Quality Risk Management Q9 (R1)*

Stage 5: Determine Action



Objective	Method	Considerations
<p>To determine corrective and preventative actions required to eliminate or minimise the cause of the quality issue to an acceptable level of risk.</p>	<ul style="list-style-type: none"> Brainstorm and identify potential actions to address the root cause and contributing factors. Evaluate potential actions using a structured method, such as the Failure Mode Effects Analysis (FMEA) tool. Apply relevant organisational risk frameworks as part of the assessment. Evaluate potential actions and refine them into a clear implementation plan. Use tools such as flowcharts and timelines, and consider associated risks to inform the development of effective mitigation strategies. Document and communicate preferred actions and assign responsibility. 	<ul style="list-style-type: none"> When evaluating actions, apply structured evaluation methods and with input from relevant stakeholders. Consider the following: <ul style="list-style-type: none"> the risk rating of the quality issue whether the root cause will be effectively addressed implementation feasibility and efficiency potential effects to upstream or downstream processes, including internal and external stakeholders resource needs and stakeholder requirements expected quality benefits assigned responsibility potential negative consequences or risks associated with implementation risks associated with not implementing, and the level of internal stakeholder buy-in. Piloting actions before formal implementation can provide valuable insights into their effectiveness.

Quick Reference:



Quality Tools for Action Determination

- A range of quality tools can be found on the American Society for Quality website: Quality Tools & Templates - List of Quality Tools | ASQ (<https://asq.org/quality-resources/quality-tools#AtoZ>), including the FMEA and decision matrix.

Stage 6: Implement Action



Objective	Method	Considerations
To implement effective actions that address the quality issue and root cause.	<ul style="list-style-type: none"> Implement identified actions to address the root cause and contributing factors of the quality issue and its associated risk. Use project planning tools, such as the Plan-Do-Check-Act cycle (PDCA), when implementing actions. Document and communicate implemented actions to relevant stakeholders, including potential impacts. 	<ul style="list-style-type: none"> Implemented actions should be proportionate to the quality issue and level of risk. When implementing actions, consider the forensic service provider’s risk appetite, along with any agency-specific criteria. Where actions will impact customers or other external stakeholders, include an appropriate communication and education strategy in the implementation plan, specifying channels, content, and frequency. The implementation plan should also define how actions will be evaluated, including success criteria, assessment methods, and review timelines to inform Stage 7.

Stage 7: Monitor and Review



Objective	Method	Considerations
<p>To monitor and review the actions taken to ensure that the root cause and associated risk have been adequately addressed, and to confirm that no adverse impacts have arisen from these actions.</p>	<ul style="list-style-type: none"> Evaluate the effectiveness of implemented actions to confirm whether the quality issue has been resolved. Use appropriate methods such as appraisal criteria, controls, comparing pre- and post- implementation data, pilots, surveys, consultations, audits, and analysis of residual risk. This evaluation approach should align with the quality issue risk rating. Determine, document and implement new actions where current actions are ineffective. Refer to Stages 5 and 6 for guidance. Communicate any updated risk evaluation arising from the risk management process, particularly for quality issues affecting stakeholders, to maintain confidence in outcomes. Assess whether the burden of the risk has shifted or is now shared with stakeholders, especially where no adverse impacts have occurred. Ensure all relevant records including RCA, risk assessment, implemented actions, and results are uploaded as evidence to the appropriate management system. Update relevant policies, procedures and training material, where appropriate. Appendix E provides an implementation worksheet for comparing policies and procedures to the Framework. 	<ul style="list-style-type: none"> Reviewing actions should be part of the quality management process. Clearly document the monitoring and review process in policies and procedures, ensuring it considers the rating of the quality issue and corrective actions taken. The forensic service provider should develop an internal method that defines quality evaluation criteria, such as demonstrating a measurable reduction in risk or a decrease in the frequency of incidents. The forensic science provider should establish criteria for closing quality issue investigations, such as closing the investigation once implemented actions have been adequately assessed and there is evidence to confirm the quality issue has been addressed.

Quick Reference:



Quality Tools for Implementing and Monitoring Actions

- A range of quality tools can be found on the American Society for Quality website: Quality Tools & Templates - List of Quality Tools | ASQ (<https://asq.org/quality-resources/quality-tools#AtoZ>), including the Plan-Do-Check-Act cycle.

A gloved hand holding a small vial of white powder. The background is a blurred laboratory setting with various glassware and equipment. A dark teal overlay is present in the bottom left corner.

Section 3: Case Studies

Section 3: Case Studies

The following case studies demonstrate how the stages of the Framework can be applied to various quality issues and are intended as guidance rather than prescriptive instructions. Italicised roles referenced in these case studies are defined in **Table 2 (Appendix B)**.



LOW
COMPLEXITY/RISK

Case Study 1: Proficiency Test Quality Issue

Process Stage	Description
01	An internal review of a proficiency test report by <i>Quality Staff</i> identified discrepancies between laboratory results and expected results.
02	<i>Quality Staff</i> notified the <i>Quality Issue Owner</i> of the individuals and instruments involved with the proficiency test that did not yield the expected results. The <i>Quality Issue Owner</i> instructed all operational staff to cease performing tasks evaluated by the proficiency test while an ongoing investigation determines whether the issue is isolated or systemic.
03	<i>Quality Staff</i> created a formal record of the quality issue, detailing the immediate action taken, and the quality issue was escalated through appropriate processes.
04	<i>Quality Staff</i> investigated the quality incident to determine the cause. This involved collating relevant information such as test results, including test results from other participants, equipment logs, and staff notes relating to the proficiency test. The following possible causes were explored using the 5 Whys method by <i>Quality Staff</i> : <ul style="list-style-type: none"> • equipment issue (machine) • procedural error (method) • test issue (material), or • training and competency related (people). The investigation revealed that the proficiency test was defective. This information informed risk-based decision making. <i>Quality Staff</i> considered the risk level to be low as no operational issues were identified, and it did not affect upstream or downstream processes.
05	Following cause analysis findings, <i>Quality Staff</i> considered the following actions to address the defective test: <ul style="list-style-type: none"> • allocate a new test to impacted individuals • analyse historical proficiency test data for quality defects, and • provide feedback to the test supplier. All actions proposed were considered feasible and would be effective at resolving the quality issue to the extent possible within the laboratory's control.
06	<i>Quality Staff</i> advised impacted staff of the outcome of the cause analysis. <i>Quality Staff</i> acquired a new proficiency test and allocated it to impacted staff. <i>Quality Staff</i> reviewed historical proficiency data from the provider to assess potential issues with past tests. No problems were identified. <i>Quality Staff</i> provided feedback to the supplier of the test, specifically on the nature of the defect. <i>Quality Staff</i> recorded communication between affected parties and updated the proficiency test register for trend analysis and reporting.
07	<i>Quality Staff</i> reviewed the results of the new allocated proficiency test to ensure alignment with expected results. The review determined no further action was required. The quality issue investigation was closed by <i>Quality Staff</i> .



MODERATE
COMPLEXITY/RISK

Case Study 2: Procedural Quality Issue

Process Stage	Description
01	During the technical review of a casefile, a <i>Forensic Service Provider Staff</i> member identified that an incorrect procedure had been used.
02	<p>The <i>Forensic Service Provider Staff</i> member notified the <i>Quality Issue Owner</i>. The <i>Quality Issue Owner</i> halted further processing of related impacted samples, and where downstream processes were affected, advised relevant staff.</p> <p>The <i>Quality Issue Owner</i> notified appropriate personnel of the incorrect procedure and provided the correct version.</p> <p>The <i>Quality Issue Owner</i> assigned a <i>Quality Issue Investigator</i> to be responsible for the quality issue investigation.</p>
03	<p>The <i>Quality Issue Owner</i> with the support of the <i>Forensic Service Provider Staff</i> member created a formal record of the quality issue, detailing the immediate action taken, and escalated the quality issue through relevant processes as required.</p> <p>The <i>Quality Issue Investigator</i> assessed the quality issue to determine the cause of the event. This included a review of the document's history and logs, and interviewing staff.</p> <p>The <i>Quality Issue Investigator</i> found that superseded document versions had not been archived and obsolete versions were not properly disposed of. The quality issue impacted only a single area.</p> <p>The <i>Quality Issue Investigator</i> identified that this failure led to an incorrect result obtained for a sample, which had not been reported to the stakeholder since it was detected in review. Subsequent retesting of the sample was possible.</p> <p>After the <i>Quality Issue Investigator</i> discovered that an incorrect result was obtained for a sample, <i>Quality Staff</i> and the <i>Quality Issue Investigator</i> determined that a broader assessment was necessary, including an evaluation on whether previous samples already reported may have been affected and not detected during the technical review.</p>
04	<p>The <i>Quality Issue Investigator</i> used the Ishikawa Diagram to identify contributing factors to the problem, which included:</p> <ul style="list-style-type: none"> • ineffective document control processes, such as documents stored in multiple locations, inadequate version control, inconsistencies in processes between departments • insufficient communication to staff on document control processes, including formal acknowledgment of procedural changes, document storage, version control and access • staff confusion with accreditation requirements, covering relevant international standards and quality management system obligations • system design inadvertently allowing for the selection of the incorrect procedure, and • procedural drift. <p>The <i>Quality Issue Investigator</i> performed a risk assessment, which included describing and analysing the risks associated with staff using an incorrect procedure and the impact to broader operations.</p> <p>The <i>Quality Issue Investigator</i> classified the risk level as moderate, given the potential for an incorrect result to be reported to stakeholders.</p>

Process Stage	Description
05	<p>With a greater understanding of the quality issue and the potential impact, the <i>Quality Issue Investigator</i> explored the following actions to address root causes and contributing factors, which included:</p> <ul style="list-style-type: none"> • enhancing version control, including archiving superseded documents, restricting access to archived version, and ensuring all staff can identify and access the latest version • distributing a controlled document to the impacted area, with the location of the controlled document recorded in a central register • reviewing document control policies and procedures, ensuring roles and responsibilities for document management are clearly outlined • scheduling regular audits to remove uncontrolled documents • coordinating document control training, covering relevant ISO standards and accreditation requirements and best practices for staff, and • communicating document updates and changes to relevant staff to promote awareness of current versions. <p>Using the FMEA tool, the <i>Quality Issue Investigator</i> evaluated possible actions to address the underlying causes to the quality issue. Consideration was given to the risk level of the quality issue, resourcing, timeliness, feasibility, efficiency, effectiveness, quality benefits, responsibility, and risks of not implementing.</p> <p>All actions proposed were considered feasible and collectively would be effective at resolving the quality issue.</p> <p><i>Quality Staff</i> and the <i>Quality Issue Investigator</i> considered a thorough review of document control processes and training to be a priority.</p>
06	<p>The <i>Quality Issue Investigator</i> and the <i>Quality Issue Owner</i> coordinated the implementation of the following corrective actions to address the root causes:</p> <ul style="list-style-type: none"> • communicating cause analysis findings to relevant personnel • distributing a controlled document to the impacted area and destroying uncontrolled copies and superseded versions • retesting the affected sample and reviewing the results, including quality control measures • conducting a thorough review of document control processes with <i>Quality Staff</i> to identify inefficiencies and areas for improvement • updating the quality issue register on corrective actions taken • attaching a formal record relating to the quality issue to the casefile of the impacted sample, and • executing document control training to relevant personnel with the support of <i>Quality Staff</i>. <p>The investigation remained open and was flagged for review following the first internal audit.</p>
07	<p><i>Quality Staff</i> scheduled periodic internal audits to evaluate the effectiveness of document control processes, including recent changes made to relating policies and procedures.</p> <p>The <i>Quality Issue Owner</i> sought feedback through a survey from forensic science staff on the following:</p> <ul style="list-style-type: none"> • whether they found recent document control changes helpful and effective • was the location of the current procedure clearer • did the changes result in an unintended negative consequence, and • whether there were any other opportunities for improvement. <p><i>Quality Staff</i> performed final sign-off on the quality issue investigation after evidence showed the actions had resolved the quality issue from the first internal audit.</p>

Case Study 3: Reporting Quality Issue



Process Stage	Description
01	<p>The <i>Quality Issue Owner</i> was notified that an internal audit had identified an instance where an incorrect result had been issued to a stakeholder.</p>
02	<p>The <i>Quality Issue Owner</i> considered the appropriateness of ceasing related processes and the release of further results. Based on an initial assessment, the <i>Quality Issue Owner</i> chose not to cease operations and approved the release of further results.</p> <p>The <i>Quality Issue Owner</i> notified external and internal stakeholders of the quality incident and requested the known affected report to be withdrawn.</p>
03	<p>The <i>Quality Issue Owner</i> created a formal record of the quality issue, detailing the immediate action taken, and escalated the quality issue through relevant processes.</p> <p>The <i>Quality Issue Owner</i> assigned a <i>Quality Issue Investigator</i> to be responsible for the quality issue investigation.</p>
04	<p>The <i>Quality Issue Investigator</i> with the support of <i>Quality Staff</i> conducted an assessment to uncover information around the quality issue. This included collating relevant information related to people, equipment, and processes involved in producing the incorrect result.</p> <p>The investigation revealed that two samples were labelled incorrectly, which caused two sample to be switched and an incorrect result obtained for each. The <i>Quality Issue Investigator</i> confirmed that the error was not detected at the casefile technical review stage and was subsequently reported to external stakeholders.</p> <p>After the <i>Quality Issue Investigator</i> discovered a second sample with an incorrect reported result, <i>Quality Staff</i> and the <i>Quality Issue Investigator</i> determined that a broader assessment was necessary, including an evaluation to identify any other instances where a sample switch may have occurred. Based on the data collected and information gained from the wider assessment, <i>Quality Staff</i> determined that the switch most likely affected only these two samples.</p> <p>To identify contributing factors to the quality issue, RCA using the Ishikawa diagram (i.e. Fishbone diagram) and question check sheets, highlighted the following:</p> <ul style="list-style-type: none"> • impact of human factors • inadequate training • communication deficiencies • procedural gaps, and • process issues. <p>The <i>Quality Issue Investigator</i> with the support of <i>Quality Staff</i> performed a risk assessment using the FMEA tool, which involved defining and analysing the risk.</p> <p>Based on the risk assessment, <i>Quality Staff</i> and the <i>Quality Issue Investigator</i> concluded that the risk rating for the quality issue was high given that the quality issue has impacted external stakeholders and the forensic service provider's service.</p>

Process Stage	Description
05	<p>With a greater understanding of the quality issue and its potential impact, <i>Quality Staff</i> and the <i>Quality Issue Investigator</i> explored the following actions to address root causes:</p> <ul style="list-style-type: none"> • implementing an additional verification step at critical points, such as labelling of samples, to detect discrepancies • implementing two unique identifiers for each sample • automating workflow to minimise human error, including replacing manual labelling components with an electronic labelling system for sample identification and tracking • streamlining task assignment and management to reduce cognitive overload • incorporating technical and administrative review checklists to enhance procedures and ensure a systematic approach to reviews • separating reviewer roles to maintain objectivity • coordinating staff training on sample handling that emphasises good practices, such as handling one sample at a time and appropriate labelling, and • scheduling regular audits and process observations to monitor compliance and identify opportunities for improvements. <p><i>Quality Staff</i> used the FMEA tool to evaluate actions to address the underlying causes to the quality issue. Consideration was given to the risk level of the quality issue, resourcing, timeliness, feasibility, efficiency, effectiveness, quality benefits, responsibility, and risks of not implementing.</p> <p>All actions proposed were considered feasible and collectively would be effective at resolving the quality issue; however, <i>Quality Staff</i> and the <i>Quality Issue Investigator</i> considered the following a priority: implementing an additional verification step at critical process points, automating the workflow, streamlining task assignments, incorporating technical and administrative review templates and checklists, and scheduling future internal audits.</p> <p>As the <i>Quality Issue Investigator</i> discovered a second sample with an incorrect reported result, the actions also included withdrawing the report containing the incorrect result.</p>
06	<p>The <i>Quality Issue Investigator</i> and the <i>Quality Issue Owner</i> created a detailed plan on the corrective actions to be implemented to address root causes, which included:</p> <ul style="list-style-type: none"> • communicating cause analysis findings to relevant staff • communicating with external stakeholders, which included progress updates • re-issuing new reports, including appropriate records about the quality issue • reviewing the relevant analytical procedure to incorporate the additional verification step • reviewing the relevant technical and administrative procedure, along with developing a standardised review checklist • purchasing and implementing a new electronic labelling system for the workflow, and • coordinating training for management on minimising cognitive overload, which included strategies on standardising workflows, balancing tasks and limiting interruptions. <p><i>Quality Staff</i> and the <i>Quality Issue Investigator</i> monitored the implemented actions to ensure they were appropriate and progressing according to the forensic service provider's defined timeframe. <i>Quality Staff</i> and the <i>Quality Issue Investigator</i> also ensured that interested parties were informed and relevant registers were updated.</p>
07	<p><i>Quality Staff</i> performed a final review of the quality issue investigation, including appropriate actions taken. Feedback was sought from the relevant areas, particularly on the procedural changes and training received.</p> <p><i>Quality Staff</i> performed final sign-off on the quality issue investigation, once evidence confirmed that the implemented actions had adequately addressed the issue.</p>

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Appendices

Appendix A: Terminology

The following table outlines the terms and definitions required to understand the contents of this document. Forensic service providers may use different but equivalent terminology to describe similar concepts.

Table 1: List of Document Terms

Term	Definition
Corrective Action	An action to eliminate the cause of a nonconformity and to prevent recurrence. ¹¹ <i>Note: There can be more than one cause for a nonconformity.</i> <i>Note: Corrective action prevents recurrence whereas preventative action prevents occurrence.</i>
Correction	An action to eliminate a detected nonconformity. ¹² <i>Note: A correction can be made in advance, in conjunction with, or after a corrective action.</i>
Detectability	The ability to discover or determine the existence, presence, or fact of a hazard. ¹³
Preventative Action	An action to eliminate the cause of a potential nonconformity or other potential undesirable situation. ¹⁴ <i>Note: There can be more than one cause for a potential nonconformity or undesirable situation.</i> <i>Note: Corrective action prevents recurrence whereas preventative action prevents occurrence.</i>
Risk	The potential of an event or circumstance occurring that will adversely impact the quality of a product or service.
Risk Assessment	The systematic process of organising information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards. ¹⁵
Risk Control	Actions implementing risk management decisions. ¹⁶
Risk Evaluation	The comparison of the estimated risk to criteria using a quantitative or qualitative scale to determine the significance of the risk. ¹⁷

FOOTNOTES

11 Australian/New Zealand Standard International Organization for Standardization. (2016). *AS/NZS ISO 9000:2016 Quality management systems – Fundamentals and vocabulary*.

12 *AS/NZS ISO 9000:2016*.

13 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *ICH Harmonised Guideline: Quality Risk Management Q9 (R1)*.

14 *AS/NZS ISO 9000:2016*.

15 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2023). *ICH Harmonised Guideline: Quality Risk Management Q9 (R1)*.

16 *Ibid*.

17 *Ibid*.

Appendix B: Roles and Responsibilities

The following table outlines general guidance on roles and responsibilities required to support quality issue investigations. Personnel may be assigned to individual roles or may fulfil multiple roles, as appropriate. Not all responsibilities listed will apply in every circumstance.

Table 2: General Roles and Responsibilities to Support the Quality Issue Investigation Process

Role	Description	Responsibilities
Forensic Service Provider Staff	Individuals employed by the forensic service provider who contribute to its goals and service delivery.	<ul style="list-style-type: none"> Identify quality issues or potential quality issues. Take immediate action to contain the quality issue and consult with the <i>Quality Issue Owner</i> if necessary to mitigate any downstream impacts on service delivery and stakeholders. Notify and escalate quality issues for investigation in accordance with the forensic service provider's policy. Participate in the investigation of quality issues, as required. Implement and monitor corrective actions, as required.
Quality Issue Owner	An individual responsible for the area where the quality issue occurred, including section manager or team leader, or an individual who has overall responsibility for the investigation and actions related to quality issue investigations.	<ul style="list-style-type: none"> Ensure immediate actions to contain the quality issue are effective at mitigating further escalation. Consult with the <i>Quality Issue Investigator</i> and implement any corrections or corrective actions, as required. Evaluate the effectiveness of agreed implemented actions and report to the <i>Quality Issue Investigator</i>, as required. Assume responsibility for verifying and confirming the completion and effectiveness of the implemented actions documented in the quality issue record. Communicate quality issue investigation outcomes to relevant stakeholders.
Quality Issue Investigator	An individual who is responsible for investigating and analysing quality issues and for determining and implementing the required actions.	<ul style="list-style-type: none"> Review the reported quality issue and determine any immediate action to prevent escalation. Raise and record the quality issue according to the forensic service provider's policy and procedures. Assess risk to determine the impact or potential impact of the quality issue and level of action required to address it (i.e. correction and/or corrective action). Where required, convene an investigation panel to perform RCA and identify corrective actions. Document the quality issue investigation, including the risk assessment, data collection, RCA, and the actions implemented, and the planned evaluation method to confirm whether these actions have resolved the quality issue.

Role	Description	Responsibilities
Quality Staff	Individuals who are responsible for the administration of the development, implementation and operational capability of the quality management system.	<ul style="list-style-type: none"> • Ensure that the quality issue investigation process is defined in policies and procedures, aligns to good practice, and is effectively implemented across the forensic service provider. • Oversee the system for recording and retaining documentation for quality issue investigations and management. • Develop resources to drive good practice and deliver training to forensic service provider personnel in quality issue investigations and associated processes (e.g. RCA, risk assessments, and documentation). • Assist and educate <i>Forensic Service Provider Staff, Quality Issue Investigators</i> and <i>Quality Issue Owners</i> in all tasks associated with quality issue investigations, as required. • Monitor the progress of quality issue investigations to ensure the risk rating, escalation and actions are appropriate, and that they are being progressed in accordance with forensic service provider defined timeframes. • Perform final review and sign-off on quality issue investigations, actions and evaluation of actions, where appropriate.¹⁸ • Ensure quality issue investigation outcomes are communicated to the relevant stakeholders.
Quality Manager	An individual who leads <i>Quality Staff</i> and oversees the development, implementation and operational capability of the quality management system.	<ul style="list-style-type: none"> • Oversee the administration of the quality issue investigation process to ensure comprehensive assessments. • Assess the potential impact of the quality issue on the quality management system and escalate accordingly, with the support of <i>Quality Staff</i>. • Provide strategic direction on quality policies and procedures, audits and compliance strategies. • Oversee educational support and the development of training programs to build capability in tasks related to quality issue investigations. • Notify executive staff and relevant governance or oversight bodies promptly about any quality issues deemed a substantial risk or potential risk to the forensic service provider operations or products. • Identify and report on quality issue metrics and trends to executive staff and relevant governance or oversight bodies as needed, advising on areas for improvement, particularly regarding policies and resources, with the support of <i>Quality Staff</i>. • Advocate continuous improvement in the investigation and management of quality issues and foster a proactive quality culture that supports good practices, with the assistance of <i>Quality Staff</i>.
Reviewer and Approver	An individual outside the work group or reporting line with the equivalent or higher knowledge or training to provide final oversight and approval for decisions, actions, and results.	<ul style="list-style-type: none"> • Provide an independent review of the investigation to ensure quality issues have been appropriately investigated and addressed. • Perform final review and sign-off on quality issue investigations, actions and evaluation, where appropriate.¹⁹

FOOTNOTES

¹⁸ Forensic science providers may have different processes for reviewing and signing off quality issues, and these processes can vary both across organisations and by issue severity. For example, lower-risk rated quality issues may be reviewed and approved at the operational level, while higher-risk quality issues may be escalated to higher management for discussion and sign-off.

¹⁹ Ibid.

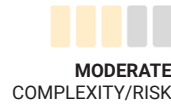
Role	Description	Responsibilities
Executive Management	The highest-level leaders at the forensic service provider who are responsible for setting the strategic direction and managing the overall service delivery.	<ul style="list-style-type: none">• Provide resources and systems to facilitate quality issue investigations and continually improve the effectiveness of the process.• Foster a proactive approach to quality management, in consultation with the <i>Quality Manager</i> and senior management, by regularly reviewing quality issue investigations data, to assess the effectiveness of risk mitigation efforts and identify trends to inform strategic planning and improvements.• Ensure effective communication processes to support information flow across all staffing levels and enable timely quality issue escalation and resolution.• Oversee and evaluate the governance structures responsible for investigating and managing quality issues within the quality system.

Appendix C: Tiered Risk-Based Approach for Quality Issue Investigation and Management

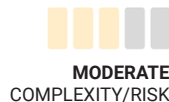
It may be helpful to categorise a quality issue’s complexity and risk according to tier levels to determine the appropriate level of effort, resources, and formality required to support an appropriate investigation. **Table 3** presents an example of a three-tier system outlining complexity or risk classification and the corresponding objectives, governance, approaches, resource requirements, responses, and documentation expectations. This system is indicative only and should be applied as a practical guide. The italicised roles referenced in the example are defined in **Table 2 (Appendix B)**.

To support effective quality issue investigations, resolution, and risk mitigation, reassess risk as new information becomes available, including reevaluating the quality issue’s complexity, tier level, and required resources.

Table 3: Example of a Three-Tiered Risk-Based Approach to Quality Issue Investigation and Management



	Tier 1: Low Complexity / Low Risk	Tier 2: Moderate Complexity / Moderate Risk	Tier 3: High Complexity / High Risk
Objective	Resolve through minimal investigation with limited oversight and documentation.	Resolve with structured investigation supported by moderate oversight and documentation.	Resolve through a comprehensive investigation requiring significant oversight and formal documentation.
Governance	Low escalation hierarchy: quality issues are primarily investigated and resolved by team leaders or operational staff, with minimal involvement from <i>Quality Staff</i> . Review and sign-off by <i>Quality Staff</i> .	Moderate escalation hierarchy: middle management and <i>Quality Staff</i> investigate and resolve the issue, supported by the <i>Quality Manager</i> . Review and sign-off by <i>Quality Staff</i> .	High escalation hierarchy: <i>Quality Manager</i> and <i>Quality Staff</i> investigate and resolve the issue, overseen by <i>Executive Management</i> . A cross-functional task force may be established to support the investigation. Require communication with external stakeholders and accreditation bodies, as applicable. Review and sign-off by the <i>Quality Manager</i> . May involve an independent review to ensure the quality issue has been appropriately investigated and addressed.
Approach	A formal investigation is unlikely; however, risk-based judgment may be applied to determine the appropriate next steps.	Formal quality tools applied for RCA (e.g. 5 Whys or Fishbone diagram) and risk assessment (e.g. risk matrix) to support an evaluation and the corrective and preventative actions required.	Comprehensive formal investigation involving in-depth root cause analysis (e.g. 5 Whys or Fishbone diagram) and the application of multiple risk management tools (e.g. risk matrix or FMEA) to support an evaluation and the corrective and preventative actions required.



	Tier 1: Low Complexity / Low Risk	Tier 2: Moderate Complexity / Moderate Risk	Tier 3: High Complexity / High Risk
Resources	Involvement is limited to a small number of personnel, with minimal external input.	Involvement from <i>Quality Staff</i> and dedicated operational personnel, with cross-discipline participation, where appropriate.	May involve a dedicated multi-functional team with participation from other disciplines, legal, and suppliers.
Response	Assigned a lower priority with an extended resolution timeframe. A minor correction to a record or method may resolve the quality issue. Preventative measures may be noted for future reference.	Prompt action may be required to control or contain the quality issue and prevent broader impact. It may involve halting processes while an investigation is undertaken. May involve escalation to the <i>Quality Manager</i> and <i>Executive Management</i> . Process or a procedural change may be needed to avoid recurrence.	Prompt action to control or contain the quality issue and prevent broader impact. It may involve halting processes while an investigation is undertaken. May involve immediate escalation to <i>Executive Management</i> for oversight to assess whether the quality issue has broader implications and if organisational remedial action is required. Involves updating quality risk registers and risk controls, as mitigation measures in the risk management plan may be inadequate or absent for the specific quality issue identified.
Documentation	May involve a brief incident notification and informal root-cause documentation provided through email.	Require a formal report that documents the personnel involved, evidence of RCA and risk assessment, and records of preventative and corrective actions.	Require a formal comprehensive report that documents the personnel involved, evidence of RCA and risk assessment results, and records of preventative and corrective actions.

Appendix D: Risk Assessment Matrix Examples

This appendix provides examples of a risk assessment tool and its application within a scientific context (refer to **Table 5** and **6**). The information provided is general and illustrative only and does not replace forensic service provider-specific practices for assessing risks.

While quality issues may introduce other types of risks, including financial and reputational risks, the Framework and the example provided in this appendix focus on the risks related to obtaining reliable and reproducible results and services. Other risk areas such as enterprise and Workplace Health and Safety are outside the scope of this Framework and management of these risks should follow local escalation pathway requirements.

Background

A risk rating is a qualitative or quantitative assessment that is used to evaluate, manage, and prioritise risks. In determining the overall risk rating, the assessment may consider:

- consequence or potential impact
- likelihood of occurrence
- ability to detect the risk, and
- existing control measures.

Consequences can range from very low, where the impact is minimal, to very high, where impacts are severe. The consequence rating may be informed by compliance with specifications or the need for executive involvement. Consequences may relate to a range of scientific themes, such:

- storage
- evidence integrity (i.e. exhibits, samples, or results of analysis)
- equipment
- chain of custody
- procedures and methods
- training and competency
- products and services
- proficiency tests
- record management
- reporting, or
- security.

The risk evaluation will also determine whether consequences for other areas should be considered, such as finance, environment, or legal.

Table 4: Calculating Likelihood Example

Calculated Likelihood (Qualitative Rating)	Frequency	Probability
Rare	Less frequent than once every three years	Less than 3%
Unlikely	Once every three years	At least 3% but less than 30%
Possible	Yearly or several times over a three-year period	At least 30% but less than 70%
Probable	Monthly or several times a year	At least 70% but less than 97%
Highly Probable	Several times a month	Greater than 97%

The ability to detect quality issues varies significantly, ranging from issues that are consistently detectable through existing monitoring solutions to those that are difficult to detect due to the absence of manual controls or monitoring solutions. Refer to method validation studies and historical data when assessing detectability.

A risk assessment matrix may be used to determine the overall risk rating by considering both consequence and likelihood. **Table 5** provides an example matrix categorised into low, moderate, high, and extreme levels, with the rating being derived from the intersection of consequence and likelihood.

The matrix example aims to assist forensic service providers in developing their own local risk assessment frameworks, by illustrating how likelihood and consequence evaluations combine. Where this example informs local policies and procedures, forensic service providers should adapt the matrix to align with their specific operational environment. In some instances, operational staff may conduct a risk assessment with the support of quality staff using systems provided by quality staff.

To streamline this process, a standardised scientific template should be developed to ensure personnel can conduct these assessments effectively. For high-risk related quality issues, quality staff should complete the assessment to ensure a thorough evaluation.

Table 5: Example of a Consequence and Likelihood Risk Matrix (intersection of consequences and likelihood).

Consequence	Severe	Moderate Risk	High Risk	High Risk	Extreme	Extreme
	Major	Moderate Risk	Moderate Risk	High Risk	High Risk	Extreme
	Medium	Low Risk	Moderate Risk	Moderate Risk	High Risk	High Risk
	Low	Low Risk	Moderate Risk	Moderate Risk	Moderate Risk	High Risk
	Very Low	Low Risk	Low Risk	Low Risk	Moderate Risk	Moderate Risk
		Rare	Unlikely	Possible	Probable	Highly Probable
		Likelihood				

Table 6: Example of a Risk Assessment Matrix for Scientific Themes

Consequence		Likelihood				
		Rarely	Unlikely	Possible	Likely	Almost Certain
Severe	Reporting Technical error that substantially impacts or has the potential to substantially impact interpretation of results, including leading to the false inclusion or exclusion of an individual or individuals for multiple cases.	Mod	High	High	Severe	Severe
	Evidence Integrity Item not packaged correctly or mishandled in such a way that the integrity of item is compromised and unable to be analysed, and other evidence has been compromised either within or external to the case, or where the event has impacted the integrity of multiple samples/cases					
	Chain of Custody Incomplete chain of custody record for external movement resulting in evidence being inadmissible in Court. Incomplete chain of custody record for multiple cases.					
Major	Reporting Technical error that substantially impacts or has the potential to substantially impact the interpretation of the result, including leading to the false inclusion or exclusion of an individual or individuals.	Mod	Mod	High	High	Severe
	Evidence Integrity Item not packaged correctly or mishandled in such a way that the integrity of item is compromised and unable to be analysed.					
	Chain of Custody Incomplete chain of custody record for external movement and no available information to complete the record.					
Medium	Reporting Technical error that does not impact the interpretation of the result nor lead to the false inclusion or exclusion of an individual or individuals.	Low	Mod	Mod	High	High
	Evidence Integrity Item not packaged correctly or mishandled in such a way that there is a potential for the integrity of item to be compromised, or the item is compromised; however, results can still be obtained.					
	Chain of Custody Incomplete chain of custody record for external movement; however, other supporting information available to complete the record.					
Low	Reporting Error in report that has no effect on results.	Low	Mod	Mod	Mod	High
	Evidence Integrity Item not packaged correctly and not detected at receipt. Integrity of item not compromised.					
	Chain of Custody Incomplete chain of custody record for internal movement and no available information to complete the record.					
Very Low	Reporting Error identified and corrected before external reporting.	Low	Low	Low	Mod	Mod
	Evidence Integrity Item not packaged correctly and able to be resolved and documented at receipt. Integrity of item not compromised.					
	Chain of Custody Incomplete chain of custody record for internal movement; however, other supporting information available to complete the record.					

Appendix E: Implementation Worksheet for Section 2

Purpose

The implementation worksheet provides forensic service providers with an aid for comparing their policies and procedures against **Section 2** of the document.

The comparison can assist in identifying gaps and addressing those considered relevant and appropriate for the forensic service provider.

Evidence	Gap Analysis	Desired State	Action Plan	Monitoring
Description of local policies and procedures that support the framework stage.	List specific gaps identified.	List specific gaps identified.	List actions to address gaps.	Descriptions of metrics for evaluation and review frequency.

Stage 1

Stage 2

Stage 3

Stage 4

Stage 5

Stage 6

Stage 7

Note: This template can be adjusted based on the specific needs of the forensic service provider.

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This document was prepared by ANZPAA NIFS and an expert working group, comprising of representatives from the Quality Specialist Advisory Group (QSAG).

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