


GOVERNMENT MICROBIOLOGY LABORATORY 	MICROBIOLOGY LABORATORY OFHOSPITAL		
	SUBJECT : Quality Manual		PAGE : Page

4.9 Identification and Control of Nonconformities

Policy: The laboratory identifies and manages activities that do not conform to its own procedures or the requirements of the Quality Management System (QMS). This ensures that no results are released, and no laboratory activities continue, if they compromise the quality or clinical safety of patient care.


Procedures:

- **Identification:** Nonconformities (NCs) are identified through various channels, including quality control failures, clinical feedback, internal audits, equipment malfunctions, or environmental breaches.
- **Immediate Action:** When a nonconformity is detected in the examination process, the laboratory immediately halts the affected work and withholds test reports.
- **Risk Assessment:** The Head of Laboratory (HOL) or a delegated Medical Officer assesses the clinical significance of the nonconformity, including any potential impact on patient safety.
- **Responsibility and Authority:** The HOL and Quality Assurance Officers (QAOs) have the authority to resume work only after the nonconformity has been resolved and documented.
- **Documentation:** All instances of nonconforming work are recorded in the **Nonconformity Register**, including the nature of the event and the immediate actions taken.
- **Nonconformity Register** should serve as a central tracking document. It must capture the entire lifecycle of an event—from identification to the verification of the corrective action's effectiveness.
- Below is a recommended structure for the register, designed to be used as a master log (either in a spreadsheet or a bound ledger).
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4.10 Corrective Action

Policy: The laboratory takes corrective action to eliminate the causes of nonconformities and prevent their recurrence. The nature and scope of the corrective action are appropriate to the impact of the nonconformities encountered.

Title: Quality Manual				Code: MIC/HOSP/QM/1	
Issue: 01	Issue date: 30.03.2026	Rev:	Rev date:	Page 1 of 4	
Prepared by: Laboratory Team		Reviewed by: Consultant Microbiologist		Approved by: Head of Laboratory	

GOVERNMENT MICROBIOLOGY LABORATORY 	MICROBIOLOGY LABORATORY OFHOSPITAL							
	SUBJECT : Quality Manual		<table border="1"> <tr> <td>PAGE</td> <td>:</td> <td>Page</td> </tr> <tr> <td></td> <td>:</td> <td></td> </tr> </table>	PAGE	:	Page		:
PAGE	:	Page						
	:							

Procedures:

- **Root Cause Analysis:** For every significant nonconformity, a structured investigation is conducted using tools such as the "5 Whys" or Fishbone diagrams to determine the underlying cause.
- **Implementation:** Based on the root cause, a corrective action plan is developed and implemented to address the source of the error.
- **Monitoring and Verification:** The effectiveness of the corrective action is monitored by the QAOs. If the action fails to prevent recurrence, the investigation is reopened.
- **Reporting:** All corrective actions and their outcomes are reported to the HOL and discussed during Management Review Meetings (MRM).

4.11 Preventive Action

Policy: The laboratory proactively identifies opportunities for improvement and potential sources of nonconformities to prevent their occurrence.

Procedures:

- **Data Analysis:** The laboratory analyzes trends in quality indicators, audit findings, and risk assessments to identify potential system weaknesses before they result in a nonconformity.
- **Risk Management:** Preventive actions are heavily informed by the laboratory's risk management process, which evaluates risks across pre-examination, examination, and post-examination phases.
- **Action Planning:** When a potential nonconformity is identified, a preventive action plan is established, including resource allocation and a timeline for completion.
- **Review of Effectiveness:** The results of preventive actions are reviewed periodically to ensure they have successfully mitigated the identified risks.

Reference Documents:

- Nonconformity Register (..... NAME OF LAB...../REC/NC-01)
- SOP for Management of Nonconforming Work (..... NAME OF LAB...../QSP/4.9/NCW)

Title: Quality Manual			Code: MIC/HOSP/QM/1	
Issue: 01	Issue date: 30.03.2026	Rev:	Rev date:	Page 2 of 4
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NONCONFORMITY REGISTER (NCR)

Organization: National Institute of Health Sciences (NIHS) – Microbiology Laboratory

Document Ref: NIHS/MICRO/REC/4.9/NC-01

Field	Details / Entry
NCR Serial No.	NC / 2026 / _____
Date & Time of Detection	____ / ____ / 2026 ____ : ____ AM/PM
Detected By (Name/Desig.)	_____
Source of NC	<input type="checkbox"/> Internal Audit <input type="checkbox"/> QC Failure <input type="checkbox"/> EQA/PT <input type="checkbox"/> Complaint <input type="checkbox"/> Other: _____

1. DESCRIPTION OF NONCONFORMITY

Describe the deviation from the Standard Operating Procedure (SOP) or ISO 15189 requirement:

2. IMMEDIATE ACTION TAKEN (CORRECTION)

Steps taken to contain the issue and mitigate immediate risk to patient care:

Was work halted? Yes No | **Were results recalled?** Yes No | **Authorized by:** _____

3. ROOT CAUSE ANALYSIS (RCA)

Identify why the event occurred (e.g., Equipment, Method, Manpower, Materials, Environment):

4. CORRECTIVE ACTION PLAN

Long-term action to prevent recurrence:

_____ **Responsibility:** _____
Target Date: ____ / ____ / 2026

5. VERIFICATION OF EFFECTIVENESS (CLOSURE)

To be filled by the Quality Manager / Head of Lab after the monitoring period: Evidence of Effectiveness: No recurrence noted Staff retraining completed Audit verified **Final Status:** CLOSED RE-OPENED (New NC No: _____)

Signature (QAO/HOL): _____ **Date:** ____ / ____ / 2026