**Job Aid: Audit Closure 4-72**

**The Audit Report – A Suggested Format**

**Summary Page –** describes key information related to the audit

* Names of Auditors
* Date(s) of the audit
* Scope of the audit including the process(es) audited and the areas visited during the audit.
* Audit criteria applied
* List of Findings – note whether any findings are repeated from a previous internal or external audit
  + Summary of nonconformances
  + Observations noted
  + Opportunities for improvement noted
* Examples of outstanding performance or evidence of improvement since the last audit
* Expectations for corrective action responses – a plan for corrective action and implementation date
* Signature of Team Leader

**Attachments**

* Copies of the initiated NCEs that contain the problem statement and the specific objective evidence
* Action Item List

The report should be issued within 24 hours and should be distributed at or before the closing meeting so that NCEs can be addressed without undue delay. (*ISO15189:2022 8.8.3.2.g) implementation of appropriate correction and corrective actions without undue delay.)*

**Laboratory Management is responsible for:**

* Reviewing the findings and documenting the review
* Determining the actions necessary to rectify nonconformances
* Establishing what ongoing monitoring is needed to ensure continued compliance
* Meeting all due dates included in the audit report

**Verification**

**Purpose:** Ensure corrective action was taken **AND** was effective at resolving the NCE

1. Auditee agrees to respond to the NCE by a specific date during the closing meeting.
2. The lead auditor or audit director reviews the auditee’s responses to determine whether the investigation and proposed corrective actions are adequate.

Criteria for Response Adequacy

* + 1. An identifiable root cause and not a restatement of the symptoms
    2. Proposed corrective action that relates logically to the identified root cause

1. Auditee notifies lead auditor or audit director when corrective action has been implemented
2. Lead auditor or audit director determines effectiveness by auditing the records, actions, or both depending on the risk the original NCE posed to the laboratory.

Criteria for successful implementation

1. Full implementation of the corrective action proposed by the auditee
2. Evidence that the root cause of the original nonconformity has been eliminated

**Audit Closure**

* All audit records are retained according to the site’s record retention documentation
  + Include auditor field notes to demonstrate how conformity or nonconformity was determined
  + The developed checklists and templates can aid in planning future audits
* Audit findings are included in the management review’s quality report for discussion and review.