Purpose

To detail the systematic approach for closed loop corrective action to find and eliminate the actual root cause(s) of nonconforming work or departures from policies and procedures in the quality management system or technical operations.

Scope / Field of Application

This procedure is governed by the requirements specified within the quality management system.

Definitions and Acronyms

Correction – action taken to resolve a problem.

Corrective Action – is the action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

Corrective Action Request (CAR) – form used to initiate corrective action.

Root Cause – fundamental deficiency that results in nonconformity and must be corrected to prevent recurrence of the same or similar nonconformity.

Nonconformity – A non-fulfillment of a specified or implied requirement of the Quality Management System(Level 1 and Level 2 non-conformities are defined in QSP- Control of Non-Conforming Work)

Responsibilities

The appropriate authorities for the implementation of a corrective action include; Quality Manager, Technical Leader and person responsible.

Materials Required

Corrective Action Request form
4-11-1-L1, CAR/NCR/PAR Log

Procedure

The goals of this corrective action policy are to identify the root cause of a problem; correct nonconformities; implement a solution to avoid recurrence; and maintain the highest level of quality.

Corrective Action

Situations requiring corrective action investigation generally include:

- non-compliance with test methods including all applicable procedures
- repeated failure in method performance as demonstrated by results provided by quality control samples
- non-compliance with quality audit, proficiency testing, or other quality directive
- issues involving contamination or cross contamination
- repeated clerical / administrative errors
- Are unexpected
- Require inquiry to determine root cause
- Requires comprehensive action with documentation
- Requires management involvement
- May affect quality of work

Section I of the Corrective Action Request shall be completed by the Originator.

Over the course of the investigation, the person responsible shall determine and document the following:

- The non-conformity.
- Event(s) which identified the non-conformity.

- Extent of the non-conformity.
- Effect(s) of the non-conformity on the quality of work.
- Short term response.
- Root cause(s) of the corrective action. Examples of findings or root causes may include, but are not limited to, equipment failure; incomplete or nonexistent procedures; non-compliance with procedures and regulations; improper collection, storage, handling, or preparation; calculation errors or transcription errors; misidentification; running the wrong sample; and lack of training.

Once a corrective action plan is determined, Section II will be completed by QM and Section III of the CAR shall be completed and signed by the person responsible and the CAR returned to the QM for review and approval.

A tentative corrective action plan shall be developed by person responsible and provided via CAR to the QM within 30 days.

Section IV shall be complete by either the Quality Manager or the Technical Leader depending upon whether it is a quality or operations nonconformity. A person responsible for the action shall be designated.

The person responsible shall implement and complete the action. The person responsible shall complete Section V. The person responsible shall complete the sign off section and return to Quality Manager.

The QM in collaboration with the Technical Leader shall determine if the corrective plan has been completed or specify if further action is warranted. If deemed necessary, additional follow-up actions shall be identified by the QM and a new date for completion set and approved.

After completion of the corrective action, the QM shall evaluate the effectiveness of the plan and complete Section VI of the Corrective Action Record. If there is objective evidence that the actions are complete and effective, the QM shall approve and close the corrective action, signing Section VI of the CAR.

If the QM determines the Corrective Action Plan has not adequately addressed the non-conformity, then Sections II-V of the CAR will be repeated.

If an employee is removed from casework or if casework in a particular discipline has been suspended as a result of a CAR inquiry, then casework in that discipline or casework by the

employee shall not be allowed to resume until released by the Quality Manager and/or Technical Leader.

The QM shall maintain all original documentation on corrective actions for (10) years.

Data, reports, and actions shall not be released until the problem is resolved and verified by the QM.

In the event that nonconformity has been identified and a Laboratory Report has been released through Records Management System (RMS), the Client shall be notified. The Lab Director or designee may request resubmission of evidence for analysis. An amended report shall be issued to the submitting agency and the CAR shall be included in the Master case file.

Documentation

Root cause analysis and corrective action taken is recorded on the CAR form.

Required Record	Custodian
Completed *4-11-1-L1, CAR/NCR/PAR Log*	Quality Manager
CAR/NCR Log	Quality Manager

Reference Procedure

N/A

References

Quality Manual Section 4.11 and 4.9.1

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2016/07/01	Original version
2	2018/04/01	Remove level1 and level 2 non-conformities from this procedure, change issue date to effective date, change rev# to ver# , change revision history table. Add reference in definitions to QSP for non-conforming work .Change RMS case file to Master case file