Purpose

The purpose of this Guide is to define the steps necessary in carrying out corrective actions when nonconforming work or departures from the policies and procedures in the quality management system have been identified.

Scope

The Guide covers only those corrective actions directly associated with or influencing calibration and testing services.

Definitions

N/A

Equipment

N/A

Health & Safety Precautions

N/A

Protocol

1. The responsible party shall investigate to determine the root cause of the problem, complete the first and second section of the Corrective Action Plan and identify nonconforming work on the form in Appendix RPD-G-08.

   NOTE: Depending on the nature of the problem, the investigation may be delegated to any staff member. The Group Leader and/or the Quality Manager may be required to conduct the investigation.

2. Corrective actions appropriate to the root cause and designed to eliminate the problem and prevent recurrence shall be selected. This action shall be recorded in the third section of the Corrective Action Plan.

3. The Group Leader shall review and sign acceptance of the Corrective Action Plan.

4. The responsible party shall notify any affected organization(s). Guide RPD-G-12 shall be applied to this action.

5. The responsible party shall document (in the appropriate laboratory records) and implement any required changes resulting from corrective action investigations.

6. Upon completion of the corrective action, the results shall be monitored to ensure that the desired effect has occurred. This monitoring shall be appropriate to the nature of the corrective action. The Guide RPD-G-09, on preventive actions and the associated form can be used to identify a monitoring plan for the corrective action.

   NOTE: In the case of calibration or equipment nonconformance, a calibration of a secondary standard shall take place to ensure that corrections have indeed been made.

7. When the nonconformance is of such magnitude that doubt is cast on the laboratory's compliance with its own policies and procedures or on its compliance with the NIST Quality Management System, the appropriate areas of activity shall be audited in accordance with Guide RPD-G-10.

Acceptance Criteria

Once it has been demonstrated that quality has been restored to the calibration services (through an appropriate comparison) regular calibration and testing services may resume.

If the corrective action requires a change in procedure, that change shall be implemented prior to resumption of the calibration service to which it applies.

After it is determined that the corrective action has succeeded, the investigator, the Group Leader, the Quality Manager, and the Division Chief shall acknowledge by signing the Corrective Action Plan form.

References

N/A

Documentation

RPD Corrective action plan
Logbooks

Filing and Retention

The Quality Manager files the original Corrective Action Plan in the Corrective Action Plan folder. Copies may be made as needed.
Logbooks are kept in the calibration facilities and are kept indefinitely.

Appendix RPD-G-08

This form is found as a Word document at: https://www.nist.gov/pml/radiation-physics/quality-system-services/radiation-physics-division-quality-system-guide-forms

CORRECTIVE ACTION PLAN

SOURCE OF DETERMINATION OF NEED FOR CORRECTIVE ACTION:

_____

ROOT CAUSE OF PROBLEM DATE _____

_____

_____

_____

_____

Investigator _____

CORRECTIVE ACTION

_____

_____

_____

_____

Group Leader Approval _____

MONITORED RESULTS

_____

_____

_____

PROBLEM IS RECTIFIED

Investigator _____ Date _____

Group Leader _____ Date _____

Quality Manager _____ Date _____

Division Chief _____ Date _____