Purpose

The purpose of this Guide is to present a proactive approach to identify service improvement opportunities. The Radiation Physics Division (RPD) Preventive Form documents the preventive action and risk assessment plan.

Scope

This Guide applies to any technical or quality management systems that relate to the calibration/testing services of the Radiation Physics Division.

Definitions

Equipment

N/A

Health & Safety Precautions

N/A

Protocol

Opportunities for needed improvement and potential sources of nonconformance may be identified in several ways. These include, but are not limited to, observations in other laboratories, suggestions from visiting scientists, ideas based on the experience of NIST personnel, and necessary upgrades of equipment or computer programs. Risks will be assessed to prevent or reduce undesired impacts and potential failures in NIST measurement service activities. Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

Initiation of preventive action

The initiator of the preventive action should discuss the action plan thoroughly with their Group Leader and other staff members, when appropriate, to determine the plan's feasibility.

When it is decided to implement the plan, a Preventive Action Form will be completed and signed by the preparer and the Group Leader (Appendix RPD-G-09. A). The Preventive Action Form will then be delivered to the Quality Manager, who shall sign acknowledging receipt. The Quality Manager will place the original in the Preventive Action folder and return a copy of the signed document to the preparer and Group Leader.

Implementation

Once the Preventive Action Form is completed, the preparer will devise an implementation program. This will include testing before and after the installation of the action to ensure consistency. The program need not be written down formally, but all results from the program shall be documented. The implementers of the program shall determine what constitutes acceptance.

Monitoring Results

Once the implementation is accepted, the results of the preventive action shall be monitored for a period appropriate to the action to ensure that it is indeed an improvement to the overall system. The Group Leader (or someone they delegate) shall decide how long the monitoring shall take place. There is no formal documentation of the monitoring unless test results are produced, but logbook entries are recommended for tracking purposes.

Acceptance Criteria

The action plan is accepted when it passes all implementation tests and proves to be consistent through routine monitoring for a designated period. Once the action plan has been implemented in full service, the preparer of the plan will request the Division Chief's signature and record the date on the original Preventive Action Form. All changes to the technical procedures that result from a preventive action and risk assessment shall be documented in the sub-level quality documents.

If the action plan is rejected, for whatever reason, a separate sheet(s) shall be prepared indicating the implementation and/or monitoring test results and the reason for rejection. This will be attached to the original Preventive Action Form.

If the action plan is modified, no further indications are required on the Preventive Action Form unless a complete change of action is indicated. In that instance, a new Preventive Action Form will be prepared and the first rejected.

References

N/A

Documentation

Preventive Action Form
Logbook and electronic records
All changes to the technical procedures that result from a preventive action and risk assessment shall be documented in the sub-level quality documents.

Filing and Retention

The completed Preventive Action Form will be placed in the Preventive Action folder. The RPD Quality Manager shall include a description of each new preventive form in the NIST quarterly report.

Appendix RPD-G-09. A

PREVENTIVE ACTION FORM

REASON FOR PREVENTIVE ACTION

_____

_____

_____

_____

PREVENTIVE ACTION TAKEN

___ New protocol

___ Revised protocol

___ Modify equipment (explain below or on separate sheet of paper)

___ Addition or replacement of equipment

Equipment _____

Vendor _____

___ Other (explain below or on separate sheet of paper)

_____

_____

_____

Preparer _____ Date _____

Group Leader _____ Date _____

Quality Manager _____ Date _____

Division Chief _____ Date _____

Date preventive action implemented into full service _____