Purpose

The purpose of this Guide is to outline the steps to be taken when any aspect of the testing or calibration work is changed, resulting in a change to the currently disseminated calibration or measurement values.

Scope

The Guide applies to any change in the measurement facility, system or method, procedures, processes or controlled parameters that results in changes in currently disseminated calibration and measurement values.

Definitions

N/A

Protocol

1. The responsible party shall investigate to determine the root cause of the change and complete the first and second section of the Change in Disseminated Value(s) form (Appendix IRD-G-12.A).

   NOTE: Depending on the nature of the change, the Division Chief, Group Leader or Quality Manager may delegate the investigation to any staff member. The Group Leader and/or the Quality Manager may be required to conduct or assist in the investigation.

2. Corrective actions appropriate to the root cause and designed to eliminate the problem and prevent recurrence shall be selected. Guide IRD-G-08, Corrective Action, should be consulted and applied if appropriate.

3. The Group Leader shall review and sign acceptance of the Change in Disseminated Value(s) form.

4. The responsible party shall notify the affected organization(s) in a timely manner.

5. If appropriate, a replacement report of calibration or certification shall be issued. It shall be uniquely identified and contain a reference to the original that it replaces. To identify the reissue, add Rx (where x = 1, 2, 3…) as a suffix to the original test folder number. The report should also contain a reference to the original that it replaces.

6. Standard Reference Materials (SRM) certificates must retain their original number. Changes to SRM certificates may be made in the form of an

addendum to the certificate. Current owners of the SRM affected by this change shall be sent a new certificate accompanied by the addendum and any other relevant information. These changes will also be posted on the NIST SRM website.

7. The impact of the change in disseminated value should be documented in the Change in Disseminated Value(s) form (Appendix IRD-G-12.A).

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.

After it is determined that the corrective action has succeeded, the investigator, the Group Leader, the Quality Manager and the Division Chief sign the Change in Disseminated Value(s) form (Appendix IRD-G-12.A).

References

N/A

Documentation

Change in Disseminated Value(s) form
Logbooks

Filing and Retention

The Quality Manager files the original Change in Disseminated Value(s) form in the Change in Disseminated Value(s) folder. Copies may be made as needed.

Logbooks are kept with the individual calibration services and are maintained indefinitely.

Change in Disseminated Value(s) forms are retained indefinitely.

Appendix IRD-G-12.A

CHANGE IN DISSEMINATED VALUE(S)

SOURCE OF DETERMINATION OF CHANGE IN DISSEMINATED VALUE(S):

_____

ROOT CAUSE OF CHANGE DATE _____

_____
_____
_____
_____

Investigator _____

CORRECTIVE ACTION

_____
_____
_____
_____

Group Leader Approval _____

IMPACT OF CHANGE

_____
_____
_____

ACTION COMPLETE

Investigator _____ Date _____

Group Leader _____ Date _____

Quality Manager _____ Date _____

Division Chief _____ Date _____