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 and all amended reports and certificates.

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. The scope includes any change to customer issued reports or certificates.

Definitions

N/A

Protocol

CHANGE IN DISSEMINATED VALUE

1. The responsible party shall investigate to determine the root cause, the corrective action and the impact of the disseminated value change. This investigation shall be documented using the Change in Disseminated Value(s) form (Appendix RPD-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 RPD-G-08, Corrective Action, should be consulted and applied if the root cause relates to nonconformances in the work or departures from the policies and procedures in the quality management system.

3. The Group Leader shall review and declare acceptance (by signing the corrective action section) of the Change in Disseminated Value(s) form.

4. A replacement report of calibration or certification shall be issued. The change and the reason for the change shall be clearly identified. It shall be uniquely identified and contain a reference to the original that it replaces. Amendments to a report or certificate are made in the form of a further

document that meets all the requirements of the original report and includes the statement "Amendment to Report, serial number... [or as otherwise identified]". To identify the reissue, a new version number suffix to the original order number must be added. The report should also contain a reference to the original that it replaces. A revised report shall contain a revision history. When it is necessary to issue a complete, new report, the new report is uniquely identified and contains a reference to the original that it replaces, NIST-QM-I requirements (see Section 7.8.8).

5. Standard Reference Material (SRM) certificates must retain their original number. A revised certificate shall contain a revision history. Changes to SRM certificates that do not affect certified values may be made in the form of an addendum to the certificate. When appropriate, 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.

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

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

AMENDED CUSTOMER REPORT OR CERTIFICATE

1. If the customer report or certificate needs to be amended due to a grammatical or editorial error or other change that does not require corrective action nor a change in the disseminated value, then the investigator shall amend the report to correct the error.

2. The investigator shall determine the root cause and the corrective action of the change and document it, using the Change in Customer Issued Report or Certificate form (Appendix RPD-G-12. B).

3. Corrective actions, appropriate to the root cause and designed to eliminate the problem and prevent recurrence, shall be selected. Guide RPD-G-08, Corrective Action, should be consulted and applied if the root cause relates to nonconformances in the work or departures from the policies and procedures in the quality management system.

4. A replacement report of calibration or certification shall be issued. The change and its reason shall be clearly identified. It shall be uniquely identified and contain a reference to the original that it replaces. Amendments to a report or certificate are made in the form of a further document that meets all the requirements of the original report, and includes the statement "Amendment to Report, serial number... [or as otherwise identified]". To identify the reissue, a new version number suffix to the original order number

must be added. The report should also contain a reference to the original that it replaces. A revised report shall contain a revision history. When it is necessary to issue a complete, new report, the new report is uniquely identified and contains a reference to the original that it replaces, per NIST-QM-I requirements (see Section 7.8.8).

5. Standard Reference Material (SRM) certificates must retain their original number. A revised certificate shall contain a revision history. Changes to SRM certificates that do not affect certified values may be made in the form of an addendum to the certificate. When appropriate, 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.

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

Acceptance Criteria

Quality should be demonstrated as restored to the calibration or SRM services (through an appropriate corrective action) prior to resumption of regular calibration and testing services.

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 Change in Disseminated Value(s) form. This acknowledgment authorizes the resumption of services.

References

N/A

Documentation

Change in Disseminated Value(s) form Appendix RPD-G-12. A
Change in Customer Issued Report of Certificate form Appendix RPD-G-12.B
Logbooks

Filing and Retention

The Quality Manager files the original Change in Disseminated Value(s) form or the Change in Customer Issued Report of Certificate form in the Change in

Disseminated Value(s) folder in the RPD Quality office paper files. The form is also maintained electronically on the RPD Quality Website. Copies may be made as needed. Amended reports shall be tracked through the E-commerce by providing an electronic copy of the amended report to the Quality Manager, who will provide it to the E-commerce.

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

Both forms are retained indefinitely.

Appendix RPD-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 _____

AMENDED REPORT, TRACKED THROUGH THE E-COMMERCE

Quality Manager _____ Date _____

Appendix RPD-G-12. B

CHANGE IN CUSTOMER ISSUED REPORT OR CERTIFICATE

SOURCE OF DETERMINATION OF CHANGE TO REPORT:

_____

ROOT CAUSE OF CHANGE DATE _____

_____
_____
_____
_____

Investigator _____

CORRECTIVE ACTION

_____
_____
_____
_____

IMPACT OF CHANGE

_____
_____
_____

ACTION COMPLETE

Investigator _____ Date _____

Quality Manager _____ Date _____

AMENDED REPORT, TRACKED THROUGH THE E- COMMERCE,

Quality Manager _____ Date _____