Purpose

The purpose of this Guide is to outline the steps to be taken when any aspect of the testing or calibration work, including the results of the work, is found to be out of conformance with RPD procedures or the agreed requirements of the client.

Scope

The Guide applies to all calibration activities. The nonconformance of the test/calibration may be due to shipping damage, operator error, equipment malfunction, or any other parameter that jeopardizes the integrity of the work. It may also be due to any previously undiscovered change in the measurement facility, system or method, procedures, processes, or controlled parameters that results in changes in currently disseminated calibration or measurement values.

Definitions

Item – an all-inclusive term used in place of any of the following: assembly, component, equipment, material, module, part, structure, system, unit, software or results.

Nonconformance – any deviation from standard practice or operation that renders the quality of a calibration/test unacceptable.

Equipment

N/A

Health & Safety Precautions

N/A

Procedure

General

Nonconforming work may be identified through a variety of activities such as internal or external audits, management reviews, the calibration or testing process, feedback from clients, or staff member observations.

Complaints received from clients may result in the identification of nonconforming calibration and/or testing work. The RPD-G-04 explains complaints within the division.

The calibration personnel involved shall:

1. Identify whether the work is truly non-conforming (*e.g.*, not simply due to improper electrical connections).
2. Evaluate the significance of the nonconforming work and determine the root cause by following the Corrective Actions (RPD-G-08) guide and completing the form found in the Appendix of 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. RPD-G-08 quality forms are not required for nonconforming work associated with these cases: the inspection of a client calibration item and the calibration item is operating in a manner inconsistent with design.

   NOTE: Other calibration personnel, the Group Leader and/or the Quality Manager may be requested to assist with this step.

Inspection of client calibration item

1. Client calibration items shall be inspected by calibration personnel according to criteria specific to the Procedure used.
2. Items that fail inspection should be addressed in a timely manner.
3. Client shall be notified of inspection failure.
4. Calibration personnel may rectify the failure upon receipt of a written request to do so by the client.
5. If the failure cannot be rectified, the item shall be returned to the client.
6. All actions shall be documented.
7. No RPD quality forms are required.

Results outside the scope of desired calibration/test efforts

1. Make note of nonconforming work on data sheets corresponding to the results. Place data sheets in the calibration file.

2. Notify the client to ascertain if he/she wishes to recalibrate or accept the nonconforming work.

3. If applicable, inquire if the client would like to send replacement items.

4. If the client wishes to accept the nonconforming work, the acceptance must be in writing. The acceptance note shall be placed in the client's file. Make note of the nonconformance issue in the calibration report, if applicable.

5. If a need for revision of procedures is determined, proceed to Corrective Actions (RPD-G-08).

Calibration item is operating in a manner inconsistent with design

1. Notify the client immediately of the problem.

2. At the client's written request, the calibration personnel may repair the item. All repairs shall be noted in the client's calibration file. Upon repair, repeat the calibration.

3. If not repaired, the item shall be returned to the client.

4. No RPD quality forms are required.

Malfunction of calibration equipment or software

1. Stop all calibration work.

2. Notify the Group Leader when repairs will involve new equipment or repair services provided by an outside vendor.

3. If a delay in the work is expected, notify all clients affected.

4. Proceed to Corrective Actions (RPD-G-08).

Application of incorrect conditions

1. Make note of incorrect conditions (i.e., wrong technique, incorrect time or distance, etc.) on data sheets corresponding to nonconforming results. Place data sheets in calibration file.

2. Repeat calibration if applicable.

3. If the item has been sent to the client, request the client to return the item for recalibration or to send replacement items if applicable.

4. If a need for revision of procedures is determined, proceed to Corrective Actions (RPD-G-08).

Acceptance Criteria

N/A

References

N/A

Documentation

Calibration data documents

Filing and Retention

1. Calibration data documents are filed in the calibration files. All incidents of nonconforming work are documented in the Division's quarterly quality report.