

Introduction

This document describes the process during calibration activities when an instrument is found out-of-tolerance or the when calibration cannot confirm the ability of an asset to make adequate measurements. The process includes both investigation and remediation and minimally shall be applied to all measurements assigned a critical calibration classification.

Roles/ Responsibilities

Calibrator:

Initiate the investigation and remediation process by identifying an applicable condition on the appropriate calibration record.

Provide any comments that will assist in the evaluation of the investigation.

Investigator:

When an investigation is required, the potential for product impact must be assessed. Investigation must include, at a minimum:

- Use of the equipment
- Product impact analysis

Quality:

- Review and approval of calibration investigation.
- Review and approval of proposed remediation actions, as applicable.

Requirements

Calibration investigation and remediation conditions may include the following:

- Found out of tolerance
- Found inoperative or
- Unable to have an end calibration performed

Upon detection of an applicable condition, notify a responsible individual, such as the area coordinator. Document the date and party notified on the calibration record.

An investigation does not need to be completed during an initial calibration if there is direct knowledge that the instrument is new and has never been used. A documented explanation is required on the calibration record.

Investigation Content

The investigation/remediation plays a critical role in the calibration program and quality system. It is critical that the investigation and corresponding impact analysis are written in a clear, concise manner with an external audience in mind. The investigation should stand on its own merit and should not require knowledge specific to a particular application or manufacturing area in order to review the completed impact analysis.

If a calibration is not possible, including if the asset is unable to locate, the investigation must initially proceed with the assumption that the calibration may have been out-of-tolerance.

The investigator should consider and document the following elements with the investigation as appropriate:

- The magnitude and significance of the error or condition in regards to the specific use of the instrument
- Instrument usage during the period in question
- Bracketing of time period within scope of the investigation
- Detailed description of documentation reviewed as a result of the investigation. Examples include calibration management system data, logbooks, work orders, manufacturing batch records, chart recorders or data collection system records
- Detailed Product impact analysis
- Detailed analysis of recent calibration history, including indication of any repeated issues
- Reference to any follow-up actions

Requirements (continued)

Many out-of-tolerance conditions may not impact measurement of the end product or critical process. In these cases, it is still necessary to document the analysis in the investigation. Factors that can help isolate or dismiss the condition's impact on product quality are given below:

- Instrument not used for any critical applications since last calibration
- Measurement(s) in question verified at the time of use through another measuring instrument (redundant or downstream measurement available)
- Out-of-tolerance condition occurred in a range/function/channel not used by the application
- Out-of-tolerance condition results in more stringent challenge to processor product (error results in a more conservative limit being applied to the process or measurement)
- Out-of-tolerance condition is justified as insignificant to, or accounted for within the overall process requirements

Reference any supporting documentation as applicable.

Timeliness:

Metric should be established to ensure a timely initiation, response and approval of the investigations.

Approvals:

Quality Assurance

- Overall responsibility for content of investigations
- Oversee timeliness of initiation, response and approval of investigations and any associated remediations.

Optional Approvers may be included for technical review as appropriate

If the investigation is rejected at any time during the approval process, investigation needs to be re-routed through all approvers.

END OF DOCUMENT