

Fluke Calibration, American Fork – Primary Temperature Lab

INSTRUCTION NO.
HSQ003

799 East Utah Valley Drive
American Fork, UT 84003

REVISION NO.
27

TYPE:

Quality Assurance

DESCRIPTION:

Calibration Program and Activities Quality Assurance Manual

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TECHNICAL/QA APPROVAL:



DIRECTOR OF METROLOGY, TEMPERATURE

7 Jun 2011

DATE

QUALITY APPROVAL:



QA MANAGER, TEMPERATURE PRODUCTS

7 Jun 2011

DATE

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1. QUALITY POLICY STATEMENT



QUALITY POLICY STATEMENT

Fluke Electronics Corporation, American Fork, has a commitment to provide its customers with high quality instruments and services delivered on time and augmented with the best customer service possible each and every time.

The executive management of Fluke Electronics Corporation, American Fork, is committed to upholding the quality standards of the Fluke Calibration, American Fork – Primary Temperature Lab. The purpose of the management system is to ensure quality requirements of the accrediting body shall be met or exceeded at all times within the laboratory. The service provided by the Calibration Program shall be in compliance with the overall quality commitment of the company.

The management and staff of the Calibration Program shall be committed to the overall quality policy of the company. This shall include a commitment to good professional practice and to providing quality testing and calibration services to our customers. All personnel concerned with testing and calibration activities shall familiarize themselves with the quality documentation and implement the quality policies and procedures in their work.

The overall objective of Fluke Electronics Corporation, American Fork’s, management system is outlined in the definition of quality:

Quality: Each individual will exercise due professional care in meeting internal and external customer needs and expectations while always exceeding company standards.

The calibration procedures established by Fluke Electronics Corporation, American Fork’s managing metrologists and company management generally follow commonly accepted calibration practice, national laboratory recommended procedures, and requirements of the accreditation bodies from which Fluke Electronics Corporation, American Fork, seeks accreditation. The executive management and calibration management shall ensure compliance with the NCSL/ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*, for all testing and calibration activities and continually improve the effectiveness of our management system.

Ankush Malhotra
Ankush Malhotra
Business Manager, Temperature

Thomas J. Wiandt
Thomas J. Wiandt
Director of Metrology, Temperature

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QA Manager, Temperature

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2. GENERAL

2.1. Purpose

2.1.1. This procedure provides guidelines for the calibration of Measuring and Test Equipment (M&TE) and measurement standards to maintain traceability to nationally known standards. This procedure is applicable to all calibration services provided by Fluke Electronics Corporation, American Fork, as listed below:

2.1.1.1 M&TE/Standards owned by Fluke Electronics Corporation, American Fork.

2.1.1.2 M&TE/Standards from customers who invoke ISO/IEC 17025:2005.

2.1.1.3 M&TE/Standards from customers who invoke ANSI/NCSL Z540-1-1994.

2.1.1.4 M&TE/Standards from customers who invoke MIL-STD 45662A.

2.1.2 Control and Maintenance

2.1.1.1. The Director of Metrology and Quality Manager review this document periodically to ensure its continuing suitability and effectiveness. Improvements and changes will be made as needed. The time interval between consecutive reviews shall not exceed 12 months.

3. USE OF THE NVLAP LOGO AND REFERENCING NVLAP ACCREDITATION

3.1. The NVLAP logo is not to be used in a manner inconsistent with NVLAP requirements as outlined in Annex A, of NIST Handbook 150:2006.

3.2. In referencing NVLAP or using the logo, no part of the company is to bring disrepute to NVLAP or misrepresent the scope of the laboratory in any manner.

3.3. When the term NVLAP or the NVLAP logo is used in reference to the laboratory's accreditation, it will include the NVLAP Lab Code.

3.3.1. When the NVLAP logo is used, the NVLAP approved caption indicated in Figure 1, Annex A of NIST Handbook 150:2006 is utilized.

3.3.2. The required logo aspect ratio (1:2.25) is utilized at all times.

3.3.3. The logo shall stand by itself and is not to be combined with any other logo, symbol or graphic.

3.3.4. The logo and caption is of a size that allows the caption to be easily read. The size of the caption does not exceed the size of the logo.

3.3.5. The logo appears in black ink - filled.

3.3.6. When referencing NVLAP accreditation in articles or documents pertaining to the laboratory, the NVLAP lab code is clearly referenced within the article. However, it is not necessary to reference the NVLAP lab code each time the accreditation is referred to in the article.

3.4. For a Report of Calibration that displays the NVLAP logo, the original signature of at least one Approved Signatory appears on the report. The signature of the Approved Signatory may be electronically generated for approved processes.

3.5. The logo is only used in conjunction with those calibrations or services for which accreditation has been granted. The laboratory does not subcontract calibrations as indicated in [Section 4.5](#) of this manual.

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- 3.5.1. Each calibration report displaying the NVLAP logo includes the following statement:
 “This calibration report applies only to the item described. It shall not be used to claim product endorsement by NVLAP or any agency of the U.S. Government.”
- 3.5.2. If the laboratory’s accreditation is referenced in a contract or proposal, the term and logo is accompanied by a description of where the laboratory’s scope may be downloaded and the current accreditation status.
- 3.5.3. Any questions regarding use of the NVLAP logo, or the laboratory’s accreditation in Fluke Electronics Corporation, American Fork, literature will be directed to the laboratory’s Authorized Representative. If clarification is required from NVLAP, the Authorized Representative will contact NVLAP for clarification. Any decision made by the Authorized Representative regarding the use of the NVLAP logo or the laboratory’s accreditation is final.

4. MANAGEMENT REQUIREMENTS

4.1. Organization

- 4.1.1. A formal review is conducted annually to insure that all Calibration Program personnel are aware of the significance of their activities, the consequences of not following critical processes/procedures within the company and the importance of their role in achieving the objectives set forth concerning the Calibration and Activities Quality Program
 - 4.1.1.1 The annual review is conducted as outlined in HCQ012, Calibration Program Personnel Annual Review.
- 4.1.2. Fluke Electronics Corporation, American Fork, ensures communication is established and takes place between all levels of staff, management and employees regarding the effectiveness of the management system using the following processes:
 - 4.1.2.1. Internal Auditing reviews, VOC and CA meetings and one on one discussions between Manager and Employee.
 - 4.1.2.2. Fluke Electronics Corporation, American Fork, also maintains an Open Door Policy in which this communication is informal.
- 4.1.3. Fluke Electronics Corporation, American Fork’s, Calibration Program is aligned to provide a degree of separation from manufacturing demands ensuring quality calibration work. The direct responsibility for the Calibration Program falls under the purview of the Director of Metrology, Temperature, while the day-to-day calibration activities fall under the Calibration Laboratory Manager reporting directly to the Fluke Calibration Primary Service Manager. The Director of Metrology, Temperature, and the Fluke Calibration Primary Service Manager, with the support of the company Business Manager, Temperature, work closely together ensuring that calibration personnel are free from any unnecessary pressures that may adversely affect the quality of the laboratory’s work.
- 4.1.4. The organizational structure is shown in Figure 1.
- 4.1.5. Calibration personnel shall avoid involvement in any activities that could diminish confidence in the laboratory’s ability to provide impartial, competent calibration results. Operational integrity and judgment with regards to the laboratory’s work product shall never be compromised.
 - 4.1.5.1. Involvement in any activities that violate this policy shall be reviewed by the Business Manager, Temperature, and the Director of Metrology, Temperature, and appropriate action shall be taken.

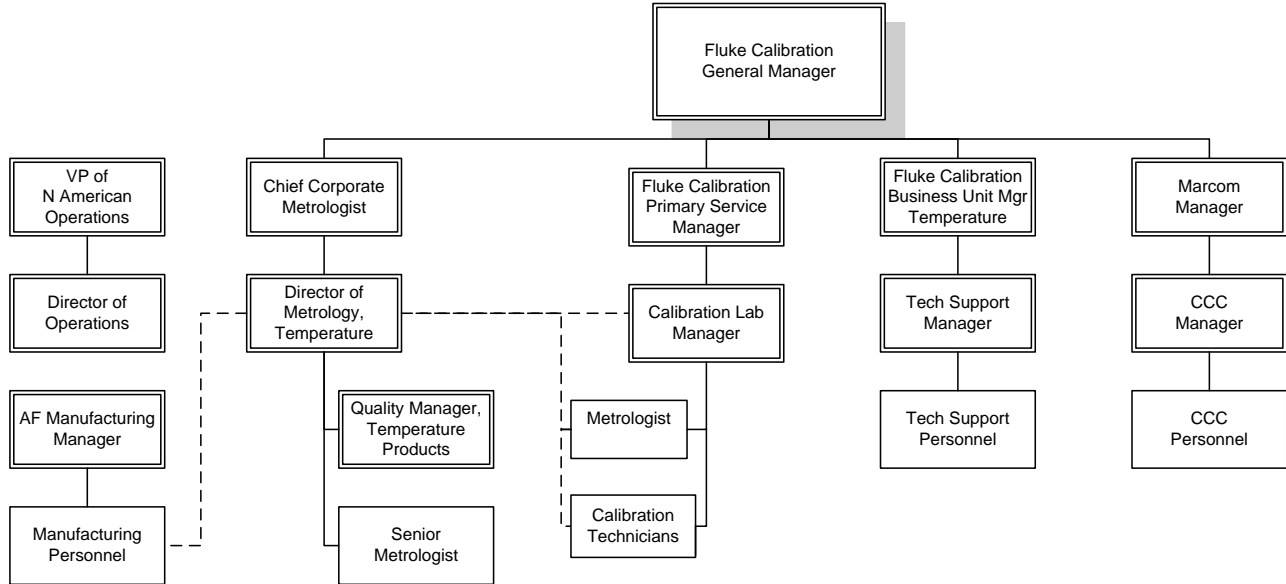


Figure 1: Organizational Chart

4.1.6. Key Managerial Personnel Authority and Responsibilities

4.1.6.1. Director of Metrology, Temperature

The Director of Metrology, Temperature, (Director of Metrology) reports to the Chief Corporate Metrologist. The Director of Metrology is the technical manager of the Calibration Program. As the technical manager of the Calibration Program, the Director of Metrology is responsible for ensuring the laboratory compliance with the international standard, NCSL/ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. The Director of Metrology is the primary signatory and authorized representative for the NVLAP Accreditation program at Fluke Electronics Corporation, American Fork, This individual is responsible for all documentation, records, and procedures as they apply to metrology and calibration activities. The calibration program training is under the purview of the Director of Metrology. The Directory of Metrology is designated as an approved signatory for all calibration procedures, calibrations, and testing performed in the laboratory and/or performed by production personnel.

4.1.6.2. Quality Manager, Temperature Products

The Quality Manager, Temperature Products (QA Manager) reports to the Director of Metrology. The QA Manager is the quality manager of the Calibration Program and Activities. As the quality manager of the Calibration Program and Activities, the QA Manager is responsible for ensuring the program compliance with the international standard, NCSL/ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. This individual is responsible for all documentation, records, and procedures as they apply to quality and calibration activities. The QA Manager is the approved quality signature for all calibration and quality procedures/ documentation used in the laboratory and/or performed by production personnel. The QA Manager is

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an approved signatory for the laboratory and/or production. Upon approval, the QA Manager may be responsible for writing and approving calibration instructions. This individual is the designated alternate for the Director of Metrology.

4.1.6.3. Calibration Lab Manager

The Calibration Lab Manager reports directly to the Fluke Calibration Primary Service Manager. The Calibration Lab Manager is responsible for managing the day to day operation of the calibration laboratory. The Calibration Lab Manager oversees the daily logistics and metrics of the laboratory and is involved in personnel and budgetary decisions involving metrology and calibration activities. This position is responsible for maintaining the calibration standards of the company. The Calibration Lab Manager interfaces between manufacturing, other areas of the company and the laboratory and assists in insulating the laboratory personnel from production pressures that may adversely affect quality. The Calibration Lab Manager shall work closely with the Director of Metrology to ensure proper operation of the calibration laboratory. As the designated deputy for the Director of Metrology, the Calibration Lab Manager is responsible to support the Director of Metrology in ensuring the compliance of the laboratory to the international standard, NCSL/ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*. The Calibration Lab Manager is the secondary signatory and authorized representative for the NVLAP Accreditation program at Fluke Electronics Corporation, American Fork, The Calibration Lab Manager is an approved signatory for all calibration procedures, calibrations, and testing performed in the laboratory and/or performed by production personnel and is the deputy for the Director of Metrology.

4.1.6.4. Senior Metrologist

The Senior Metrologist reports directly to the Director of Metrology. He assists in developing and improve temperature calibration processes for the Fluke Calibration, American Fork – Primary Temperature Lab. He is responsible to support the Director of Metrology and the Calibration Lab Manager in ensuring the compliance of the laboratory to the international standard, NCSL/ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*. The Senior Metrologist assists the Calibration Lab Manager in computing the metrology statistics and applicable uncertainties. To the extent possible, he is insulated from production pressures that may adversely affect quality. The Senior Metrologist may write calibration instructions. The Senior Metrologist is designated as an approved signatory for calibrations and testing performed by the secondary lab and production personnel.

4.1.6.5. Metrologists

Metrologists report to the Calibration Lab Manager. They are responsible for the calibration of customer equipment and some Fluke Electronics Corporation, American Fork, measurement standards. The Metrologists are responsible to support the Calibration Lab Manager in ensuring the compliance of the laboratory to the international standard, NCSL/ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*. The Metrologists may assist the Calibration Lab Manager in computing the metrology statistics and applicable uncertainties.

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To the extent possible, they are insulated from production pressures that may adversely affect quality. Upon approval, the metrologists may write calibration instructions.

4.1.6.6. Calibration Technicians

Calibration Technicians report to the Calibration Lab Manager. They are responsible for calibration of customer equipment and some Fluke Electronics Corporation, American Fork, measurement standards. Calibration Technicians perform most of the calibrations carried out in the calibration laboratory. Calibration Technicians are directly responsible for the quality of their work. To the extent possible, they are insulated from production pressures that may adversely affect quality. When approved by the Calibration Lab Manager, the Calibration Technician is designated as an approved signatory for calibrations and testing performed by production personnel.

4.1.6.7. Production Personnel

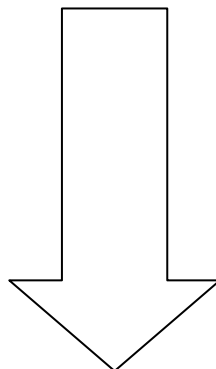
Production Personnel are responsible for the calibration of products manufactured by their group. Production Personnel performing calibrations are directly responsible for the quality of their work. They are accountable to the Director of Metrology for all calibration work. To the extent possible, they are insulated from production pressures that may adversely affect quality.

4.1.6.8. Engineering Personnel

On occasion, Engineering personnel will be required to perform calibrations and are exempt from training. This is sometimes necessary with the development and introduction of new products or if problems arise with existing calibration techniques or product performance. When this occurs, the assigned engineer shall work closely with the responsible Production Technician and will fill the role of a Calibration Technician in the organizational structure. Engineering personnel may be involved in the development of a specific calibration procedure and/or calibration uncertainty for instruments they designed.

4.1.6.9. Approved Signatories

4.1.6.9.1. Personnel are authorized to approve calibration reports and/or calibration procedures as shown in Table 4-1, Approval Authority.



Name	Position	Report Types	Calibration Instructions
Thomas Wiandt	Director of Metrology	All	All
Mike Coleman	Calibration Lab Manager	All	All
Tom Harper	Senior Metrologist	Secondary Lab Calibrations Production Calibrations	Author
Tom Kolat	Metrologist	None	Author
Jeff Nelson Roger Sims Emmanuel Narvaez Rachel Strasberg* Matt Newman*	Calibration Technician	Production Calibrations	None
Rose Heaton	Quality Manager	Alternate for Thomas Wiandt	By Approval

*When training is complete.

Table 4-1: Approval Authority

4.2. Management System

4.2.1. Quality System Documentation is communicated to (4.2.1.1), understood by (4.2.1.2), available to (4.2.1.3) and implemented by (4.2.1.4) appropriate personnel per the following:

- 4.2.1.1. Once a document is released originally or revised, Change Form CQF043 requires the author to determine whether training is required or not. If training is required the communication of the document is performed via the training. If no training is required then communication about the procedure is at the discretion of the QA Manager.
- 4.2.1.2. Training Attendance Form CQF044 is initialed by all appropriate personnel indicating they have understood the applicable documentation.
- 4.2.1.3. Documentation is available to personnel in all locations of the company where operations essential to the effective functioning of the Calibration Program are performed by having electronic access to these documents.
- 4.2.1.4. All aspects of implementation of the Quality System Documentation is performed by the QA Manager in accordance with Section 4.3.1-4.3.5.

4.2.2. The Quality Policy Statement is located on page two of this document.

4.2.3. The Calibration Program Master List references the supporting procedures not contained in the Quality Manual including technical procedures.

4.2.4. The structure of the documentation used in the management system is outlined in FHS001.

4.2.5. [Section 4.1.6](#) outlines the roles and responsibility of technical management and the quality manager including their responsibility of ensuring compliance to ISO/IEC 17025:2005.

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4.3. Document Control

4.3.1. General

4.3.1.1. Purpose

- A) FHS001, The Fluke Calibration, American Fork, Calibration Program Document Control and Retention Policy, is the governing document for document control. All document control procedures and processes shall support this policy.

FHS001 supports the corporate document retention policy outlined in QSD111.50, Records Retention Policy.

- B) The purpose of this procedure is to outline the Calibration Program and Activities Document Control process.
- C) The Calibration Program and Activities Documentation Master List is located at Foxpro>Hart>Document Mgmt>Calibration Master List

4.3.2. Calibration Policy Statement

4.3.2.1. The [Quality Policy Statement](#) in HSQ003 Calibration Program & Activities QA Manual outlines the quality assurance policy for the Calibration Program.

4.3.2.2. All other Quality Assurance documents support the policy statement.

4.3.3. Document Approval and Issue

4.3.3.1. Access

- A) All locations of the company have electronic access to documents where operations essential to the effective functioning of the Calibration Program are performed.

4.3.3.2. Review

- A) Calibration Program documents are reviewed bi-annually by the document owner to ensure they are suitable to comply with current requirements.
- B) The last review date and the next review due date are maintained by the QA Manager in a spreadsheet.

4.3.3.3. Source Documents

- A) Source documents that require controlled access are stored in a secured directory on the appropriate company server.
- B) Access is password controlled.
- C) Technicians are allowed to keep hardcopies of calibration/test instructions. However, the technicians must verify that the hardcopy is the current revision.

4.3.3.4. View Documents

- A) View documents are available to all personnel through the DMS using Portable Document Format (PDF) files.


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4.3.3.5 Format

- A) All documents are identified by revision number, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority (ies).
- Forms do not contain issuing authority signatures to avoid confusion. The issuing authority signatures can be found on the appropriate CQF043, Document Change, form for changing/releasing the form.
 - Standards/External Reference documents are controlled by the issuing body. No changes to standards shall be made by the company. It is the responsibility of the QA Manager to ensure that American Fork personnel have access to the relevant version of applicable standards.
- B) New Document Template/Procedure
- All new Calibration Program documents (excluding Calibration/Test instructions) should use the document template file, HCQ093. Other document types may be used where applicable, such as PowerPoint. When used, one of the standard Fluke Calibration Template files should be used. The PowerPoint Template files are located on the network.
 - New Calibration/Test Instructions should be written in accordance with HCQ043 Writing Equipment/Test Calibration Instructions Procedure.

4.3.3.6 Release

- A) Form CQF043 Calibration/Test Document or Uncertainty Analysis Change Form is used to release documents into DMS.
- B) Electronic signatures and release date are applied to the source document only after the source document has been signed by the issuing authorities. \\us-amf-fs01-p.danahertm.com\workgrps\Calibration Documents\gronly\signatures
- C) The QA Manager is responsible for updating the DMS in Foxpro by performing the following:
- Placing a new approved/revision in the appropriate Source file folder in \\us-amf-fs01-p.danahertm.com\workgrps\Calibration Documents\gronly\
 - Placing a new .pdf/view file in the appropriate file folder in \\us-amf-fs01-p.danahertm.com\workgrps\CalibrationDocuments\public\
 - Add Docname, the revision, the description, View and Source file , custodian, author , location, owner, review date, due date and edit the revision log in the Master List in Foxpro>Hart>Document Mgmt>Calibration Master List.
- D) The change form CQF043 and new released document(s) are filed in the QA document files by Document Name.

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4.3.4 Document Revision

4.3.4.1 General

- A) Changes to documents are reviewed and approved by the same function that performed the original review unless a company restructure has changed the function or control of that area of the company.
- B) The designated personnel for review and approval have access to pertinent background information upon which to base their review and approval.

4.3.4.2 Hardcopy Changes

- A) Form CQF043 Calibration/Test Document change form is used to make changes to documents in the DMS.
 - Standards/External Reference documents are controlled by the issuing body. No changes to standards shall be made by the company. It is the responsibility of the QA Manager to ensure American Fork personnel have access to the relevant version of applicable standards. No amending of Calibration Documents is allowed.
 - Changes are to be submitted to QA.
 - A revised document shall be issued as soon as reasonably possible.
- C) Prior to the QA Manager making the changes in Foxpro the following documents are required:
 - CQF043 filled out by requestor with Validator, Author, and Director of Metrology signatures.
 - Redlined documents showing the changes to the old revision document. This can be done by drawing a single line through the text and initialing/dating the new changes or by using change tracking software.
 - Contact the QA Manager to obtain a soft copy of the latest revision source file.
 - Electronic copy of corrected copy sent to Quality Manager.
 - Remove old Electronic Signatures and dates
- D) Changes or deletions to a controlled document shall only be made by the author, the engineer, or appropriate quality personnel. If technicians identify an issue with a controlled document, they should bring that issue to the notice of the Author/Engineer/QA Manager or document the issue per HCQ068 Nonconformance Procedure.
- E) All changes are filed in the QA document files by Document Name.

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4.3.4.3 Changes in DMS

A) The QA Manager is responsible for updating the DMS in Foxpro by performing the following:

- Archiving the old revision document (Source File) per [Section 4.3.5.4](#).
- Placing the new approved revision document with Electronic signature/dates in the appropriate Source file folder in \\us-amf-fs01-p.danahertm.com\workgrps\Calibration Documents\grponly\
- Placing a new .pdf/view file in the appropriate file folder in \\us-amf-fs01-p.danahertm.com\workgrps\Calibration Documents\public\
- Edit/Update the revision, revision log, Owner, Author, Location , the new review date and due date in the Master List in Foxpro>Hart>Document Mgmt>Calibration Master List.

4.3.4.4 The revision numbers are sequential beginning with zero (0).

4.3.4.5 Correction of the following types of errors without changing revisions is acceptable.

- A) Typographical
- B) Formatting
- C) Duplication
- D) Accreditation Expiration date (i.e. HCQ009)
- E) Names/Roster (i.e. CQF044)

4.3.4.6 The final decision for the assigning of revision numbers and new approval of a document is left to the Director of Metrology and Quality Manager. The decision is based on the guidelines provided in this manual.

4.3.5 Invalid or Obsolete Document

4.3.5.1 In DMS, invalid or obsolete documents are archived.

4.3.5.2 Invalid or obsolete documents are removed from all points of issue or work.

4.3.5.3 Obsolete documents retained for either legal or knowledge preservation are marked as “history” or “archived”.


4.3.5.4 The archived source file is placed in the appropriate history folder on the server and is not accessible to unauthorized personnel. Access to these documents can only be gained by contacting the QA Manager.

4.3.6 Document Backup

4.3.6.1 All controlled documents and any additional documents stored on the company servers are differentially backed up every night.

4.3.6.2 Normal backup of the company servers is scheduled weekly.

4.3.6.3 Backup tapes are removed from the premises daily.

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4.3.7 Document Disposal

4.3.7.1 When controlled documents require disposal, they are thrown away, shredded or deleted as needed to maintain confidentiality.

4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

4.4.1 General

4.4.1.1 Basic requirements for contract review are set forth in QSD111.0, Corporate Quality Manual, Section 4.2, Customer-related Processes.

4.4.1.2 The review process follows the general guidelines set forth in the corporate document, LWI 212.8, CSS Contract Review Process.

4.4.1.3 The purchase order review process specific to the Calibration Program is set forth in HCI015, Calibration Program Purchase Order Review Instructions.

4.4.1.4 The only work that can commence without differences resolved is work that is not NVLAP Accredited or is outside the scope of such Accreditation.

4.4.2 Review

4.4.2.1 Routine Calibrations

- A) A Routine Calibration is defined as a calibration for which Fluke Electronics Corporation, American Fork, has an existing Model Number.
- B) Requests, tenders, and contracts for calibrations are processed through Customer Care Center or Technical Support.
- C) The calibration is designated on the Sales Order by the current model number.
- D) Special customer requests, excluding custom calibration requirements, are outlined specifically in the note section of the Sales Order.
- E) Customer specified calibration intervals shall be explicitly described in the note section of the Sales Order.

4.4.2.2 Custom Calibrations

Custom calibrations are defined as any calibration outside those activities as outlined by normal procedures or a defined model number.

The Director of Metrology or an appropriate designee reviews the requirements, including the methods to be used and uncertainties desired, to ensure they are adequately defined, documented and understood. The review ensures that methods used do not compromise sound metrological principles and uncertainties do not go beyond the scope of accreditation.

4.4.3 Differences

4.4.3.1 The customer is contacted verbally or in writing to resolve the differences between the request/tender and the contract.

4.4.3.2 Verbal differences resolved with the customer and accepted by American Fork are noted by initialing and dating each exception on the Purchase Order.

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4.4.3.3 Written/E-mail differences resolved with the customer and accepted by American Fork are attached to the Purchase Order.

4.4.4 Amendments

4.4.4.1 Amendments/Pertinent discussions with the Customer are recorded in the Special Notes section of the Sales Order.

4.4.4.2 Amendments/Pertinent discussions with the Customer are communicated to all personnel via the special notes section of the Sales.

4.4.5 Records

4.4.5.1 Records of Contract Reviews are maintained per FHS001.

4.5 SUBCONTRACTING OF TESTS AND CALIBRATIONS

4.5.1 No tests or calibrations shall be subcontracted.

4.6 PURCHASING SERVICES AND SUPPLIES

4.6.1 HCQ011 Purchasing of Calibration Program Services and Supplies Procedure.

4.6.2 CQF011 Calibration Program and Activities Approved Supplier Log.

4.6.3 Per HCQ011, ISO-017025:2005 Accredited Suppliers do not require an on-site evaluation as long as their accreditation is current. These Suppliers are listed on the ASL (Approved Supplier List) per CQF011.

4.7 SERVICE TO THE CUSTOMER

4.7.1 At the discretion of the Director of Metrology, Fluke Electronics Corporation, American Fork, is willing to provide our Calibration Customers with access to and witnessing of calibrations performed at our facility per company policy.

4.7.2 Net Promoter Score (NPS) Surveys

4.7.2.1 Two weeks after a serviced instrument is returned back to the customer, the customer is contacted through e-mail asking them to provide feedback on our level of service. The e-mail includes a link that the customer can click on taking them to the Fluke NPS web survey.

4.7.2.2 Once the NPS survey is completed, it triggers an e-mail to the corporate quality coordinator.

4.7.2.3 All unfavorable responses (0 to 6) trigger a customer complaint to be entered into the Fluke ClearAudit system (Customer Feedback Database). This in turn requires action from the appropriate person to follow up with the customer as well as to take corrective action to prevent a recurrence.

4.7.2.4 At the end of each month, a report is generated which shows all of the responses for the given month. These reports are sent to each of the Fluke lab managers.

4.8 COMPLAINTS

4.8.1 Customer complaints are handled through ClearAudit system under the corporate document, Complaints 001, #D2016410, Fluke Quality Feedback Action System Complaint Work Instructions.

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4.9 CONTROL OF NONCONFORMING TESTING AND/OR CALIBRATION WORK

4.9.1 HCQ068 Calibration Program and Activities Non-conformance report

4.9.1.1 HCQ068 contains the instructions for completing and processing the non-conformance report, CQF068.

4.9.2 The Director of Metrology and/or the QA Manager depending on the severity/cause of the Non-conformance decide whether HCQ024 Corrective Action Procedure is implemented directly rather than HCQ068 Calibration Program/Activities Non-conformance Procedure/Report.

4.9.3 Manufacturing/Assembly non-conformances are processed outside of the scope of HSQ003, Calibration Program and Activities Manual.

4.9.4 Customer calibration failures/non-conformances are processed as described in the appropriate calibration procedure.

4.9.5 If investigation of the nonconformance indicates that calibration personnel have been involved in any activity that violates the stipulations of Section 4.1.3, the Director of Metrology and/or the Business Manager, Temperature, is notified and appropriate actions taken.

4.9.6 Fluke Calibration, American Fork – Primary Temperature Lab Equipment Calibration Failures

4.9.6.1 When Calibration Equipment is found to be out of tolerance, a calibration failure evaluation will be performed to determine the impact on instruments calibrated by the out of tolerance Equipment. The out of tolerance evaluation shall be completed according to the Metrology System Out of Tolerance Procedure (HCQ007).

4.9.6.2 When during the course of use, the performance of test equipment is suspect; HCQ068 Non-conformance Report Procedure is implemented.

4.9.6.3 When during an interim check performed according to HCI001, Cal Lab Interim Check Instructions or HCI002, Factory Interim Check Instructions, the UUT (Unit under Test) is suspect, HCQ068 Non-conformance Report Procedure is implemented.

4.10 IMPROVEMENT

4.10.1 Refer to Sections 1, 4.11, 4.12, 4.14, 4.15 and 5.9 for specific improvement procedures/activities.

4.11 CORRECTIVE ACTION

4.11.1 HCQ024 Corrective Action Procedure

4.12 PREVENTATIVE ACTION

4.12.1 The Preventive Action Meeting is held in conjunction with the annual Management Review.

4.12.2 Management shall determine potential nonconformities and their causes from the following processes:

4.12.2.1 Cal Lab Manager – SPC/Analysis of Calibration Data

4.12.2.2 Director of Metrology – Benchmarking of other Calibration Companies/processes

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4.12.2.3 QA Manager – QA Management System

4.12.2.4 All – Other potential nonconformities/causes.

4.12.3 Actions resulting from the meeting will be initiated, monitored and verified using the Corrective Action Procedure, HCQ024.

4.13 CONTROL OF RECORDS

4.13.1 FHS001 Fluke Fluke Electronics Corporation, American Fork, Division Document Control and Retention Policy.

4.14 INTERNAL AUDITS

4.14.1 HCQ037 Internal Audit Procedure

4.15 MANAGEMENT REVIEWS

4.15.1 General

4.15.1.1 This Management Review Procedure outlines the review process utilized by top management to review the Calibration Program/Activities and Quality System in accordance with requirements outlined in ISO 17025:2005.

4.15.1.2 The Management Review is scheduled, performed and reviewed under the direction of the Business Manager, Temperature.

4.15.2 Personnel

4.15.2.1 Management Reviews will include the applicable management, laboratory and quality personnel

4.15.3 Review Process

4.15.3.1 The initial step in the process is to review the most recent Management Review records to determine the effectiveness of the results of the last review including the corrective actions resulting from the review.

4.15.3.2 The Management Review of the laboratory will take account of all sections listed in Management Review Form CQF065.

4.15.3.3 A management review will be held each fiscal year.

4.15.4 Results

4.15.4.1 Any findings from management reviews and the actions that arise from them are recorded and implemented in accordance with HCQ024 Corrective Action Procedure.

4.15.4.2 The results and findings of the review are formally recorded on the Management Review Form, CQF065

4.15.5 Records

4.15.5.1 A file is maintained of management review activities per FHS001. All applicable information for the year pertinent to the calibration laboratory or other calibration activities within the company will be included.

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4.15.6 Timeframe

- 4.15.6.1 All actions that are deemed necessary by management during the review to be completed are given an appropriate due date agreed upon by the management review team and action item owner.
- 4.15.6.2 Action item due dates are recorded as part of 4.15.6.1 above and then follow the notification/escalation process outlined in HCQ024 Section 4.1.3 until closed.

5 TECHNICAL REQUIREMENTS

5.1 GENERAL

- 5.1.1 There are many factors that contribute to the accuracy and consistency of calibration reports produced through the Calibration Program and Activities. These factors include human competency, accommodations and environment, methodology and validation, equipment, measurement traceability, and handling of standards and calibration items.

5.2 PERSONNEL

- 5.2.1 Training shall be conducted in accordance with HCQ039, Calibration/Test Training Procedure.
- 5.2.2 The complete job descriptions for the managerial, technical and key support personnel are in separate documents on the Fluke Word Wide Website.

5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

5.3.1 Accommodation and Access to Calibration Areas

- 5.3.1.1 The Primary and Secondary Calibration Labs are NVLAP accredited calibration areas and have restricted access. No signs are posted for these areas.
- 5.3.1.2 The IR Lab is a NVLAP accredited calibration area and has restricted access. Access to this area is restricted through the location. No walkthrough is logistically capable. A sign is posted at the entrance to the IR calibration area designating it as a restricted calibration area.
- 5.3.1.3 A designated calibration area in production may be separated from other production areas with "blue tape" at the Production Manager's discretion. Signs are posted in these areas to restrict access.
- 5.3.1.4 Access to designated restricted areas is limited to:
 - A) Laboratory personnel;
 - B) The appropriate calibration technician(s) for the area;
 - C) Appropriate production personnel or those individuals with specific needs to interact with laboratory personnel.
- 5.3.1.5 At no time is a designated calibration or test area used as a walkway or unlimited access area.
- 5.3.1.6 Incompatible operations are separated.

5.3.2 Environmental Conditions

5.3.2.1 The temperature and relative humidity of Calibration areas is controlled, monitored, and recorded. The defined conditions are as follows:

Calibration Area	Temperature	Humidity
Calibration Primary Laboratory Rooms 1 and 2	23°C ± 2 °C	20% to 55 %
Calibration Primary Laboratory Rooms 3 and 4	23°C ± 4 °C	below 60 %
Calibration Secondary Laboratory	23°C ± 2 °C	20% to 55 %
Calibration IR Laboratory	23°C ± 3°C	below 60%
Thermometry/Repair	23°C ± 2°C	15% to 60%
IR Room 1	23°C ± 3°C	below 60 %
Production	23°C ± 4 °C	below 60 %

5.3.2.2 Description of System

All areas where ambient conditions are controlled are monitored using Model 1620A Thermo-hygrometers (loggers) and the LogWare III Client/Server software (LogWare). All loggers are connected to the network. The LogWare server (data storage) files and client application (client) are installed on a computer designated as the Environmental Monitoring Server (server).

The LogWare client software runs on the server computer and records real-time ambient conditions data from all loggers in the designated areas. These real-time log sessions are configured with the appropriate high/low alarm settings for each area, which are recorded with the measurement data. All data is stored in the central data storage system on the server. The real-time log sessions on the server are also configured to send e-mail notifications of out of control conditions to the appropriate personnel for each area as the data is being recorded.

The LogWare client software is installed on a minimum of one computer in each designated area. On this computer, LogWare's Remote Monitoring feature is used to allow technicians to view the data being logged in the area in real-time. Audible alarms are setup to alert the technicians for out of control conditions.

5.3.2.3 Cal-One Calibration Software

The Cal-One calibration software includes features to monitor the ambient conditions for the designated area in real-time while performing calibrations by accessing LogWare's data storage system directly. Cal-One is designed to automatically suspend all testing if the ambient conditions are found out

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of control, and resume testing after the equal amount of time has elapsed when ambient conditions have come back into control up to a maximum of 8 hours. Cal-One does not observe the “or overnight, whichever is less” clause.

5.3.2.4 Environmental OOC (Out of Control) process (excluding 5.3.2.3 above).

- A) Technician is notified by LogWare system alarm from designated PC that the area is environmentally out of control.
- Designated PC’s are to have LogWare open and alarms activated at all times.
 - The alarm will cease once the area is environmentally in control and the LogWare system auto-resets.
 - The e-mail alert system is used for backup only.
- B) The technician stops calibration work and notifies area Owner.
- C) The Owner reviews OOC condition, calculates the time Calibration work can resume and completes the Environmental OOC Log. (<\\us-amf-fs01-p.danahertm.com\workgrps\ISO9000\qrponly\Environmental\OOC Environmental Log.xls>)
- Calibration work will cease until such time as the environmental conditions are within the specified limits for a period equal to the out of limits period or overnight, whichever is less.
 - The point of the overnight soak is to allow work to resume in the morning the day after control is regained after control has been lost for a long period of time (several days for example).
 - If the environment is oscillating it should be considered out for the entire period.
 - Any deviations to 5.3.2.4.C above are to be documented per HCQ068 (Non-conformance report).
- D) The Owner informs the Technician when Calibration work can be resumed/restarted.

5.3.2.5 Instruments that are adversely affected by vibration are stored and used in such a manner as to isolate them from its effects.

5.3.2.6 The temperature and humidity in the receiveing and shipping staging areas are monitored and recorded but are not controlled.

5.3.3. Housekeeping

5.3.3.1 General

Measurement area housekeeping is such that conditions are conducive to good laboratory practices. Efforts are made to control dust, dirt, and debris. Unused documents, literature, and computer accessories are filed or stored to avoid accumulation. Spills shall be wiped up immediately.

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5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION

5.4.1 Calibration Procedures

5.4.1.1 Written calibration procedures are used in the performance of all routine calibration activities. The procedures are validated and approved. The technician will use the current, approved revision. A list of calibration procedures applicable to the laboratory is included in the Calibration Program and Activities Documentation Master List. The procedures contain at least the following:

- A) Appropriate identification as to the Document Name and the Document Description.
- B) The scope should be unambiguously stated.
- C) A clear description of the applicable instruments to be calibrated or tested.
- D) The range and calibration tolerance or target uncertainties of item being calibrated including pass/fail calculations at test points, where appropriate.
- E) The generic description of all items needed in performance of the calibration instruction. The description includes specifications pertaining to the parameters of use.
- F) Representative types (manufacturer/model) of items described above.
- G) Reference to the applicable environmental requirements as outlined in HSQ003, Section 5.3.2.1.
- H) Ensure that any required stabilization times are outlined.
- I) Detailed instructions which outline the steps necessary in performance of the calibration instruction including any checks required prior to starting the calibration process, i.e. calibration equipment in working order.
- J) Any safety precautions are to be clearly outlined.
- K) Criteria for acceptance/rejection of the instrument calibration, i.e. shunt resistance criteria.
- L) Statement of what data is to be recorded and analysis methodology and transition to FoxPro or other transfer of data to the calibration report.
- M) The uncertainty evaluation as an appendix or attachment.

5.4.1.2 As outlined in Section 4.3.3.1 and 4.3.1.3 the procedures are available to all personnel on-line at all times. For convenience, current written calibration procedures, manuals, and reference data relevant to the laboratory are kept in the applicable work area.

5.4.1.3 One-off Calibrations

- A) For one-off instrument calibrations, written calibration procedures are not available. The calibration is performed using methods that are considered acceptable in the metrological discipline involved. Whenever

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practical, these methods should follow nationally or internationally published procedures.

- B) The method used is described on the Report of Calibration in a clear and concise manner and an uncertainty analysis must be performed if traceability is claimed.
 - C) All one-off calibration methods shall be approved by the customer prior to performing the calibration. Written acceptance by the customer in the form of an e-mail or other document shall be filed with the Report of Calibration.
 - D) One-off calibration methods shall be validated according to Section 5.4.4 prior to performing the calibration.
- 5.4.1.4 Data collection is performed according to the guidelines in the HCI010, As Found Data Instructions.
- 5.4.1.5 Deviation from routine calibrations is discouraged. When deviations occur, they are considered Custom Calibrations and are addressed in accordance with Section 4.4.2.2 Custom Calibrations with regards to the Review of Requests, Tenders and Contracts.
- 5.4.1.6 Adjustment Policy
- A) Automated calibrations: Under normal circumstances, UUTs that are calibrated on automated test stations are adjusted during the course of calibration whether or not the UUT is found to be in tolerance. In these cases, as left data is taken
 - B) Manual or semi-automated calibrations: When, during the course of calibration, the UUT indication is found to exceed 80% of its allowable tolerance, it is adjusted or aligned unless an exemption has been specifically designated in the calibration instruction for the instrument or family of instruments or the customer has designated that no adjustment is to be performed. If adjustment is performed, As Left data is taken
 - C) Guard banding: Guard band limits are established for each instrument according to manufacturer's recommendations or the best available information about the long term performance of the instrument. The purpose of the guard band is to ensure that once the instrument has been adjusted, it will remain within specifications for the entire manufacturer's recommended calibration interval. The guard band limits apply to as left conditions and generally do not exceed 80% of the accuracy specification.
 - D) Guard band exemptions: Certain instruments are exempted from the guard band limits due to performance limitations. In these cases, the test or calibration instructions specifically designate the exemption and the technical rationale.

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5.4.2 Calibration Program Scope

5.4.2.1 Scope of Accreditation

Calibration Program capabilities with regards to NVLAP accreditation are documented in the scope of NVLAP accreditation, NVLAP Lab Code 200348-0.

5.4.2.2 Work outside the published scope of the laboratory is evaluated by the Director of Metrology or designee on a case by case basis. Work that is believed to be within the capabilities of the laboratory and that is commercially viable is generally accepted. As applicable, the procedure for custom calibrations and contract review in [Section 4.4](#) is to be followed.

5.4.3 Method Determination

5.4.3.1 Procedures are based on current scientific literature pertinent to the process.

5.4.3.2 With the exception of custom calibrations or client specified instructions, all calibration procedures are internally generated.

A) The development of calibration procedures for use in the laboratory are in conjunction with the planned activity of the laboratory.

B) The development of calibration procedures are only assigned to qualified personnel. The table in [Section 4.1.6.8](#) indicating the designated signatories also indicate who is qualified to develop specific procedure types.

C) As the planned activities of the laboratory change, applicable calibration procedures are updated or developed. These changes are communicated to all applicable personnel.

5.4.3.3 The customer determines the calibration method by selecting the appropriate “model number” from the published calibration options. No calibrations can be performed in the laboratory without a specified model number.

5.4.3.4 The calibration procedures are linked with specific model numbers ensuring that each customer ordering a particular model number receives the selected method of calibration.

5.4.3.5 When an obsolete method or procedure is requested by the customer, the customer is encouraged to select a current procedure or directed to a different laboratory that will utilize obsolete procedures. Work required to use an obsolete procedure is not accepted by the laboratory.

5.4.4 Validation of Methods

5.4.4.1 All calibration procedures are validated prior to approval and implementation.

5.4.4.2 Records of the validation and the results obtained are retained. The validator signs the Calibration Instructions Revision Form, CQF043, indicating that the validation is complete and the procedure is fit for the intended use. All records of the development and validation of the procedure are retained with the signed form.

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5.4.5 Estimation of Uncertainty Measurement

5.4.5.1 Uncertainty Analysis

Various techniques exist which are considered acceptable in determining and reporting measurement uncertainty. Most of these techniques are discussed in detail in ANSI/NCSL Z540-2-1997, "U.S. Guide for the Expression of Uncertainty in Measurement". It is the general policy of this laboratory to rigorously apply the most current methods of uncertainty evaluation at the time that the evaluation is undertaken for a specific calibration procedure. The method which is considered (by the developer of the calibration procedure and the technical manager) as most appropriate for the given procedure is used. When applicable for the type of equipment calibrated, deemed necessary to the customer for the calculation of their uncertainty budget, and the uncertainty for a calibration has been evaluated using one of these accepted methods, the uncertainty will be reported on the Report of Calibration.

Uncertainty analyses are controlled in the DMS the same as a controlled document.

5.4.5.2 Test Uncertainty Ratio (TUR)

The calibration test uncertainty ratio is often used to show the relationship between the calibration uncertainties and the UUT calibration tolerances. A minimum ratio of 4:1 is considered by many to be a requirement for compliance to ANSI/NCSL Z540-1. Use of a test uncertainty ratio does not imply that the uncertainty has not been evaluated. Rather, it implies that the level of calibration uncertainty is acceptably small as compared to the UUT calibration tolerance. When practical and TURs are used, the calibration uncertainty shall not exceed 25% of the acceptable tolerance for each characteristic being calibrated (test uncertainty ratio of 4:1). In these instances, the uncertainty ratio may be stated on the Report of Calibration in addition to or in lieu of the measurement uncertainty.

5.4.6 Control of Data

5.4.6.1 Calibration data including calculations and data transfers are subject to appropriate checks. The checks may be part of the automated calibration system. However, the final check is conducted before the Report of Calibration is signed by the person performing the calibration and the approval signatory.

5.4.6.2 In utilization of an automated calibration process involving computer acquisition of data, the laboratory will ensure that:

- A) The computer software is sufficiently documented to enable calibration technician use.
- B) The computer software is suitably validated to ensure calibration integrity utilizing the procedure outlined in HCS006, *Calibration Software Final Validation Instructions*.
- C) Data generated in the calibration process is protected to ensure the integrity and confidentiality of the data entry or collection, storage, transmission or processing by limiting access to the databases where

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the data is stored. Access is limited by password control in the editing of the Report of Calibration.

- D) Calibration/testing technicians are trained on the integrity of the calibration data. Any calibration/testing technician caught tampering with, destroying, or in any way changing any calibration/test data, i.e. raw data or report data, is subject to discipline as outlined in [Section 4.1.3](#). This discipline may include removal of status as a calibration technician or dismissal as determined by the Director of Metrology and the Business Manager, Temperature.
- E) Computers and automated equipment utilized in calibration data acquisition, generation, and storage are maintained in proper working order and environmental conditions required to preserve the integrity of the data.

5.4.6.3 In utilization of an automated calibration process involving computer (Mathcad, Excel) processing of data, the laboratory will ensure that:

- A) Director of Metrology, Calibration Lab Manager, and Metrologists are the only personnel allowed to make changes to the software.
- B) In cases where the software does not record revision changes, a revision change log will accompany the current version of software and contain as a minimum:
 - Change revision.
 - Initials of person authorized to make the change.
 - Date the change was made.
 - Description of the change.
- C) HCS001, Cal SW Final Validation Instructions, is used to validate any new processing software implementation.

5.5 EQUIPMENT

5.5.1 General

- 5.5.1.1 The Foxpro System includes a Calibration Management System (CMS). The CMS incorporates a database of all measurement standards and M&TE used or supported by the metrology program and is used, in part, to support the recall program ([Section 5.5.7](#)).
- 5.5.1.2 Equipment shall only operated by authorized personnel using the latest instructions on use and/or maintenance of the equipment.
- 5.5.1.3 Relevant manuals for operation of the equipment shall be readily available to appropriate lab personnel.
- 5.5.1.4 In the process of completing calibration measurements, the laboratory does not use any equipment that is outside of its permanent control.
- 5.5.1.5 Before placing equipment into service, the equipment is calibrated or checked to ensure that it meets the laboratory's requirements. For standards calibrated by approved laboratories, i.e. standard resistors, the

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calibration report is checked to ensure that the instruments meet the laboratory requirements.

- 5.5.1.6 Equipment that has been mishandled, is malfunctioning, or giving suspect results will have the status changed in the Cal Login system to avoid inadvertent use. A visible indication that the equipment shall not be utilized shall be placed on the instrument. Once the instrument has been repaired, recalibrated, or verified that it is operating correctly, the Cal Login system shall be updated and the visible indication removed.
- 5.5.1.7 If an investigation of the equipment indicates that the defect affects previous test and/or calibrations, HCQ007, OOT Procedure, shall be utilized.
- 5.5.2 The laboratory tries to control all equipment and does not normally allow equipment to be taken outside the direct control of the laboratory. If equipment is taken outside the control of the laboratory, it is checked to ensure that it meets applicable specifications before the laboratory utilizes it to perform calibration work.
- 5.5.3 When applicable, intermediate checks required to ensure confidence in the calibration or operating status of the equipment are completed in accordance with HCI001, Cal Lab Interim Check Instructions and HCI002, Factory Interim Check Instructions.
- 5.5.4 Protection and/or update of calibration constants
 - 5.5.4.1 When calibrations include adjustments that produce a new set of calibration constants, the applicable calibration personnel ensures that the correct calibration constants are entered in to his/her system.
 - 5.5.4.2 For automated test software that calculates and uploads the new calibration constants to the instrument eliminating the possibility of human error, the applicable calibration personnel review the constants against the Report of Calibration to ensure their accuracy.
 - 5.5.4.3 For most test equipment manufactured by Fluke Electronics Corporation, American Fork, there is firmware control to the access of calibration parameters. This control is deemed sufficient for trained personnel or personnel involved in OJT. Non-trained personnel are not allowed to access these parameters.
- 5.5.5 Storage and transport of test equipment
 - 5.5.5.1 The handling, transport, storage and use of test equipment are extremely important to the integrity of the calibration. As part of the training for calibration technicians, the use and care of test equipment is emphasized.
 - 5.5.5.2 Only authorized personnel handle test equipment.
 - 5.5.5.3 All test equipment is stored in a designated storage area applicable to that standard. The designated storage area ensures that the test equipment is not subjected to anything that could cause contamination or deterioration of the reference standard.
 - 5.5.5.4 Any test equipment found to be stored improperly are removed from service as outlined in [Section 5.5.1.4](#). The calibration personnel in that area are informed of the removal of the equipment. The equipment is not returned until it has been verified that the integrity of the calibration has not been

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compromised and that future calibration work performed with the equipment shall not be compromised.

5.5.5.5 Transport of calibration instruments within American Fork may only be undertaken by authorized personnel. The technician ensures that the instrument is transported in such a manner as to ensure that the instrument is not damaged in any way that could affect the integrity of the calibration, i.e. SPRTs and PRTs are hand-carried from the manufacturing area to the calibration laboratory by trained personnel who ensure that the probe does not incur any mechanical shock.

5.5.6 Definition of M&TE and Measurement Standards

5.5.6.1 M&TE is defined as devices or systems used to calibrate, measure, gage, test, inspect, or control in order to determine compliance with design, specifications, or other technical requirements.

5.5.6.2 M&TE does not include permanently installed operating plant equipment, nor test equipment used for preliminary checks where the data obtained will not be used to determine acceptability nor be the basis for design or engineering evaluation.

5.5.6.3 Measurement standards are devices used to measure or calibrate M&TE and other standards or otherwise determine compliance with prescribed technical requirements. Measurement standards are used in a calibration program and establish the basic accuracy limits for the program. Measurement standards are also known as reference standards.

5.5.6.4 A description and current status of the M&TE is part of the CMS.

5.5.7 Identification and Controls for Inventory/Recall

5.5.7.1 Measurement standards and M&TE are identified by model number-serial number combination.

5.5.7.2 A recall list is generated by the QA Manager which lists all American Fork owned measurement standards and M&TE coming due. Lists may be generated as frequently as needed. This list is used to recall calibrations.

5.5.7.3 Measurement standards and M&TE that are overdue for calibration are labeled or segregated to avoid inadvertent use. (In this context, the term “use” designates use as outlined in 4.5.6.1.)

5.5.7.4 The CMS will not allow an overdue measurement standard to be listed as a standard in the calibration of M&TE or other standards.

5.5.7.5 For emergency purposes, it is permissible that calibration due dates be extended. The extension is predicated on the likelihood that the instrument will remain in tolerance during the extension interval. This determination requires that the most recent calibration resulted in an “As Found” condition of “In Tolerance”. The extension action is recorded on Form CQF018 by the Director of Metrology or Calibration Lab Manager only.

5.5.8 Calibration Intervals

The Director of Metrology or Calibration Lab Manager shall approve the initial recall interval and subsequent adjustments to the interval.

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- 5.5.8.1 The initial recall interval is based on the manufacturer specifications, the customer recommendations, industry standards, or historical data (i.e. required accuracy, purpose, frequency of usage, stability of characteristics, and repair history).
- 5.5.8.2 The initial recall interval shall be assigned and entered into the CMS with the associated equipment information.
- 5.5.8.3 Change in recall interval: The reduction or lengthening of a recall interval shall be based on the criteria listed in Section 5.5.8.4 and Section 5.5.8.5. A Calibration Interval Change Form (CQF016) shall be completed for each interval change. The form is filed with the applicable calibration report.
- 5.5.8.4 Recall interval reduction: Recall intervals are shortened by 50% after two consecutive out of tolerance calibrations. Recall Intervals for customer owned equipment are not shortened without authorization from the customer.
- 5.5.8.5 Recall interval lengthening: Recall intervals may be lengthened by 50% after three consecutive in tolerance calibrations. Recall Intervals for customer owned equipment are not lengthened without authorization from the customer.
- 5.5.8.6 The reliability target for calibration standards is 86.7% (approximately 1.5σ).

5.5.9 Labels and Seals

5.5.9.1 In-house Standards

Status labels shall be affixed to all calibrated M&TE and measurement standards or their containers (when it is impractical to apply the label directly to the item). The label shall include as a minimum, the item identification number, the date calibrated, and the initials or stamp of the individual who performed the calibration. The calibration interval shall be completed as indicated in Section 5.5.8. The labels used are listed below.

5.5.9.2 Customer Calibrated Standards

The calibration labels for customer instruments are attached to the certificate rather than be affixed to the instrument allowing the customer can affix the label to the instrument.

5.5.9.3 “Calibrated” label shall be used to designate routine calibration.

5.5.9.4 “Calibrated with Report” label shall be used to designate that the item has a Report of Calibration which includes information or data required for proper use of the item. The label shall include the report number pertinent to the calibration.

5.5.9.5 “Limited Calibration” label shall be used to designate that the calibration may be incomplete and/or done to specifications other than the manufacturer’s specifications. The label shall include a description of the limitation or a reference to where that information is located. In cases where “Calibration with Report” and “Limited Calibration” apply, the “Calibration with Report” label shall be used and the report shall state the limitation.

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5.5.9.6 “System Calibration - Calibrated As Part of and Must Be Used With” label shall be used to designate when a thermometer readout device and a probe thermometer are calibrated as a system and should not be separated. Each instrument shall receive an identical label.

5.5.9.7 “Do Not Use not Calibrated” label shall be used to designate that the item is not to be used as outlined in Section 5.5.1.4.

5.5.9.8 “No Calibration Required” label shall be used to designate that the item does not require calibration. Instruments with this label shall not be used to take quantitative data.

5.5.9.9 “Void if Broken” Calibration seals shall be used when practical to prevent unauthorized tampering with internal calibration adjustments. These seals serve no purpose with “soft-cal” instruments and need not be used on these types of items.

Note: Soft-cal is defined for instruments where the calibration is controlled by firmware and access to the calibration constants is protected by the firmware.

5.5.9.10 Equipment with a broken tamper-resistant seal shall be removed from service. A “Do Not Use not Calibrated” label shall be placed on the unit until the unit is checked or recalibrated.

5.5.10 Equipment Maintenance

All equipment shall be maintained according to the HCQ008, Calibration Laboratory Equipment (including M&TE) Maintenance Procedure and HCI008, Factory Calibration Equipment Maintenance Instruction.

5.6 MEASUREMENT TRACEABILITY

5.6.1 Calibration of Reference Standards

5.6.1.1 The use, handling, calibration and maintenance of all reference standards is covered in Section 5.5.

5.6.2 The traceability of measurement and reference standards is established and maintained as follows:

5.6.2.1 Top level reference standards such as primary fixed point cells are evaluated and/or calibrated directly by an N.M.I. with appropriate levels of uncertainties for the needs of Fluke Electronics Corporation, American Fork,

5.6.2.2 Working level reference standards such as working fixed point cells are calibrated in-house against primary fixed point cells according to assigned procedures.

5.6.2.3 Ancillary reference standards such as Reference resistors, Chilled mirror hygrometers and long scale DMM’s are calibrated either in-house if American Fork possesses the capability or at accredited laboratories when American Fork does not possess the capabilities.

A) Accredited Laboratories are listed in HCQ009 Calibration Program and Activities Approved Supplier Log.

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- 5.6.2.4 Working level reference and measurement standards such as SPRT's are calibrated in-house against higher level working standards according to assigned procedures.
- 5.6.3 Measurement and reference standards exhibit traceability through an unbroken chain to one or more of the following.
 - 5.6.3.1 Standards maintained by the National Institute of Standards and Technology or other accepted national laboratories.
 - 5.6.3.2 Intrinsic standards.
 - 5.6.3.3 Ratiometric calibration techniques.
 - 5.6.3.4 Consensus standards.
- 5.6.4 Traceability diagrams are maintained for the following disciplines. Each traceability diagram is part of the QA Document System.
 - 5.6.4.1 HCQ001 Resistance
 - 5.6.4.2 HCQ002 Standard Platinum Resistance Thermometers (SPRT)
 - 5.6.4.3 HCQ003 Thermocouples
 - 5.6.4.4 HCQ004 Platinum Resistance Thermometers (PRT) and Thermistors
 - 5.6.4.5 HCQ005 Infrared
 - 5.6.4.6 HCQ006 Humidity
- 5.6.5 Intermediate checks for reference standards are scheduled per HCI001, Cal Lab Interim Check Instructions, and the factory standards per HCI002, Factory Interim Check Instructions.
- 5.7 SAMPLING
 - 5.7.1 The Calibration Program does not permit sample testing
- 5.8 HANDLING OF TEST AND CALIBRATION ITEMS
 - 5.8.1 Customer Calibrations on Sales Orders
 - 5.8.1.1 Packaging contents shall be inspected for physical damage and agreement with shipping documents. Any abnormalities shall be recorded on the Repair Depot notes field and the Customer shall be contacted when necessary to determine resolution of discrepancies.
 - 5.8.1.2 A Work Order is generated which will accompany the item until completion of work.
 - 5.8.1.3 The calibration item is delivered to the appropriate staging area where it is entered into the queue and stored until the item is brought into the calibration lab for calibration.
 - 5.8.1.4 All instruments are tracked through the model and serial number. The identification through model and serial number shall be maintained throughout the life of the product.

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Note: It is the Supervisor's discretion to facilitate the use of tags to retain the identity throughout the life of the item in the laboratory, i.e. SPRTs are tagged with an identification tag that stays with the instrument throughout the calibration cycle.

- 5.8.1.5 The model, serial number, and customer are utilized to ensure that items cannot be confused physically or when referred to in records or other documents.
- 5.8.1.6 At the time of calibration, any abnormality that can affect the calibration results for the specified calibration method shall be noted.
- 5.8.1.7 If there is doubt as to the suitability of the instrument for calibration, the calibration method requested, or the instrument does not match the description provided, the customer shall be contacted for more information and instructions before proceeding with the calibration. Customer service shall note the discussion with the new instructions and forward that information to the applicable laboratory personnel.
- 5.8.1.8 The instruments shall be handled and stored in the laboratory in such a way as to avoid deterioration or damage to the instrument.
- 5.8.1.9 Any handling instructions provided by the customer shall be followed unless the laboratory personnel determine that the instructions could endanger the instrument or the integrity of the calibration. In this case, the customer shall be contacted and the handling process discussed.
- 5.8.1.10 The staging areas for the laboratory, the in-lab storage, the applicable laboratory area for the calibration, and shipping staging areas are all environmentally monitored as necessary to ensure the integrity of the calibration and prevent damage to the instrument.
- 5.8.1.11 Upon completion of an acceptable calibration the item and associated documentation is delivered to the shipping staging area.
- 5.8.1.12 From the shipping staging area it is taken to FGI (Finished Good Inventory) where it awaits invoicing and packaging for delivery to the customer.

5.8.2 In-house Calibrations (No Sales Order)

- 5.8.2.1 Refer to Section 5.5.5

5.9 ASSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

- 5.9.1 In addition to criteria pertaining to instrument specifications, calibration and test procedures include criteria relating to the quality of the data intended as a check on the validity of that data. Examples of this would be limitations on the standard deviation allowed before the data is considered valid or limitations on the magnitude of the calibration coefficients (correction factors) required for a digital readout to meet specification.
- 5.9.2 Calibration data is checked for internal consistency using known relationships within a given instrument or among instrument families. Examples of this would include the correlation of W_{Hg} and W_{Ga} for an individual SPRT and inclusion within a range of values expected for W_{Sn} among a given family of SPRTs.

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5.9.3 The results of all tests and calibrations are reviewed for compliance and validity by at least two qualified individuals, the technician or metrologist who performed the test/calibration and the approval authority.

5.9.4 Interim Checks and Statistical Process Control

5.9.4.1 Control Charts are managed per the Control Chart Procedure (HCQ115).

5.9.4.2 Other laboratory processes employ statistical process control (SPC) techniques using check standards to monitor the stability of the calibration process. These processes are documented within each individual calibration procedure. If and when the process goes out of control, calibrations are halted and an investigation is undertaken. Calibrations will continue only after control is reestablished.

5.9.4.3 Most laboratory reference standards are routinely checked against other reference standards as a verification of continued performance. When possible, these checks are performed in situ.

5.9.4.4 Interim checks are performed according to the interim check instructions, HCI001, Cal Lab Interim Check Instructions, and HCI002, Factory Interim Check Instructions.

5.9.5 Redundant data

5.9.5.1 When possible redundant measurements are taken during the course of calibration and the results of redundant data are verified against the results of other calibration data. If the results exceed expectations then an investigation is undertaken. For example, an SPRT calibrated over the range triple point of water to freezing point of zinc requires the following fixed point cells – triple point of water, freezing points of tin and zinc only. The calibration procedure specifies that the redundant points; melting point of gallium and freezing points of indium; be included as quality checks. Details are contained in the individual calibration procedures.

5.9.6 Interlaboratory Comparisons and Proficiency Tests

5.9.6.1 Fluke Electronics Corporation, American Fork maintains interlaboratory comparisons with Hart Scientific-Norwich.

5.9.6.2 Third Party Interlaboratory comparisons for temperature calibration are rare. The laboratory participates when these programs become available and the laboratory is invited to participate.

5.9.6.3 The laboratory participates in the NIST NVLAP Proficiency Test program for SPRT calibration. This program constitutes the only proficiency test available for SPRT calibration at this time.


5.10 REPORTING OF RESULTS

5.10.1 General

5.10.1.1 The results of each test or calibration performed under the umbrella of the Calibration Program are reported accurately, unambiguously and objectively according to the application test or calibration instructions. A list of applicable procedures is referenced in the Calibration Master list.

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- 5.10.1.2 For internal customers or in the case of a written contract requirement for an external customer, the results of the calibration may be reported in a simplified manner. Any information normally collected and provided to the customer is maintained and readily available. In-house Calibration Reports are reported in a simplified manner.
- 5.10.2 Opinions and Interpretations
- 5.10.2.1 The Calibration Program reports factual data only, opinions and interpretations are not offered to the customer. Therefore, no personnel are authorized to offer opinions and interpretations.
- 5.10.3 Reports of Calibration
- 5.10.3.1 Reports of Calibration are used to present the results of a calibration.
- 5.10.3.2 Each Report of Calibration has a unique report number.
- 5.10.3.3 When the approver's name is not printed on the Report of Calibration the approver is to stamp his/her name and function under their signature using the stamp provided.
- 5.10.4 Amended Reports of Calibration
- 5.10.4.1 Reports of Calibration may not be amended with additional data.
- 5.10.4.2 No "Calibration Report Supplements" may be issued.
- 5.10.4.3 Changes to a calibration report are handled through the revision process.
- 5.10.5 Revisions to Reports of Calibration
- 5.10.5.1 FoxPro Calibration Software programmed to facilitate revisioning:
- A) Concatenated to the unique report number is a revision number which shall be for tracking and internal audit trail and shall be considered an indication of revision to the original report.
- 5.10.5.2 Foxpro Calibration Software not programmed to facilitate revisioning:
- A) New report number generated:
- Original report must be changed to indicate "Invalid Report" in the Customer Address Section of the report.
- B) Original Report Revised
- The revised report must indicate reason for the revision in the remarks section.
 - Not applicable if the original report has not been shipped or left the building and can be replaced/destroyed.
- 5.10.6 Duplicate or Corrected Reports of Calibration
- 5.10.6.1 Duplicate Reports of Calibration provided to the customer are stamped with a "Duplicate Copy" stamp.
- 5.10.6.2 Corrected Reports of Calibration provided to the customer are stamped with a "Corrected Copy" stamp.

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- A) Stamping “Corrected Copy” on revisioned Calibration Reports (See Section 5.10.5.1.A is not required unless requested by the Customer.

5.10.7 Customer Equipment Calibration Failures

5.10.7.1 When, during the calibration process, customer instruments are found to be out of tolerance, the customer is notified and provided with associated measurement data as follows:

- A) If calibration data was not requested by the customer, an out of tolerance received condition is noted on the Report of Calibration and the out of tolerance data will be provided upon request.
- B) If calibration data was requested by the customer, an out of tolerance received condition is noted on the Report of Calibration and the out of tolerance data is identified.
- C) The tolerance condition of characterized transducers, such as thermistors, PRTs, etc. cannot be determined without previous data. The tolerance status of characterized transducers may be provided, upon customer request, when previous calibration data is available and a performance specification has been provided. Otherwise the report will reflect the status “recalibration” and the tolerance status determination will be the responsibility of the customer.
- D) If the instrument has been calibrated previously by Fluke Electronics Corporation, American Fork, the difference between the current calibration and previous calibration may be reported to the customer as a service. Tolerance status determination is the responsibility of the customer.

5.10.8 Calibration Intervals

5.10.8.1 The Calibration Program does not make any recommendations on calibration interval. For selected instruments, Fluke Electronics Corporation, American Fork, as an OEM, recommends a calibration interval based on the design of the instrument.

- A) As an OEM, Fluke Electronics Corporation, American Fork, may state the recommended calibration interval for new products. The Sales, Terms and Conditions states this in order to clarify for the customer that new products will be shipped with the OEM-recommended calibration interval.
- B) The Fluke Electronics Corporation, American Fork, catalog states this practice clearly in the applicable section.

5.10.8.2 Reports of Calibration

- A) Reports of Calibration follow the practice outlined. Reports generated for new products indicate the OEM recommended calibration interval unless otherwise indicated by the customer.
- B) The Report does not indicate a calibration interval for items sent in for recalibration unless requested by the customer in the purchase order or noted in the Return Material Authorization (RMA). This is indicated by

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“Not Defined” in place of the Calibration Due Date on the Report of Calibration.

5.10.8.3 Calibration Labels

- A) The calibration status label follows the practice outlined. Labels generated for new products indicate the OEM recommended calibration interval.
- B) For items sent in for calibration, the calibration status label due date is not completed by Fluke Electronics Corporation, American Fork, personnel unless requested by the customer in the purchase order or noted in the Return Material Authorization (RMA).

6 REFERENCES

- 6.1 Fluke Electronics Corporation, American Fork, Documents
 - 6.1.1 “Scope of NVLAP accreditation (NVLAP Lab Code: 200348-0)”
 - 6.1.2 Fluke Electronics Corporation, American Fork, Published Catalog
 - 6.1.3 Fluke Electronics Corporation, American Fork, Published Price List
- 6.2 Fluke Documents
 - 6.2.1 QSD 111.50 Records Retention Policy
 - 6.2.2 LWI 212.8 CSS Contract Review Process
 - 6.2.3 QSD 111.0 Corporate Quality Manual
 - 6.2.4 Complaints 001 Fluke Quality Feedback Action System Complaint Work Instructions
- 6.3 NIST Documents
 - 6.3.1 NIST Handbook 150, 2006 Edition.
 - 6.3.2 NIST Technical Note 1297-1994 Edition, “Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results.”
- 6.4 Other Documents
 - 6.4.1 NCSL/ISO/IEC 17025:2005, “General Requirements for the Competence of Testing and Calibration Laboratories.”
 - 6.4.2 ANSI/NCSL Z540-1-1994, “Calibration Laboratories and Measuring and Test Equipment-General requirements.”
 - 6.4.3 NCSL Z540-1 Handbook, “Handbook for the Interpretation and Application of Z540-1-1994.”
 - 6.4.4 ANSI/NCSL Z540-2, “U.S. Guide to the Expression of Uncertainty in Measurement.”
 - 6.4.5 MIL-STD 45662A, “Calibration System Requirements.”
 - 6.4.6 MIL-HDBK 52B, “Evaluation of Contractor’s Calibration System.”