

# Quality Manual for Fluke Customer Support Services (CSS)

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This Quality Manual may be released to customers as an uncontrolled document.



**Fluke Corporation**  
Everett, Washington

## **Fluke's Quality Policy**

To create and maintain a quality system of continuous improvement of key work processes focused on customer expectations.

## **Fluke's Customer Support Service Quality Policy**

*The Fluke Customer Support Services team is committed to deliver the Fluke Brand Promise by providing exceptional quality and support services through continuous improvement of efficient worldwide processes.*

*Fluke Customer Support Services management is committed to good professional practices as established by industry standards, Fluke corporate and local quality system processes and documentation in compliance with ISO 9001 and ISO 17025.*

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## Authorization Approvals

An electronic authorization approval in the Tem Center system is the preferred method for revision control. Signature approvals are optional.

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## Distribution

Printed copies of this document are uncontrolled and users must verify the revision is current before use. All previous revisions must be discarded. Current documents and revision index are available on Fluke's Intranet.

## Document Change Record

**NOTE:** Documents new to the Team Center system start at Revision 001, documents under a previous Rev. Control system going into the Team Center system begin at Rev. 100. All change history should be reflected in the change history block of the new system. Changes are reflected by the use of italics text in the body of the document.

<b>REV/ DATE</b>	<b><u>BRIEF DESCRIPTION OF CHANGE(S)</u></b>
001 April 2006	Combined LPD 300 – Technical Quality Manual for Everett Service Center Rev 003 LPD 301 – Technical Quality Manual for Dallas Service Center Rev 001 Updated to reflect ISO 17025:2005 Standard
002 August 2006	Changes to each specifies section are in italics 4.1.1 Updated names 4.1.3 Updated section 4.1.4 Updated section 4.1.5 Added repair technicians 4.2.4 Added section 4.3.2 Updated section 4.4.3 Updated section 4.5.1 Added Section 4.5.2 Updated section 4.6.1 Added Lab Manager or Technical Lab Manager 4.6.3 Clarified items that affect calibration 4.10.1 Added Section 5.2.2 Para. 3 added “being performed” 5.3.2 Para. 3 added online system 5.4.4 Updated section 5.4.6 Updated section 5.9.1 Updated section 5.9.2 Updated section 5.9.3 Updated section 5.10.2 Added electronic signatures 5.10.6 Updated section
003 March 2007	Updated references from PDM and Sherpa to Team Center  Quality Policy – Added Fluke Customer Support Services Quality Policy 4.3.2 Updated location of Master List for Dallas 4.5.1 Corrected language 5.9 Added Proficiency Testing personnel requirements 6.0 Added procedure for who manages A2LA logo use  Added Information for Canada Service Center Added CLAS Requirements  5.3.2 Added link to EVL Temperature and humidity records  4.8 Added Fluke Canada CFS system regarding complaints
004 June 2007	Bumped revision due to Team Center issue for approvals  2 and 4.8 Added CSS FEC LPD 410 Customer Feedback Process for Fluke Canada LP

**1. PURPOSE AND SCOPE**

This Quality Manual defines or identifies the policies, procedures and requirements of the Fluke Customer Support Services (CSS) Management System. The purpose of the CSS Management System is to:

1. Contribute to Fluke product quality by furnishing high quality product support throughout its lifecycle.
2. Meet our customer's contractual requirements, stated or implied needs. Ensure their instruments and replacement parts meet specifications. Provide confidence to our customers that their requirements for quality are being fulfilled.
3. Create a customer-focused environment where our services and key work processes are continuously improved using the required resources.
4. Meet the ISO 17025 and ISO 9001 Standards and Corporate Quality Policy.

This Quality Manual may be sent to customers as an uncontrolled copy. Some documents referenced by this manual are company confidential, and may not be copied and distributed outside the company.

**2. REFERENCE/SUPERSEDE**

This document supersedes the previous revision as stated on Change Record page.

- ANSI / ISO 17025-2005 (hereafter referred to as ISO 17025)
- ANSI / ISO 9001:2000 (hereafter referred to as ISO 9001)
- NIST TN 1297
- A2LA Advertising Policy
- A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories
- CAN-P-4E - ISO/IEC 17025-2005
- ANSI/INCIS. Z540.1 – 1999 (2002)
  
- Fluke Quality System Documents (QSDs)
  - QSD 111.0 Corporate Quality Manual
  - QSD 111.2 Corporate Training
  - QSD 111.39 Product Data & Configuration Management Manual
  - QSD 111.44 Calibration System
  - QSD 111.50 Record Retention Policy
  - QSD 111.4 Supply Chain Quality Assurance Requirements
  - QSD 111.3 VOC (Voice of the Customer)
  - QS-001 Internal Audit Procedure
  
- CSS Local Process Documents (PD's)
  - CSS LPD 401 CSS Document, Record & Data Control
  - CSS LPD 402 CSS Approved Supplier List (ASL)
  - CSS LPD 403 CSS Training Requirements
  - CSS LPD 430 CSS Modular Exchange (MEC)
  - CSS PD 104 Writing Automated Calibration Procedures
  - *FEC LPD 410 Customer Feedback Process for Fluke Electronics Canada LP*

- Applicable Service Center Local Work Instructions (LWI's)
  - CSS LWI 100 Call Center
  - CSS LWI 110 Handling, Shipping and Receiving
  - CSS LWI 121 Contract Review
  - CSS LWI 180 OOT Conditions and Notifications

**3. TERMS AND DEFINITIONS**

CAR	Correction Action Request
CFS	Customer Feedback System
CSS	Customer Support Services
DBS	Danaher Business System
DG	Business system for Canada Service Center
LWI	Local Work Instruction
Oracle	Business system for Everett and Dallas Service Centers
PD (or LPD)	Local Process Document
PDM	Product Data Management (also referred to as Sherpa)
QAR	Quality Assurance Representative
QMS	Quality Management System
QSD	Quality System Document (corporate)
RMA	Return Materials Authorization
SI	International System of Units
SQDIP	Safety, Quality, Delivery, Inventory and Productivity Chart
Team Center	Corporate Document Control System
VOC	Voice of the Customer

**4. MANAGEMENT REQUIREMENTS**

**4.1 Organization**

- 4.1.1 The Fluke Everett Service Center, Fluke Dallas Service Center and Fluke Canada Service Center are part of Fluke Corporation, a wholly owned subsidiary of Danaher Corporation.
- 4.1.2 The purpose of the Laboratory Quality Management system is to ensure that the operations of the Calibration Laboratory conforms on a continuing basis to the requirements of the ISO 17025 Standard/ A2LA Accreditation body *and the CLAS Accreditation body*, in conjunction with the Corporations ISO 9001 quality system.
- 4.1.3 All work carried out by the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities are handled in accordance with this CSS Quality System document.
- 4.1.4 The CSS Lab Organization Charts located at w:\cssdoc\public\CSS\_Org\_Chart\_LAB.doc illustrate the management structure for the Customer Service Centers and their relationship to the Corporation.
- 4.1.5 The areas of responsibility for the Calibration Laboratory are as follows:

**Laboratory Manager** has the overall responsibility for the achievement of budgeted targets including revenue profitability, overhead and cash flow management. They are also responsible for ensuring the provisions of adequate resources and financial controls and deal with personnel and staffing issues.

**Laboratory Technical Manager** has responsibility for the overall management of the Calibration Laboratory. They are responsible for ensuring compliance with ISO 17025 and the A2LA or CLAS requirements. They are also responsible for the verification and approval of measurement procedure and the determination of uncertainties. The Everett Laboratory Technical Manager does not report directly to the Laboratory Manager.

The Dallas Laboratory Technical Manager does report directly to the Laboratory Manager due to the field location, but interacts extensively with Corporate Metrology personnel.

The Canada Laboratory Technical Manager does report directly to the Laboratory Manager due to the field location, but interacts extensively with Corporate Metrology personnel.

**Laboratory Technical Deputy** has responsibilities for reviewing calibration results and approving certificates of calibration and proposing changes to calibration procedures in the absence of the Laboratory Technical Manager.

**CSS Quality Coordinator / Manager** has responsibility for implementing and maintaining the effectiveness of the company's ISO 9001 Quality Management System. Responsibilities include administration and management of document control, Internal Audits, Customer Complaints, in addition to conducting the Quality System Management Reviews. The CSS Quality Coordinator / Manager does not report directly to the Laboratory Manager.

**Technicians** have the responsibility for repair and/or calibration of in-house and customer instruments following approved procedures.

Upon review of the organization, no potential conflicts of interest have been identified.

Personnel review daily their contribution to the management system objectives through daily cell stand-up meetings and review of each cells SQDIP and Daily Progress.

- 4.1.6 Top management ensures communication through daily, cell stand-up meetings; weekly, lab Stand-Up Meetings; and, monthly Corporate "Fresh Sheet" communications.

## 4.2 Management System

- 4.2.1 The Calibration Laboratory documents its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the calibration results. The system's documentation is communicated to, understood by, available to and implemented by the appropriate personnel.
- 4.2.2 This document defines the management commitment to good professional practices, the standard of service, objectives of the Management system, requirements for training on the quality process and documentation system and the management's commitment to compliance with the ISO 17025 and ISO 9001 standards.
- 4.2.3 Top management utilizes yearly strategic planning, Value Stream Mapping and DBS tools to continually improve the effectiveness of the Management system.
- 4.2.4 Top management utilizes staff and stand-up meetings to communicate to the organization the importance of meeting customer requirements and needs as well as statutory and regulatory requirements.
- 4.2.5 The LPD 401, CSS Document, Record and Data Control outlines the CSS documentation structure, including the supporting procedures and technical procedures of the laboratory.
- 4.2.6 The roles and responsibilities of the Laboratory Technical Manager and the Quality Coordinator / Manager are outlined in this document (see 4.1.5).
- 4.2.7 Top management ensures management system integrity during planned changes by ensuring the responsible parties are included in the implementation and final review of process changes. Integration Teams, Lab Metrology Meetings and Lab Staff Meetings are some examples of on-going groups that monitor Management system integrity.

## 4.3 Document Control

- 4.3.1 General

The Laboratory uses the documentation control procedures outlined in QSD 111.39, Product Data & Configuration Management Manual and CSS LPD 401, CSS Document, Record and Data to control all laboratory documents and procedures.

#### 4.3.2 Document approval and issue

The approved signatories for the labs will be the Lab Manager, Technical Manager or Deputy as identified per the organizational chart, the Quality Coordinator or QAR (Quality Assurance Representative) and other designees.

The issuing of the company's Quality Manuals and procedures will be via the "Team Center System". The "Team Center System" is the electronic document management system for the company's ISO 9001 Quality system documents and is administered by the Corporate Quality Manager. The Laboratory documents are first authorized by the approvers listed above and then passed, in electronic format to the CSS Quality Coordinator / Manager for distribution. The current revision status is readily available from the system to ensure that invalid or obsolete documents are not used.

A master list of the Everett Laboratory Technical Procedures along with their latest issue and issue dates is located at w:\callab\. A master list of the Dallas Laboratory Technical Procedures along with their latest issue and issue dates is located at r:\Documents\public\Proc Files drive. A master list of the Canada Laboratory Technical Procedures along with their latest issue and issue dates is located at r:\ drive.

The CSS associates are responsible for ensuring that the latest revision of the document is being used.

The Laboratory Technical Manager has responsibility for maintaining any hard copies of controlled documents where these are required for reference purposes.

#### 4.3.3 Document Changes

Amendments to documents will be via the "Team Center System". Amendments are first authorized by the approvers listed, who then pass the documents in electronic format to the CSS Quality Coordinator/Manager for recording the changes and for distribution.

Amendments to documents must be identifiable: this may be by the use of revision history page, italicized text or by detailing the changes directly on the "Team Center System".

Hand-written amendment of a procedure is permitted at the discretion of the Laboratory Technical Manager. Such amendments must be written clearly in permanent ink and require the specific authorization and dated signature of the Laboratory Technical Manager or Deputy. Hand-written amendments will be incorporated into a revision of affected document as soon as is practicable.

### 4.4 Review of Requests, Tenders and Contracts

4.4.1 Contracts are reviewed according to LWI 100, Call Center and LWI 121, Contract Review, in order to ensure that customer requirements are fully defined and documented and that the Laboratory has the capability and resources to meet these requirements.

Any problems or deviations from the contract must be discussed with the customer before further action is taken.

4.4.2 All records of reviews, including any significant changes are maintained in Oracle or DG for the life of the order and retained per QSD 111.50, Records Retention Policy.

4.4.3 Subcontracted 17025 accredited calibrations are done in accordance with Section 4.5 of this document.

Non Accredited calibrations that are sub-contracted, are performed in accordance with CSS LPD 402 Approved Supplier List (ASL).

4.4.4 If it becomes clear that the customer requirements cannot be satisfied, the customer will be notified immediately.

4.4.5 Contracts that require additional review after the work has begun will follow the above processes, including additional communication with the customer, as required.

## 4.5 Subcontracting of Tests and Calibrations

ISO 17025 accredited calibrations subcontracting:

The laboratory can subcontract accredited calibrations to competent subcontractors. A competent subcontractor is a laboratory that meets the following requirements:

- The Laboratory is accredited by an Accreditation Body signatory of a Mutual Recognition Agreement (MRA) for mutual acceptance of calibration data with one of the following Accreditation Systems:
  - Asia Pacific Laboratory Accreditation Cooperation (APLAC);
  - European Cooperation for Accreditation (EA);
  - Inter-American Accreditation Cooperation (IAAC);
  - International Laboratory Accreditation Cooperation (ILAC);
  - *Calibration Lab Assessment Service (CLAS)*.
- It is an ISO 17025 accredited Fluke Service Center or is part of the Accredited Approved Supplier List (ASL) in accordance with CSS LPD 402.

Prior to the subcontract, the laboratory will advise the customer of the arrangement and obtain their approval, when possible, in writing.

The laboratory will maintain a record in the ASL (Approved Supplier List) of the evidence of compliance with ISO 17025 standard of the subcontractors for the work in question.

### 4.5.1 Non ISO 17025 accredited calibrations subcontract

Non Accredited calibrations that are sub-contracted, are performed in accordance with CSS LPD 402 Approved Supplier List (ASL).

Prior to the subcontract, the laboratory will advise the customer of the arrangement in writing and obtain his approval, when possible, in writing.

The subcontractor shall issue the calibration certificate to the contracting laboratory.

4.5.2 In both cases the subcontractor shall issue the calibration certificate to the contracting laboratory. The originals are archived and preserved in the laboratory for future reference if necessary. They should be preserved as per the quality records requirements.

## 4.6 Purchasing Services and Supplies

4.6.1 The Corporate Supply Chain organization qualifies vendors used for purchased products, replacement parts and consumables as documented in QSD 111.4, Supply Chain Quality Assurance Requirements. Calibration Services are qualified through the policies and procedures documented in CSS LPD 402, CSS Approved Suppliers. Any equipment /standards used for accredited calibrations must be approved by the Laboratory Manager or Laboratory Technical Manager.

4.6.2 The laboratory uses very few consumable items that could affect the outcome of a calibration. Items such as oil for the resistor baths and cables, if bought as specified in the relevant calibration procedure, do not require inspection before use. If an item is purchased that has not been specified on a drawing or in a procedure, it will be verified against the purchase order before use.

4.6.3 Purchasing documents are maintained by the Corporate Supply Chain organization. Technical approval is required prior to purchase items that affect calibration.

4.6.4 When required to purchase critical consumables, the laboratory will evaluate the suppliers, maintain evaluation records and provide and approved list of suppliers.

## 4.7 Service to the Customer

4.7.1 The laboratory will provide reasonable access to the customers or their approved representative so that they may monitor the calibration of their instrument(s). Any such monitoring must be by prior

arrangement with the CSS Quality Coordinator / Manager or their designee. Care will be taken to ensure the confidentiality of other customer's work in progress. Access may be refused at specific times to ensure such confidentiality.

The laboratory will also provide reasonable access to staff for further information regarding calibration matters and technical issues.

- 4.7.2 Customer feedback, using On-Line Customer Reply Cards, provides service and communication with the customer. The On-Line Reply Cards are automatically entered into a database to capture the customer information. Any On-Line Reply Cards with comments or a rating below a three (3) are automatically e-mailed to the CSS Quality Coordinator /Manager for Resolution through the CFS System, outlined in 4.8.

#### 4.8 Complaints

A customer complaint may be received verbally or in writing. Complaints will be captured in the Customer Feedback System (CFS) and monitored in the Voice of the Customer (VOC) according to QSD 111.3, Voice of the Customer.

The Canada Service Center captures customer feedback in accordance *LPD 410 FEC Customer Feedback Process* and conducts regular review meetings of all customer feedback.

#### 4.9 Control of Nonconforming Testing and / or Calibration Work

- 4.9.1 Out-Of-Tolerance (OOT) Forms will be completed per LWI 180, Out-Of-Tolerance Conditions and Notification.

Where it is believed that previous calibrations could be in error, the Laboratory Management will determine the type and form of the customer notification that must take place, and if necessary, the instruments recalled.

All customers' instruments and calibration certificates that are still on the premises must be held until it is proven that they were not affected by the problem.

If calibration work has been halted, work cannot resume until authorized by the Laboratory Technical Manager or Deputy.

- 4.9.2 If preliminary investigation indicates a systemic problem with the calibration process, all related calibration work must stop until the cause and extent of the problem is known and the appropriate corrective action has been taken.

#### 4.10 Improvement

- 4.10.1 The laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analyses of data, corrective and preventive actions and management review.

#### 4.11 Corrective Action

- 4.11.1 General

Corrective actions will be taken in response to identified non-conformities in products, production equipment, processes, measuring and testing equipment and the Management system itself. Corrective Action may be identified through policy deployment, countermeasures, or through the use of the corporate Corrective Action Request (CAR) system.

- 4.11.2 Cause Analysis

Corrective action will include, per QSD 111.39, Corrective Action Requests (CAR):

- Problem description
- Root cause
- Authorization
- Actions plan(s) to eliminate problem

- 4.11.3 Selection and Implementation of Corrective Actions

Corrective action taken to eliminate the causes of actual non-conformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

If any in-house measurement standards or M & TE have been affected, they shall be removed from service until the effect of the out-of-tolerance condition has been corrected. The Senior Metrologist / Laboratory Technical Manager or appointed delegate shall authorize a return to service.

#### 4.11.4 Monitoring of Corrective Actions

Corrective action effectiveness shall be monitored with visual management charts and/or process improvements and via monthly Lab and CSS WW Operations Reviews.

#### 4.11.5 Additional Audits

When there is doubt regarding the laboratories compliance with its own policies and procedures, the laboratory shall ensure that appropriate areas are audited in accordance with this document.

### 4.12 Preventative Action

4.12.1 Opportunities for improvements and potential sources of non-conformities are identified. The Danaher Business System (DBS) and the DBS Kaizen tools are some of the methods utilized to identify areas for improvements. The DBS Tools are available on the Danaher Corporate intranet. The corporate CAR (Corrective Action Request) Tool also can be utilized to maintain Preventive Action Plans and monitor improvements.

4.12.2 Countermeasures and / or action plans are developed, implemented and monitored to ensure the effectiveness of the preventative action.

### 4.13 Control of Records

#### 4.13.1 General Procedures

Procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records are detailed in QSD 111.50, Records Retention Policy.

#### 4.13.2 Technical Records

Technical records are maintained through a variety of electronic formats, including (but not limited to), Met/Cal®, Data Proof System, Microsoft Office® tools. These records are maintained on the corporate intranet and are periodically archived by the Corporate IT group. Met/Cal® is protected by password access. Access to other technical records are only available to laboratory technicians by network controlled access.

### 4.14 Internal Audits

Internal audits are carried out in accordance with a pre-determined schedule and procedure to verify that the operations comply with the requirements of the Management system and ISO 17025.

Procedures regarding internal auditing are found in QS-001, Quality Systems Internal Audit Procedures.

### 4.15 Management Review

4.15.1 Separate Management Review will occur at least once per year with the CSS Laboratory Manager and staff (to include, at a minimum, Supervisors, CSS Quality Coordinator / Manager and Laboratory Technical Manager) to assess opportunities for improvement and the need for changes to the quality management system, including quality policy and quality objectives. These reviews ensure continuing suitability, adequacy and effectiveness of the Management system as a whole.

CSS Management review will include at a minimum the following:

- The CSS Quality Coordinator / Manager Report
- Process performance

- Changes that could effect the Quality Management System (Danaher Business System (DBS) review)
- Follow up actions from previous Management Review meetings
- Status of preventive and corrective actions
- Internal & external quality audit results
- Customer Reply Card data / Customer Feedback
- Policy Deployment
- Training needs analysis
- Analysis of the results of interlaboratory comparisons or proficiency testing
- Recommendations for improvement

CSS Management review output will include at a minimum the following:

- Any decisions or actions related to:
  - Improvement of the QMS and its processes
  - Improvement of product related to customer requirements
  - Resource needs

4.15.2 Management Review minutes will note any adverse trends and any subsequent decisions to correct those trends and will summarize the topics reviewed and include any corrective and preventive actions.

Action items or plans which may result from Management Review are communicated to affected personnel.

## 5. TECHNICAL REQUIREMENTS

### 5.1 General

The laboratory takes into account the various factors that effect the calibrations.

These factors include:

- Human factors
- Environmental and accommodation conditions
- Test and calibration methods and validation methods
- Equipment
- Measurement traceability
- Handling of test and calibration items

### 5.2 Personnel

5.2.1 The Calibration Laboratory will use only permanent staff who have been trained, and have demonstrated competence to perform specific calibration work. Temporary or part time staff may be used, however staff who are temporary or undergoing training must be closely supervised by qualified staff.

5.2.2 The Laboratory Technical Manager is responsible for ensuring that all staff involved in 17025 calibrations receives training appropriate to their current and future responsibilities.

Training needs are reviewed and monitored by the Laboratory Technical Manager and the Service Center Manager. Everett monitoring is achieved through the "Skill Matrix". Dallas monitoring is achieved through the "Training Sheet". Reviews will take place annually, at a minimum. Canada monitoring is achieved through a Training Sheet.

It is the policy of the Fluke to send its Laboratory Staff to any course that is deemed to be of benefit to the Fluke and is directly related to work being performed.

Training alone does not ensure competence. After appropriate training, the Laboratory Technical Manager or Deputy will determine competency. Competence is determined after talking with the instructor, looking at the results of the training and reviewing the Skill Matrix or Training Sheet. The Skills Matrix or Training Sheet will be signed off during the assessment period and upon the determination of competency.

CSS LPD 403, CSS Training Requirements, outline training requirements and effectiveness of training for all staff in the Laboratory.

Records are kept and maintained for all staff. Training is recorded using the Corporate Training Database and the CSS Training File.

5.2.3 The Laboratory Staff must not be involved in activities that could lead to a conflict of interest, or in any way diminish the confidence in the quality of the laboratory's work.

5.2.4 Job descriptions are available for all staff. Job descriptions are maintained by the Human Resources (HR) department, and are available on the Fluke Intranet. Job Descriptions include, at a minimum:

- The responsibilities with respect to performing calibration
- The responsibilities with respect to planning calibrations and the evaluation of the results
- The responsibilities with respect to procedure/method modification and development and validation of new methods
- Expertise and experience required
- Qualification and training programs

Job Descriptions used in the Laboratory: (but not limited to)

- Administrator, International Order II
- Administrator, Sales Support II
- Administrator, Sales Support Sr.
- Assembler Sr.
- Clerk, Packaging and Shipping III
- Coordinator, Production and Development Associate
- Coordinator, Quality
- Engineer, Sales Support – Assoc.
- Metrologist, Senior
- Technician, Electronic I
- Technician, Specialty Assoc.
- Technician, Specialty
- Technician, Specialty Sr.
- Technician, Specialty Chief
- Supervisor, Domestic Order Processing II
- Supervisor, Laboratory
- Service Center Manager

### 5.3 Accommodation and Environmental Conditions

5.3.1 The Calibration Laboratory facilities are maintained in such a way as to not adversely affect the outcome of any calibration work carried out.

5.3.2 The Calibration Laboratory environmental conditions are controlled, monitored and recorded to ensure that they meet the required quality for the temperature and humidity. QSD 111.44, Calibration Systems, outlines the environmental conditions required for the laboratories. The Calibration Lab is a Type 2 lab while the remainder of the Service Center is maintained as a Type 3 lab.

Everett monitoring is accomplished by an on-line system with probes in various locations. The on-line system alerts the technicians and leads immediately of an out-of-tolerance condition. There is a back-up system to manually track the environmental conditions if required. Electronic records can be found at `W:\srs\public\bldg4HumidityHumidityNT.exe`

Dallas monitoring of the Type 2 lab is accomplished by an on-line system with probes at various locations. The on-line system alerts the technicians and leads immediately of an out-of-tolerance condition. There is a back-up system to manually track the environmental condition if requires. The Type 3 lab areas are monitored via the on-line system or by chart recorders.

Canada monitoring is accomplished through chart recorders in the laboratory.

All calibration work will stop when the environmental conditions jeopardize the validity of the result of any calibration. Work will not commence until authorized by the Laboratory Technical Manager or Deputy.

Environmental records are maintained for the Laboratory by the Quality Coordinator /Manager or the QAR (Quality Assurance Representative):

- Hardcopies are filed and retained only if the on-line system failed (Dallas and Everett)
- Hardcopies are filed and retained (Canada)
- On-line records are archived and kept permanently

- 5.3.3 The Calibration Lab (Type 2) is enclosed and separated from the rest of the Service Center by double-doors to prevent cross-contamination.
- 5.3.4 Access to the Calibration Laboratory is restricted to lab assigned personnel, those having immediate business or those being escorted by CSS personnel.
- 5.3.5 Housekeeping in the Calibration Laboratory is accomplished internally by 5S and externally by the contracted custodial services for Fluke.

## 5.4 Test and Calibration Methods and Method Validation

### 5.4.1 General

The method used for calibration greatly influences the uncertainty that can be achieved. For some calibrations, the laboratory may have multiple procedures for the calibration of the same instrument or quantity. The laboratory shall use appropriate methods and procedures for the calibration to achieve the desired uncertainties and to meet the customer needs.

### 5.4.2 Selection of methods

Generally, the method is not specified by the customer and is responsibility of the laboratory to select the appropriate method. However, the customer will sometimes specify the method or the standards to which the calibration must comply. The lab will determine if it is capable of performing the calibration, using the method specified and if it is the appropriate method for this calibration. The customer will be informed in the case that the method proposed by the customer is found inappropriate or out of date.

The laboratory shall have procedures or instructions such as manufacturer's operator's manuals for its equipment. These procedures and instructions shall be maintained current for the calibration. When manuals are used for calibration methods of customer equipment, the revision of the manual or other instructions shall be a part of the calibration record. When necessary, appropriate manuals will be downloaded, borrowed, purchased, or requested from the customer. Deviations from the test method shall be technically justified, documented, and communicated to the customer for his authorization and/or acceptance by the customer.

- 5.4.3 The laboratory may develop its own methods or use those which have been published in national or international standards or in the technical literature.

The development of calibration methods is the responsibility of the Laboratory Technical Manager. The methods shall be planned, and reviewed by peers or technical supervision. The development shall include the calculation of uncertainties and validation.

- 5.4.4 Non-standard methods should be discussed with the customer and agreed upon. The method development must be validated before use.

5.4.4.1 The method of validation may vary for different calibrations. Methods may include one of, or a combination of, the following:

- Verification of manual procedures using another manual method or process;
- Verification of automated procedures with manual measurements;
- Verification of automated procedure with a previously released automated procedure;
- Comparison with an external calibration of the same unit;
- Interlaboratory comparisons;
- Special tests and apparatus constructed or configured for independent validation;
- Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience;
- Systematic assessment of the factors influencing the result;

The method chosen should have uncertainties comparable or better, if possible, than the system being validated.

The magnitude of the validation is function of the method or procedure complexity under review and is defined case by case by the laboratory technical manager.

Validation is documented using Form 425 CSS Cal Validation

5.4.5 The means of determining measurement uncertainty are based on NIST TN 1297. When calculating uncertainties, the laboratory shall use a coverage factor of 2 when the degrees of freedom are relatively large and shall use the effective degrees of freedom and the Student's t distribution to calculate a coverage factor corresponding to approximately 95% when the degrees of freedom are not large. All significant contributors to uncertainty shall be identified and taken into account. It is good practice to list others identified which are assumed to contribute insignificantly to the overall uncertainty to document they were not overlooked.

Paragraph 7.5 of TN 1297 is interpreted as applying to the measurement uncertainty at the time of test by the Laboratory. It shall not preclude the laboratory from stating an opinion regarding the future performance of the item. These opinions should be issued with caution and with appropriate disclaimers. They shall not be used as a "marketing tool" but to allow the laboratory's knowledge of the performance of a particular item or a class of like items to be shared for the benefit of the customer.

Certificates may be issued without uncertainties when claiming compliance with an identified metrological specification. However, those uncertainties are calculated and available to be consulted.

#### 5.4.6 Control of Data

##### 5.4.6.1 General

Calculations and data transfers must be checked in a systematic way. Manual calculations may be checked by re-inspection, during the certificate review or re-confirming with a spreadsheet. Data being input manually shall also be checked for errors. For software transfers, the integrity of the data can be checked by manual review or by integrating checking features into the system to which the data is transferred.

Software used to control instruments, acquire data, process the data and generate reports shall be validated and documented. Master copies of software will reside in the Laboratory Technical Manager's office or on networked computer systems with limited access and with IT backup support. Data should reside in local computers only until it can be uploaded to a network system. Obsolete versions are identified and archived and only the current version is available to the technicians.

Software used in PC's will normally be written using the MET/CAL® software package. The Laboratory Technical Manager may authorize software written by other means for technical or economic reasons.

Fluke considers that commercial off-the-shelf software (e.g. EXCEL®, MET/CAL®) doesn't need further validation.

#### 5.4.6.2 Software Revision

Software revision is the responsibility of Laboratory Technical Manager, and shall be undertaken by Metrology Operations or authorized personnel only with prior permission of the Laboratory Technical Manager.

No Calibration/Verification or report writing software revision or correction file revision, including revision 000, shall be authorized for use without proper review and authorizing signatures.

This procedure is documented in PD104, Writing Automated Calibration Procedures. The responsibility of the Project manager referred to in PD104 is assigned to the Laboratory Technical manager.

## 5.5 Equipment

5.5.1 The Laboratory holds all equipment necessary to perform the calibrations. All items are uniquely identified and records are maintained of their performance to ensure that they are capable of achieving the accuracy required.

5.5.2 Equipment must meet the manufacturer's specification or the equipment performance will be validated and approved by the Laboratory Technical Manager. The acceptance criteria for the calibration results is:

1)  $TUR \geq 4:1$   $E > UUT$  Specification

2)  $TUR < 4:1$   $\sqrt{E^2 + U^2} \leq UUT$  \_ Specification

Definitions:

E – Calibration result expressed as the difference from the nominal values

U – Uncertainty of calibration

TUR – calculated as the relation between the UUT specification and the expanded calibration uncertainty.

5.5.3 Authorized personnel are calibration technicians with training and/or experience on the calibration equipment. All manuals regarding the equipment are available in the Service Center.

5.5.4 All Everett Laboratory equipment is uniquely identified by a B or C number, all Dallas Laboratory equipment is uniquely identified by a J or L number and all Canada Laboratory equipment is uniquely identified by a FC number.

5.5.5 Records for each item are tracked through the Met/Track® software and/or original certificates are kept on file.

5.5.6 Procedures are available for the safe handling, storage, maintenance and calibration of all laboratory equipment. The procedures are outlined in LWI 110, Handling, Shipping and Receiving.

5.5.7 Equipment that has been subjected to overloading, mishandling or given rise to suspect results or is defective or shown to be outside specified limits will be removed from use, clearly labeled and segregated. It will not be put back into service until it has been shown to perform correctly and authorization has been given by the Laboratory Technical Manager or Deputy.

5.5.8 The calibration status of all equipment may be readily determined from a label affixed to the equipment. Equipment is safeguarded from adjustment that would invalidate the calibration results by use of integrity seals covering adjustment access holes or cover screws.

5.5.9 The Calibration Laboratory uses its own equipment. If a unit has been out of the control of the Calibration Laboratory the unit will be calibrated before using. Reference Standards will be measured before and after calibration to ensure function and calibration status are found to be satisfactory prior to returning to service.

- 5.5.10 Calibration intervals are chosen based on the equipment history and the accuracy required in taking into account of the risk of detecting performance outside of the specified limits per QSD 111.44, Calibration System.
- 5.5.11 When correction factors are required, there are two methods – automatically updated by the programs or manually moved with the equipment. This is dependent on the equipment and procedure.
- 5.5.12 Equipment is safeguarded by the use of tamper evidence seals which are affixed to access holes and cover removal screws. Software is safeguarded through read-only accessible files and drive access.

## 5.6 Measurement Traceability

### 5.6.1 General

All equipment that has an affect on the validity of any calibration work is calibrated according to a pre-determined plan and procedure. This is done using the Met/Track® system.

### 5.6.2 Specific Requirements

#### 5.6.2.1 Calibration

All measurements are traceable to the International Systems of Units (SI). This is achieved by using standards that have been calibrated by National Laboratories, other accredited Calibration Laboratories, by the use of approved ratio techniques, from accepted values of natural physical constants or by the use of check standards that are calibrated by an accredited laboratory.

#### 5.6.2.2 Testing – Not Applicable

### 5.6.3 Reference Standards and Reference Materials

#### 5.6.3.1 Reference Standards

Reference Standards must be calibrated by National Laboratories, other accredited Calibration Laboratories, by the use of approved ratio techniques, from accepted values of natural physical constants or by the use of check standards that are calibrated by an accredited laboratory. Reference Standards are not used for any other purpose *other than* for calibration.

#### 5.6.3.2 Reference Materials – Not Applicable

#### 5.6.3.3 Intermediate Checks

No intermediate checks are performed. Calibration intervals are set in such a way that there is confidence that the reference and working standards are in good condition.

#### 5.6.3.4 Transport and storage

Procedures are available for the transport and storage of all laboratory equipment. The procedures are outlined in LWI 110, Handling, Shipping and Receiving.

## 5.7 Sampling

Sampling is not currently used in the Calibration Laboratory.

## 5.8 Handling of Test and Calibration Items

- 5.8.1 Procedures are available for the transportation, receipt, safe handling, protection, storage, retention and disposal of calibration items. The procedures are outlined in LWI 110, Handling, Shipping and Receiving.
- 5.8.2 Calibration items are clearly identified by a RMA attached to the item on receipt and remains on the item. The RMA shows the item serial number, job number and information regarding the types of calibration required. The Met/Track® system will be used to record calibration information about the items. The Oracle® or DG system is used to track the order and customer information.
- 5.8.3 Upon receipt of an item, if there are abnormalities, shipping damage, no RMA, or the item is in some way not suitable for calibration, the Calibration Laboratory will contact the customer for further details. Customer contact is detailed in the “Notes” section of the Oracle or DG system.

5.8.4 Procedures and facilities are available to ensure that the unit will not deteriorate, be lost or damaged. Procedures are found in LWI 110, Handling, Shipping and Receiving.

## 5.9 Assuring the Quality of Test and Calibration Results

5.9.1 All calibration results are compared against pre-determined limits to assure quality. Additionally, the Calibration Laboratory reference standards are plotted and trends analyzed. Where practicable, other techniques are used, these include:

- Participation in interlaboratory comparisons
- Plotting an trend analysis
- Correlation of results with different characteristics/function of an item
- Repeat calibrations using the same or different methods.

The Everett and Dallas laboratories comply with the A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories. The Canada laboratory complies with the CLAS Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories.

The Technical Laboratory Manager ensures that Proficiency Testing is accomplished by an equal distribution of personnel trained and qualified for the relevant tests.

5.9.2 The quality control results are evaluated by the laboratory technical manager. If they are found outside a predefined criteria, they are treated as an OOT (out of tolerance condition) as per par. 4.9 Control of Nonconforming Testing and / or Calibration Work.

5.9.3 Providing the accreditation body with ILC/PT results

All the Interlaboratory Comparison (ILC) and Proficiency Test (PT) results are sent to the accreditation body once a year at time of renewal process unless there's an outlier or unacceptable result reported. The results are reported using the A2LA Proficiency Testing Data Submission form for the Everett and Dallas Laboratories and the CLAS Proficiency Testing Data Submission form for the Canada Laboratory.

All ILC/PT results are evaluated using the criteria described in "A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories" document. An  $E_n > 1$  is considered an unacceptable result.

$$E_n = \frac{|Lab - Ref|}{\sqrt{(U_{95Lab})^2 + (U_{95Ref})^2}}$$

Detailed corrective actions are taken if an outlying or unacceptable result is reported. In this case the result of the ILC or PT is immediately sent to the accreditation body with the respective corrective action.

## 5.10 Reporting the Results

5.10.1 General

Certificates shall report results accurately, clearly, unambiguously and objectively. The layout of the certificate will be in accordance with 17025 and A2LA requirements for the Everett and Dallas Laboratories and in accordance with 17025 and CLAS requirements for the Canada Laboratory.

Abbreviated certificates or reports may be issued to internal customers or to external customers if prior written approval has been given. If an abbreviated certificate or report is issued, any information listed in this section that is not issued, should be readily available.

5.10.2 Test Reports and Calibration Certificates

The calibration certificate shall include, at a minimum:

- Title e.g. "Calibration Certificate"
- Certificate number – a unique identification to appear on each page of the certificate

- Name and address of the Calibration Laboratory
- Page number and total number of pages
- Date the calibration was performed
- Name and address of the customer
- Identification of the methods used (e.g. procedure number)
- Unambiguous identification of the item being calibrated (Description, Model Number, Serial Number, Manufacturer)
- If requested by the customer, a statement of compliance or otherwise with a specification. Where a statement is made, the specification must be identified and the uncertainty of measurement allowed for.
- A statement that the results apply only to the item calibrated
- A statement that the Calibration Certificate will not be reproduced except in full, without written approval of the laboratory
- The name and title of the approved signatory. The certificate can only be signed by an approved signatory, approved for that type of calibration. See 17025 Approved Signer List (Lab).
- Electronic signatures may be used on certificates for the Technical Manager. Each electronic signature will be unique to one individual and controlled in the Met Base system.

In addition to the above requirement, certificates will also include:

- Any conditions that have an influence on the results of the calibration (e.g. environmental)
- Statement of Traceability
- Calibration results including the unit of measurement, the uncertainty of measurement at a stated confidence level which will normally be 95%

If a calibration certificate is issued with a specification of compliance, the Calibration Laboratory will maintain the results for future reference. Where a statement of compliance is made, the specification must be identified and the uncertainty of measurement allowed for.

When an instrument needs to be adjusted or repaired, before and after measurements will be taken and recorded if possible.

The calibration certificate will not include:

- A recommendation on the calibration interval except where this has been agreed to with the customer.

#### 5.10.3 Test Reports – Not applicable

#### 5.10.4 Calibration Certificates – see above

#### 5.10.5 Opinions and Interpretations

Opinions and interpretations, if included on the Calibration Certificate, must be clearly marked and have references to how the opinions and interpretations were formulated.

#### 5.10.6 Testing and Calibration Results Obtained from Sub Contractors

The subcontractor shall issue the calibration certificate to the contracting laboratory.

When the complete calibration work is subcontracted, the contracting laboratory reports the results to the customer in one of two ways:

- Issue of a new calibration certificate containing the data obtained by the subcontractor, with the explicit mention that the present calibration was subcontracted.
- Issue of a calibration certificate coversheet, with the explicit mention that the present calibration was subcontracted and attach a copy of the subcontractor calibration certificate.

If the laboratory only subcontracts a portion of the work, it should reports the results to the customer in one of following ways:

- Issue a calibration certificate that contains the subcontracted data, clearly identified and explicit mention that a portion of the present calibration was subcontracted.
- Issue two separated calibration certificates, one with the laboratory calibration data and the other a calibration certificate coversheet, with a copy of the subcontractor calibration certificate attached and the explicit mention that the present calibration was subcontracted.

#### 5.10.7 Electronic Transmission of Results

Certificates shall only be issued electronically if they are protected from change and meet all the requirements listed above. An example would be to issue the certificate as a protected document in a .PDF format.

#### 5.10.8 Format of Reports and Certificates

The format of the Certificates and Reports has been designed to help minimize the possibility of miss-understanding and misuse. Certificates and Reports are controlled per CSS LPD 401, CSS Document, Record and Data Control.

#### 5.10.9 Amendments to Test Report and Calibration Certificates

Amendments to a calibration certificate can be made only by:

- Issue of a complete, new certificate, with a new, unique identifier, that utilizes the original certificate number with a "-1" added and a statement that this is a replacement for certificate #\*\*\*\*\*, or
- Issue of a supplemental certificate that includes the statement "Supplement to Calibration Certificate Number \*\*\*\*\*"

Re-issued certificates should include a brief explanation for re-issue in the "Remarks" section of the Certificate.

## 6. ADDITIONAL REQUIREMENTS

### 6.1 Use of the A2LA Logo

The A2LA logo shall be used in compliance with the A2LA Advertising Policy.

The logo is controlled by the Technical Lab Managers for use of certificates and all laboratory documentation and by the CSS Quality Coordinator / Manager for use on the Fluke web sites.

### 6.2 A2LA Scope

The Accredited Scope of the Laboratory is located on the A2LA Web Site by Laboratory name and address.

Dallas Certificate Number 1899.01

Everett Certificate Number 2166-01

### 6.3 CLAS Scope

The Accredited Scope of the Laboratory is located on the CLAS Web Site by Laboratory name and address.

Canada Certificate Number 95-02