

Quality Assurance Manual Customer Support Services

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Authorization Approvals

An electronic authorization approval in the Customer Support Services (CSS) Document Control Index system is the preferred method for revision control.

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 CSS Document Control Index. This Quality Assurance Manual (QAM) may be sent to customers as an uncontrolled copy. Some documents referenced by this QAM are company confidential, and may not be copied and distributed outside the company.

Responsibility and Authority

The Quality Coordinator is responsible for the maintenance and notification to process owners of changes made to this document. Process owners must have access and maintain current revisions of each Quality Management System (QMS) document that is pertinent to their area. Notification of changes and current revisions are accessed via electronic network.

It is the responsibility of the process owner to provide training for major changes to this document (i.e.: new, total process rewrite other than format changes, changes that could significantly impact business plan, etc). This will ensure that the changes are interpreted, understood, and implemented at the appropriate levels of the organization. Once training has been performed, the process owner will provide a record of the training to the Quality Coordinator, or designee.

Document Change Record

REV/ DATE	<u>BRIEF DESCRIPTION OF CHANGE(S)</u>
001 March 2010	Previous release of document under LPD 400 D2025751 last rev 005 Complete rewrite Training: Required

1. PURPOSE AND SCOPE

This Quality Assurance Manual (QAM) defines or identifies the policies, procedures, and requirements of the Fluke Customer Support Services (CSS) Quality Management System (QMS). This QAM covers the Everett, Washington and Mississauga, Canada CSS. The purpose of the QMS is to:

- 1.1 Contribute to Fluke product quality by furnishing high quality product support throughout its lifecycle.
- 1.2 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.
- 1.3 Create a customer-focused environment where our services and key work processes are continuously improved using the required resources.
- 1.4 Meet the ISO 17025:2005 Standard and the Corporate Quality Manual.

2. REFERENCE/SUPERSEDE

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

2.1 Internal References

- 2.1.1 Approved Suppliers List
- 2.1.2 CA-001-Corrective Actions Work Instructions
- 2.1.3 Danaher Standards of Conduct
- 2.1.4 FEC LPD 401-Document, Record & Data Control
- 2.1.5 FEC LPD 410-Customer Feedback
- 2.1.6 FEC LWI 121-Contract Review
- 2.1.7 FEC LWI 110-Handling, Shipping and Receiving
- 2.1.8 LPD 301-Confidentiality
- 2.1.9 LPD 302-Document and Record Control
- 2.1.10 LPD 303-Levels of Service
- 2.1.11 LPD 304-Purchasing
- 2.1.12 LPD 305-Feedback, Complaints, Corrective Action and Preventive Action
- 2.1.13 LPD 306-Nonconforming Work
- 2.1.14 LPD 307-Control of Data
- 2.1.15 LPD 308-Management Review
- 2.1.16 LPD 310-Training
- 2.1.17 LPD 311-Metrology Procedures
- 2.1.18 LPD 312-Processing of M & TE
- 2.1.19 LPD 314-Quality of Results
- 2.1.20 LPD 315-Environmental Control and Monitoring
- 2.1.21 LWI 212.8- Contract Review
- 2.1.22 LWI 212.5-Handling, Shipping and Receiving
- 2.1.23 Organizational Charts
- 2.1.24 QS-001-Quality Systems Internal Audit
- 2.1.25 QSD 111.0 Corporate Quality Manual

2.2 External References

- 2.2.1 ISO 9001:2000 Quality management system-Requirements (hereafter referred to as ISO 9001)
- 2.2.2 ISO/IEC 17025-2005 General Requirements for the competence of Testing and Calibration Laboratories (hereafter referred to as ISO 17025)
- 2.2.3 NIST TN 1297 Guidelines for the Evaluating and Expressing the Uncertainties of NIST Measurement Results (hereafter referred to as NIST TN 1297)
- 2.2.4 A2LA Advertising Policy (P101) (http://www.a2la.org/policies/A2LA_P101.pdf)
- 2.2.5 A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories (R103)(http://www.a2la.org/requirements/A2LA_General_Requirements_for_Proficiency_Testing.pdf)
- 2.2.6 A2LA Specific Requirements Calibration Laboratory Accreditation Program (R205)(http://www.a2la.org/requirements/17025_CALIBRATION_REQ.pdf)

3. TERMS AND DEFINITIONS

- 3.1 5S - Simplify Straighten Scrub Stabilize Sustain
- 3.2 A2LA - The American Association for Laboratory Accreditation
- 3.3 ASL - Approved Supplier List
- 3.4 CLAS - Calibration Laboratory Assessment Service
- 3.5 CSS - Customer Support Services
- 3.6 DG System - Data General System
- 3.7 FEC - Fluke Electronics Canada
- 3.8 ILC - Inter-Laboratory Comparison
- 3.9 LPD- Local Process Document
- 3.10 LWI - Local Work Instructions
- 3.11 M & TE - Measurement and Test Equipment
- 3.12 NEO - New Employee Orientation
- 3.13 PT - Proficiency Testing
- 3.14 QAM - Quality Assurance Manual
- 3.15 QMS - Quality Management System
- 3.16 RMA - Returned Material Authorization
- 3.17 SI - International System of Units
- 3.18 SQDIP - Safety Quality Delivery Inventory Productivity
- 3.19 Traveler- a document which identifies the equipment and travels with equipment throughout the process

4. MANAGEMENT REQUIREMENTS

4.1 Organization

- 4.1.1 The Fluke Everett Service Center and Fluke Canada Service Center are part of Fluke Corporation, a wholly owned subsidiary of Danaher Corporation.
- 4.1.2 It is the responsibility of the respective service centers to carry out their calibration activities, when applicable, in such a way as to meet the requirements of the ISO 17025 and ISO 9001 standards, and to satisfy the needs of the customer, the regulatory authorities and the organizations providing recognition.
- 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 QAM and supporting documentation.
- 4.1.4 The laboratory's relationship to the corporate organizational structure is shown under "The Organization" button in the home page of the Fluke internal website, <http://fww.tc.fluke.com/>
- 4.1.5 The laboratory shall have

- 4.1.5.1 **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 financial controls, managing personnel, staffing issues and communicating the need for resources.

Laboratory Technical Manager has responsibility for the technical aspects of the laboratory. They are responsible for ensuring compliance with ISO 17025 requirements. They are also responsible for the verification and approval of measurement procedures and uncertainties. The Everett Laboratory Technical Manager does not report directly to the Laboratory Manager.

The Canada Laboratory Technical Manager does report directly to the Laboratory Manager due to the field location, but has the Corporate Metrology personnel available for assistance if required.

- 4.1.5.2 Management shall ensure that they and personnel of the laboratory are free from any undue internal and external commercial, financial and other influences that may adversely affect the quality of their work.
 - 4.1.5.3 It is the laboratory's policy to ensure the protection of our customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results. This procedure is documented in LPD 301 Confidentiality.
 - 4.1.5.4 It is the laboratory's policy to avoid involvement in any activities that would diminish confidence in our competence, impartiality, judgment or operational integrity. This procedure is documented in the Danaher Standards or Conduct.
 - 4.1.5.5 The organization and management structure of the laboratory, its place in our parent organization and the relationships between quality management, technical operations and support services has been defined in the related organizational charts; see section 4.1.4 of this QAM.
 - 4.1.5.6 The related organization chart specifies the responsibility, authority, and interrelationships of all personnel who manage, perform or verify work affecting the quality of the calibrations.
 - 4.1.5.7 Adequate supervision shall be provided for calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each calibration, and with the assessment of the calibration results.
 - 4.1.5.8 Laboratory Technical Manager as described in section 4.1.5.1 in this QAM
 - 4.1.5.9 The Quality Coordinator is responsible for ensuring that the QMS is in compliance with the ISO 17025 standard. The Quality Coordinator has the responsibility and authority for ensuring that the QMS related to quality is implemented and followed at all times. The Quality Coordinator has direct access to the highest levels of management at which decisions are made on laboratory policies and resources.

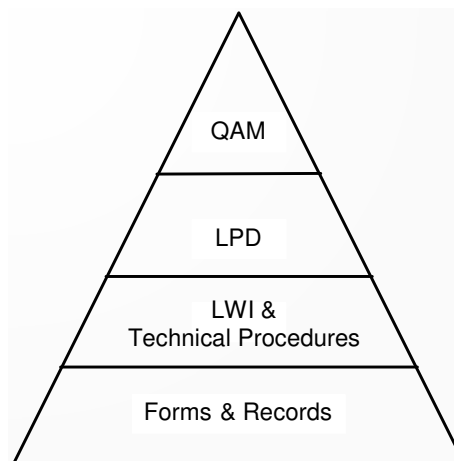
- 4.1.5.10 In the event the Quality Coordinator is absent the Deputy Quality Coordinator assumes the responsibility and authority for the Quality Coordinator. In the event the Laboratory Technical Manager is absent the Laboratory Technical Deputy assumes the responsibility and authority for the Laboratory Technical Manager.
- 4.1.5.11 The management of the laboratory ensures that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the QMS.
- 4.1.6 Top management ensures communication through cell stand-up meetings; weekly lab Stand-Up Meetings; and, monthly corporate communications. Personnel review their contribution to the management system objectives through cell stand-up meetings, and review of each cell's SQDIP and Daily Progress.

4.2 Management System

- 4.2.1 The laboratory has established, implemented, and maintains a QMS appropriate to the scope of its activities. The laboratory has documented its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the calibration results. The QMS documentation is communicated to, understood by, available to, and implemented by the appropriate personnel.
- 4.2.2 The laboratory's QMS policies relating to quality, including the quality policy statement, are defined in this QAM. The overall objectives are established and are reviewed during Management Review; see section 4.15 of this QAM for further details. The Quality Policy is issued under the authority of top management and is as follows:

Management is committed to best professional practice and to the quality of our calibration in servicing our customers. The purpose of our QMS is directly related to quality and our laboratory's standard of service. All personnel concerned with calibration activities within our laboratory must be familiar with the quality documentation and actively implement these policies and procedures in their work. Management is committed to complying with the ISO 17025 standard, meeting our customers requirements and continually improving the effectiveness of the QMS.

- 4.2.3 Top management is committed to the development and implementation of the QMS and to continually improve its effectiveness. Evidence of this commitment includes the review and approval of this QAM and participation in Management Review process.
- 4.2.4 The importance of meeting customer requirements as well as statutory and regulatory requirements is communicated to the organization during New Employee Orientation (NEO) training and periodic reminders during lab stand up meetings.
- 4.2.5 The structure of the documentation used in the QMS is as follows:



- 4.2.6 The roles and responsibilities of the Laboratory Technical Manager are described in section 4.1.5.1 of this QAM. The roles and responsibilities of the Quality Coordinator are described in section 4.1.5.9 of this QAM.

- 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. Quality Coordinator, Integration Teams, Lab Metrology Meetings, and Lab Staff Meetings are some examples of on-going groups that monitor QMS integrity.

4.3 Document Control

- 4.3.1 The Laboratory uses the documentation control procedures outlined in LPD 302 Document and Record Control to control all laboratory documents and procedures. For Fluke Electronics Canada, FEC LPD 401 Document, Record & Data Control is used.

4.3.2 Document Approval and Issue

- 4.3.2.1 All documents issued to personnel in the laboratory as part of the QMS are reviewed and approved prior to use. A master list identifying the current revision status and distribution is readily available to preclude the use of invalid or obsolete documents. These provisions are documented in LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record & Data Control is used.

- 4.3.2.2 LPD 302 Document and Record Control procedure and FEC LPD 401 Document, Record & Data Control procedure ensure that;

4.3.2.2.1 Authorized editions of documents are available at all locations where operations essential to the effective functioning of the laboratory are performed.

4.3.2.2.2 Documents are periodically reviewed and revised when necessary to ensure continuing suitability and compliance.

4.3.2.2.3 Invalid or obsolete documents are promptly removed from all points of issue or use or are otherwise assured against unintended use

4.3.2.2.4 Obsolete documents retained for either legal or knowledge preservation are suitably marked.

- 4.3.2.3 QMS documentation is uniquely identified as per LPD 302 Document and Record Control and FEC LPD 401 Document, Record & Data Control procedure.

- 4.3.3 Changes made to the QMS documentation are handled in accordance with LPD 302 Document and Record Control and FEC LPD 401 Document, Record & Data Control.

4.4 Review of Requests, Tenders and Contracts

- 4.4.1 It is the laboratory's policy to review the requests, tenders, and contracts before any work commences. LWI 212.8 Contract Review procedure and FEC LWI 121 Contract Review for Fluke Electronics Canada are the procedures that document this policy.

- 4.4.2 Records of reviews, including significant changes, are maintained per LPD 302 Document and Record Control and for Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control. These records may include but are not limited to; pertinent discussions with customers relating to the customer's requirements or the results of the work during the period of execution of the contract.

- 4.4.3 The reviews of 4.4.2 also cover any work that is subcontracted by the laboratory.

- 4.4.4 The customer is informed of any deviation from the contract as described in LWI 212.8 Contract Review and FEC LWI 121 Contract Review.

- 4.4.5 If a contract needs to be amended after work has commenced, the same contract review process and communications with the customer as defined in LWI 212.8 Contract Review and FEC LWI 121 Contract Review is followed.

4.5 Subcontracting of Calibrations

- 4.5.1 When the laboratory subcontracts work because of unforeseen reasons or on a continuing basis, this work is placed with an approved subcontractor. This procedure is further defined in LPD 304 Purchasing.

- 4.5.2 The laboratory shall advise the customer as per LPD 304 Purchasing

4.5.3 The laboratory is responsible to the customer for the subcontractors' work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.4 The laboratory maintains an Approved Supplier List (ASL)

4.6 Purchasing Services and Supplies

4.6.1 It is the policy of the laboratory to ensure that the selection and purchasing of services and supplies it uses that affect the quality of calibrations are done in accordance with LPD 304 Purchasing.

4.6.2 The laboratory ensures that purchased supplies, reagents, and consumable materials that affect the quality of the calibration, are not used until processed as per LPD 304 Purchasing.

4.6.3 Purchasing documents for the items affecting the quality of laboratory output shall contain data pertaining to the items purchased and are processed as defined in LPD 304 Purchasing.

4.6.4 The laboratory evaluates suppliers of critical consumables, supplies, and services which affect the quality of calibration in accordance with LPD 304 Purchasing. All records of these evaluations are maintained as per LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

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 Quality Coordinator or 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. A charge may be quoted for visits requiring substantial time from the laboratory's staff. A non-disclosure agreement may also be required for some visits.

4.7.2 The laboratory seeks feedback, both positive and negative, from its customers. This feedback is used and analyzed to improve the QMS, calibration activities and customer service as defined in LPD 305 Feedback, Complaints, Corrective Action and Preventive Action. For Fluke Electronics Canada, FEC LPD 410 Customer Feedback is used.

4.8 Complaints

4.8.1 It is the policy of the laboratory to ensure the resolution of complaints from customers or other parties. These complaints are resolved in accordance with LPD 305 Feedback, Complaints, Corrective Action and Preventive Action. For Fluke Electronics Canada, FEC LPD 410 Customer Feedback is used. Records of the complaints, of the investigations and corrective actions taken are maintained in accordance with LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

4.9 Control of Nonconforming Calibration Work

4.9.1 It is the laboratory's policy to ensure that when any aspect of its calibration work, or the results of this work, do not conform to the QMS or agreed customer requirements, LPD 306 Nonconforming Work is followed. LPD 306 Nonconforming work defines:

4.9.1.1 The responsibilities and authorities for the management of nonconforming work. It defines the actions, including the halting of work and withholding of calibration certificates, as necessary and ensures actions are taken when nonconforming work is identified.

4.9.1.2 The evaluation of the significance of the nonconforming work.

4.9.1.3 Corrective action is taken immediately; together with any decision about the acceptability of the nonconforming work.

4.9.1.4 Where necessary the customer is notified and work is recalled.

4.9.1.5 The responsibility for authorizing the resumption of work.

4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations within the QMS, the corrective action procedures defined in section 4.11 shall be promptly followed.

4.10 Improvement

- 4.10.1 The laboratory continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective action, preventive action, and management review.

4.11 Corrective Action

- 4.11.1 It is the policy of the laboratory to implement corrective actions when nonconforming work, departures from the QMS, or technical operations has been identified in accordance with LPD 305 Feedback, Complaints, Corrective Action and Preventive Action.

4.11.2 Cause Analysis

CA-001 Corrective Action Work Instructions, documents the investigative process to determine the root causes of the problem.

4.11.3 Selection and Implementation of Corrective Actions

Where corrective action is needed, the laboratory selects corrective actions based on the degree appropriate to the magnitude and risk of the problem, then selects and implements the actions most likely to eliminate the problem and to prevent recurrence as defined in LPD 305 Feedback, Complaints, Corrective Action and Preventive Action.

4.11.4 Monitoring of Corrective Actions

The laboratory shall monitor the results to ensure that the corrective action taken have been effective and is done in accordance with LPD 305 Feedback, Complaints, Corrective Action and Preventive Action..

4.11.5 Additional Audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with the QMS or ISO 17025, the appropriate area of activity shall be audited in accordance with section 4.14 of this QAM.

4.12 Preventive Action

- 4.12.1 Needed improvements and potential nonconformities, either technical or concerning the QMS, are identified in accordance with LPD 305 Feedback, Complaints, Corrective Action and Preventive Action. When improvement opportunities are identified or if preventive action is required action plans are developed, implemented, and monitored in accordance with LPD 305 Feedback, Complaints, Corrective Action and Preventive Action.

- 4.12.2 LPD 305 Feedback, Complaints, Corrective Action and Preventive Action define the initiation of actions and the application of controls to ensure that they are effective.

4.13 Control of Records

4.13.1 General

4.13.1.1 LPD 302 Document and Record Control define the identification, collection, indexing, access, filling storage, maintenance, and disposal of quality and technical records. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

4.13.1.2 All records are legible and stored in accordance with LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

4.13.1.3 All records are held secure and in confidence.

4.13.1.4 Daily back ups are performed by corporate IT department and back ups are stored off site.

4.13.2 Technical Records

4.13.2.1 Technical records are the documentation regarding all the conditions of a calibration including the methods used, standards and their traceability, condition of the laboratory, original observations, and personnel conducting the measurements and reviewing the results. In so far as possible, the records should be of sufficient detail to allow the calibration to be repeated under similar conditions as the original.

4.13.2.2 Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.

4.13.2.3 Electronic records are considered to be records that exist in electronic form such as data stored on a computer hard drive, network or other storage media. Appropriate measures are implemented by the laboratory that safeguard against loss or change of the originally recorded data.

4.14 Internal Audits

- 4.14.1 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 QMS and ISO 17025. Procedures regarding internal auditing are found in QS-001, Quality Systems Internal Audit Procedures.
- 4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's calibration results, the laboratory shall take timely corrective action as per section 4.11 of this QAM.
- 4.14.3 The area of activity audited, the findings, and corrective actions that arise are recorded in accordance with QS-001, Quality Systems Internal Audit and section 4.11 of this QAM.
- 4.14.4 Follow up activities verify and record the implementation and effectiveness of the corrective action taken in accordance with LPD 305 Feedback, Complaints, Corrective Action and Preventive Action.

4.15 Management Review

- 4.15.1 In accordance with LPD 308 Management Review, the laboratory's top management conducts a review of the laboratory's QMS and calibration activities to ensure a continuing suitability and effectiveness, and to introduce necessary changes or improvements. This review is done annually as defined in LPD 308 Management Review.
- 4.15.2 Findings from the management review and the actions that arise are recorded in accordance with LPD 308 Management Review. The management ensures that actions are carried out within an appropriate and agreed timescale.

5. TECHNICAL REQUIREMENTS

5.1 General

- 5.1.1 There are many factors that contribute to the accuracy and consistency of calibrations performed by the laboratory. These factors include human competency, accommodations and environment, methodology and validation, equipment, measurement traceability, and handling of standards and calibration items.
- 5.1.2 The laboratory takes into account the effects of various factors which contribute to the uncertainty of measurement when developing calibration methods and procedures, selecting equipment, and during training and qualification of personnel.

5.2 Personnel

- 5.2.1 The laboratory will use permanent, temporary and or part-time staff that 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 It is the laboratory's policy to identify training and skills of laboratory personnel. Goals are formulated in respect to education, training and the skills needed in accordance with LPD 310 Training. The training program defined in LPD 310 Training is relevant to the present and anticipated tasks of the laboratory.
- 5.2.3 The laboratory employs personnel who have been trained and have demonstrated competence to perform specific calibration work. Temporary or part time staff or those undergoing training must be closely supervised by qualified staff to ensure they are competent, and that they work in accordance with the QMS.
- 5.2.4 Job descriptions for managerial, technical, and support personnel are maintained by the Human Resources (HR) department and are available on the Fluke intranet.

- 5.2.5 Authorization and training records for personnel authorized to perform specific calibrations, to issue calibration certificates, and to operate certain types of equipment are maintained in accordance with LPD 310 Training.

5.3 Accommodation and environmental conditions

- 5.3.1 The Laboratory facilities are maintained in such a way as to not adversely affect the outcome of any calibration work carried out. Environmental conditions are monitored and recorded when calibrations are performed outside the permanent laboratory location. Requirements for accommodation and environmental conditions are documented in LPD 315 Environmental Control and Monitoring.
- 5.3.2 The laboratory monitors, controls, and records applicable environmental conditions in accordance with LPD 315 Environmental Control and Monitoring.
- 5.3.3 The Laboratory maintains effective separation between incompatible areas.
- 5.3.4 Access to the laboratory is restricted to assigned personnel, those having immediate business, or those being escorted by laboratory personnel.
- 5.3.5 Housekeeping in the 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. All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and are readily available to personnel in accordance with LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.4.2 Selection of methods

Generally, the method is not specified by the customer and is the 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 Laboratory-developed methods

The laboratory may develop its own methods or use those which have been published in national or international standards or in 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. An evaluation of TUR (Test Uncertainty Ratio) may be conducted in lieu of an uncertainty analysis for non-accredited procedures or those supporting CLAS non Type1 accredited calibrations.

Non-standard methods

Non-standard methods are discussed with the customer and agreed upon. The method developed must be validated and approved by the Laboratory Technical Manager before use.

5.4.4 Validation of methods

5.4.4.1 Validation is the confirmation by examination. This validation is performed in accordance with LPD 311 Metrology Procedures. Objective evidence that the particular requirements for a specific intended use are fulfilled is maintained in accordance with LPD 311 Metrology Procedures and LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.4.4.2 The laboratory validates non-standard methods; laboratory designed/ developed methods, standard methods used outside of their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. This validation is performed and documented in accordance with LPD 311 Metrology Procedures. Records of validation are maintained in accordance with LPD 311 Metrology Procedures and LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.4.5 Estimation of Uncertainty of Measurement

5.4.5.1 The means of determining measurement uncertainty are based on NIST TN 1297.

5.4.5.2 The laboratory does not perform testing

5.4.5.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in a given situation are taken into account using the appropriate methods of analysis.

5.4.6 Control of Data

5.4.6.1 Calculations and data transfers must be checked in a systematic way.

5.4.6.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data the laboratory ensures that:

5.4.7.2.1 Computer software developed by the laboratory is documented in sufficient detail and is suitably validated in accordance with LPD 307 Control of Data. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.4.7.2.2 The protection of data is defined in LPD 307 Control of Data. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.4.7.2.3 Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of the calibration data.

5.5 Equipment

5.5.1 The laboratory is furnished with all measurement equipment required for the proper performance of the calibration. In those cases where the laboratory needs to use equipment outside its permanent control, the laboratory ensures that the equipment meets the requirements of the ISO 17025 standard.

5.5.2 Equipment and its software used for calibration are capable of achieving the accuracy required and comply with the specifications relevant to the calibrations concerned. Calibration programs are established for values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment shall be calibrated in accordance with LPD 312 Processing of M & TE, and section 5.6 of this QAM.

5.5.3 Equipment is operated by authorized personnel in accordance with LPD 310 Training. Up-to-date instructions on the use and maintenance of equipment are readily available for use by the appropriate laboratory personnel in accordance with LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.5.4 Each item and its software used for calibration which is significant to the result is uniquely identified as defined in LPD 312 Processing of M & TE.

5.5.5 Records of each item of equipment and its software significant to the calibrations performed are defined in LPD 312 Processing of M & TE. These records are maintained in accordance with LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.5.6 The laboratory's procedure to ensure safe handling, transport, storage, use and planned maintenance of measuring equipment is LPD 312 Processing of M & TE.

- 5.5.7 Equipment that has been subject to overloading or mishandling, gives suspect results, or has been shown to be defective or outside of specified limits is taken out of service in accordance with LPD 312 Processing of M & TE. The laboratory shall examine the effect of the defect or departure from the specified limits on previous calibrations in accordance with LPD 306 Nonconforming Work.
- 5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration is identified to indicate the status of calibration in accordance with LPD 312 Processing of M & TE.
- 5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory ensures the function and calibration status before the equipment is returned to service in accordance with LPD 312 Processing of M & TE.
- 5.5.10 When intermediate checks are needed, to maintain confidence, in the calibration status of the equipment, these checks are performed in accordance with LPD 312 Processing of M & TE.
- 5.5.11 Where calibrations give rise to correction factors, the laboratory ensures that copies are correctly updated as defined in LPD 312 Processing of M & TE.
- 5.5.12 Calibration equipment, including both hardware and software, is safeguarded from adjustments which would invalidate the calibration results in accordance with LPD 312 Processing of M & TE.

5.6 Measurement Traceability

5.6.1 General

All equipment used for calibrations including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the calibration, shall be calibrated prior to being put into service in accordance with LPD 312 Processing of M & TE.

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.

There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements in accordance with LPD 312 Processing of M & TE.

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

Where reference materials are used they are handled in accordance with LPD 312 Processing of M & TE

5.6.3.3 Intermediate Checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards are carried out in accordance with LPD 312 Processing of M & TE.

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 212.5 Handling, Shipping and Receiving. For Fluke Electronics Canada, FEC LWI 110 Handling, Shipping and Receiving is used.

5.7 Sampling-Not Applicable

5.8 Handling of Calibration Items

- 5.8.1 LPD 312 Processing of M & TE defines the provisions for the transportation, receipt, safe handling, protection, storage, retention, and disposal of calibration items. For Fluke Electronics Canada, FEC LWI 110 Handling, Shipping and Receiving is used.
- 5.8.2 Calibration items are clearly identified by a traveler attached to the item on receipt and remains with the item. The traveler shows the item serial number, RMA #, and information regarding the type of calibration required. The Met/Track® system is 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 or departures from normal or specified conditions or the item is in some way not suitable for calibration, the laboratory will contact the customer. Where there is doubt as to the suitability of an item for the calibration or when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions in accordance with LWI 212.8 Contract Review. For Fluke Electronics Canada, FEC LWI 121 Contract Review is used.
- 5.8.4 Facilities are available to ensure that the unit will not deteriorate, be lost or damaged. Procedures are defined in LPD 312 Processing of M & TE. For Fluke Electronics Canada, FEC LWI 110 Handling, Storage and Receiving is used.

5.9 Assuring the Quality of Calibration Results

- 5.9.1 The laboratory monitors the validity of calibrations undertaken. The resulting data is recorded in accordance with LPD 314 Quality of Results.
- 5.9.2 Quality control data is analyzed in accordance with LPD 314 Quality of Results. Where they are found to be outside predefined criteria they are handled in accordance with LPD 306 Nonconforming Work.
- 5.9.3 **Providing the Accreditation body with ILC/PT Results**
 - 5.9.3.1 The Everett laboratory complies with the A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories. Fluke Electronics Canada laboratory complies with the CLAS Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories.
 - 5.9.3.2 All the Inter-laboratory Comparison (ILC) and Proficiency Test (PT) results are sent to the accreditation body 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 Laboratory and the CLAS Proficiency Testing Data Submission form for Fluke Electronics Canada Laboratory.

5.10 Reporting the Results

5.10.1 General

The results of each calibration or series of calibrations carried out by the laboratory are reported accurately, clearly, unambiguously, and objectively and in accordance with LPD 303 Levels of Service.

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 Calibration Certificates

Calibration certificates shall include the information defined in LPD 303 Levels of Service.

5.10.3 Test Reports-Not Applicable

5.10.4 Calibration Certificates

5.10.4.1 Calibration certificates shall include the information defined in LPD 303 Levels of Service.

5.10.4.2 Calibration certificates shall relate only to quantities and the results of functional tests. Most certificates will not make claims of compliance. It is good practices to state in the certificate that claims of compliance are not being made. The listing of specifications for reference and the

identification of measurement results that exceed specification limits shall not be interpreted as claims of compliance. If statements of compliance are made, the specific clauses of the specification to which these statements refer must be identified and the uncertainty of measurement must be taken into account. The method of accounting for the uncertainty must be listed in the certificate if claims of compliance are made.

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment, if available, shall be reported in accordance with LPD 303 Levels of Service.

5.10.4.4 The calibration certificate and calibration label shall not contain any recommendation on the calibration interval except where this has been agreed upon with the customer or a specific level of service is contracted. LPD 303 Levels of Service defines this requirement.

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 Calibration Results Obtained from Sub Contractors

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

5.10.7 Electronic Transmission of Results

Certificates shall only be issued electronically if they meet the requirements of section 5.4.7 and section 4.1.5.3 of this QAM.

5.10.8 Format of Certificates

The format of the Certificates and Reports has been designed to help minimize the possibility of misunderstanding and misuse. Certificates and Reports are controlled per LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

5.10.9 Amendments to Calibration Certificates

Material amendments to a calibration certificate after issue shall be made only in the form of a revised document. Such amendments shall meet the requirements of the QMS. When it is necessary to issue a complete new calibration certificate this shall be uniquely identified in accordance with LPD 302 Document and Record Control. For Fluke Electronics Canada, FEC LPD 401 Document, Record and Data Control is used.

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 Laboratory Technical Manager for use of certificates and all laboratory documentation and by the CSS Quality Coordinator for use on the Fluke web sites.