Fluke 17025 Quality Manual

Document Name:	QSD 111.41
Document Type:	Quality System Document
Revision:	005
Date:	Sep 2014

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.

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Authorization Approvals

Electronic authorization approval is the preferred method for approving QSD's. Signed hardcopies are only available upon request.

Approver:	Manager of Global Quality
Approver:	Chief Corporate Metrologist
Document Reviewer:	ISO Quality Manager
Document Reviewer:	Intelex Quality Council Function Representatives
Document Owner:	Fluke Metrology Quality Manager

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 Computer Network. All documents will have electronic approval. An uncontrolled copy is available to customers via the Fluke Calibration website.

Document Change Record

REV DATE	BRIEF DESCRIPTION OF CHANGE(S)
001 / July 2012	Revision 001: Released to Document Control
002 / August 2012	Revision 002: Changed to QSD 111.41 from QSD 111.59
003 / Jan 2014	1. Revision 003: New QSD format. 2. Added Fluke Corporate Quality statement. 3. Section 4.1.2: modify to include both accredited and non-accredited calibrations under the purview of the same laboratory. Exclude section 5.4.6, 5.6 and 5.10 from full compliance for non-accredited calibration. 4. Add statement (See Section 4.1.2) to Sections 5.4.6, 5.6 and 5.10 for clarity. 5. Fix formatting error in Section 4.2.5. 6. Clarified Not Applicable in Sections 5.4.6.2, 5.6.2.2, 5.7, and 5.10.3. 7. Section 5.1 removed reference to Annex B.
004 / July 2014	1. Added QSD 111.2 and ITD-00004 to the Internal References. 2. Added the VIM to definitions, Section 3.3. 3. Changed all references to "handbook" to "document". 4. Section 4.2.5: Added reference to FCM 2403.41. Changed the document tier to reflect corporate metrology SOPs and lab SOPs. 5. Section 4.2.5: Change descriptions to match new document tier. 6. Added Section 4.2.6 and 4.2.7. 7. Section 4.4.3: Deleted the extra level four number creating the correct reference. 8. Section 4.4.5: Added "are" to correct grammar. 9. Section 5.4.3: Corrected grammar. 10. Section 5.4.6.2: Clarified "Not Applicable" that was missed in Rev 003. 11. Section 5.10.4.1 c): changed reference to Note as Note 2 does not exist in reference.
005 / Aug 2014	1. Removed Martin Girard from the Quality Policy Statement as he no longer works for Fluke. 2. Removed document level specivity from the QSD to the Level 2 Document Control procedure. 3. Revised Section 4.2.5 to simply state conformance to corporate requirements with reference to FCM 2403.41 Document Control for further definition..

1. PURPOSE AND SCOPE

1.1 Purpose

This Quality System Document (QSD) defines or identifies the policies, procedures and requirements of organizations that choose to comply with the requirements of ISO 17025 as a calibration laboratory. Any local documents, procedures and policies associated with ISO 17025 compliance for calibration laboratories must comply with this document.

This document is issued under the authority of the Chief Corporate Metrologist and the Manager of Global Quality.

1.2 Fluke ISO 17025 Quality Policy

FLUKE. Calibration

QUALITY POLICY STATEMENT

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

Fluke management is committed to upholding the quality standards associated with the calibration laboratory. The purpose of the management system is to ensure quality requirements of the accrediting body shall be met or exceeded at all times within the laboratory. The service provided by the Calibration Program shall be in compliance with the overall quality commitment of the company.

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

The overall objective of Fluke's ISO 17025 management system is outlined in the definition of quality:

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

The calibration procedures established by Fluke's metrologists and company management follow best calibration practices, national laboratory recommended procedures, and requirements of the accreditation bodies from which Fluke seeks accreditation. The executive management and calibration management shall ensure compliance with the ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*, for all calibration activities and continually improve the effectiveness of our management system.

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2 REFERENCES/SUPERSEDE

2.1 Internal Reference Documents

- QSD 111.0 Corporate Quality Manual
- QSD 111.2 Corporate Training Requirements
- QSD 111.39 Document Control Manual
- QSD 111.44 Calibration System
- QSD 111.1 Manufacturing Process
- QSD 111.50 Records and Document Retention Policy
- ITD-00004 Document Control in Intelex
- FCM 2403.41 Fluke 17025 (4.3) Document Control Procedure

2.2 External References

- ISO/IEC 17025:2005
- JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

2.3 Superseded Documents

This document revision supersedes all previous revisions as stated in the Document Change Record.

3 RESPONSIBILITY/AUTHORITY/DEFINITIONS

3.1 Responsibility/Authority

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

The Intelex Quality Management System and Corporate Quality Index are the Document Control systems used to manage new releases or changes to the Quality System Documents. The Intelex system contains a training module that is linked to both the QSDs and Employees. The Intelex system will notify all affected Process Owners of changes to this document.

3.2 Definitions

Primary Laboratory: The highest echelon laboratory(ies) at Fluke responsible for maintaining the Corporation's primary reference standards for a particular measurement discipline.

Measurement Facility: A body that calibrates or performs acceptance measurements on instruments. Measurement facilities include Final Test Stations and equivalent test stations as required to meet objectives.

Other pertinent definitions are found in the VIM and QSD 111.44

4 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.1 This document is the Fluke Corporation ISO 17025 Compliance manual. Fluke Corporation was founded in 1949 and incorporated under the laws of the state of Washington, USA, On 7 October 1953. On 9 July 1998, it was acquired by Danaher Corporation, a publicly owned company. On 6 Dec 2001, Fluke Electronics Corporation was organized and both Fluke Corporation and Fluke Electronics Corporation were incorporated under the laws of the state of Delaware, USA. Fluke also operates under the entity of Fluke Precision Measurements LTD, a United Kingdom Division of Fluke Corporation. Elements of Fluke Corporation, Fluke Electronics Corporation, Fluke Precision Measurements LTD. do business under the name Fluke Calibration. Any organization within Fluke Corporation claiming compliance to ISO 17025 as a calibration laboratory or measurement facility must reference this document and work under its umbrella. For the purposes of this document, all references to legal or marketing Fluke entities will be referred to as Fluke. For the purpose of this document references to the collective Fluke calibration facilities as defined in Section 3.2 will be referred to as the laboratory.

4.1.2 For accredited calibrations, It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this document and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition. Laboratories whose work includes both accredited and non-accredited calibrations shall comply to this document, but non-accredited calibrations are not required to fully comply with sections 5.4.6, 5.6 and the reporting requirements of 5.10.

4.1.3 This management system covers work carried out in the company's permanent laboratory facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.4 Each laboratory must describe their organizational structure. The structure is described to a level of detail sufficient to identify key personnel/activities and in order to reveal possible conflicts of interest involving both calibration services and manufacturing activities involving calibration.

4.1.5 Each laboratory has:

a) Designated managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing calibrations, and to initiate actions to prevent or minimize such departures

b) Arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) Policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) Policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

e) Defined the organization and management structure of the laboratory, its place in the parent organization, and the relationships between quality management, technical operations, and support services

f) Specified the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the of calibrations;

g) Provided adequate supervision of calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each calibration, and with the assessment of the calibration results;

h) Technical management designated which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations; Technical management may be a separate function from personnel management.

i) Appointed a staff member as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) Appointed deputies for the technical and quality manager

k) Ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system

NOTE Individuals may be assigned more than one function and it may be impractical to appoint deputies for every function.

4.1.6 Top management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 Management System

4.2.1 The laboratory has established, implemented and maintained a management system appropriate to the scope of its activities. The 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 shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 Objectives for the laboratory management system are established and reviewed during management review. The quality policy statement is described in section 1.2 of this document, and always includes the following requirements

a) The laboratory management's commitment to good professional practice and to the quality of its calibration service to customers.

b) The management's statement of the laboratory's standard of service

c) The purpose of the management system related to quality

d) A requirement that all personnel concerned with calibration activities within the laboratory familiarize themselves with the quality documentation and implement policies and procedures in their work and

e) The laboratory's commitment to comply with ISO 17025 and to continually improve the effectiveness of the management system.

4.2.3 Top management provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

4.2.4 Top management communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The structure of documentation of the management system supports the corporate structure requirements and is further defined in FCM 2403.41, Fluke 17025 (4.3) Document Control Procedure.

4.2.6 The roles and responsibilities of technical management and the quality manager for Corporate Metrology and specific to each laboratory are defined in the applicable Corporate or Lab Specific SOP, respectively, including their responsibility for ensuring compliance to ISO 17025 and QSD 111.41.

4.2.7 Corporate Metrology Management ensures the integrity of the Fluke Corporation Standardized 17025 Quality management system when changes to the management system are planned and implemented. The laboratory management, under the direction of Corporate Metrology Management, ensures the integrity of the management system when changes are planned or implemented to the laboratory management system.

4.3 Document Control

4.3.1 General

The laboratory has established and maintained procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, calibration methods, as well as drawings, software, specifications, instructions and manuals.

4.3.2 Document Approval and Issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system is established and readily available to preclude the use of invalid and/or obsolete documents.

a) 4.3.2.2 The adopted procedure(s) ensure that only authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Management system documents generated by the laboratory are uniquely identified. Such identification include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document Changes

4.3.3.1 Changes to documents are reviewed and approved by the same function that performed the original review unless specifically designated otherwise. Access to pertinent background information upon which to base their review and approval is provided to the designated personnel.

4.3.3.2 Where practicable, the altered or new text is identified in the document or the appropriate attachments.

4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments are defined. Amendments are clearly marked, initialed and dated. A revised document is formally reissued as soon as practicable.

4.3.3.4 Established procedures describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

4.4.1 The laboratory has established and maintained procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for calibration ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).

Any differences between the request or tender and the contract is resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.

4.4.2 Records of reviews, including any significant changes, are maintained. Records of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract are maintained.

4.4.3 The review pertains to any work that is subcontracted by the laboratory. This is applicable to calibrations described in Section 4.5.1..

4.4.4 The customer is informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel.

4.5 Subcontracting of Calibrations

4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work is placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this document for the work in question.

a) In the case of when Fluke sends work between different laboratories where the laboratories have different certificates of accreditation, the requirements of section 4.5 apply.

4.5.2 The laboratory advises the customer of the arrangement in writing and, when appropriate, gains the approval of the customer, preferably in writing.

4.5.3 The laboratory is responsible to the customer for the subcontractor's 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 a register of all subcontractors that it uses for calibrations and a record of the evidence of compliance with this document for the work in question.

4.6 Purchasing of Services and Supplies

4.6.1 The laboratory has a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the calibrations. Procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the calibrations.

4.6.2 The laboratory ensures that purchased supplies and reagents and consumable materials that affect the quality of calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the calibrations concerned. These services and supplies used comply with specified requirements. Records of actions taken to check compliance are maintained.

4.6.3 Purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered. These purchasing documents are reviewed and approved for technical content prior to release.

4.6.4 The laboratory evaluates suppliers of critical consumables, supplies and services which affect the quality of calibration, and maintain records of these evaluations and list those approved.

4.7 Service to the Customer

4.7.1 The laboratory has a procedure stating willingness to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

4.7.2 The laboratory has a documented process to actively seeks feedback, both positive and negative, from its customers. This feedback is used and analyzed to improve the management system, calibration activities and customer service.

4.8 Complaints

The laboratory has a policy and procedure for the resolution of complaints received from customers or other parties. Records are maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).

4.9 Control of nonconforming calibration work

4.9.1 The laboratory has a policy and procedures that are implemented when any aspect of its calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. Out of Tolerance calibration standards are considered to be nonconforming calibration work. The policy and procedures ensure that:

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the customer is notified and work is recalled;

e) the responsibility for authorizing the resumption of work is defined.

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 with its own policies and procedures, the corrective action procedures given in 4.11 are promptly followed.

4.10 Improvement

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

4.11 Corrective Action

4.11.1 General

The laboratory has established a policy and a procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

4.11.2 Cause Analysis

The procedure for corrective action starts with an investigation to determine the root cause(s) of the problem.

4.11.3 Selection and implementation of Corrective Actions

Where corrective action is needed, the laboratory identifies potential corrective actions. It selects and implements the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions are to a degree appropriate to the magnitude and the risk of the problem.

The laboratory documents and implements any required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Actions

The laboratory monitors the results to ensure that the corrective actions taken have been effective.

4.11.5 Additional audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this document, the laboratory ensures that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

4.12 Preventive Action

4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, are identified. When improvement opportunities are identified or if preventive action is required, action plans are developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.12.2 Procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective.

4.13 Control of Records

4.13.1 General

4.13.1.1 The laboratory has established and maintained procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.13.1.2 All records are legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records are established in accordance with the corporate retention policy.

4.13.1.3 All records are held secure and in confidence.

4.13.1.4 The laboratory has procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.13.2 Technical records

4.13.2.1 The laboratory retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each calibration certificate issued, for a defined period. The records for each calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for the sampling, performance of each calibration and checking of results.

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 When mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records are signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures are taken to avoid loss or change of original data.

4.14 Internal Audits

4.14.1 The laboratory periodically, and in accordance with a predetermined schedule and procedure, conducts internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this document. The internal audit program addresses all elements of the management system, including the calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits are carried out by personnel trained and qualified for internal auditing to ISO 17025 and, wherever resources permit, independent of the activity to be audited. The cycle for internal audit will be completed annually.

4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's or calibration results, the laboratory takes timely corrective action, and notifies customers in writing if investigations show that the laboratory results may have been affected.

4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them are recorded.

4.14.4 Follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken.

4.15 Management Reviews

4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management periodically conduct a review of the laboratory's management system and calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The Management Review is conducted at a minimum, annually. The review takes account of:

— the suitability of policies and procedures;

— reports from managerial and supervisory personnel;

— the outcome of recent internal audits;

— corrective and preventive actions;

— assessments by external bodies;

— the results of interlaboratory comparisons or proficiency tests;

— changes in the volume and type of the work;

— customer feedback;

— complaints;

— recommendations for improvement;

— other relevant factors, such as quality control activities, resources and staff training.

4.15.2 Findings from management reviews and the actions that arise from them are recorded. Management ensures that those actions are carried out within an appropriate and agreed timescale.

5 TECHNICAL REQUIREMENTS FOR ACCREDITATION

5.1 General

5.1.1 Many factors determine the correctness and reliability of the calibrations performed by a laboratory. These factors include contributions from:

— human factors (5.2);

— accommodation and environmental conditions (5.3);

— calibration methods and method validation (5.4);

— equipment (5.5);

— measurement traceability (5.6)

— sampling (5.7);

— the handling of calibration items (5.8).

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) and between (types of) calibrations. The laboratory takes account of these factors in developing calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.2 Personnel

5.2.1 The laboratory management ensures the competence of all who operate specific equipment, perform calibrations, evaluate results, and sign calibration certificates. When using staff who are undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

5.2.2 The laboratory management formulates the goals with respect to the education, training and skills of the laboratory personnel. The laboratory has a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken is evaluated.

5.2.3 The laboratory uses only personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory ensures that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

5.2.4 The laboratory maintains current job descriptions for managerial, technical and key support personnel involved in calibrations.

5.2.5 The management authorizes specific personnel to perform particular types of sampling, and/or calibration, to issue calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory maintains records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.

5.3 Accommodation and environmental conditions

5.3.1 Laboratory facilities for calibration, including but not limited to energy sources, lighting and environmental conditions, facilitate correct performance of the calibrations.

The laboratory ensures that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of calibrations are be documented.

5.3.2 The laboratory monitors, controls and records environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention is paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Calibrations are stopped when the environmental conditions jeopardize the results of the calibrations.

5.3.3 Effective separation exists between neighboring areas in which there are incompatible activities. Measures are taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the calibrations are controlled. The laboratory has determined the extent of control based on its particular circumstances.

5.3.5 Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared where necessary.

5.4 Calibration methods and method validation

5.4.1 General

The laboratory uses appropriate methods and procedures for all calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of calibration data.

The laboratory has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for calibration, or both, where the absence of such instructions could jeopardize the results of calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and made readily available to personnel (see 4.3). Deviation from calibration methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

5.4.2 Selection of Methods

The laboratory uses calibration methods, which meet the needs of the customer and which are appropriate for the calibrations it undertakes. Preferably methods published in international, regional or national standards are used. The laboratory ensures that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

When the customer does not specify the method to be used, the laboratory selects appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer is informed as to the method chosen. The laboratory confirms that it can properly operate standard methods before introducing the calibrations. If the standard method changes, the confirmation is repeated.

The laboratory informs the customer when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.3 Laboratory-developed methods

The introduction of calibration methods developed by the laboratory for its own use are a planned activity and assigned to qualified personnel equipped with adequate resources.

Plans are updated as development proceeds and effective communication amongst all personnel involved is ensured.

5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these are subject to agreement with the customer and include a clear specification of the customer's requirements and the purpose of the calibration. The method developed is validated appropriately before use.

5.4.5 Validation of Methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory validates non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs of the given application or field of application. The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, are relevant to the customers' needs.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 The calibration laboratory has and applies a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

5.4.6.2 Fluke accredited measurement facilities perform calibrations. Testing is not performed under accreditation. Thus, Section 5.4.6.2 of ISO 17025 is Not Applicable.

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

5.4.7 Control of data

5.4.7.1 Calculations and data transfers are subject to appropriate checks in a systematic manner.

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

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) 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 calibration data.

5.5 Equipment

5.5.1 The laboratory is furnished with all items of sampling, measurement and test equipment required for the correct performance of the calibrations (including sampling, preparation of calibration items, processing and analysis of calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it ensures that the requirements of this document are met.

5.5.2 Equipment and its software used for calibration and sampling are capable of achieving the accuracy required and complies with specifications relevant to the calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) is calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It is checked and/or calibrated before use (see 5.6).

5.5.3 Equipment is operated by authorized personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software used for calibration and significant to the result are, when practicable, be uniquely identified.

5.5.5 Records are maintained of each item of equipment and its software significant to the calibrations performed. The records include at least the following:

a) the identity of the item of equipment and its software;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification (see 5.5.2);

d) the current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

g) \the maintenance plan, where appropriate, and maintenance carried out to date;

h) any damage, malfunction, modification or repair to the equipment.

5.5.6 The laboratory has procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits is taken out of service. It is isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration to perform correctly. The laboratory examines the effect of the defect or departure from specified limits on previous calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration is labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory ensures that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks are carried out according to a defined procedure.

5.5.11 Where calibrations give rise to a set of correction factors, the laboratory has procedures to ensure that copies (e.g., in computer software) are correctly updated.

5.5.12 Test and calibration equipment, including both hardware and software, is safeguarded from adjustments which would invalidate the calibration results.

5.6 Measurement Traceability

5.6.1 General

All equipment used for calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the calibration or sampling is calibrated before being put into service. The laboratory has an established program and procedure for the calibration of its equipment.

5.6.2 Specific Requirements
5.6.2.1 Calibration

5.6.2.1.1 For calibration laboratories, the program for calibration of equipment is designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE Calibration laboratories fulfilling the requirements of ISO 17025 are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration provides confidence in measurements by establishing traceability to appropriate measurement standards such as:

— the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

— the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable program of interlaboratory comparisons is required where possible.

5.6.2.2 Section 5.6.2.2 of ISO 17025 is Not Applicable to accredited Fluke measurement facilities.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

The laboratory has a program and procedure for the calibration of its reference standards. Reference standards are calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards are calibrated before and after any adjustment.

5.6.3.2 Reference materials

Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

5.6.3.4 Transport and storage

The laboratory has procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.7 Sampling

Fluke accredited measurement facilities do not sample. Thus, Section 5.7 of ISO 17025 is Not Applicable.

5.8 Handling of calibration items

5.8.1 The laboratory has procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of calibration items, including all provisions necessary to protect the integrity of the calibration item, and to protect the interests of the laboratory and the customer.

5.8.2 The laboratory has a system for identifying calibration items. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. If appropriate, the system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory.

5.8.3 Upon receipt of the calibration item, abnormalities or departures from normal or specified conditions, as described in the calibration method, are recorded. When there is doubt as to the suitability of an item for calibration, or when an item does not conform to the description provided, or the calibration required is not specified in sufficient detail, the laboratory consults the customer for further instructions before proceeding and records the discussion.

5.8.4 The laboratory has procedures and appropriate facilities for avoiding deterioration, loss or damage to the calibration item during storage, handling and preparation. Handling instructions provided with the item are followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded. Where a calibration item or a portion of an item is to be held secure, the laboratory has arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

5.9 Assuring the quality of calibration results

5.9.1 The laboratory has quality control procedures for monitoring the validity of calibrations undertaken. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring is planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programs;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

5.9.2 Quality control data is analyzed and, where they are found to be outside pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.

5.10 Reporting the results

5.10.1 General

The results of each calibration, or series of calibrations carried out by the laboratory is reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration methods.

The results are reported, usually in a calibration certificate, and include all the information requested by the customer and necessary for the interpretation of the calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

In the case of calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer is readily available in the laboratory which carried out the calibrations.

5.10.2 Calibration Certificates
Each calibration certificate includes at least the following information, unless the laboratory has valid reasons for not doing so:

a) title (e.g., “Calibration Certificate”);the name and address of the laboratory, and the location where the calibrations were carried out, if different from the address of the laboratory;

b) unique identification of the calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the calibration certificate, and a clear identification of the end of the calibration certificate;

a) the name and address of the customer;

b) identification of the method used;

c) a description of, the condition of, and unambiguous identification of the item(s) calibrated;

d) the date of receipt of the calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the calibration;

e) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

f) the calibration results with, where appropriate, the units of measurement;

g) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the calibration certificate;

h) where relevant, a statement to the effect that the results relate only to the items calibrated.

5.10.3 Test Reports

All accredited Fluke measurement facilities perform calibrations and issue calibration certificates. Thus, Section 5.10.3 of ISO 17025 dealing with Test Reports is Not Applicable.

5.10.4 Calibration Certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates include the following, where necessary for the interpretation of calibration results:

a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

c) evidence that the measurements are traceable (see the Note in 5.6.2.1.1).

5.10.4.2 The calibration certificate relates only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this identifies which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory records those results and maintains them for possible future reference.

When statements of compliance are made, the uncertainty of measurement is taken into account.

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, are reported.

5.10.4.4 A calibration certificate (or calibration label) does not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory documents the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such in a test report.

5.10.6 Calibration results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results are clearly identified. The subcontractor reports the results in writing or electronically.

When a calibration has been subcontracted, the laboratory performing the work issues the calibration certificate to the contracting laboratory.

5.10.7 Electronic Transmission of results

In the case of transmission of calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this document are met (see also 5.4.7).

5.10.8 Format of calibration certificates

The format is designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse.

5.10.9 Amendments to calibration certificates

Material amendments to a calibration certificate after issue are made only in the form of a further document, or data transfer, which includes the statement:

> "Supplement to Calibration Certificate, serial number . . . [or as otherwise identified],"

or an equivalent form of wording.

Such amendments meet all the requirements of this document.

When it is necessary to issue a complete new calibration certificate, this is uniquely identified and contains a reference to the original that it replaces.

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