

# FLUKE 17025 QUALITY MANUAL

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## 1. Purpose and Scope

This Quality System Document defines or identifies the policies, procedures and requirements of organizations that choose to conform to the requirements of ISO/IEC 17025:2017.

Any organization within Fluke claiming conformance to ISO/IEC 17025:2017 shall reference this document and work under its purview. For the purposes of this document, all references to Legal or Marketing Fluke entities shall be referred to as Fluke. This document applies to Fluke ISO/IEC 17025:2017 accredited facilities. References to the collective Fluke ISO/IEC 17025:2017 accredited facilities shall be referred to as the laboratory or the laboratories throughout this document. Fluke manufacturing facilities and Fluke service facilities that are accredited are considered laboratories in the context of this document.

Laboratories whose work includes both accredited and non-accredited calibrations shall conform to this document. Non-accredited calibrations are not required to fully conform to the results of 7.8, reporting the results, or the decision rule and statements of conformity requirements of [Appendix A](#). These exceptions are described in more detail where necessary in the appropriate sections.

Laboratories whose work only includes non-accredited calibrations need only to conform with QSD111.0 Fluke Quality Manual, QSD111.44 and QSD111.26 and do not need to conform to this manual.

This quality manual is available to the Public. Links provided in this document for procedures are intended for Fluke use only.

## 2. References

### 2.1. Internal

2.1.1. [QSD111.44 Measurement Management System](#)

2.1.2. [QSD111.26 Certificate of Calibration Format Requirements](#)

2.1.3. FCM series documents. These are identified throughout this document. These documents are available to internal personnel in the corporate document control system.

Documents that are available for external download are as follows:

FCM 7001.1 [NA Reasonable Access Policy](#)

FCM 7001.2 [Europe Reasonable Access Policy](#)

FCM 7001.3 [China Reasonable Access Policy](#)

FCM 7008.1 [Policy - Statements of Conformity for Fluke Accredited Cal Certs](#)

FCM 7008.3 [Policy on NMI Test Numbers](#)

## 2.2. External

- 2.2.1. JCGM 200, International vocabulary of metrology – Basic and general concepts and associated terms (VIM)
- 2.2.2. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
- 2.2.3. ILAC G8:09/2019, Guidelines on Decision Rules and Statements of Conformity
- 2.2.4. ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration
- 2.2.5. JCGM 100, Evaluation of measurement data - Guide to the expression of uncertainty in measurement

## 3. Terms and Definitions, Acronyms and Interpretations

### 3.1. Definitions

- 3.1.1. **Laboratory:** A service or manufacturing facility that calibrates or performs acceptance measurements on instruments. Laboratories include Final Test Stations and equivalent test stations as required to meet objectives.

### 3.2. Acronyms

- 3.2.1. **FCM:** Fluke Corporate Metrology
- 3.2.2. **NMI:** National Metrology Institute
- 3.2.3. **PO:** Purchase Order
- 3.2.4. **QSD:** Quality System Document

3.2.5. **SI:** International System of Units

### 3.3. Interpretations

3.3.1. **Purchase Order Review vs. Contract Review:** Purchase Order Review means Contract Review in the context of ISO/IEC 17025:2017.

3.3.2. **Procedure vs. Method:** Calibration Procedure, also referred to as Procedure in this document, is synonymous with the term Method in the context of ISO/IEC 17025:2017.

## 4. General Requirements

### 4.1. Impartiality

- 4.1.1. Laboratory activities are undertaken impartially and structured and managed so as to safeguard impartiality.
- 4.1.2. The laboratory management are committed to impartiality. Evidence of this commitment may include but is not limited to the [Corporate Standards of Conduct](#) and a SPEAK UP program, however named.
- 4.1.3. The laboratory is responsible for the impartiality of its laboratory activities and does not allow commercial, financial or other pressures to compromise impartiality.
- 4.1.4. The laboratory identifies risks to its impartiality on an on-going basis. This includes those risks that arise from its activities, or from its relationships, or from the relationships of its personnel.
- 4.1.5. If a risk to impartiality is identified, the laboratory demonstrates how it eliminates or minimizes such risk.

#### **P1 - Policy on Impartiality**

*It is the Policy of Fluke Corporation that all personnel that have an influence on ISO/IEC 17025 accredited processes are required to comply with the Company's Integrity and Compliance Program to ensure that any activities that would diminish confidence in our competence, impartiality, judgment or operational integrity are avoided and to ensure consistent operation of our management system in order to minimize risks that may arise from laboratory activities. Personnel associated with ISO/IEC 17025 functions have access to the Corporate Standards of Conduct.*

*The Corporate Standards of Conduct does not allow inappropriate favoritism and is considered a violation of conduct if favoritism is confirmed to occur for any individual performing work for the laboratory.*

- 4.1.6. Fluke Corporation identifies and safeguards risks to impartiality, which is covered in [FCM 4120](#).

## 4.2. Confidentiality

- 4.2.1. The laboratory is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory informs the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential.
- 4.2.2. The [Corporate Standards of Conduct](#) states that, if the laboratory is required by law or authorized by contractual arrangements to release the customer's confidential information, that the customer is notified of the information released unless notifying the customer is prohibited by law.
- 4.2.3. If the laboratory receives a complaint about its customer from sources other than the customer (e.g. complainant, regulators), the customer and the provider (source) of the information is confidential and is not shared with the customer, unless agreed by the source. Complaints may be, but are not limited to, product related issues.
- 4.2.4. Personnel, including any contractors, personnel of external bodies, temporary employees or individuals acting on the laboratory's behalf are held to the same confidentiality requirements as Fluke personnel. All information obtained or created during the performance of laboratory activities, except as required by law, are kept confidential.

### **P2 - Policy on Confidentiality**

*It is the policy of Fluke Corporation to ensure the protection of our customers' confidential information and proprietary rights. The laboratory will not put customer information on the public domain without the advance consent of the customer, except for the information that the customer makes publicly available, or when agreed between the laboratory and the customer.*

- 4.2.5. Fluke has a procedure to address the requirements of confidentiality and it is documented in [FCM 4120](#).

## **5. Structural Requirements**

### **5.1. Legal Entity**

- 5.1.1. Fluke was founded in 1948 and incorporated under the laws of the state of Washington, USA. Fluke originally joined the Danaher portfolio in 1998, and as of July 2016 became part of the Fortive portfolio when Danaher completed its separation of its Test & Measurement segment.
- 5.1.2. Today, Fluke belongs in Fortive's Intelligent Operating Solutions division . Fluke also operates under the entities of Anhui Shifu instruments, Co., Fluke (UK) Limited and Fluke Precision Measurements Ltd or Fluke Customer Support Services (CSS).

These Fluke operations may market under brands such as Fluke Calibration, Fluke Biomedical, Fluke Networks and Fluke Process Instruments.

### **5.2. Overall Responsibility**

- 5.2.1. Minimum requirements to meet Sections 5.2 – 5.7 are documented in [FCM 5062](#).
- 5.2.2. Technical Management has overall responsibility for the laboratory compliance to ISO/IEC 17025:2017 and is identified in each laboratory's Organizational Chart. Upper-level organizational charts based on region are maintained in accordance with [FCM 5062](#).

### **5.3. Range of Activities**

- 5.3.1. The range of laboratory activities for which it conforms with this document is identified on each laboratory's Scope of Accreditation and Fluke Price Lists. Fluke does not put their accreditation symbol on reports from external providers.

### **5.4. Laboratory Activities**

- 5.4.1. Laboratory activities are carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and accrediting bodies. This includes laboratory activities performed in all its permanent facilities, at sites away from its permanent

facilities, in associated temporary or mobile facilities or at a customer's facility.

## 5.5. Relationship Structure, Authority

5.5.1. In accordance with FCM documents, the laboratory:

- a) defines the organization and management structure of the laboratory, its place within Fluke, and the relationships between management, technical operations and support services;
- b) specifies the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
- c) documents its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.5.2. [FCM 5001.1 17025 Metrology and Quality Org. Chart](#) defines the overall structure of personnel responsible for supporting the requirements of this document.

## 5.6. Quality Management

5.6.1. Each laboratory has identified a Quality Manager, however named, who irrespective of other responsibilities, has the authority and resources needed to carry out their duties, including:

- a) implementation, maintenance and improvement of the ISO/IEC 17025 management system;
- b) identification of deviations from the management system or from the procedures for performing laboratory activities;
- c) initiation of actions to prevent or minimize such deviations;
- d) reporting to laboratory management on the performance of the management system and any need for improvement;
- e) ensuring the effectiveness of laboratory activities.

## 5.7. Laboratory Management

5.7.1. Laboratory Management ensures that:

- a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;



- b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

## 6. Resource Requirements

### 6.1. General

- 6.1.1. Fluke has a procedure to address the minimum resource, training and competence requirements of personnel that may influence the results of the laboratory activities, and it is documented in [FCM 5062](#).
- 6.1.2. Resources include personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

### 6.2. Personnel

- 6.2.1. All personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system and the Company's [Integrity and Compliance Program](#).
- 6.2.2. The laboratory documents the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. Competence requirements are established to the extent necessary based on the process.
- 6.2.3. The laboratory ensures that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.
- 6.2.4. The management of the laboratory communicates to personnel their duties, responsibilities and authorities at time of hire and throughout their employment with the laboratory.
- 6.2.5. The laboratory has procedure(s) and, in accordance with [FCM 8004](#), retains records for:
  - a) determining the competence requirements;
  - b) selection of personnel;
  - c) training of personnel;

- d) supervision of personnel;
- e) authorization of personnel;
- f) monitoring competence of personnel.

6.2.6. The laboratory authorizes personnel to perform specific laboratory activities, including but not limited to, the following:

- a) development, modification, verification and validation of procedures;
- b) analysis of results, including statements of conformity or opinions and interpretations;
- c) report, review and authorization of results;
- d) review of Contracts and Purchase Orders;
- e) packaging and handling of calibration items and laboratory equipment.

### 6.3. Facilities and Environmental Conditions

6.3.1. The facilities and environmental conditions are suitable for the laboratory activities. The laboratory has processes and procedures to ensure they do not adversely affect the validity of results.

6.3.2. The minimum requirements for facilities and environmental conditions necessary for the performance of the laboratory activities are documented in [FCM 6000](#).

6.3.3. The laboratory monitors, controls and records environmental conditions in accordance with relevant specifications, procedures or where they influence the validity of the results. Records of relevant environmental conditions are controlled in accordance with [FCM 8004](#).

6.3.4. Measures to control facilities are implemented, monitored and periodically reviewed and include, but are not limited to:

- a) access to and use of areas affecting laboratory activities;
- b) prevention of contamination, interference or adverse influences on laboratory activities;
- c) effective separation between areas with incompatible laboratory activities;
- d) safety of laboratory personnel and the environment.

- 6.3.5. Laboratories that perform laboratory activities at sites or facilities outside its permanent control ensure that the requirements related to facilities and environmental conditions of this document are met.

#### 6.4. Equipment

- 6.4.1. The laboratory has access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.
- 6.4.2. When the laboratory uses equipment outside its permanent control, it ensures that the requirements of ISO/IEC 17025:2017 for equipment are met.
- 6.4.3. Laboratory procedures for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration are documented in accordance with [FCM 6000](#).
- 6.4.4. The laboratory verifies that equipment conforms to specified requirements before being placed or returned into service.
- 6.4.5. The equipment used for measurement is validated to be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.
- 6.4.6. Measuring equipment will be calibrated when:
- the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
  - calibration of the equipment is required to establish the metrological traceability of the reported results.
- 6.4.7. The laboratory has established requirements for the calibration program and is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.
- 6.4.8. All equipment requiring calibration, or which has a defined period of validity is labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

- 6.4.9. Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, is taken out of service. Such equipment is isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory examines the effect of the defect or deviation from specified requirements and initiates the management of nonconforming work procedure (see 7.10).
- 6.4.10. When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to a procedure.
- 6.4.11. When calibration and reference material data include reference values or correction factors, the laboratory ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.
- 6.4.12. The laboratory takes practicable measures to prevent unintended adjustments of equipment from invalidating results.
- 6.4.13. In accordance with [FCM 8004](#), records are retained for equipment which can influence laboratory activities. The records include the following, where applicable:
- a) the identity of equipment, including software and firmware version;
  - b) the manufacturer's name, type identification, and serial number or other unique identification;
  - c) evidence of verification that equipment conforms with specified requirements;
  - d) the current location;
  - e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
  - f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
  - g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
  - h) details of any damage, malfunction, modification to, or repair of, the equipment.

- 6.4.14. The minimum requirements for the control of internal laboratory equipment are documented in [FCM 6000](#).

## 6.5. Metrological Traceability

- 6.5.1. The laboratory has established and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.
- 6.5.2. The laboratory's **Policy** for NMI Test Numbers is documented in [FCM 7008.3](#).
- 6.5.3. When a laboratory establishes traceability through a national metrology institute (NMI), the NMI selected is one that has CMCs established in the International Committee for Weights and Measures Mutual Recognition Arrangement (CIPM MRA) and may not necessarily be in the same country as the Fluke calibration laboratory.
- 6.5.4. Fluke calibration laboratories that maintain their own primary standard or representation of the International System of Units (SI) units based on fundamental physical constants can claim metrological traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a NMI.
- 6.5.5. When the laboratory does a direct realization of the SI, metrological traceability to SI is achieved by reference to an appropriate primary standard or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).
- 6.5.6. When traceability is maintained through an NMI, it is suitable if the NMI has documented capabilities for the service needed in the BIPM (International Bureau of Weights and Measures – Bureau International des Poids et Mesures) key comparison database (KCDB). When metrological traceability is supplied by laboratories other than NMIs or if the NMI is not listed in the KCDB, traceability must be assured through the use of calibration laboratories that are accredited to ISO 17025, by an ILAC recognized accreditation body or through other qualification sufficient to ensure traceability to the SI.

6.5.7. When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference, e.g.:

- a) certified values of certified reference materials provided by a competent producer;
- b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.5.8. When situations arise where SI units are not technically possible, Fluke Metrology Management must review and provide guidance on suitable measurement assurance.

## **6.6. Externally Provided Products and Services**

6.6.1. The laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- a) are intended for incorporation into the laboratory's own activities;
- b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
- c) are used to support the operation of the laboratory.

6.6.2. The laboratory has a procedure and retains records for:

- a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;
- b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
- c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
- d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3. Records for externally provided products and services are controlled in accordance with [FCM 8004](#).

6.6.4. The laboratory communicates its requirements to external providers for:

- a) the products and services to be provided;
- b) the acceptance criteria;
- c) competence, including any required qualification of personnel;
- d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

### **P3- Policy on Externally Provided Services**

*It is Fluke's Policy that external suppliers providing products and services used by the laboratory that affect the quality of the calibration are selected based on established criteria. Suppliers are not to be used by the laboratory until they have been inspected or otherwise verified by the laboratory as complying with standard specifications or requirements defined in the procedures for the calibrations concerned.*

6.6.5. The procedure for selection, inspection and verification of suppliers is documented in [FCM 6000](#).

## **7. Process Requirements**

### **7.1. Review of Requests, Tenders and Purchase Orders**

7.1.1. The laboratory has a procedure for the review of requests, tenders and purchase orders. The procedure ensures that:

- a) the requirements are adequately defined, documented and understood;
- b) the laboratory has the capability and resources to meet the requirements;
- c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;
- d) the appropriate procedures are selected and are capable of meeting the customers' requirements.

7.1.2. The laboratory informs the customer when the procedure requested by the customer is considered to be inappropriate or out of date.

7.1.3. When the customer requests a statement of conformity to a specification or standard for the calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule is clearly defined. Unless inherent in the requested specification or standard, the

decision rule selected is communicated to, and agreed with, the customer. The laboratories Policy for decision rules and guardbanding is documented in 13 Appendix A. As stated in 1 this is not required for non-accredited calibrations.

- 7.1.4. Any differences between the request or tender and the purchase order are resolved before laboratory activities commence. Each purchase order will be acceptable both to the laboratory and the customer. Deviations requested by the customer and accepted by the laboratory must not impact the integrity of the laboratory or the validity of the results.
- 7.1.5. The customer is informed of any deviation from the purchase order.
- 7.1.6. If a purchase order is amended after work has commenced, the purchase order review is repeated, and any amendments are communicated to all affected personnel.
- 7.1.7. The laboratory cooperates with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. The Reasonable Access Policy states Fluke's willingness to cooperate with customer requests to monitor the laboratory's performance in relation to the work performed. Access to the laboratory's work is consistent with the confidentiality commitments as defined in [FCM 4120](#).
- 7.1.8. Records of reviews, including any significant changes, pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities are retained in accordance with [FCM 8004](#).

#### **P4 - Policy on Review of Requests, Tenders and Purchase Orders**

*It is Fluke's policy that requests, tenders and purchase orders are reviewed prior to work proceeding on the equipment and that any differences between the request or tender and the purchase order is resolved before any work commences. Each purchase order shall be acceptable both to the laboratory and the customer. It is also Fluke's policy that the requirements of the service and the procedures to be used are adequately defined, documented and understood, the laboratory has the capability and resources to meet the requirements and when the procedures are not specified by the customer the laboratory selects the most appropriate method in accordance with Section 7.2 of this document.*

- 7.1.9. The procedure for the review of purchase orders, requests and tenders is documented in [FCM 7000](#).



## 7.2. Selection, Verification and Validation of Calibration Procedures

### 7.2.1. Selection and Verification of Calibration Procedures

- 7.2.1.1. The laboratory uses appropriate calibration procedures for all laboratory calibration activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.
- 7.2.1.2. In accordance with [FCM 8230](#), all procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, are kept up to date and made readily available to personnel.
- 7.2.1.3. The laboratory ensures that it uses the latest valid version of a procedure unless it is not appropriate or possible to do so. When necessary, the application of the procedure is to be supplemented with additional details to ensure consistent application.
- 7.2.1.4. When the customer does not specify the procedure to be used, the laboratory selects an appropriate procedure and informs the customer of the procedure chosen. Procedures 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, are recommended. Laboratory-developed or modified procedures can also be used.

#### **P5 - Policy on Selection of Calibration Methods**

*Fluke's method of communicating calibration procedures is through the selection of the products or the service item numbers. These procedures have been validated per 7.2.2 and may include aspects of procedures published by international, regional or national standards but not necessarily used directly.*

- 7.2.1.5. The laboratory verifies that it can properly perform procedures before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained in accordance with [FCM 8004](#). If the method is revised by the issuing body, verification will be repeated to the extent necessary.
- 7.2.1.6. Procedure development is a planned activity and is assigned to competent personnel equipped with adequate resources. As procedure development proceeds, periodic review is carried out to

confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan are approved and authorized.

7.2.1.7. Deviations from procedures for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

## 7.2.2. Validation of Calibration Procedures

7.2.2.1. Non-standard procedures, laboratory-developed procedures and standard procedures used outside their intended scope or that are otherwise modified are validated by the laboratory to the extent necessary. The validation must ensure that the method meets the needs of the given application or field of application.

7.2.2.2. When changes are made to a validated procedure, the influence of such changes are to be determined and where they are found to affect the original validation, a new procedure validation is performed.

7.2.2.3. The performance characteristics of validated procedures, as assessed for the intended use, are relevant to the customers' needs and consistent with specified requirements.

7.2.2.4. The laboratory retains the following records of validation in accordance with [FCM 8004](#):

- a) the validation procedure used;
- b) specification of the requirements;
- c) determination of the performance characteristics of the method;
- d) results obtained;
- e) a statement on the validity of the procedure, detailing its fitness for the intended use.

## 7.3. Sampling

7.3.1. Fluke does not maintain QSD or FCM procedures for sampling requirements. Any Fluke laboratory performing sampling and issuing sampling reports must document their requirements in accordance with ISO/IEC 17025 requirements and any requirements of the accrediting body.

## 7.4. Handling of Calibration Items

- 7.4.1. The laboratory has a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return 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. To avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for calibration, precautions are taken. Handling instructions provided with the item are followed.
- 7.4.2. The laboratory has a system for the unambiguous identification of calibration items. The identification is retained while the item is under the responsibility of the laboratory. The system ensures that items will not be confused physically or when referred to in records or other documents. When appropriate, the system accommodates a sub-division of an item or groups of items and the transfer of items. Items are identified in such a way that they do not harm the integrity of the instrument. When items are delivered in special packaging the special packaging is re-used for return packaging, if still in good condition.
- 7.4.3. Upon receipt of the calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for calibration, or when an item does not conform to the description provided, the laboratory will consult the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be calibrated acknowledging a deviation from specified conditions, the laboratory includes a disclaimer in the certificate of calibration indicating which results may be affected by the deviation.
- 7.4.4. When items need to be stored or conditioned under specified environmental conditions not already defined by the laboratory, these conditions are maintained, monitored and recorded.
- 7.4.5. The procedure for handling of calibration items is documented in [FCM 7000](#). Records are controlled in accordance with [FCM 8004](#).

## 7.5. Technical Records

- 7.5.1. The laboratory ensures that technical records for each laboratory activity contain the results and a copy of each certificate of calibration issued. If possible, the records for each calibration will contain sufficient information

to facilitate identification of factors affecting the measurement result and its associated measurement uncertainty, which enables the repetition of the laboratory activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

7.5.2. The laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files are retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.5.3. Technical records are maintained in accordance with [FCM 8004](#).

## **7.6. Evaluation of Measurement Uncertainty**

7.6.1. Fluke Laboratories identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, are taken into account using appropriate methods of analysis.

7.6.2. Fluke evaluates measurement uncertainty for all calibrations including of its own equipment.

7.6.3. Fluke does not maintain QSD or FCM procedures for testing requirements. Any Fluke laboratory performing testing and issuing test reports must document their requirements in accordance with ISO/IEC 17025 requirements and any requirements of the accrediting body.

7.6.4. The procedure for the evaluation of measurement uncertainty is documented in [FCM 7000](#).

## **7.7. Ensuring the Validity of Results**

7.7.1. The procedure for monitoring the validity of results is documented in [FCM 7000](#). The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;

- b) use of alternative instrumentation that has been calibrated to provide traceable results;
- c) functional check(s) of measuring and testing equipment;
- d) use of check or working standards with control charts, where applicable;
- e) intermediate checks on measuring equipment;
- f) replicate calibrations using the same or different procedures;
- g) retesting or recalibration of retained items;
- h) correlation of results for different characteristics of an item;
- i) review of reported results;
- j) intralaboratory comparisons;
- k) N/A – Fluke does not perform sampling.

7.7.2. The laboratory monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but is not limited to, either or both of the following:

- a) participation in proficiency testing;
- b) participation in interlaboratory comparisons other than proficiency testing.

7.7.3. Data from monitoring activities are analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported.

## **7.8. Reporting of results**

### **7.8.1. General**

7.8.1.1. Results of calibrations are reviewed and authorized prior to release.

7.8.1.2. The results are provided accurately, clearly, unambiguously, and objectively, in a certificate of calibration as applicable. Certificates of calibration include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued certificates of calibration are retained as technical records in accordance with [FCM 8004](#).

7.8.1.3. When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer is readily available.

## 7.8.2. Common Requirements for Certificates of Calibration

7.8.2.1. Each Certificate of Calibration includes at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

- a) The title, i.e. "Certificate of Calibration";
- b) the name and address of the laboratory;
- c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
- d) unique identification that all its components are recognized as a portion of a complete certificate of calibration and a clear identification of the end;
- e) the name and contact information of the customer; Note: for manufactured items customer information may not be known at the time of calibration.
- f) identification of the procedure and revision used;
- g) a description, unambiguous identification, and, when necessary, the condition of the item;
- h) the date of receipt of the calibration item(s) where this is critical to the validity and application of the results;
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the certificate of calibration;
- k) N/A – Fluke does not perform sampling;
- l) a statement to the effect that the results relate only to the items calibrated;
- m) the results with, where appropriate, the units of measurement;
- n) additions to, deviations, or exclusions from the procedure;
- o) identification of the person(s) authorizing the certificate of calibration;
- p) clear identification when results are from external providers.

7.8.2.2. The laboratory is responsible for all the information provided in the certificate of calibration, except when information is provided by the

customer. Data provided by a customer is clearly identified. In addition, a disclaimer is put on the certificate of calibration when the information is supplied by the customer and can affect the validity of results.

### 7.8.3. Specific Requirements for Test Reports

7.8.3.1. Fluke does not maintain QSD or FCM procedures for test report requirements. Any Fluke laboratory performing testing and issuing test reports must document their requirements in accordance with ISO/IEC 17025 requirements and any requirements of the accrediting body.

### 7.8.4. Specific Requirements for Certificates of Calibration

7.8.4.1. In addition to the requirements listed in 7.8.2, certificates of calibration issued by Fluke laboratories include the following:

- a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent), (not applicable to non-accredited certificates);
- b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
- c) a statement identifying how the measurements are metrologically traceable;
- d) the results before and after any adjustment or repair, if available;
- e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6), (not applicable to non-accredited certificates);
- f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2. N/A - Fluke does not perform sampling.

7.8.4.3. A certificate of calibration or calibration label will not contain any recommendation on the calibration interval, except where this has been agreed with the customer. If a calibration interval is required, this must be clearly indicated on each Purchase Order or in another form of documented communication between the customer and the laboratory.

### 7.8.5. Reporting Sampling – Specific Requirements

7.8.5.1. N/A – Fluke does not perform sampling.

7.8.6. Reporting Statements of Conformity (does not apply to non-accredited certificates)

7.8.6.1. When a statement of conformity to a specification or standard is provided, the laboratory documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

7.8.6.2. The laboratory reports on the statement of conformity, such that the statement clearly identifies:

- a) to which results the statement of conformity applies;
- b) which specifications, standards or parts thereof are met or not met;
- c) the decision rule applied (unless it is inherent in the requested specification or standard).

7.8.6.3. Fluke's decision rules for statements of conformance are documented in 13 Appendix A.

7.8.7. Reporting Opinions and Interpretations

7.8.7.1. When opinions and interpretations are expressed, the laboratory ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory documents the basis upon which the opinions and interpretations have been made.

7.8.7.2. The opinions and interpretations expressed in reports are based on the results obtained from calibrated item and are clearly identified as such.

7.8.7.3. When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained.

7.8.8. Amendments to Certificate of Calibration

7.8.8.1. When an issued certificate of calibration needs to be changed, amended or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change included in the certificate of calibration.



7.8.8.2. Amendments to a certificate of calibration after issue are made only in the form of a further document, or data transfer, which includes the statement: “Amendment to certificate of calibration, certificate number... [or as otherwise identified]”, or an equivalent form of wording.

7.8.8.3. Such amendments meet all the requirements of this document.

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

#### **P6 - Policy on Certificates of Calibration**

*It is the Policy of Fluke laboratories that in addition to the requirements of this document, the laboratory evaluates and complies with any additional requirements of its accrediting body in regards to Certificates of Calibration. Requirements established by an accrediting body may include control of the accrediting body logo or symbol.*

7.8.8.5. The minimum format and content requirements for certificates of calibration issued by Fluke laboratories are documented in.  
[QSD111.26 Certificate of Calibration Format Requirements](#)

7.8.8.6. Laboratories issuing Test Certificates or Sampling Reports must ensure they have documented their requirements for the Test Certificate or Sampling Report.

### **7.9. Complaints**

7.9.1. The work instructions detailing the process of the receipt, evaluation and decision making on complaints is documented in [FCM 7910](#).

7.9.2. Fluke has made available a Flowchart describing the handling process for complaints in Appendix B of this document. Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that it is responsible for. The laboratory is responsible for all decisions at all levels of the handling process for complaints. If the laboratory is not responsible for the complaint, best effort will be made to direct the complainant to the appropriate department/group.

7.9.3. The process for handling complaints includes the following elements and methods:

- a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken.

7.9.4. The laboratory responsible for the complaint is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5. Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6. The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question. Fluke will make a best effort to resolve customer complaints through customer contact, investigation, corrective action and/or accommodation.

7.9.7. Whenever possible, the laboratory or functional department assigned the complaint gives formal notice of the end of the complaint handling to the complainant.

## 7.10. Nonconforming Work

7.10.1. The procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria) is [FCM 7910](#). The procedure ensures that:

- a) the responsibilities and authorities for the management of nonconforming work are defined;
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
- d) a decision is taken on the validity of the nonconforming work;
- e) where necessary, the customer is notified, and work is recalled;
- f) the responsibility for authorizing the resumption of work is defined.

7.10.2. The laboratory retains records of nonconforming work and actions as specified in 7.10.1, bullets b) to f) in accordance with [FCM 8004](#).

7.10.3. Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory implements corrective action.

## **7.11. Control of Data and Information Management**

7.11.1. The laboratory has access to the data and information needed to perform laboratory activities.

7.11.2. The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software are authorized, documented and validated before implementation.

7.11.3. The laboratory information management system(s):

- a) are protected from unauthorized access;
- b) are safeguarded against tampering and loss;
- c) are operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- d) are maintained in a manner that ensures the integrity of the data and information;
- e) include recording system failures and the appropriate immediate and corrective actions.

7.11.4. When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory ensures that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5. The laboratory ensures that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6. Calculations and data transfers are checked in an appropriate and systematic manner.

7.11.7. The procedure for control of data is documented in [FCM 7000](#).

## 8. Management System Requirements

### 8.1. Options A and B

#### 8.1.1. General

The laboratory has established, documented, implemented and maintained a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of sections 4 to 7, the laboratory has implemented a management system in accordance with Option A or Option B.

#### 8.1.2. Option A

As a minimum, the management system of the laboratory addresses the following:

- management system documentation (see 8.2);
- control of management system documents (see 8.3);
- control of records (see 8.4);
- actions to address risks and opportunities (see 8.5);
- improvement (see 8.6);
- corrective actions (see 8.7);
- internal audits (see 8.8);
- management reviews (see 8.9).

#### 8.1.3. Option B

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001 and that is capable of supporting

and demonstrating the consistent fulfilment of the requirements of ISO 9001 sections 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

[FCM 8001](#) describes the minimum requirements, whether the laboratory is choosing to implement Option A or Option B.

## 8.2. Management System Documentation (Option A)

- 8.2.1. Laboratory management has established, documented, and maintains policies and objectives for the fulfilment of the purposes of this document and ensures that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.
- 8.2.2. The policies stated throughout this document ensure the impartiality and competency of the laboratory activities and its personnel.
- 8.2.3. Methods of providing evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness are documented in [FCM 8006](#).
- 8.2.4. In accordance with [FCM 8230](#), all documentation, processes, systems, records, related to the fulfilment of the requirements of this document are included in, referenced from, or linked to the management system.
- 8.2.5. All personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.
- 8.2.6. [FCM 5062](#) establishes minimum competency requirements of personnel to ensure consistent operations of the laboratory.

## 8.3. Control of Management System Documents (Option A)

- 8.3.1. [FCM 8230](#) defines the minimum requirements for the control of documents (internal and external) that relate to the fulfilment of this document.
- 8.3.2. [FCM 8230](#) establishes minimum requirements to ensure:
  - a) documents are approved for adequacy prior to issue by authorized personnel;
  - b) documents are periodically reviewed, and updated as necessary;

- c) changes and the current revision status of documents are identified;
- d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- e) documents are uniquely identified;
- f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

#### 8.4. Control of Records (Option A)

- 8.4.1. [FCM 8004](#) ensures legible records are retained to demonstrate fulfilment of the requirements in this document.
- 8.4.2. [FCM 8004](#) establishes the minimum requirements to control record identification, storage, protection, back-up, archive, retrieval and disposal of its records. The laboratory retains records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality commitments as defined in [FCM 4120](#), and records are readily available.

#### 8.5. Actions to Address Risks and Opportunities (Option A)

- 8.5.1. In accordance with [FCM 8005](#), the laboratory considers the risks and opportunities associated with the laboratory activities in order to:
  - a) give assurance that the management system achieves its intended results;
  - b) enhance opportunities to achieve the purpose and objectives of the laboratory;
  - c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
  - d) achieve improvement.
- 8.5.2. The laboratory plans:
  - a) actions to address these risks and opportunities;
  - b) how to:
    - integrate and implement these actions into its management system;
    - evaluate the effectiveness of these actions.
- 8.5.3. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

## 8.6. Improvement (Option A)

- 8.6.1. [FCM 8006](#) defines the minimum requirements for the identification and selection of opportunities for improvement and the laboratory implements any necessary actions.
- 8.6.2. The laboratory seeks feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service. The process for feedback is documented in [FCM 8006](#).

### **P7 - Policy on Improvement**

*The laboratory continually improves the effectiveness of its management system through the use of customer feedback, internal or external audits and Fortive Business System activities.*

## 8.7. Corrective Actions (Option A)

- 8.7.1. In accordance with [FCM 7910](#), when a nonconformity occurs, the laboratory:
  - a) reacts to the nonconformity and, as applicable:
    - takes action to control and correct it;
    - addresses the consequences;
  - b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
    - reviewing and analyzing the nonconformity;
    - determining the causes of the nonconformity;
    - determining if similar nonconformities exist, or could potentially occur;
  - c) implements any action needed;
  - d) reviews the effectiveness of any corrective action taken;
  - e) updates risks and opportunities determined during planning, if necessary;
  - f) makes changes to the management system, if necessary.
- 8.7.2. Corrective actions implemented are appropriate to the effects of the nonconformities encountered.
- 8.7.3. The laboratory retains records as evidence of:

- a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
- b) the results of any corrective action.

### **P8 - Policy on Corrective Action**

*It is Fluke's policy that an investigation of the potential causes of the departure from work is completed and documented. Corrective Action shall be implemented when a discrepancy with the management system or with technical operations of the laboratory have been identified during internal or external audits, feedback from customers, or staff observations.*

#### **8.8. Internal Audits (Option A)**

8.8.1. Internal Audits are conducted at planned intervals in accordance with [FCM 8008](#) and ensure that the management system:

- a) conforms to:
  - the laboratory's own requirements for its management system, including the laboratory activities;
  - the requirements of ISO/IEC 17025;
  - any requirements, in addition to ISO/IEC 17025, that are mandated by the accreditation body of the laboratory.
- b) is effectively implemented and maintained.

8.8.2. In accordance with [FCM 8008](#), the laboratory:

- a) plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
- b) defines the audit criteria and scope for each audit;
- c) ensures that the results of the audits are reported to relevant management;
- d) implements appropriate correction and corrective actions without undue delay;
- e) retains records as evidence of the implementation of the audit program and the audit results.

8.8.3. Records are controlled in accordance with [FCM 8004](#).



## 8.9. Management Reviews (Option A)

8.9.1. Laboratory management reviews its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document. Minimum requirements to meet this are established in [FCM 8009](#).

8.9.2. The inputs to management review are recorded and include information related to the following:

- a) changes in internal and external issues that are relevant to the laboratory;
- b) fulfilment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcome of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the work or in the range of laboratory activities;
- i) customer and personnel feedback;
- j) complaints;
- k) effectiveness of any implemented improvements;
- l) adequacy of resources;
- m) results of risk identification;
- n) outcomes of the assurance of the validity of results; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3. The outputs from the management review record all decisions and actions related to at least:

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- c) provision of required resources;

d) any need for change.

8.9.4. Records are controlled in accordance with [FCM 8004](#).

## 9. Responsibility and Authority

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

## 10. Records

Listed throughout document

## 11. Approvals and Notifications

Process/Document Owner:	Chief Corporate Metrologist
Approver:	Chief Corporate Metrologist
Approver:	Corporate 17025 Metrology Manager
Document Reviewer:	Corporate Quality Council
Document Reviewer:	Metrology Council

The Metrology and Quality Council will be notified of changes to this document through Intalex. The required review is applicable to Quality and Metrology Council members with responsibilities in an ISO/IEC 17025 accredited laboratory only. The Metrology and Quality Council members are responsible for communicating the changes to their facilities.

## 12. Change History

The translated version(s) of this document must be reviewed and revised each time this document is revised to ensure changes area easily identified for translation purposes.

Revision No.	Brief Description of Change(s)	Training required?
001 July 2012	-Released to Document Control	Yes
002 August 2012	-Changed to QSD 111.41 from QSD 111.59	No

Revision No.	Brief Description of Change(s)	Training required?
003 Jan 2014	<ul style="list-style-type: none"> <li>-New QSD format.</li> <li>-Added Fluke Corporate Quality statement.</li> <li>-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.</li> <li>-Add statement (See Section 4.1.2) to Sections 5.4.6, 5.6 and 5.10 for clarity.</li> <li>-Fix formatting error in Section 4.2.5.</li> <li>-Clarified Not Applicable in Sections 5.4.6.2, 5.6.2.2, 5.7, and 5.10.3.</li> <li>-Section 5.1 removed reference to Annex B.</li> </ul>	Yes
004 May 2014	<ul style="list-style-type: none"> <li>- Added QSD 111.2 and ITD-00004 to the Internal References.</li> <li>- Added the VIM to definitions, Section 3.3.</li> <li>- Changed all references to “handbook” to “document”.</li> <li>- Section 4.2.5: Added reference to FCM 2403.41. Changed the document tier to reflect corporate metrology SOPs and lab SOPs.</li> <li>- Section 4.2.5: Change descriptions to match new document tier.</li> <li>- Added Section 4.2.6 and 4.2.7.</li> <li>- Section 4.4.3: Deleted the extra level four number creating the correct reference.</li> <li>- Section 4.4.5: Added “are” to correct grammar.</li> <li>- Section 5.4.3: Corrected grammar.</li> <li>- Section 5.4.6.2: Clarified “Not Applicable” that was missed in Rev 003.</li> <li>- Section 5.10.4.1 c): changed reference to Note as Note 2 does not exist in reference.</li> </ul>	Yes
005 Sep 2014	<ul style="list-style-type: none"> <li>- Removed Martin Girard from the Quality Policy Statement as he no longer works for Fluke.</li> <li>- Removed document level specificity from the QSD to the Level 2 Document Control procedure.</li> <li>-Revised Section 4.2.5 to simply state conformance to corporate requirements with reference to FCM 2403.41 Document Control for further definition.</li> </ul>	No
006 May 2019	<ul style="list-style-type: none"> <li>- Complete rewrite to update to comply with ISO/IEC 17025:2017</li> <li>- Incorporated policy on guardbanding and Statements of Conformity</li> <li>- Included policy on NMI Test Numbers</li> </ul>	Yes

Revision No.	Brief Description of Change(s)	Training required?
007 May 2020	- Updated document number references, removed policy on NMI Test Numbers	No
008 July 2022	<ul style="list-style-type: none"> <li>- Numbered policies throughout</li> <li>- Included metrology quality org chart reference</li> <li>- Corrections on some references to internal documents including FCM 7910 and FCM 7000</li> <li>- Added dates to the revision list</li> <li>- defined maximum permissible error in Appendix A</li> <li>- Some general wording improvements throughout</li> </ul>	No
009 Feb 2024	<ul style="list-style-type: none"> <li>- Updated all links to PLM links and added PLM q number.</li> <li>- Added back the requirement in 8.8 for accreditation body specific requirements separate from ISO/IEC 17025</li> <li>- Added the definition of "Maximum Permissible Error" in Appendix A (was not done in rev 008 as thought). Also clarified Statement of Conformity, and also that it is not applied to As Left results if there is an As Left Guardband.</li> </ul>	No

## 13. Appendix A – Statements of Conformity and Guardbanding

### 13.1. Purpose

This appendix is an expansion of the Fluke policy FCM 7008.1 Statements of Conformity in Calibration Certificates. The reason for this appendix and FCM 7008.1 is primarily driven from the requirements of Section 7.1.3 and 7.8.6 in this manual. The added information that is not in FCM 7008.1 and included here is more detail on the decision rules used and information on the policies for As-Left guardbanding.

### 13.2. Scope

For calibrations where the resultant measurement error, i.e. the difference between the measured quantity value and the reference quantity value, is evaluated by verification to a product specification. There are many calibrations where the result of a measurement is not verified to a specification or is simply a reported metrological value. These requirements are not applicable to those calibrations.

### 13.3. Terms and Definitions

**Statement of Conformity** – An indication that a verification point result meets a specification, such as Pass/Fail with a stated false accept risk.

**Maximum Permissible Error** – Limit in certificate of calibration defined by the stated specification for the instrument being calibrated.

**As-Left Guardband** – A guardband that has been developed to ensure that the product remains within published specifications throughout its calibration interval.

**NOTE:** An As-Left guardband can be proactively applied to As-Found data to determine if adjustment and As-Left verification is required.

**Test Uncertainty Ratio (TUR)** – The ratio of the published specification of the instrument of interest to the expanded uncertainty of measurement at a given test point.

### 13.4. Statements of Conformity

When making statements of conformity, Fluke conservatively guarantees a 2% false accept risk estimate. This is accomplished by the following methods assuming a worst-case end of period reliability of 85%. The methods used to control this are as follows:

1. Maintenance of a 4:1 or greater TUR. Fluke's goal is to always provide a calibration with an expanded uncertainty that is four times less than the specification. In this case 2% probability of false accept is assured, and there is no need to guardband.

2. Use of a Guardband. In cases where it is not possible to ensure an expanded uncertainty to be four times less than the specification Fluke uses guardband methods that ensure there is a maximum false accept risk of 2%. In this case there is some possibility that there may be a conditional pass result. This is where the measurement error is less than the specification (i.e. in tolerance or pass), but because of expanded uncertainty the false accept risk may exceed 2%. Note that it is extremely rare, even with TURs approaching 1:1 to have a false accept risk greater than 10%. The possible guardband methods used are:

a. Root-difference-square (RDS) guardband (G), ILAC-G8:09/2019, APPX B, example 3. The square root of the square of the specification (S) minus the square of the expanded uncertainty (U) at a 95% confidence level.

$$G = \sqrt{S^2 - U_{95\%}^2}$$

b. ILAC-G8:09/2019, APPX B, example 2. Specification minus the expanded uncertainty at a 95% confidence level.

$$G = S - U_{95\%}$$

c. Dobbert method. Based on the paper "A Guard-Band Strategy for Managing False-Accept Risk", Michael Dobbert, Keysight Technologies Inc., 2008 NCSL International Workshop and Symposium.

$$G = S - U_{95\%} \times [1.04 - e^{(0.38 \times \log(\text{TUR}) - 0.54)}]$$

This method is not limited to the end of period reliability of 85% as defined in 13.4 but does assume the worst-case end of period reliability when considering false accept risk.

d. Calculated using RiskGuard™ software, Integrated Sciences Group. By entering 2% as false accept limit, uncertainty and confidence, the appropriate end of period reliability and using the resultant guardband.

NOTE: When using methods 2a, 2b, 2c or 2d, the resultant guardband limits may create a zone between the guardband and specification limit that is designated as conditional pass or conditional fail.

The screenshot shows the ISG RiskGuard software interface with the following sections:

- UUT Parameter**:
 

	Values	Units
Nominal Value	100	V
Upper Tolerance Limit	0.01	V
Lower Tolerance Limit	-0.01	V
In-tolerance Probability	85.00	%
Distribution	Normal	
Bias Std Uncertainty	0.0069	V
Max Allowable Risk	2	%
- Tolerance Options**:
  - ☒ Two-Sided
  - ☐ Single-Sided Upper
  - ☐ Single-Sided Lower
- Measurement Process Uncertainty**:
 

Expanded Uncertainty	0.0050	V
Confidence Level (%)	95.00	100
Standard Uncertainty	0.0025	V
- Classical Method** (selected):
 

Control Variables	± Guardband Limits		
TUR		0.0092	V
2.00 : 1	k - Factor	0.3227	
- Computed Risks**:
 

False Accept Risk	2.0000	%
False Reject Risk	5.6283	%
- False Accept Risk**:
  - ☒ Consumer Option
  - ☐ Producer Option
- ☒ Include Guardbands

**Figure A1:** Example of guardband determined from RiskGuard for 2:1 TUR, 85% end of period reliability and 2% false accept risk.

In place of the software the actual calculations that RiskGuard uses may be used. These can be found in the paper “Alternative Risk Analysis Methods”, Howard Castrup, Ph.D., Integrated Sciences Group. This paper is found in the help menu of the RiskGuard software.

These methods are not available options for every calibration but are possibilities based on the laboratory location and the product being calibrated. The calibration certificate must state the decision rule but may only describe the method used by referencing this policy and applicable paragraph such as “FCM 7008.1, paragraph 2a revision xxx.yyy”.

The limit these rules are applied to may be called the Maximum Permissible Error in the certificate of calibration. This is defined as: The instrument specification computed from the published specifications, or a value agreed upon by the customer.

If the methods described above are not acceptable, it must be indicated at the time a request is submitted to Fluke. This may be done through a purchase order, in the RMA request, or by communicating directly to one of our call center personnel.

Though we always want to comply to our customer's request, it is possible we may not be able to accommodate a different decision rule depending on the complexity or laboratory constraints.

### 13.5. As-Left Guardband

An As-Left guardband is defined as a limit that has been developed to ensure that the product remains within published specifications throughout its calibration interval. The As-Left guardband is a limit that if exceeded would require the instrument to be repaired or adjusted. The As-Left guardband is equal to or more conservative than those methods described in Section 13.4.

The As-Left guardband is typically applied in the decision to determine whether or not the instrument is acceptable to ship (i.e. As-Left results). Note that it is common practice to proactively apply the As-Left guardband to As-Found data to determine if an instrument should be adjusted. Note that if there is not an As-Left Guardband applied, a statement of conformity guardband using the product specification is applied as necessary (see 13.4 in this Appendix).

#### 13.5.1. General Practice:

When the General Practice is used, no further documentation of methodology is required. Whether an instrument is new and initially calibrated, or if it is being returned for recalibration, an As-Left guardband should be applied as an adjustment/repair limit. This is dependent on the ability of the device under test to be adjusted. As a guideline the general practice As-Left guardband should not be any higher than 80% of the specification, with 70% being more common and preferred. It is possible that for the general practice on non-Fluke instruments, that it cannot be adjusted within the general practice limits due to linearity, resolution or some other characteristic, so is only a general policy.

#### 13.5.2. Other Practices:

In many cases As-Left guardbands are determined during the product development and manufacture for a specific model or type of device. These guardbands should only be used if they are supported by an instrumental measurement uncertainty analysis that is sufficiently documented and published in the calibration or service manual. For items currently available for purchase from Fluke the As-Left guardband



may be a specification under warranty, or may require repair if not met and not under warranty.

## 14. Appendix B – Handling of Complaints

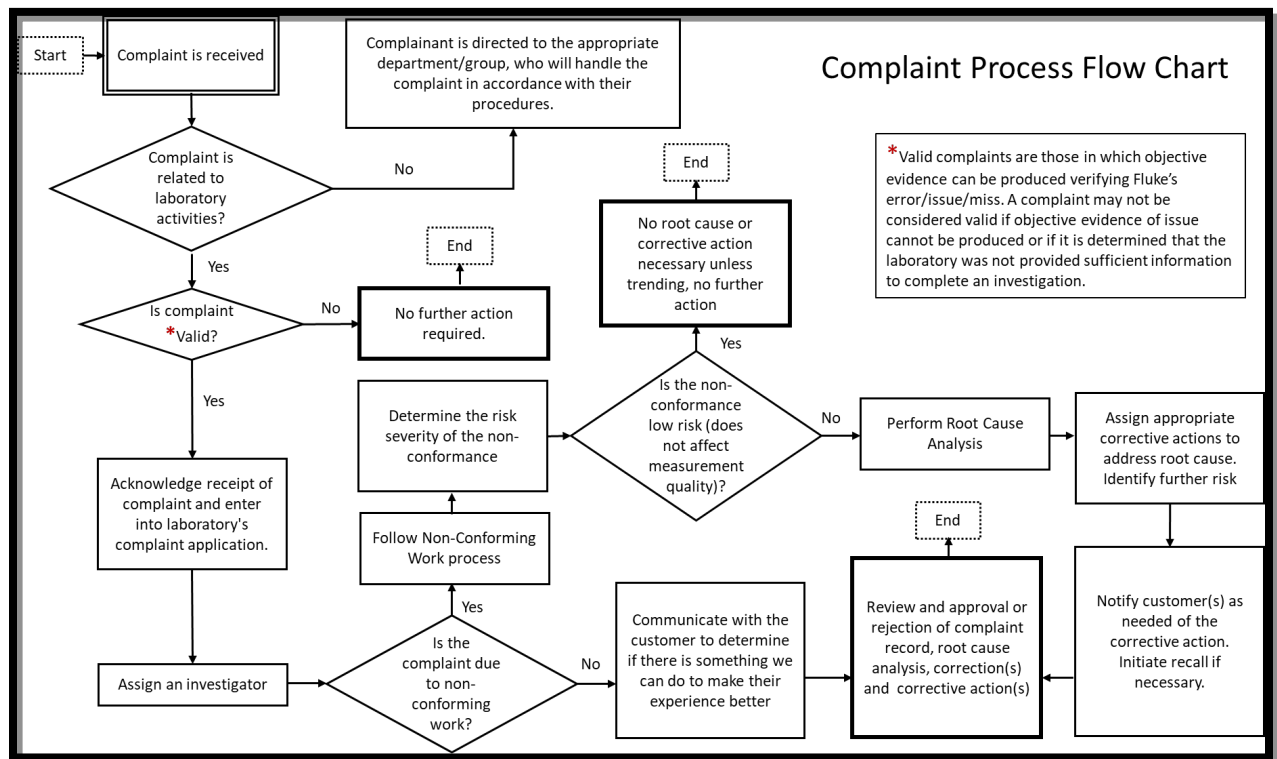


Figure B1: Laboratory Complaint Process Flow Chart.

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