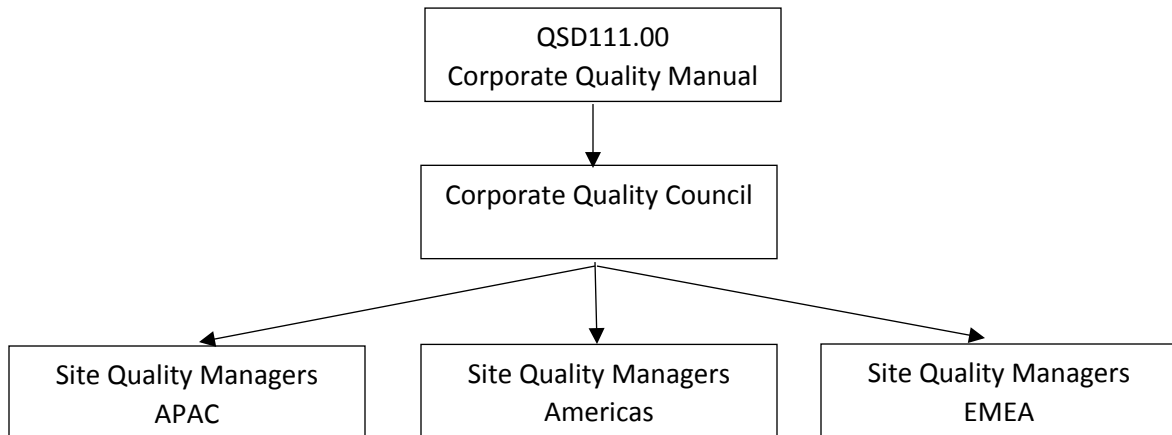


Corporate Quality Manual

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	Rev. 120
Approver:	Director of Global Quality
Approver:	Quality Systems Manager
Document Reviewer:	Corporate Quality Council
Document Owner:	Quality Systems Manager
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Notifications/Distribution

The Corporate Quality Council will be notified of changes to the Corporate Quality Manual through Intelx. Corporate Quality council members are responsible for communicating changes to their functional groups.



Quality Policy

To establish, monitor and continuously improve our quality system to meet all applicable requirements and customer expectations.

Purpose

This procedure defines the policies and related procedures Fluke follows in order to comply with the requirements of the ISO 9001:2015 and ISO/IEC 80079-34 standards.

Introduction

Fluke Corporation (Fluke) is a leading manufacturer of measurement and test equipment with corporate headquarters located in Everett, Washington, USA with global operations and subsidiaries.

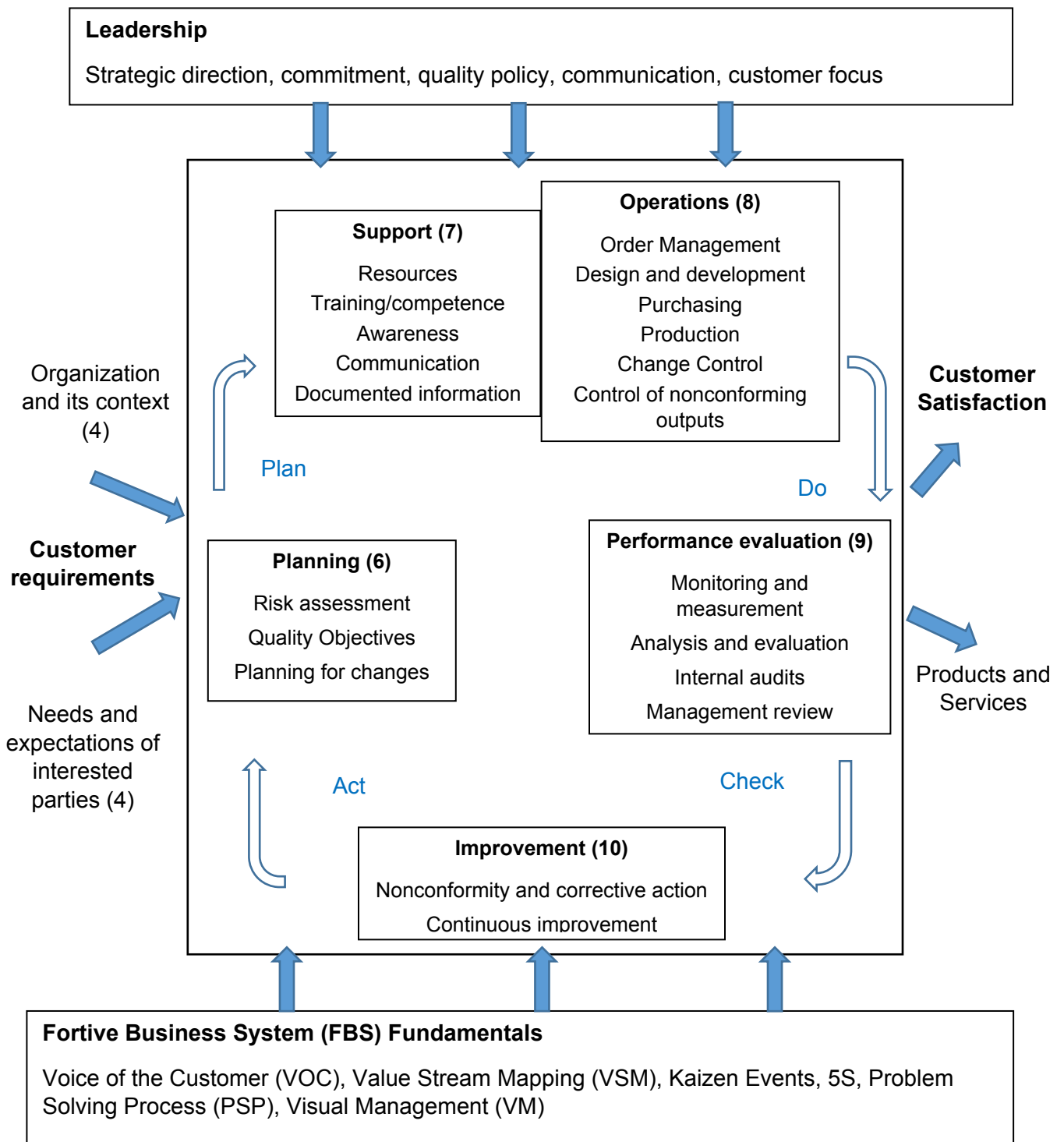
Fluke uses a process approach in our Quality Management System (QMS) where required inputs and desired outputs are identified and monitored to ensure applicable requirements and customer expectations are met.



Fluke is part of the Fortive Corporation and employs the [Fortive Business System](#) (FBS) as the cornerstone of our culture and our competitive advantage. FBS drives continuous improvement of our Quality Management System. Tools include Kaizen events, Problem Solving Process (PSP), risk analysis using the DIVE methodology (define the problem, investigate to drive root cause, verify and implement countermeasures, ensure sustainment) and other tools as appropriate.

Fluke's interaction of processes of the Quality Management system is shown in the following diagram.

Fluke Quality Management System



10 Procedure scope

All locations, departments, divisions, operating companies (OpCos) and acquisitions of the Fluke Corporation follow the requirements of this Quality Manual, unless otherwise noted. Facilities may have supplementary policies, processes and local procedures to further define their specific requirements and activities.

2 References

Internal

[Fluke Corporate Scope and Context Statement](#)

[QSD111.01 Manufacturing Process](#)

[QSD111.02 Corporate Training Policy and Requirements](#)

[QSD111.03 External Product Quality](#)

[QSD111.07 Control of Nonconforming Material](#)

[QSD111.09 Corrective/Preventive Action Procedure](#)

[QSD111.10 Internal Audit Process](#)

[QSD111.37 Product Development Process](#)

[QSD111.39 Document Control Policy](#)

[QSD111.41 Fluke 17025 Quality Manual](#)

[QSD111.44 Measurement Management System](#)

[QSD111.50 Records Retention Policy](#)

[QSD111.56 Serialized and Non-Serialized Product Marking Requirements](#)

[QSD19.1 Electrostatic Discharge Policy](#)

External

[ISO 9001 Quality Management System Requirements](#)

[ISO 17025 Quality Management System Requirements for Accredited Laboratories](#)

[ISO/IEC 80079-34 Explosive atmospheres – Application of quality systems for equipment manufacture](#)

3 Terms and definitions

Defined within the context of this procedure.

4 Fluke scope and context

The overview of Fluke, its organization, context and interested parties as well as their needs and expectations are located in the [Fluke Corporate Scope and Context Statement](#). Each facility has a Scope and Context statement that further defines their context and interested parties based on the activities performed and products manufactured within that facility or functional area.

Fluke has established, maintains and continually improves our Quality Management System in accordance with the ISO 9001 standard.

As part of our Quality Management System, Fluke has determined the processes needed and their application throughout the company and continually:

- determines required inputs and expected outputs from these processes,
- determines the sequence and interaction of processes,
- determines and applies criteria and methods needed to ensure the effective operation and control of our processes
- determines the resources needed for these processes and ensures their availability and suitability
- assigns the responsibilities and authority for these processes
- addresses the risks and opportunities for improvement as determined in accordance with our planning processes
- evaluates these processes and implements changes needed to ensure that these processes achieve their intended results
- improves the processes and the Quality Management System.

To the extent necessary, Fluke maintains documented information necessary to support our processes and retains documented information as required to demonstrate that these processes are being carried out as planned.

5 Leadership

Leadership and commitment

Top management demonstrates leadership and commitment with respect to the Quality Management System by:

- taking accountability for the effectiveness of the Quality Management System in achieving its intended results through active participation in management review
- ensuring that the quality policy and quality objectives are established and are compatible with the strategic direction of Fluke (policy deployment, key performance indicators (KPI's), and employee performance objectives).
- ensuring integration of the Quality Management System requirements with Fluke's business processes
- promoting continuous improvement, the use of a process approach and risk based thinking through use of our FBS tools
- ensuring that the resources needed for the Quality Management System are available
- communicating the importance of effective quality management and conforming to Fluke's Quality Management System requirements

Top management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- customer and applicable regulatory requirements are determined, understood, and consistently met
- risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed,
- focus on enhancing customer satisfaction is maintained through appropriate setting of performance objectives.
- ensuring customers have a method to provide quality feedback to Fluke

Quality policy

Top management has established Fluke's Quality Policy which is documented in the [Fluke Corporate Scope and Context Statement](#) and is available in Intelex. The Quality Policy is communicated throughout the company.

Roles and responsibilities

Top management ensures that responsibilities and authorities for relevant roles are assigned, communicated and understood throughout Fluke. This is done through departmental organizational charts and job descriptions.

Top management has assigned the Director of Global Quality as the Management Representative with responsibilities for:

- ensuring that the Quality Management System conforms to the ISO 9001 standard requirements
- ensuring that the Quality Management System conforms to the IEC80079-34 standard requirements as applicable for the manufacture of products intended for use in explosive atmospheres. See QSD111.11 Fluke 80079-34 Ex Quality Manual
- ensuring that processes are delivering their intended outputs
- reporting on the performance of the Quality Management System and on opportunities for improvements
- ensuring the promotion of customer focus throughout Fluke
- ensuring that the integrity of the Quality Management System is maintained when changes are planned and implemented.

6 Planning

When planning for the Quality Management System, Fluke considers the context of the organization, its customers and their requirements and determines the risks and opportunities that need to be addressed in order to:

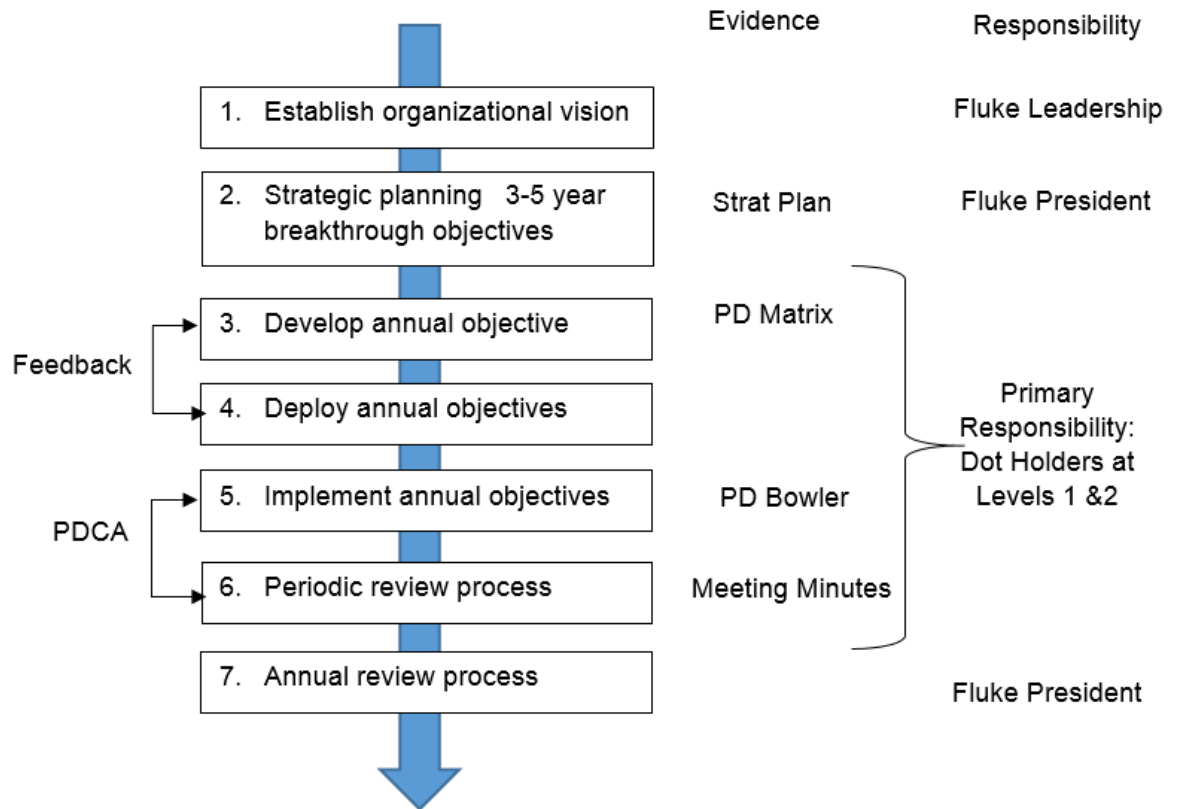
- give assurance that the Quality Management System can achieve its intended results
- prevent or reduce undesirable effects and enhance desired effects
- achieve improvement.

Fluke addresses these risks and opportunities by integration and implementation of actions into the Quality Management System and evaluation of the effectiveness of these actions through use of tools such as daily and visual management, Key Performance Indicator (KPI) bowlers and other measurement processes. Actions taken are proportional to the potential impact on the conformity of products and services.

Policy Deployment and Operational KPI reviews are used to establish objectives, measure performance and drive continuous improvement. Policy deployment is a 7 step process used by Fluke to focus on impactful, breakthrough objectives that are critical for achieving world-class status. The crucial cornerstones to achieving this success are the focus on the Voice of the Customer (VOC) and the planning process that links that focus to specific support plans describing how we will satisfy the innovation, delivery and cost objectives to meet the customer needs.

Operations KPIs are defined and flowed to the relevant functions, levels and processes to measure the sustaining business processes. Improvement objectives are established as part of the annual planning process and Operations Reviews are held monthly to review results and countermeasures to misses.

Policy Deployment diagram



7 Support

Resources

Fluke determines and provides the resources needed for the operation and improvement of the Quality Management System to ensure the products and processes achieve their planned results. When considering resources, Fluke considers the capabilities and constraints on existing resources as well as needs from external sources. Resources are determined and addressed at each facility and functional area. These may include:

- infrastructure
- environment

- materials and equipment
- personnel

Monitoring and measurement resources

Fluke determines the type and extent of the resources required to ensure valid and reliable results are obtained when monitoring and measuring is used to verify the conformity of products and services.

Manufacturing policies, requirements and monitoring activities are defined in [QSD111.01 Manufacturing Process](#) and [QSD111.44 Measurement Management System](#) defines the policies, procedures and requirements of the Measurement Management System.

Competence and awareness

Fluke determines the type and extent of training required for personnel performing work that affects the performance and effectiveness of its Quality Management System. Fluke provides training as necessary to meet these requirements.

Personnel are considered competent with respect to their assignment and/or job description, based on their education, training, skills, experience, and demonstrated results. Documented information as record of competence shall be retained in accordance with [QSD111.02 Corporate Training Policy and Requirements](#) and local process documents.

Personnel performing work under Fluke's control shall be aware of:

- the quality policy
- relevant quality objectives
- their contribution to the effectiveness of the Quality Management System
- implications of not conforming to the Quality Management System.

Communications

Fluke determines the communications (internal and external) relevant to the Quality Management System and on relevant levels. Fluke uses standard processes to determine communications including:

- what will be communicated

- when to communicate
- with whom to communicate
- how to communicate
- who communicates

Documented information

Fluke's Quality Management System includes documented information required by the ISO 9001 standard, as well information determined necessary by Fluke to ensure the effectiveness of the Quality Management System.

Fluke's document structure and its control is defined in [QSD111.39 Document Control Policy](#). This policy ensures documents are created with the necessary information to ensure proper control and are documented in the acceptable formats. Documented information is made available to all necessary personnel through the use of control systems, such as Intelex, SharePoint and Team Center. These systems ensure only the current approved versions of documented information is available to the users.

Retention of documented information is defined in either [QSD111.50 Records Retention Policy](#) or the specific document. These procedures provide direction on how and where documented information is retained as well as the retention period and the disposition methods.

Organizational knowledge

Fluke has identified and documented organizational knowledge that is necessary for the operation of its processes and to achieve conformity of products and services. Organizational knowledge is maintained by the functional groups and made available as necessary. As processes change, Fluke will determine whether additional information is necessary and if so, how it will be obtained.

8 Operations

Operational planning and control

Fluke plans, implements and controls processes needed to meet the requirements for the provision of products and services by:

- determining requirements for the products and service
- establishing criteria for the processes and for the acceptance of the products and services

- determining the resources needed to achieve conformity to the product and service requirements
- implementing control of the processes in accordance with the criteria
- determining, maintaining and retaining documented information to the extent necessary to demonstrate the conformity of products and services to their requirements.

[QSD111.01 Manufacturing Process](#) defines Fluke's manufacturing process policy and requirements.

Fluke controls changes to products and processes, including out-sourced processes, and reviews the consequences of unintended changes, taking action as necessary to mitigate any adverse effects.

Requirements for products and services

Fluke's communication with its customers includes:

- providing information relating to the products and services
- handling inquiries, contracts or orders, including changes
- obtaining customer feedback relating to products and services, including customer complaints
- handling or controlling customer property
- establishing specific requirements for contingency actions, when relevant.

Fluke uses the BOB process, [QSD111.37 Product Development Process](#), when determining the requirements for the products and services to be offered to customers, and ensures that:

- the requirements for the product and services are defined, including any applicable statutory and regulatory requirements
- requirements considered necessary by Fluke are defined
- Fluke can meet the claims for the product and services it offers.

Contract review occurs during the order process to ensure fulfillment of all contract/order requirements; resolve any discrepancies, and coordinate the requirements with all affected areas of the company. The contract/order process includes quotations, order entry and subsequent contract/order changes.

As part of the quotation process, each department involved will communicate Fluke's terms of sale to the customer.

Before committing to supply product or services, Fluke reviews the contract/order to verify:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities
- requirements not stated by the customer but necessary for the specified or intended use, when known
- requirements specified by Fluke
- statutory and regulatory requirements applicable to the products and services
- contract or order requirements differing from those previously expressed.

Fluke maintains documented information on the results of these reviews and on any new requirements for the products or services in accordance with local process documents and [QSD111.50 Records Retention Policy](#).

When the requirements for products and services change, Fluke ensures that relevant documented information is amended and that relevant persons are made aware of the changed requirements.

Design and development of products and services

Fluke uses the BOB process, [QSD111.37 Product Development Process](#) (PDP), along with its sub-processes, guidelines and checklists to control and verify the design of products to ensure that specified requirements are met. These processes ensure consistent and effective management of design activities in all divisions of Fluke.

Design and development activities include:

- determining the design input requirements relating to the product, including applicable statutory and regulatory requirements, and their identification, documentation and review.
- verification and validation of the design to ensure that the designed products meets all input requirements as well as performance, durability, reliability, serviceability, safety, regulatory, and contractual requirements.

All process step output documentation will be under change control procedures established by the Project Manager and described in the BOB process. At the end of the project, design disclosure drawings (e.g. drawings, component specifications, software, CAD databases) that are under Configuration Control, will be released in the approved Product Data Management (PDM) system.

Control of externally provided processes, products and services

Fluke ensures that externally provided processes, products and services conform to requirements. Fluke determines the controls to be applied to externally provided processes, products and services when:

- products and services from external providers are intended for incorporation into Fluke's own products and services
- products and services are provided directly to the customer(s) by external providers on behalf of Fluke
- a process, or part of a process, is provided by an external provider as a result of a decision by Fluke.

Fluke determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Fluke retains documented information of these activities and any necessary actions arising from the evaluations.

Fluke ensures that externally provided processes, products and services do not adversely affect its ability to consistently deliver conforming products and services to our customers.

Fluke ensures that externally provided processes remain within the control of its Quality Management System and defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.

Fluke takes into consideration the potential impact of the externally provided processes, products and services on Fluke's ability to consistently meet customer's requirements, applicable statutory and regulatory requirements and the effectiveness of the controls applied by the external provider.

Fluke determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. Fluke ensures the adequacy of requirements prior to their communication to the external provider.

External providers of measurement services, including calibration and repair of Fluke M&TE are managed in compliance with [QSD111.44 Measurement Management System](#).

Fluke communicates to external providers our requirements for:

- the processes, products and services to be provided
- the approval of
 - products and services
 - methods, processes and equipment

- the release of products and services
- competence, including any required qualification of persons
- the external providers' interactions with Fluke
- control and monitoring of the external providers' performance to be applied by Fluke
- verification or validation activities that Fluke, or our customer, intends to perform at the external supplier's premises.

Fluke retains documented information of these activities and any necessary actions arising from evaluations.

Product and service provision

Production, installation, support and servicing processes that directly affect quality have been identified and planned to ensure those processes are carried out under controlled conditions that include:

- the availability of documented information that defines the characteristic of the products which includes design disclosure information
- the availability of work instructions and procedures
- the availability and use of suitable equipment
- the implementation of monitoring and measurement devices at appropriate stages in the process with acceptance criteria
- the use of suitable infrastructure and environment
- the appointment of trained and competent persons, including any required qualifications
- the validation, and periodic revalidation, of the ability to achieve planned results where the resulting output cannot be verified by subsequent monitoring or measurement
- the implementation of error-proofing (poka-yoke) activities
- documented information for the release, delivery and post-delivery activities where required.

Calibration and repair services are provided for all our products as well as for a wide range of products manufactured by other companies. The service centers have established processes and procedures to ensure these activities are carried out under controlled conditions. Calibration and repair services are the responsibility of our service organization.

Fluke has a network of strategically located service centers which provide:

- Repair services

- Calibration services
- Service agreements
- Extended warranty agreements
- Asset management agreements

Service centers also provide warranty failure data to the factory for the purpose of monitoring product failure trends.

All Fluke calibration services are in compliance to [QSD111.44 Measurement Management System](#). Where appropriate, accredited calibration services are provided in accordance with [QSD111.41 Fluke 17025 Quality Manual](#).

The Service Parts department maintains replacement parts and manual inventory for Fluke service centers and direct parts sales to customers. All replacement parts are subjected to the same inspection and quality assurance programs applicable to parts used in production.

A product exchange service provides rebuilt assemblies for self-maintenance customers, fast turn-around-time and low cost products and accessories.

Identification and traceability

Fluke defines its part marking and traceability requirements in [QSD 111.56 Serialized and Non-Serialized Product Marking Requirements](#).

Records are established and maintained providing evidence the product has been inspected and/or tested. These records identify the person responsible for the release of the conforming products.

Process owners identify the inspection and test status of products by indicating conformance or nonconformance by using stamps, labels and/or physical locations. This identification is maintained and understood, as defined in local work instructions, throughout production, installation and servicing of products to ensure only products that have passed the required inspections and tests are shipped, used or installed. All departments are responsible for complying with [QSD111.07 Control of Nonconforming Material](#) and for taking corrective action as appropriate per [QSD111.09 Corrective/Preventive Action Procedure](#).

Customer and external provider property

Fluke identifies customer property as “product and accessories” returned for repair or calibration. Fluke does not use any other type of customer or provider property.

Fluke identifies customer property upon receipt and exercises care to prevent damage. In the event a customer's property is damaged or lost, Fluke reports this to the customer and takes action to address the situation.

Preservation

Fluke has implemented local processes for the handling and preservation of product as necessary in order to prevent damage and deterioration.

Materials and stores departments are responsible for establishing processes for purchased parts. Production departments are responsible for establishing processes for work in process. The distribution centers are responsible for establishing processes for shipping product to the customer.

All organizations handling printed circuit assemblies (PCAs) shall comply with [QSD.19.1 Electrostatic Discharge Policy](#).

Post-delivery activities

Fluke determines and meets requirements for post-delivery activities related to its products and services. In determining post-delivery activities, Fluke considers:

- statutory and regulatory requirements
- potential undesired consequences associated with its products and services
- the nature, use and intended lifetime of our products and services
- customer requirements
- customer feedback.

Post-delivery activities are documented in local process documents as required.

Control of changes

Fluke reviews and controls changes for production and service provisions, to the extent necessary to ensure continuing conformity with applicable requirements. Fluke retains documented information on these changes and the person(s) authorizing the change as well as any necessary actions arising from the review.

Release of products and services

Fluke has planned checks at appropriate stages in production and service to verify that requirements have been met. Products are not released to the customer until the planned checks have been successfully completed unless otherwise approved by the relevant authority, and where required by the customer.

Documented information is retained providing evidence the product has been inspected and/or tested. Records identify the inspection and test authority responsible for the release of conforming products.

Control of nonconforming outputs

Fluke ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery through local processes as defined in [QSD111.07 Control of Nonconforming Material](#) for materials or [QSD111.41 Fluke 17025 Quality Manual](#) for calibrations.

Fluke takes appropriate actions based on the nature of the nonconformity and its effect on the conformity of products and services determined at our facilities and after delivery or service as defined in [QSD111.09 Corrective/Preventive Action Procedure](#).

Fluke retains documented information that describes the nonconformity, describes the actions taken, describes any concessions obtained and identifies the authority deciding the actions.

9 Performance evaluation

Monitoring, measurement, analysis and evaluation

During new product development, or when an existing product design change is required, the responsible engineering organization will determine the measurements to be made, the accuracy required, the frequency of the measurement and will select the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision.

Test systems are defined as any hardware or software used in production or service to verify the acceptability of the product or service. Test systems will be validated prior to their initial use and whenever a product or test system requires a change that could affect the acceptability of the product or service. Test system use, validation, maintenance and control will be described in local work instructions.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure the specified requirements are met.

The requirements for qualification of process operations, including associated equipment and personnel shall be specified.

Supervisors/process owners are responsible for in-process and final inspection, testing, and monitoring per documented work instructions and design control information. Equipment maintenance documentation will list all equipment in the process owner's area of responsibility, maintenance schedules, maintenance instructions, and training records for all personnel performing maintenance.

Customer satisfaction

Fluke monitors customer satisfaction through surveys, data collected through the External Product Quality Database, and the customer feedback system as defined in local process documents.

Analysis and evaluation

Measuring and monitoring of processes and process outputs are used to determine the effectiveness of various processes as appropriate. These measurements also roll-up to strategic goals related to, among other things, the Core Value Drivers of Core Growth, Operating Margin Expansion (OMX) and Quality. The goals are documented in the policy deployment matrices and/or KPI bowlers at the top, divisional and departmental levels of the company. Countermeasures will be written for corrective action as determined by top management.

The results of analysis are used to evaluate:

- conformity of products and services
- the degree of customer satisfaction
- the performance and effectiveness of the Quality Management System
- whether planning has been implemented effectively
- the effectiveness of actions taken to address risks and opportunities
- the performance of external providers
- the need for improvements to the Quality Management System.

Internal audits

[QSD111.10 Internal Audit Process](#) defines Fluke's internal audit policy and program for verifying the Quality Management System has been effectively implemented and that processes conform to internal requirements and ISO standard requirements.

Frequency of audits, selection of auditors and corrective action requirements are defined in [QSD111.10 Internal Audit Process](#).

Management review

Fluke's senior management reviews the Quality Management System at least once a year to ensure its continuing suitability, adequacy, effectiveness and alignment with Fluke's strategic direction.

Management Review inputs include:

- status of actions from previous Management Reviews
- changes in external and internal issues that are relevant to Fluke's Quality Management System
- information on the performance and effectiveness of Fluke's Quality Management System including:
 - customer satisfaction and feedback from relevant interested parties;
 - the extent to which quality objectives have been met;
 - process performance and conformity of products and services;
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
 - the performance of external providers;
 - equipment intended for use in explosive atmospheres, as applicable
- adequacy of resources
- effectiveness of actions taken to address risks and opportunities
- opportunities for improvement.

Management Review outputs include decisions and actions related to:

- opportunities for improvement;
- any need for changes to the Quality Management System;
- resource needs

The preferred method for storage of Management Review records is in InteleX.

10 Improvement

Continuous improvement

Fluke continuously improves the suitability, adequacy and effectiveness of our Quality Management System through the use of Fortive Business System (FBS) which includes tools such as problem solving and Kaizen activities.

Improvement opportunities include:

- improving products and processes to better address customer needs and expectations,
- correcting or preventing undesired effects,
- improving the effectiveness of the Quality Management System.

Nonconformances and corrective actions

Fluke takes action to address nonconformances, correct or control the situation and address the consequences at a level that is appropriate for each nonconformance. Records of the nonconformance, actions taken and the results are created and maintained in accordance with [QSD111.07 Control of Nonconforming Material](#) and [QSD111.09 Corrective/Preventive Action Procedure](#)

The need for taking action to eliminate the cause is evaluated by reviewing and analyzing the nonconformity, determining the cause and determining whether similar situations can or do exist.

Fluke implements actions as needed and reviews the effectiveness of the actions taken. If necessary, risks and opportunities for this product or service are evaluated and updated and, if required, changes are made to the Quality Management System.

Corrective action policies are further defined in [QSD111.03 External Product Quality](#) and [QSD111.09 Corrective/Preventive Action Procedure](#).

Change History

Revision No.	Brief Description of Change(s)	Training required (Y/N)
Rev 117 July 2014	Updated Introduction to address Global locations and added Quality Manual section. Removed references to the ISO standard throughout the	

	document. Section 1.2 – Updated to match the current definitions of QSD111.39. Section 2.3 Management Review – Changed training requirements from the PDM department to managers and added manager responsibility to train their organizations. Section 2.5.1.3 - Rewrote section to reflect the current configuration of the Corporate QA group. Section 4.1 Added QSD111.56 to reference list. Section 4.2.5 - Changed reference of VOC to External Product Quality. Section 4.5 – Changed CSS reference to Service. Section 4.5.4 - Updated Serial number requirements to include category rated products. Section 4.6 – Changed NIST to SI and Z540 to ISO17025. Section 5.5.2 - Removed reference to online CAR Tool. Section 5.5.4 - Preventative Action – complete rewrite of the section. Renumbered document to match the 8 section format defined in the introduction.	
Rev 118 Aug 2014	Removed comments left in edited document.	
Rev 119 May 2017	Changed document number from “QSD 111.0” to “QSD111.00” for consistency and tracking purposes; complete re-write to meet the requirements of ISO 9001:2015; reformatted to align with the ISO 9001:2015 standard; added requirements for ISO/IES 80079-34 standard; text from all but the last 3 revisions in hidden.	Yes
Rev 120 May 2017	Revised to remove editing marks. No details were changed.	

*Training column added at revision 119.

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