FLUKE®

Corporate Quality Manual

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Date:	August, 2009

Fluke Quality–
a continuing tradition

Fluke Corporation
Everett, Washington

Fluke's Mission

"Be the leading world-wide supplier of portable test tools and related equipment for the service, installation and maintenance of electrical and electronic equipment."

Fluke's Quality Policy

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

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Authorization Approvals

Approval records are located in the electronic document control system.

Responsibilities

Approver:	Barbara Hulit, President.
Approver:	Dean Worden, Corporate Quality Manager
Owner:	Dean Worden, Corporate Quality Manager

Distribution

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

Document Change Record

REV DATE	BRIEF DESCRIPTION OF CHANGE(S)
1/93	Rev B - Minor rewrite of original Quality Manual
6/95	Major rewrite of many sections to incorporate 1994 ISO 9001 revisions, reformatted into new QSD format.
12/96	Major rewrite of para 1.2 and 1.3 to reflect current corporate quality organizational structure. Minor rewrite of para 2.3, 5, 18 and 20 for clarification purposes.
4/97	Added Note 2 to section 1.2 Management Review, added section describing which organizations will produce work instructions to section 5.2 Document and Data Approval and Issue.
12/97	Changed area code to 425 on page 2; Section 1.2.1 Changed location of organization chart from p:\ drive to Fluke Wide Web under organization; Section 10.3 changed production departments to supervisors; deleted paragraph stating QA is responsible for auditing work-in-process; Section 11.0 changed MIL Standard to ANSI/NCSLZ540-1-1994; Section 14.1 Changed feedback to complaint; complete re-write of trend analysis paragraph. DCO#54580.
10/98	Changed Corporate Quality Systems Manager to ISO Management Representative in TOC and section 1.2.4. Section 6.2 changed to reflect signature requirements for QA Manual. Section 20 and 21.1changed titles of QA Manager from Corporate Quality Systems Manager per CAR # IA99075 DCO # 55874.
2/99	Rewrote Management Review to incorporate Policy Deployment. Changed Quality Planning to reflect coverage in 111.37 and eliminate the need for a separate plan. Rewrote the description of the quality organization to reflect actual structure due to corporate changes. Minor tweaks to Receiving Inspection and Testing to reflect a review of records to determine if inspection is necessary. Added e-mail and phone to options for customer complaint management. Rewrote Statistical techniques to eliminate references to the Quality Index and to tie in to QDC. DCO 56246.
8/99	Changed the ISO Management rep. back to Corporate Quality Manager and changed the name to Don Kaiser, changed distribution statement to current statement and added sentence about Corporate Quality Manual; changed section 1.3 Management Review para 3 to state "suitability and effectiveness in satisfying the requirements of the ISO 9001 standards, our quality policy and our quality objectives"; removed all references to QSD 111.5 Discrepant Material Request (DMR) and Material Review Board (MRB) – replaced with non-conforming material occurrence; deleted references to QSD 111.8 Workmanship standards, 111.54 Maintenance of Equipment Procedure, and 111.43 Instrument Serial numbers – replaced reference with QSD 111.1 Manufacturing Process; changed section 5.2 par 8, process of controlling documents from old system to Product Data Management System (PDM); changed section 5.3 par. 2 to state Engineering change order (ECO) from Document Change Order (DCO); removed Customer Feedback (complaint) System from section 14.1 para 1.
Rev 101 January, 2000	Changed signature page from Larry Culp President to Tom Gross; Changed all references of document control to Product Data Management; added at a minimum to section 1.3 para. 3.; Danaher Business System (DBS) to section 2.1, and 2.2 a); deleted prior to order entry in section 3.3. last para.; changed section 5.2 para, to state all QSD masters are maintained in the PDM system with hard copy signatures kept in the PDM department; changed section 8 para.3 from six digit part number to nine digit part number; changed section 14.1 para. 5 from the divisional quality department to the quality group; added Reference QSD 111.2 Corporate Training in section 4.18 W1008892
Rev 102 January, 2000	Changed review of policy deployment from monthly to a minimum of quarterly and records will be kept three calendar years.

REV DATE	BRIEF DESCRIPTION OF CHANGE(S)
Rev 103 Feb, 2000	Updated "Signature Page" to Authorization Approvals – stating that an electronic authorization approval in the PDM system is the preferred method for approving QSD's. Signed hardcopies will be retained in the PDM group.
Rev 104 April, 2000	Deleted and Chief Operating Officer from section 1.2.2; deleted shared resource vice presidents from section 1.2.6; changed policy deployment retention time from 1 calendar year to three calendar years in section 1.3, Changed section 2.3 quality plans back to wording of previous revisions. Updated 1.3 Management Review, defining Policy Deployment. Added new QSD 111.3 (Voice of the Customer). Updated 14.1 Responsibility, b) added Policy Deployment or Corrective Action. Added min quality records for management review to PD chart
Rev 105 Sept. 2000	Added reference to QSD 111.4 (Supply Chain Quality Assurance Requirements) in section 6.4. Updated signature page to reflect new President.
Rev 106 Oct. 2000	Updated the Corporate Mission Statement.
Rev 107 March 2001	Update Corrective action system to current system, section 14 fifth para, added reports dotted line to president to 1.2.5
Rev 108 Sept 2002	Complete rewrite to ISO 9001:2000 standard
Rev. 109 March 2003	Updated signature page.
Rev 110 August 2004	Updated the "Introduction" section as per NQA observation during the March 2004 surveillance audit. C.A.R. # 2777
Rev 111 February, 2006	Updated signature page and "Introduction" section.
Rev 112 January, 2008	Updated the "Introduction" section. Added of the Fluke Thermography Group in Plymouth, MN. Changed the Buford, GA location to Duluth, GA. Deleted the Camarillo, CA location. Changed the statement in the "Authorization Approvals" section to reflect the change to an electronic approval record in the document control system. Changed the "Signatures" section. Changed name of section to "Responsibilities"
Rev 113 June 2008	Corrected footer "rev" number error in issue 112 from 111 to 113. Updated Section 2.4.1 Quality Objectives – page 11 "Training & Materials" section Deleted the following text on page 9 (h) "That part of the corporate library that maintains external standards" – the library no longer exists Changed Reference: CSS PD 400 CSS Quality Assurance Manual to LPD 400 Quality Assurance Manual for Fluke Customer Support Service (CSS) on the following pages: Page 18 – Section 4.5.1 Page 19 – Section 4.5.2 Page 20 – Section 4.6 Page 21 – Section 4.6.1 No training required for changes in this revision of the document.
Rev 114 August 2009	Updated "Introduction" section with new ISO 9001:2008 reference.

INTRODUCTION

Fluke Corporation is a leading supplier of compact, professional electronic test tools. Fluke test tools are used by technicians and engineers to install, service and maintain equipment containing electrical and electronic components.

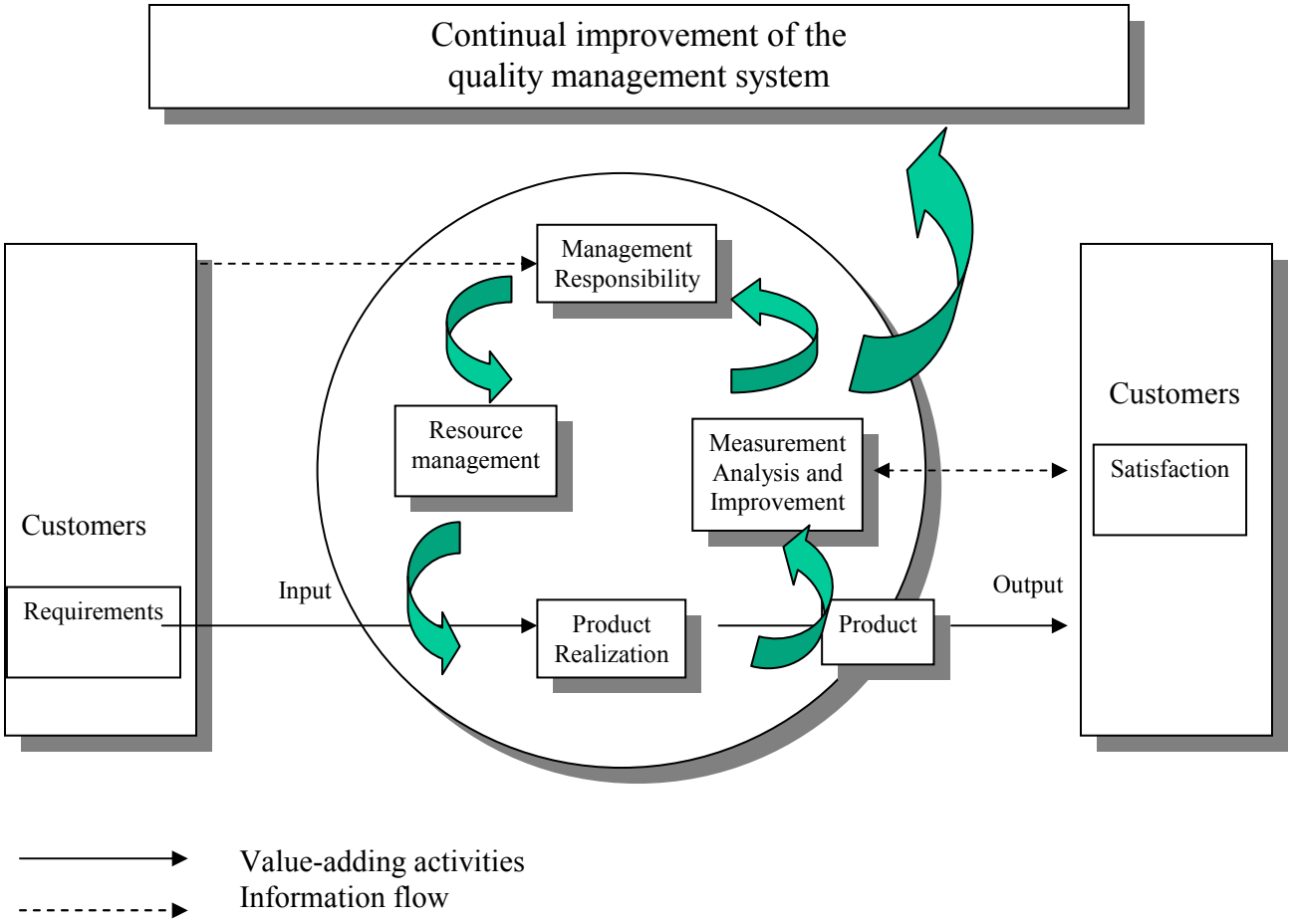
Our mission: To be the leading world-wide supplier of portable test tools and related equipment for the service, installation and maintenance of electrical and electronic equipment.

Fluke employs a total quality strategy that empowers employees to use their talents, take pride in their association with Fluke, and assume responsibility for its success. This philosophy directs our efforts toward continuous improvement focused on customer satisfaction.

Fluke Electronics Corporation and Fluke Networks operations and subsidiaries located in Everett, WA, Colorado Springs, CO, Santa Cruz, CA (Raytek), Plymouth, MN (Fluke Thermography) and Mississauga, ONT, Canada, perform within the requirements of this quality manual and ISO 9001:2008, and its technical equivalent, ANSI/ASQC Q9001-2008.

In addition to this Quality Manual, some locations may have a local quality manual or plan to address specific local exceptions or additions to this Quality Manual.

A process approach is promoted when developing, implementing and improving the effectiveness of the quality management system, to enhance customer satisfaction by meeting customer requirements.



(The following sections have the ISO 9000:2008 section in parenthesis beside the main title of the section)

1. QUALITY MANAGEMENT SYSTEM (4)

1.1 General requirements (4.1)

Fluke shall establish, document, implement and maintain a quality management system and improve it's effectiveness with the requirements of ISO 9001:2008 by the following methods:

a) Identify the processes needed for the quality management system and their application throughout the organization.

b) Determine the sequence and interaction of these processes

c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective

d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes

e) Monitor, measure and analyze these processes

f) Implement actions necessary to achieve planned results and continual improvement of these processes

1.2 Documentation requirements (4.2)

1.2.1 General (4.2.1)

Fluke Corporation will establish and maintain documented procedures to control all documents and data that relate to the requirements of the ISO 9001 standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

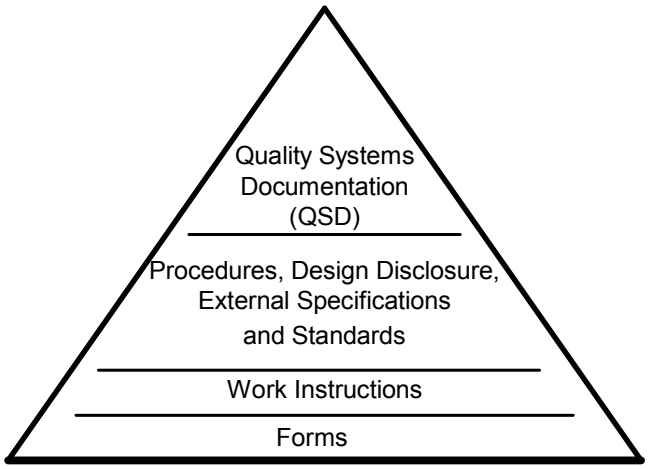
Our document and data control system is defined by QSD 111.39, Product Data and Configuration Management Manual and consists of four types of documents:

a) Corporate Quality System Documents (QSD's); (these documents define the different policies to be followed throughout Fluke, including the quality manual)

b) Design Disclosure Documentation; procedures, external specifications and standards. (These documents define how the policies defined in the QSD's will be met – Fluke's how to documents)

c) Work Instructions; (these documents define sequential steps needed to build a product or complete a process)

d) Forms (used to collect data for processes)



For the purposes of Fluke's documented quality system, data shall be differentiated in the following two ways:

a) Documentation Data - any data that controls how to manufacture product and provide services. This data must meet all the requirements of QSD 111.39, Product Data & Configuration Management Manual.

b) Quality Records Data - any data that results from the output of a process, product or service. This data must meet the requirements of a quality record. Quality records and retention times for corporate will be defined in QSD 111.50 Records Management Manual. Quality records for local areas will be identified with retention times in local documents.

1.2.2 Quality manual (4.2.2)

The intent of this Quality Manual is to guide each organization within Fluke in maintaining our documented quality system. This is a living document requiring periodic changes to reflect new technology, changing customer expectations and improvements to the quality system.

This manual is divided into 8 sections that correspond to quality system requirements of the ISO 9001 standard. Each section begins with a general policy statement expressing the commitment to implement the principles of the quality system element that is the subject of that section. The general policy statement is followed by more specific procedural policies outlining how the general policy should be carried out and referencing the relevant operational procedures.

Each individual or organization within the company is expected to comply with the guidelines established in this manual.

Referenced in this Corporate Quality Assurance Manual are corporate quality system documents (QSD's) which are used by all organizations to meet these requirements. Each organization also maintains local procedures, detailed work instructions, drawings and/or process flow charts to support their products and processes. Process owners are expected to share an awareness of this manual and its electronic location with their employees.

1.2.3 Control of documents (4.2.3)

Documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b) invalid and/or obsolete documents are promptly removed from all points of issue or use;

c) any obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.

d) documents are archived in accordance with QSD 111.50, Records Management Manual.

The Corporate Quality Manager and the Company President are responsible for approving the Corporate Quality Assurance Manual. A management member of the QA is responsible for approving all other QSD's. All QSD's masters will be maintained in the PDM system, with hard copy signatures available if requested.

Operating division new product development teams will produce design disclosure documentation.

Our Product Data Management (PDM) system controls, stores, archives, and maintains all revision status of all QSD's and design disclosure documentation electronically. Distribution and reproduction of documents, is accomplished by pulling documents electronically from the PDM system. The PDM system maintains the Master Index.

The Corporate Library is responsible for controlling, storing, reproducing, distributing, archiving, maintaining the master index, and revision status of all external standards.

Local, departmental process owners are responsible for writing, approving, controlling, storing, reproducing, distributing, archiving, maintaining the master index, and revision status of work instruction documents.

The following internal organizations and functions will produce work instructions that comply with the requirements of this Quality Manual and QSD 111.39, Product Data and Configuration Management Manual:

a) Those departments within US Sales Operations that perform customer order quoting, order entry, contract administration and support of those associated systems.

b) Those departments that perform design and development of new products, or parts used in new products, including industrial design, mechanical design, mechanical development, IC design, electrical design, marketing and sales support design, software design, user documentation, manufacturing process development, service support and component engineering.

c) All production departments and their direct supporting organizations that produce finished products, or parts used in finished products, including materials departments, material distribution, production engineering, methods engineering, process engineering, manufacturing engineering and test engineering and that part of facilities maintenance that maintains production and production support equipment and facilities.

d) Those customer support services organizations that perform repair and/or calibration of customer and internally supplied finished products including service engineering, parts department, calibration laboratory and service sales support.

e) Those parts of the purchasing organization not previously described that are directly involved with the purchasing of parts used in finished Fluke products.

f) Corporate Product Data Management department.

g) That part of management and technical information services involved with controlling access to, storage and preservation of corporate computing information systems data and information.

i) Those parts of human resources and development that are directly involved with employee job descriptions and providing job qualification training.

j) All quality departments, including operations quality assurance, CSS quality assurance, corporate metrology, product evaluation and material quality support.

In addition to the above, all document process owners are responsible for complying with the following:

a) Assuring the appropriate people review and approve all changes to the document;

b) Identifying a history of all changes in the document;

c) Maintaining a document master index that identifies the current revision status of all documents;

d) Notification and distribution of the current document to all users.

1.2.3.1 Document and Data Changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon that to base their review and approval.

Corporate QSD's and design disclosure documents shall be under engineering change order (ECO) control as described in QSD 111.39 Document and Configuration Management Manual.

References:

QSD 111.39	Document and Configuration Management Manual
QSD 111.50	Records Management Manual

1.2.4 Control of records (4.2.4)

Documented procedures will be established and maintained for identification, collection, indexing, access, filing, storage, maintenance, retention times, and disposition of quality records.

Local process owners are responsible for the control of quality records relating to product and process quality. These controls will be described in local procedures.

QA is responsible for the control of quality records relating to corporate quality system documents, internal audits, and other quality records relating to our quality system.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Records may be in the form of any type of media, such as hard copy or electronic media.

Reference:

QSD 111.50 Records Management Manual

2. MANAGEMENT RESPONSIBILITY (5)

2.1 Management commitment (5.1)

Fluke's top management is committed to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements through the design and development of new products process and the environmental testing process

b) establishing the quality policy and communicating to the organization through the QSD's and training

c) ensuring the quality objectives are established through the Policy Deployment process

2.2 Customer focus (5.2)

Fluke's top management shall ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction through the use of the Voice Of the Customer (VOC) measurement process.

2.3 Quality Policy (5.3)

Fluke Corporation's quality policy is to create and maintain a quality system of continuous improvement of key work processes focused on customer expectations. It is management's responsibility to ensure this policy is understood, implemented, and maintained at all levels of the organization.

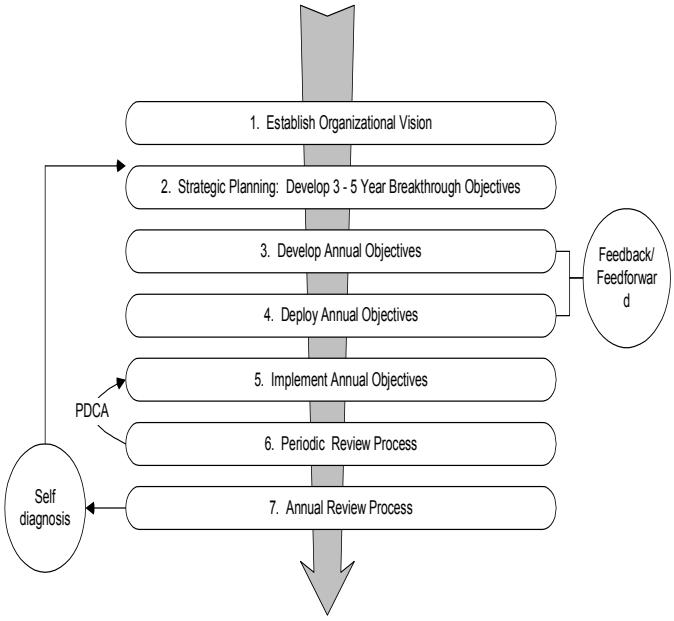
It is the responsibility of the document owner and the Product Data Management (PDM) group to provide training for major changes to this document (i.e.: new, total process rewrite other than format changes, changes that could significantly impact business plan, etc) . This will ensure that the changes are interpreted, understood and implemented at the appropriate levels of the organization. Once training has been performed, PDM department will provide record of the training event to the Human Resource Department. Records will be maintained in the Corporate Training database.

2.4 Planning (5.4)

2.4.1 Quality objectives (5.4.1)

Policy Deployment is a 7-step continuous improvement process used by Fluke to focus on the impact, 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 and the planning process that links that focus to specific support plans describing how we will satisfy the quality, delivery and cost objectives to meet the customer's needs.



Evidence	Responsibility
	Fluke Leadership
STRAT plan	Fluke President
PD Matrix	Primary Responsibility Dot holders at Levels 1 & 2
PD Bowling chart	
Meeting minutes	
	Fluke President

Development:
The system is designed in a closed-loop fashion that considers, assesses and assures the continuing suitability and effectiveness in satisfying the requirements of the ISO 9001 standards, our quality policy and our quality objectives. This continuous improvement process begins at the executive level of the business and cascades through the subsequent organization levels until effective implementation detail and measurable goals have been agreed to on the Matrix and Bowling charts.

Training & Materials:
Policy Deployment, training is recommended and available through PDM group or Danaher web site at http://fww.tc.fluke.com/~dbsfluke/ISI%20ECO/ECO_DBSLO%20POLICY%20DEPLOYMENT%20LEADERSGUIDE%20REV8-20050627-172743.pdf .

2.4.2 Quality management system planning (5.4.2)

Quality management system planning is done during the strategic planning process by top management. Policy Deployment is created annually from organizational vision by developing 3-5 year breakthrough objectives which are translated into annual objectives for which measurable business targets are established by the management and support teams in the areas impacted.

During continuous improvement events, changes to the quality system are implemented and communicated through report out presentations and tracked by the Continuous improvement group.

2.5 Responsibility, authority and communication (5.5)

2.5.1 Responsibility and authority (5.5.1)

All organizations which have employees who manage, perform, and verify work affecting quality in design, development, production, installation, and service shall define and document the interrelation of those employees in organization charts. Corporate level organization charts can be found on the Fluke Wide Web under organization or by contacting your organization's administrative assistant. Lower level organization charts are maintained by the process owner or designee.

Our Human Resources Department will maintain and control Employee Job Descriptions who describe those employees' responsibilities and authority

2.5.1.1 President

Has the responsibility to align organizational structure, allocate resources, and develop policies to assure the implementation of Fluke Corporation's quality system.

2.5.1.2 Leadership Team

The Leadership Team consists of the president and his/her staff. They are responsible for the development and periodic review of strategic and quality plans and initiation of corrective action when necessary. They are also responsible for implementing the quality system and quality planning within their organizations as well as performing management review activities.

2.5.1.3 Quality Assurance (QA) Group

The QA group consists of the Corporate Quality Manager (reports dotted line to the President), the ISO/Product Data Management Department, and Quality Engineers. They are chartered to establish, maintain and ensure compliance with corporate quality procedures, policies and systems. The QA group maintains ownership of the corporate quality manual and all other corporate QSD's; designs, prepares and distributes product quality reports; actively participates in external customer supplier quality programs; and is the corporate group responsible for the implementation and maintenance of ISO 9001 standards throughout the company. The QA group is responsible for specifically assuring that the individuals performing internal audit of the quality system are trained.

2.5.1.4 Operating Division and Shared Resource Units (SRUs)

Operating Division and Shared Resource Unit Staffs consists of operating division vice presidents/general managers and their respective staffs. They have responsibility for implementing the quality system and quality planning within their organizations, as well as, performing management review activities.

2.5.2 Management representative (5.5.2)

The Corporate Quality Manager is our designated ISO 9001 management representative. His/her responsibility is to ensure that the quality system is established, implemented and maintained in accordance with ISO 9001:2008 and ANSI/ASQC Q9001-2000 and to report on the performance of the quality system to the Leadership Team for review and as a basis for improvement of the quality system. He/she is responsible for ensuring the promotion of awareness of customer requirements throughout the organization.

2.5.3 Internal communication (5.5.3)

Top management ensures that communication processes are established within the organization through policy deployment, letters from the president, the employee newsletters, all employee meetings, leadership forums

2.6 Management Review (5.6)

2.6.1 General (5.6.1)

Top management reviews the organization's quality system through the Policy Deployment Review meetings and again at President's staff at a minimum of once a quarter.

2.6.2 Review input (5.6.2)

Input for management review shall include

a) results of audits

b) customer feedback

c) process performance and product conformity

d) status of preventive and corrective action

e) follow-up actions from previous management reviews

f) changes that could affect the quality management system and

g) recommendations for improvement

2.6.3 Review output

The output from the management review includes any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and its processes

b) improvement of product related to customer requirements

c) resource needs

3. RESOURCE MANAGEMENT (6)

3.1 Provision of resources (6.1)

Fluke determines and provides resources needed

a) to implement and maintain the quality management system and continually improves its effectiveness by the use of ISO 9001, lean manufacturing and Kaizens

b) to enhance customer satisfaction by meeting customer requirements through the use of our design process and data collected through the Voice of the Customer database

Reference:

QSD 111.3 Voice of the Customer

3.2 Human Resources (6.2)

3.2.1 General (6.2.1)

Personnel performing work affecting product quality are considered competent on the basis of their education, training, skills, and experience as described in the job descriptions maintained by Human Resources. Organization charts are developed by the individual areas and may be kept locally, while corporate organization chart is kept by the Human Resource Department.

3.2.2 Competence, awareness and training (6.2.2)

Fluke shall

a) determine the necessary competence for personnel performing work affecting product quality by defining minimum training requirements needed to perform the job

b) provide training or take other actions to satisfy these needs

c) evaluate the effectiveness of the training and actions taken by locally determined methods

d) ensure that its personnel are aware of the relevance and importance of their and how they contribute to the achievement of the quality objectives through policy deployment

e) maintain records of education, training, skills and experience in the corporate or local training databases. Corporate training and education will be maintained in the corporate training database while job specific training will be kept in local training databases.

Reference:

QSD 111.2 Corporate Training

3.3 Infrastructure (6.3)

Fluke has determined, provided and maintains the infrastructure needed to achieve conformity to product requirements. The infrastructure includes:

a) buildings, workspaces and utilities

b) process equipment (both hardware and software) monitored through the recall system as needed

c) supporting services including trucks, forklifts, etc.

3.4 Work environment (6.4)

Fluke has determined and manages the work environment needed to achieve conformity to product requirements through the design process and continuous improvement kaizen events.

Reference:

QSD 111.37 Product Development Guidelines

4. PRODUCT REALIZATION (7)

4.1 Planning of product realization (7.1)

Fluke plans and develops the processes needed for product realization and is consistent with the requirements of the other processes of the quality management system.

Fluke determines the following in the planning of product realization:

a) quality objectives and requirements for the product through the design and build processes

b) the need to establish and improve processes through kaizens, and the design process, document processes as needed with procedures and work instructions where the absence of such documents may affect the quality of the product, and provide resources specific to the product including work areas, equipment and personnel

c) required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance which will be defined in procedures or work instructions Documented procedures for inspection and testing activities shall be established and maintained to assure the specified requirements for the product are met. Inspection and test records will be detailed in documented procedures.

d) records needed to provide evidence that the realization processes and resulting product meet requirements as determined by local areas

Reference:

QSD 111.1 Manufacturing Process

4.2 Customer-related processes (7.2)

4.2.1 Determination of requirements related to the product (7.2.1)

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities as defined in the design and manufacturing processes

b) requirements not stated by the customer but necessary for specified or intended use, where known

c) statutory and regulatory requirements related to the product as defined in the design process

d) any other requirements by determined by the organizations

Reference:

QSD 111.1 Manufacturing Process
QSD 111.37 Product Development Guidelines

4.2.2 Review of requirements related to the product (7.2.2)

Fluke has established and maintains documented procedures for the review and coordination of all orders and contracts to assess if customer's requirements are adequately defined, understood, and if the company has the ability to meet those requirements. All departments involved in the contract/order process will create and maintain written local procedures governing their review process.

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.

4.2.3 Review

Before submission of a quotation, or at the order entry of a contract or order (statement of requirement), the quotation, contract or order shall be reviewed to ensure that:

a) the order received conforms to a valid Fluke quotation. In the absence of a quotation, the contract/order personnel are responsible for verifying that Fluke is able to comply to all order requirements;

b) the requirements are adequately defined and documented. Where no written statement of requirement is available for a verbal order, Fluke shall ensure that the order requirements are agreed upon before their acceptance;

c) any differences between the contract and accepted order requirements and those in the quotation are resolved;

d) Fluke has the capability to meet the contract or accepted order requirements.

Any order requirements that Fluke is unable to fulfill or that are not in accordance with Fluke terms of sale must be resolved with the customer and coordinated with affected internal departments.

4.2.4 Records

Quote, order, and contract files will be maintained for the life of the order and archived in accordance with QSD 111.50, Records Management Manual.

Records of contract reviews shall be maintained as specified in contract/order process department local procedures.

References:

QSD 111.50 Records Management Manual

4.2.5 Customer communication (7.2.3)

Fluke has determined and implemented effective arrangements for communicating with customers in relation to:

a) product information with marketing material

b) enquiries, contracts or order handling, including amendments: All departments involved in the contract/order process will maintain written local procedures that identify how an amendment to an order or contract is made and correctly communicated to the organizations affected.

c) Customer feedback, including customer complaints using the customer feedback system and VOC data

References:

QSD 111.50 Records Management Manual
QSD 111.3 Voice of the Customer

4.3 Design and Development (7.3)

Fluke Corporation has established and maintains documented procedures to control and verify the design of products in order to ensure that the specified requirements are met.

Our design control process is described in corporate procedure QSD 111.37 (Product Development Process) which, along with sub-process procedures, provides guidelines and checklists used for product development to support Fluke's mission to be "The leader in compact, professional electronic test tools". These guidelines and checklists insure consistent, professional and effective management by all divisions.

QSD 111.37 and its sub-process documents contain policies committing the company to plan and organize design activities, identify and document design input, conduct design reviews, control design output, and verify the design. It is the responsibility of the Project Manager and the divisional Management Review Committee (MRC) to use QSD 111.37 to plan and manage product development activities.

4.3.1 Design and development planning (7.3.1)

Product development planning is accomplished during the Plan process step using inputs from the Concept and/or Validation process steps. The PDP identifies how the Project Manager and the core team plan to design, develop, market, manufacture and support a product. Included in the plan are the responsibilities, activity assignments, communication and control methods between various disciplines. Detailed information on PDP content is given in QSD 111.37 and its sub-process procedures. The project manager will define in the PDP which of the following appendices are required and attached to the PDP:

- Marketing Approach (Draft Marketing Plan)
- Mechanical Packaging Approach (E/MRS)
- Electrical Design Approach (HRS)
- Software Approach (SDP & SRS)
- Manufacturing Approach (Preliminary Manufacturing and Test Plans)
- Service Approach (Product Service Support Plan - PSP)

4.3.2 Design and development inputs (7.3.2)

Determining design input requirements relating to the product, including applicable statutory and regulatory requirements, including their identification, documentation, and their review, is described in QSD 111.37.

4.3.3 Design and development outputs (7.3.3)

The Division MRC and selected company managers as shown in QSD 111.37 review all product development projects. This review(s) are conducted at the end of each process step used by the Project Manager. This review(s) will result in the approval of the process step outputs by the division MRC. Details and documentation used for process step output review(s) can be found in QSD 111.37 and sub-process documentation.

4.3.4 Design and development reviews (7.3.4/7.3.5)

The purpose of design review/verification is to review conformance of designs to the requirements of the Concept and/or Validation process steps using calculations, comparisons, tests, demonstrations, and documentation. These periodic technical reviews will occur in preparation for document release at the end of the Implement process step and will be planned by the Project Manager. Review plans will include frequency, scope and participants, will vary depending on project complexity, and will be documented in the PDP (reference QSD 111.37). All reviews will be documented and the Project Manager will keep records.

4.3.5 Design and development validation (7.3.6)

Validation of the design is performed in the Implement process step. The output of this process step is the MRR. As defined in QSD 111.37 and sub-process documentation, the validation will assure that the designed product meets all performance, durability, reliability, serviceability, safety, regulatory, and contractual requirements as defined and required by the PDP. Documentation of these validation tests is defined in QSD 111.37 and sub-process procedures

4.3.6 Control of design and development changes (7.3.7)

All process step output documents will be under change control procedures established by the Project Manager and described in the PDP. At the end of the Implement process step, design disclosure drawings (e.g. drawings, component specs, software, CAD databases) that are under Configuration Control, will be submitted to Document Control. At the end of the Transition process step, project documents (e.g. meeting minutes, engineering notebooks, team member journals, trip reports, detailed design notes, project e-mail files) will be submitted to the Corporate Records Warehouse, which is governed by retention schedules in the Records Management Manual, QSD 111.50.

References:

QSD 111.37 Product Development Process
QSD 111.50 Records Management Manual

4.4 Purchasing (7.4)

Corporate Purchasing procures goods and services for the corporation. They shall assure that purchased products conform to specified requirements by monitoring on-time delivery, quality, and cost performance

4.4.1 Purchasing process (7.4.1)

Fluke ensures that purchased product conforms to specified purchase requirements with the use of the APPROVED SUPPLIERS LIST located in Oracle. Suppliers are evaluated and selected based on their ability to supply product in accordance with criteria for selection, evaluation and re-evaluation defined by the Purchasing department.

4.4.2 Purchasing information (7.4.2)

Purchasing documents reference a six digit to nine digit item number associated with a specification or drawing for the item being purchased. Additionally, descriptions of the item such as type, class, grade, style, color or finish is printed in the body of the purchase order. Unless contractually required by the customer, material is not purchased to a national or international standard. Purchasing documents are reviewed and approved prior to release.

4.4.3 Verification of purchased product (7.4.3)

Upon receipt of the product, verification is completed in accordance with documented criteria by part number.

When verification occurs at the supplier's premises, inspection requirements will be documented in the purchase order.

Verification by the customer at either the sub-contractor's site or at Fluke will not influence our standard verification processes.

Incoming inspection and testing is performed on an as-needed basis determined by an on-going review of the quality records for the material and components. This review consists of non-conforming material occurrence and other known discrepancy reports and may include review of scrap quantities. Through daily operations issue arise which cause review of materials and components. If those issues result in a non-conforming material occurrence, the material or components may be placed back on an incoming inspection status. This decision is made by purchasing and manufacturing management in conjunction with the quality manager and the product evaluation and safety manager.

The Receiving Inspection Department is responsible for verifying that purchased items comply with component specifications and/or drawings and Qualified Manufacturer Listings. The Receiving Inspection Department will also perform more detailed inspection if an Inspection Guide Sheet (IGS) is present.

References:

QSD 111.4 Supply Chain Quality Assurance Requirements
QSD 111.7 Control of Non-Conforming Material

4.5 Production and service provision (7.5)

4.5.1 Control of production and service provision (7.5.1)

Production, installation, and servicing processes that directly affect quality shall be identified and planned to ensure those processes are carried out under controlled conditions that include the following:

a) the availability of information that describes the characteristics of the product which includes design disclosure documents (prints),
b) the availability of work instructions and procedures
c) the use of suitable equipment including preventive maintenance
d) the availability and use of monitoring and measuring devices
e) the implementation of monitoring and measurement and
f) the implementation of release, delivery, and post-delivery activities as defined in local procedures

Our engineering, production, quality assurance and customer service organizations have responsibility to identify, document, and control product and process characteristics, equipment capability, and maintenance of equipment. Where appropriate, documented work instructions, drawings, procedures, and process flow charts will be used to define the manner of production, installation, or service.

Calibration and repair services are provided for all our products, as well as for a wide range of products manufactured by other companies. This activity is the responsibility of our Customer Support Services (CSS) organization.

CSS Manager

The CSS Manager sets the strategic direction and policies for the worldwide CSS organization, and is responsible for meeting goals and objectives established by senior corporate management.

CSS Quality Assurance

The CSS Quality Assurance Manager ensures the requirements of the CSS Quality System are documented, implemented and maintained. He/she coordinates CSS quality activities and policies with other Quality Assurance activities in the company.

Service Centers

Service is provided by a network of strategically located Fluke service centers. Services provided by these centers include:

- 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.

Service Parts and Product Exchange

The CSS Service Parts Department maintains a dedicated 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, and fast turn-around-time for low cost products and accessories.

Reference:

CSS LPD400 Quality Assurance Manual for Fluke Customer Support Services (CSS)

4.5.2 Test System Development, Validation and Control

During new product development, or when an existing product design change is required, the responsible engineering organization will determine the measurements to be made and the accuracy required, and 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.

4.5.3 Validation of processes for production and service provision (7.5.2)

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, 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 that the specified requirements are met.

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

It is the responsibility of each process owner to establish and maintain documented procedures for the maintenance of all equipment that may affect the quality of the process, product, or service as described in QSD 111.1, Manufacturing Process. Equipment maintenance documentation will, at a minimum, list all equipment in the process owner's area of responsibility, maintenance schedules, maintenance instructions, and training records for all personnel performing maintenance.

References:

QSD 111.1 Manufacturing Process
CSS LPD400 Quality Assurance Manual for Fluke Customer Support Services (CSS)

4.5.4 Identification and traceability (7.5.3)

Product identification requirements apply to materials, components, and subassemblies intended for incorporation into final products, and to the final products themselves.

Fluke Corporation will establish and maintain documented procedures for identifying the product during all stages of production, delivery, and installation for the purposes of configuration management, inventory control and failure analysis.

Fluke operating divisions and Component Engineering are responsible to assure materials, components, subassemblies, and a *nine* digit part number, descriptive noun, or assembly name identifies final products. Serial numbers will be affixed to all final products, except accessories, prior to shipment.

Records are established and maintained providing evidence the product has been inspected and/or tested. Records shall identify the inspection and test authority responsible for the release of conforming products.

Process owners shall identify the inspection and test status of products by indicating conformance or non-conformance by using stamps, labels, and/or physical locations. This identification will be maintained and understood, as defined in local work instructions, throughout production, installation, and servicing of products to ensure that only products that have passed the required inspections and tests are shipped, used, or installed.

References:

QSD 111.1 Manufacturing Process
QSD 111.39 Document & Configuration Management Manual

4.5.5 Customer property

Fluke identifies customer property as accessories returned with the products for repair or calibration. Fluke does not use any other type of customer property.

4.5.6 Preservation of product

Documented procedures will be established and maintained for handling, storage, packaging, preservation, and delivery of products that describe the methods and means used to prevent product damage and deterioration of their quality or reliability.

Our materials and stores departments are responsible for establishing procedures for purchased materials. Production departments are responsible for establishing procedures for work-in-process.

The Distribution Center is responsible for establishing procedures for shipping final products to the customer.

All organizations will comply with QSD 19.1, Electrostatic Discharge Policy.

References:

QSD 19.1 Electrostatic Discharge Policy

4.6 Control of monitoring and measuring devices (7.6)

Fluke Corporation has established and maintains documented procedures to control, calibrate, and maintain inspection, measuring and test equipment (including test software) used to demonstrate conformance of products to specified requirements. Our system to accomplish this and our control procedures are described in QSD 111.44, Calibration System; CSS LPD400 Quality Assurance Manual for Fluke Customer Support Services (CSS); and QSD 111.39, Document & Configuration Management Manual. .

Additionally, all Fluke calibration and standards laboratories will comply with ANSI/NCSL Z540-1-1994.

Fluke ensures valid results with measuring equipment that shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement providing traceability to the National Institute of Standards and Technology (NIST), and/or to other nationally or internationally recognized standards. Additionally, those documents control all purchased, rented, leased and/or borrowed standards and test and measurement equipment.

b) be adjusted or re-adjusted as necessary by prescribing calibration and adjustment intervals.

c) be identified to enable the calibration status is determined including the identification of inspection, measuring and test equipment with a suitable indicator or approved identification records to show the calibration status.
d) safeguard inspection and measuring test hardware and test software from adjustments that would invalidate the calibration setting
e) ensure that handling, preservation, maintenance and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are maintained.

Fluke assesses and documents the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration and takes action on the equipment and any product affected using the Out Of Tolerance notification.

4.6.1 Organization

Fluke Corporation's Metrology Council is responsible for assuring traceability of electrical, physical, mechanical, and other standards utilized in the design, manufacture, and service of Fluke products

Our Primary Standards Laboratory is responsible for establishing and/or maintaining corporate reference standards for which traceability is required. Additionally, this laboratory will maintain a Type I environment that meets generally accepted practices for electronic equipment described by QSD 111.44.

Fluke Service Centers contain calibration laboratories for the purpose of providing high volume calibrations of internal and external customer owned measuring and test equipment utilizing standards supported by our Primary Standards Laboratory or other approved certifying entity. These calibration laboratories will maintain a Type II, III or IV environment, as appropriate for claimed calibration uncertainties, as described CSS LPD400 Quality Assurance Manual for Fluke Customer

Support Services (CSS).

References:

QSD 111.44 Calibration System
QSD 111.39 Document and Configuration Management Manual
CSS LPD400 Quality Assurance Manual for Fluke Customer Support Services (CSS)

5. MEASUREMENT, ANALYSIS AND IMPROVEMENT (8)

5.1 General (8.1)

Documented procedures for inspection and testing activities shall be established and maintained to assure the specified requirements for the product are met. Inspection and test records will be detailed in documented procedures.

5.2 Monitoring and measurement (8.2)

5.2.1 Customer satisfaction (8.2.1)

Fluke maintains customer satisfaction through surveys, data collected through the Voice of the Customer, and the customer feedback system.

5.2.2 Internal Audit (8.2.2)

The Quality Systems Internal Audit Department has established and maintains documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results are meeting planned expectations and to determine the effectiveness of the quality system.

Audits may be regularly scheduled, prompted by a significant change in a process, or by a need to follow-up on corrective or preventive actions and will be performed by a Quality Systems Internal Auditor. The auditor shall be independent of those having direct responsibility for the activity being audited. Deficiencies found during these audits will require corrective action per QSD 111.9.

Audit results will be recorded and presented to the senior manager of the organization being audited. Audit summary reports will be presented for corporate level management review at least twice per year.

References:

QS001 Internal Audit System

5.2.3 Monitoring and measurement of processes (8.2.3)

Statistics are used to determine the effectiveness of various processes on a daily basis. These measurements also roll-up to strategic quality goals related to Quality, Delivery and Cost. These strategic goals are documented in the policy deployment matrices at the top, divisional and departmental levels of the company. Countermeasures will be written for preventive action as determined by top management.

Statistics are also used to control the process components of our manufacturing processes that cannot be verified through visual inspection means due to process complexity, lack of visual verification or because it is the more appropriate method of assuring the process is in control.

Because of the linkage to the voice of the customer and policy deployment, such techniques provide a means of assuring focus, fact-based management and reporting and linkage to key breakthrough objectives.

5.2.4 Monitoring and measurement of product (8.2.4)

Supervisors are responsible for in-process and final inspection, testing, and monitoring per documented work instructions, IGSs, and design control drawings.

The inspection and test status of all work-in-process and final products will be identified to indicate whether it is conforming or non-conforming material. All departments are responsible for complying with QSD 111.7, Control of Non-Conforming Material and for taking corrective action as appropriate per QSD 111.9, Corrective Action Request.

Records are established and maintained providing evidence the product has been inspected and/or tested. Records shall identify the inspection and test authority responsible for the release of conforming products.

References:

QSD 111.7 Control of Non-Conforming Material
QSD 111.9 Corrective Action Request (CAR)

5.3 Control of Non-conforming material (8.3)

Documented procedures shall be established and maintained to ensure that products that do not conform to specified requirements are prevented from unintended shipment, use, or installation.

Materials, production, incoming inspection, production engineering, and quality assurance departments are responsible for establishing local work instructions that ensure the identification, segregation, handling, storage, and disposition of nonconforming material found during any phase of assembly, testing, inspection, and shipping processes.

References:

QSD 111.7 Control of Non-Conforming Material
QSD 111.9 Correction Action Request (CAR)

5.4 Analysis of data (8.4)

Statistics are used to determine the effectiveness of various processes on a daily basis. These measurements also roll-up to strategic quality goals related to Quality, Delivery and Cost. These strategic goals are documented in the policy deployment matrices at the top, divisional and departmental levels of the company. The analysis of data shall provide information relating to

a) customer satisfaction through the VOC
b) conformity to product requirements
c) characteristics and trends of processes and products including for preventive action,
d) suppliers (statistics determined by Purchasing)

5.5 Improvement (8.5)

5.5.1 Continual improvement (8.5.1)

Continuous improvement of the effectiveness of the quality system and different processes is done with the use of the Danaher Business System (DBS) which includes tools for monitoring, problem solving, kaizens, etc.

5.5.2 Corrective action (8.5.2)

Corrective and preventive actions will be taken in response to identified non-conformities and potential non-conformities in products, production equipment, processes, measuring and testing equipment and the quality system itself. All activities that can potentially identify non-conformities will use the described system, below, for implementing corrective and preventive action.

Documented procedures shall be established and maintained for implementing corrective and preventive action.

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

Any changes to documented procedures resulting from corrective and preventive action shall be implemented and recorded.

Everyone within the company is able to initiate a CAR using the on-line CAR/Stop Shipment System when a non-conformity or potential non-conformity in products, production equipment, processes, measuring and testing equipment or in the quality system is identified. The system, and its associated procedures, must include the following:

a) The review of nonconformities using appropriate sources of information such as processes and work operations that affect product quality, audit results, quality records, service reports, and customer complaints to detect, analyze, and prevent potential causes of non-conformities;

b) determination and investigation of the cause of non-conformities the relating to product, process, and quality system, and the recording of the results of that investigation

c) evaluating the need for action to ensure that nonconformities do not occur

d) Corrective and preventive action will be documented on the Corrective Action Request Form described in QSD 111.9, Corrective Action Request. Records will be retained for a time period as specified by the corrective action system process owner

e) Reviewing corrective action taken is done by the manager of the product, process through the on-line corrective action system

5.5.3 Responsibility

Any employee who receives a customer complaint or is aware of a nonconformance or potential nonconformance in a process, product, or service, that could adversely affect customer satisfaction, is able to initiate corrective action, using the corrective action system or the e-mail or by phone.

Process owners may choose to use a locally controlled procedure for tracking corrective and preventive actions provided those procedures meet the requirements of this manual and QSD 111.9, Corrective Action Request.

Trend analysis of quality records and other data will be carried out systematically by the quality department. Specific quality records and other data to be analyzed shall be defined in local procedures and presented for management review as described in par. 1.3. of the manual.

Senior managers are responsible to review preventive actions recorded on completed Corrective Action Request forms initiated by our Quality Systems Department's internal auditors.

References:

QSD 111.3 Voice of the Customer
QSD 111.9 Corrective Action Request (CAR)

5.5.4 Preventive action (8.5.3)

Management is responsible for reviewing process and quality records, such as the internal audit results, service reports, customer complaints, etc., to detect, analyze and eliminate potential causes of non-conformities through policy deployment countermeasures or VOC data. QSD 111.9 defines requirements for

a) determining potential nonconformities and their causes
b) evaluating the need for action to prevent occurrence of nonconformities using countermeasures and the corrective action system
c) determining and implementing action needed
d) records of results of action taken and
e) reviewing preventive action taken

References:

QSD 111.3 Voice of the Customer

QSD 111.9 Corrective Action Request (CAR)

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