

QUALITY SYSTEM GUIDELINE

OVERVIEW

Fluke has adopted ISO as the basis for its quality requirements. The contents of this section of the supplier handbook reflect these requirements and are intended as a guide to suppliers who are not familiar with ISO.

Suppliers do not need to become ISO registered, only compliant to its requirements. However, the supplier will look for an ISO certification as part of Fluke requirement.

QUALITY AND RELIABILITY SYSTEM

The supplier should maintain a quality system which supports the requirements specified in this section 4 of the handbook and the Lean Enterprise System. The Fluke lean enterprise system checklist can be found in Appendix A02.

MANAGEMENT RESPONSIBILITY

The supplier's management shall define and document its policy for quality, including objectives for and its commitment to quality. The supplier shall ensure that this policy is communicated, understood and maintained at all levels in the organization. The supplier shall clearly identify a management representative who, irrespective of other responsibilities, has authority and responsibility for ensuring that a quality system is established, implemented and maintained.

The supplier's quality assurance organization must:

- Operate with full authority to facilitate control
- Identify and correct identified problems
- Define and document the responsibility and authority of all personnel affecting quality.

The supplier's management shall review the quality system at defined intervals sufficient to ensure its continuing effectiveness. The supplier shall maintain records of the quality system reviews. The reviews should include at a minimum:

- results of internal audits
- management effectiveness
- nonconformance
- resolution of customer complaints
- identification and resolution of internal quality problems
- implementation of previous solutions

- real-time log of nonconforming material area
- adequacy of statistical techniques

To ensure economic viability, the supplier shall:

- develop a formal, documented, comprehensive business plan
- base goals and plans on competitive analysis that cover both short-term and long-term objectives
- document quality and operational performance trends
- compare data and information to business objectives
- generate and prioritize solutions and continuous improvement efforts
- document and utilize processes for determining customer satisfaction and dissatisfaction

QUALITY SYSTEM

GENERAL

Fluke has adopted ISO as the base for its quality system requirements. The contents of this section of the supplier handbook reflect these requirements.

Suppliers do NOT need to become ISO registered, only compliant to it's requirements. In verifying compliance Fluke assessors will use the DHR Supplier profile and Self Audit.

The quality system reflects management's philosophy and decisions concerning quality.

Suppliers shall establish, document and maintain a quality system as a means of ensuring the product conforms to specified requirements. The system shall be documented by means of a quality manual and quality system procedures.

Suppliers shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation.

Suppliers shall establish and maintain a Product Quality Planning (PQP) system that shall be an integral part of product design and development, tooling and equipment design and selection, manufacturing methods and inspection procedures.

Suppliers shall convene internal cross-functional teams to prepare for production of new or changed products. Cross-functional teams should typically include Design, Manufacturing Engineering, Quality, Production and Purchasing personnel. Suppliers are expected to review designs for manufacturing feasibility and cost savings opportunities. Suppliers are to communicate feasibility and cost savings ideas in writing using the Manufacturing Feasibility Concern and Cost Savings Opportunity Form. (See Appendix C10). Fluke review and approval is required prior to implementation.

Product quality planning must include procedures for:

1. The procurement and review of FLUKE drawings and applicable specifications.
2. Selection of sub-suppliers and the communication of requirements.
3. Process Failure Mode and Effect Analysis (FMEA) (See appendix C06).
4. Feasibility assessment of print or specification requirements as to whether control characteristics can be consistently achieved. Initial feasibility must be provided with the quotation.
5. Determination of inspection requirements. (See appendix C23)
6. Procurement and qualification of gaging and test equipment.
7. Gage R&R studies on designated characteristics. (See appendix C070)
8. Identification and qualification of SPC characteristics.
9. Process flow diagram. (See appendix C15)
10. Preparation of quality records.
11. Material certifications
12. Development of a control plan for each Fluke part number or product type. (See appendix C05).

Control Plans are to be living documents and shall be reviewed, updated and approved when:

- Product is changed,
- Processes are changed,
- Processes become unstable, or
- Processes become non-capable.

PRODUCTION PART APPROVAL PROCESS (PPAP)

To ensure all Fluke engineering design and specification requirements are properly understood and to ensure the process has the ability to produce quality products; suppliers shall have Fluke approval via the following PPAP. See appendix C01 for PPAP requirements and the example forms:

- Part Submission Warrant (See appendix C02)
- Dimensional Results Data Sheet (See appendix C03)
- PFMEA (See appendix C06)
- Control Plan (See appendix C05)
- Performance Test Results (See appendix C04)
- Gage R&R (See appendix C07)
- Ballooned Fluke drawing.

Using production tooling and processes, an initial 300 piece sample run is required (note: alternative sample sizes may be warranted dependent upon the nature of the

product and anticipated production quantities). Parts from each position of a multiple cavity die, mold, tool or multiple spindle machines are to be measured and included in the submission.

The submission levels are as follows:

Level I	Part submission warrant only
Level II	Part submission warrant with product samples and the dimensional / test data report form.
Level III	Part submission warrant with complete supporting data.
Level IV	Part submission warrant with complete supporting data, excluding product samples.
Level V	Part submission warrant with complete supporting data reviewed at the supplier's location.

Level III is the default level to be utilized for all submissions unless specifically advised otherwise by Fluke on the purchase order. Specific requirements are listed per commodity; for instance, Metals (See appendix C18) and plastics (See appendix C19) otherwise the standard level three are described in appendix C20. Level V will be stipulated to the supplier when a new technology is utilized or when desired by any member of the supply base commodity team, consisting of representatives from purchasing, SQA assurance, production control, manufacturing engineering and design engineering.

Production part approval is always required prior to the first production shipment of product in the following situations:

- A new part or product.
- Correction of a discrepancy on a previously submitted part.
- Product modified by an engineering change to design, specifications, or materials.
- Use of another optional construction or material than was used in the previously approved part.
- Production from new or modified tools (except perishable tools), dies, mold, patterns, etc.
- Production following refurbishment of existing tooling or equipment.
- Production following change in process or method of manufacture.
- Production from tooling and equipment transferred to a different plant location or from an additional plant location.
- Change of source or subcontracted parts, materials services.
- Product re-release after the tooling has been inactive for production for two years or more.
- Following a Fluke request to suspend shipment due to a SQA concern.

Documentation is required in accordance with PPAP and must be completed and submitted by the supplier when any of the above situations occur.

All documents must be adequately bound and identified with the supplier name, part number, dimensional/test report number and date.

Approval and return of the dimensional/test data report by Fluke will indicate approval of the PPAP submission. After initial approval, suppliers are responsible for assuring that future product continues to meet all Fluke requirements.

Rejection and return of the dimensional/test data report by Fluke will indicate the submission, the production lot from which it was taken, and the accompanying documentation do not meet Fluke requirements. Corrected product and documentation must be re-submitted for approval prior to production quantities being accepted by Fluke.

CONTINUOUS IMPROVEMENT

A strong continuous improvement philosophy shall be evident throughout the supplier's organization. Suppliers shall continuously strive to improve in quality, service, delivery and cost. Specific action plans shall be identified and developed for continuous improvement in all elements of the supplier's organization.

Suppliers shall identify improvement opportunities for quality and productivity and implement appropriate improvement projects. Examples include unscheduled machine downtime, scrap, and rework, difficult assembly or installation, and waste of labor resources.

Appropriate measurable shall be used for determining the effectiveness of continuous improvement efforts. Examples include capability indices, control charts, design of experiments, cost of quality, value analysis, problem solving, etc.

FACILITIES AND TOOLING MANAGEMENT

Suppliers shall use a cross-functional team approach for developing facilities, processes and equipment plans in conjunction with the product quality planning process. Plant layouts should minimize material travel and handling, facilitate synchronous material flow, and maximize value-added use of floor space.

Mistake proofing is the use of process or design features to prevent the manufacture of non-conforming and/or undesirable product. Mistake proofing methodology should be considered during the planning of processes, facilities, equipment and tooling as well as during problem resolution.

Suppliers shall provide appropriate technical resources, either in house or contracted services, for tool and gage design, fabrication and dimensional inspection. Fluke owned

tools and equipment shall be permanently marked and identified so that the ownership of each item is visually apparent. Supplier is responsible to maintain the tools and equipment. The tool's condition has to be reported to Fluke specially if the tool is producing a high number of parts. (See appendix C17)

Suppliers shall establish and implement a system for tooling management, including:

- Maintenance and repair facilities and personnel
- Storage and recovery
- Set-up
- Tool change programs for perishable tools
- Tool modifications, including tool design documentation.

CONTRACT REVIEW

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities. Prior to acceptance, the supplier shall review the contract or order to ensure that:

1. The requirements and terms of acceptance are adequately defined and understood.
2. Any differences between the order and the request for quote are resolved.
3. The supplier has the capability to meet contract or order requirements.
4. All requirements, including those in this standard, can be met.

The supplier shall maintain a documented procedure for disseminating provisions of the contract to all appropriate parties. The supplier shall also identify how an amendment to a contract is made and correctly transferred to the applicable functions within the organization.

Contract review activities shall be formally documented and records of contract reviews shall be maintained.

DESIGN CONTROL

Suppliers responsible for product design shall establish and maintain documented procedures to control and verify the design of the product to ensure that specific requirements are met. The supplier shall prepare plans for each design and development activity. The design activities shall be assigned to qualified and competent personnel equipped with adequate resources.

Design input requirements relating to the product, including applicable statutory and

regulatory requirements as well as Fluke specific requirements, shall be identified and reviewed. Design input shall take into consideration the results of any contract review activities.

The design process shall include:

1. Efforts to simplify, optimize, innovate and reduce waste
2. Analysis of cost/performance/risk trade-offs
3. Use of testing and production feedback
4. Use of Design Failure Mode and Effects Analysis (DFMEA).
5. Formal documented reviews of the design results at appropriate stages of design. Participants at each design review shall include representatives of all functions concerned with the design.
6. Design verification to ensure the design output meets the design input requirements.
7. Design validation to ensure product conformance to defined needs and requirements.

All design changes shall be identified, documented, reviewed and approved by authorized personnel prior to implementation. All design changes, including those proposed by subcontractors, shall have written Fluke approval, via the Fluke initial sample process prior to production implementation. Suppliers shall maintain a formal engineering change order approval system for design waivers, deviations or modifications.

DOCUMENT AND DATA CONTROL

Suppliers shall establish and maintain a documented procedure to control all documents and data that relate to product and process requirements and the requirements of Fluke. The system must include the procurement, review, use, storage and change control of all documents. Documents include, but may not be limited to, FLUKE engineering drawings and specifications, FLUKE material specifications, military and federal standards, inspection/test instructions, work instructions and operational procedures. Documents can be in the form of any type of media, such as hard copy or electronic media.

Document and data control shall include:

1. The review and approval for adequacy by authorized personnel prior to issue. A

master list or equivalent document shall be maintained to identify current revision status and delineate the distribution of applicable documents.

2. The assurance that pertinent issues of all appropriate documents are available at all operation locations essential to the effective functioning of the quality system.
3. The review and approval of changes to the documents by the same organization that performed the original review and approval.
4. The assurance that obsolete documents are promptly removed from all points of use and destroyed or suitably identified.
5. The suppliers must document a procedure for the review, distribution, implementation, and the review of Fluke engineering standards / specifications. Where necessary, updated PPAP may be required.

PURCHASING

Suppliers are expected to require the same defect-free level of quality from their suppliers as that required by FLUKE. The supplier shall establish and maintain documented procedures to ensure that purchased product conforms to specified requirements.

These procedures shall include:

1. The evaluation and selection of subcontractors on the basis of their capabilities relative to quality requirements.
2. An approved suppliers list from which product may be purchased. Additional subcontractors may only be used after they have been added to the list by an appropriate approval process.
3. A documented system for on-going supplier evaluation. Sub-suppliers quality records shall be maintained and used to evaluate performance. The performance evaluation must be used in sourcing decisions.
4. A subcontractor development system that includes quality system audits. Assessments of subcontractors should occur at appropriate, specified frequencies.

Purchasing documents shall contain data clearly describing the product, including the type, class, style, grade, etc. and refer to the appropriate revision of the applicable specification for the product being ordered. The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release.

The use of FLUKE designated subcontractors does not relieve the supplier of the responsibility for ensuring the quality of subcontracted product and services.

When specified in the contract or order, FLUKE and/or its customers shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification by FLUKE shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by FLUKE .

CONTROL OF FLUKE SUPPLIED PRODUCT

The supplier shall establish and maintain documented procedures for the verification, storage and maintenance of customer-supplied product, tooling, and returnable packaging (if applicable). Any such product or tooling that is lost damaged or is otherwise unsuitable for use shall be recorded and reported to the FLUKE business unit.

PRODUCT IDENTIFICATION AND TRACEABILITY

Suppliers are required to establish a lot control and traceability system that provides for positive identification and documentation for each lot or batch of product from receipt of material through fabrication, processing, warehousing and shipment. Traceability should be maintained through the use of a unique identifier assigned to each lot of material.

It is the FLUKE supplier's responsibility to assure that lot control and traceability is extended to sub-contractors.

PROCESS CONTROL

The supplier shall identify and plan the production processes directly affecting quality and shall ensure these processes are performed under controlled conditions. Process control methods for each product are to stem from the PQP and control plan functions.

CONTINGENCY PLANS

The supplier shall prepare contingency plans, which reasonably protect supplier products to Fluke. (eg. Utility interruptions, labor shortages, key equipment failure and transportation delays)

WORK INSTRUCTIONS

The supplier shall prepare documented work instructions for each process. These instructions are to be accessible at the appropriate workstations and include or reference as appropriate:

1. Operation name
2. Customer Name
3. Part name and part number
4. Current engineering and/or revision level, date and approvals

5. Required equipment and gages
6. Material identification and disposition instructions
7. FLUKE and supplier designated special characteristics and features
8. SPC requirements
9. Relevant engineering and manufacturing standards
10. Inspection and test instructions
11. Reaction to non-conformance instructions
12. Visual aids
13. Tool change intervals and set-up instructions
14. Equipment and tooling maintenance to ensure continued quality production
15. Safety conditions

PRELIMINARY PROCESS CAPABILITY STUDIES

Statistical capability studies are required for each FLUKE and/or supplier designated characteristic for new products and processes. The minimum capability for first production parts is a Ppk of 1.67 or 5 standard deviations for designated characteristics. The target long term capability is Cpk of 2.0 or greater particularly on new product designs. Process capabilities falling short of these requirements will require a modified sampling plan that effectively doubles the number of samples for the same lot size to effectively decrease FLUKE 's risk of receiving non-conforming product. Ppk less than 1.00 will require a 100% product sort. In addition, unacceptable preliminary capability results require re-evaluation of mistake-proofing activities.

STATISTICAL PROCESS CONTROL

Statistical process control must be utilized for designated characteristics. The Fluke requirement will be indicated on the PO or by business unit engineering through purchasing department.

SPC documentation shall be defined as a statistical type control chart, used in the manufacture of an item requiring SPC during production. Characteristics of such items will be identified on the FLUKE part print or on some other written documentation. Designated characteristics are identified by various symbols (symbols vary by business units) for which a minimum Cpk of 1.33 must be maintained for long term capability. New product designs may target a Cpk \geq 2.0. If SPC is required on the purchase order and no designated characteristics are identified on the print, mutually determined characteristics shall be selected based on the most appropriate identifier.

When the requirement for SPC exists (on the purchase order, part print, or mutually determined characteristics), the corresponding control charts or capability results will be requested as needed. The control chart, or capability result, may be used by FLUKE , in conjunction with internal procedures, to determine acceptability of the product.

Measurement instructions must be written for each specified SPC characteristic. The instructions are to provide detailed inspection information to those persons responsible

for SPC measurements. The measurement instructions must include the following information:

1. Part name and number
2. Characteristic to be measured
3. Gage type and sensitivity
4. Special fixtures to be used (if applicable)
5. Sample size and frequency
6. Reaction to trends and out-of-control conditions

The measurement instructions must be explicit, including special instructions concerning interpretation of the gage, data recording, etc. Visual aids may be incorporated into the instructions to enhance effectiveness. The instructions must contain or reference the reaction plan in the event of an out-of-control condition. The reaction plan must include instructions and responsibilities for immediate action and correction. (Note: SPC measurement instructions must be included in the appropriate areas of the Process Control Plan.)

Personnel designated to maintain SPC control charts must be adequately trained in the use of SPC and must demonstrate proficiency in the knowledge and application skills of SPC.

CAPABILITY ASSESSMENT

Summaries of process capability for each designated SPC characteristic will be requested as needed. Capability shall be reported in the form of a capability index ratio (Cpk) and must be accompanied by a control chart illustrating process stability.

Reports must include the supplier name and location, reporting date, FLUKE part number and name, characteristic and specification, previous Cpk value and current Cpk value. If the current Cpk value has significantly changed from the previously reported value and fallen below a 1.33 value, the report must contain a comment of explanation.

Control Plan characteristics that are either unstable or non-capable require initiation of the appropriate reaction plan. When data and functional tests indicate a high degree of capability (Cpk/Ppk>3), the supplier may revise the Control Plan with FLUKE concurrence.

CHANGE NOTIFICATION AND APPROVAL

Production part approval must be granted for a new part number, engineering change level, change in manufacturing location, change in material source, tooling change and change in production process. Changes to promote continuous improvement are encouraged. A Supplier Change Request must be submitted for approval prior to the PPAP sampling process.

MAINTENANCE, REGULATIONS, ENVIRONMENT

Suppliers shall identify key process equipment, provide appropriate resources for equipment maintenance, and develop an effective preventive maintenance program. The preventative maintenance system shall include procedures for planned and scheduled maintenance activities, as well as providing for packaging and preservation of equipment, tooling and gaging.

Suppliers shall ensure compliance with all applicable government safety and environmental regulations, including those concerning handling, recycling, or disposing of hazardous materials.

Suppliers must maintain a work environment conducive to good quality of work life which will promote continuous improvement and which is in the appropriate state of order, cleanliness and repair.

INSPECTION AND TESTING

Suppliers shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, acceptance criteria, and the corresponding records, shall be detailed in the Control Plan or documented procedures.

(Note: The acceptance criteria for FLUKE product is zero defects regardless of lot size.)

Inspection and testing procedures shall provide for the following:

1. The assurance that incoming product is not used or processed until it has been inspected and/or verified as conforming to specified requirements. Verification activities shall be in accordance with the Control Plan and/or documented procedures. Receiving Inspection should include the receipt, review and approval of subcontractor submitted quality documents such as SPC data, material test reports and certifications.
2. In-process inspection and testing in accordance with the Control Plan and/or documented procedures. (Note: All process activities should be directed towards defect prevention methods in lieu of defect detection).
3. The holding of product between operations until the required inspection and tests have been completed and conformance verified.
4. Final inspection and testing in accordance with the Control Plan and/or documented procedures to ensure conformance of the finished product to the specified requirements. No product shall be dispatched until all the activities specified in the Control Plan and/or documented procedures have been satisfactorily completed.

5. Establishing and maintaining records which provide evidence that the product has been inspected and/or tested. The records shall clearly show whether the product has passed or failed the inspections or tests according to defined acceptance criteria. The records shall identify the inspection authority responsible for disposition and release of the product.
6. The maintenance or utilization of accredited laboratory facilities applicable for product verification activities. Accredited laboratories are those that have been reviewed and approved by an accreditation body (e.g. American Association for Laboratory Accreditation - A2LA). Suppliers laboratory facilities must have documented procedures / instructions, suitably experienced personnel, adequate traceability, and make proper use of process control, calibration and statistical techniques.

CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

Suppliers shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment used to demonstrate product conformance. This requirement includes employee owned gages and gages utilized by toolmakers or tool maintenance personnel. These procedures must include:

1. Selection, maintenance, and accessibility to adequate inspection, measuring and test equipment for providing all necessary verification requirements to the required level of accuracy and precision.
2. Calibration of inspection, measuring and test equipment upon receipt and at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally recognized standards.
3. Definition of the process for the calibration of inspection, measuring and test equipment. The calibration equipment, location, calibration method, acceptance criteria and the reaction to unsatisfied Fluke business unit results shall be documented.
4. Identification of inspection, measuring and test equipment with a suitable, visible indicator or approved identification record to show calibration status. Where feasible, equipment shall be identified with the last date of calibration, personnel who performed the calibration and the next calibration due date.
5. Assurance that environmental conditions are suitable for the calibrations, inspections, measurements and tests being performed and the handling, preservation and storage of equipment is such that the accuracy and fitness for use is maintained. The supplier shall secure the inspection, measuring and test facilities as applicable to ensure records and methods are not disturbed.

6. The maintenance of calibration records to include gage conditions and actual readings as received for calibration/verification. The records shall also include the reactions upon findings of equipment where the results are unsatisfied by Fluke business unit. *THESE REACTIONS SHALL INCLUDE CUSTOMER NOTIFICATION IF SUSPECT MATERIAL HAS BEEN SHIPPED.*
7. Statistical studies (gage repeatability and reproducibility) to analyze the variation present in the results of each type of measuring and test equipment system. This requirement applies to all measurement systems referenced in the Control Plan. These studies shall be performed at initial production start-up and periodically as scheduled by the supplier (annual intervals are recommended). (See Appendix C07)

INSPECTION AND TEST STATUS

Product shall be identified by suitable means (markings, stamps, tags, labels, etc.), or organized by physical location, to indicate the conformance or nonconformance of product with regard to inspection and tests performed.

The identification of inspection and test status shall be maintained throughout production, installation and servicing of the product to ensure that only conforming product is dispatched, used or installed.

Location of product in the normal production flow may constitute suitable indication of inspection and test status if inherently obvious and clearly defined in documented procedures.

CONTROL OF NONCONFORMING PRODUCT

The supplier shall establish and maintain documented procedures to ensure nonconforming or suspect product is prevented from unintended use or installation. The procedures shall include:

1. A control system for nonconforming material providing visual identification, documentation, segregation, evaluation and disposition of nonconforming product.
2. The responsibility for review and authority for the disposition of nonconforming product. Nonconforming or suspect product shall be reviewed and dispositioned (i.e. - accept, scrap, rework) in accordance with documented procedures.
3. Repair and/or rework to be performed to documented procedures. The rework procedures shall be accessible and utilized by the appropriate personnel. Repair and/or reworked product shall be re-inspected to original acceptance criteria and in accordance with the Control Plan or documented procedures.

4. Recording of all nonconformance's to permit defect analysis and the generation of internal corrective action plans.
5. FLUKE written approval is required prior to shipment of product not conforming to drawing and/or specifications requirements. Notification of shipment of suspect material and temporary requests for deviations must be submitted to the appropriate FLUKE business unit (See Appendix A07 for a supplier deviation request (SDR) form). The FLUKE business unit will determine if the request can be accommodated and return the SDR form with the documented response. The supplier shall maintain a record of the expiration date or quantity authorized. The supplier shall ensure compliance with the original requirements when the authorization expires. Product shipped on an authorization shall be properly identified on each shipping container.

CORRECTIVE AND PREVENTIVE ACTION

Suppliers shall establish and maintain documented procedures for implementing corrective and preventive action. Suppliers shall document corrective and preventive actions and shall implement and record any changes to the documented procedures resulting from corrective and preventive actions.

CORRECTIVE ACTION PROCEDURES SHALL INCLUDE:

1. The effective handling of customer complaints and product nonconformities
2. Disciplined team oriented problem solving methods
3. Investigation of the root cause of nonconformities
4. Determination of the corrective action needed to eliminate the root cause
5. Application of controls to ensure corrective action is implemented and effective through the use of mistake proofing methodologies.
6. Submission of relevant information on actions taken for management review.

Inherent in the relationship between FLUKE and suppliers is the willingness of suppliers to assume complete responsibility for the quality of their product. In the event FLUKE experiences a quality related problem with a supplier's product (either at the point of receipt, during production or as the root cause of a FLUKE customer rejection), the supplier is expected to cooperate fully in an investigation into the problem cause and the implementation of corrective action.

In the event FLUKE detects non-conforming purchased items, and production

scheduling and inventories prohibit return to the supplier, FLUKE reserves the right to perform the necessary separation of nonconforming product at the supplier's expense. Additional associated costs, as a result of the nonconformance, may be charged back to the supplier.

PREVENTIVE ACTION PROCEDURES SHALL INCLUDE:

1. Detection and elimination of potential causes of nonconforming product.
2. Review of information such as internal and external nonconformance reports, audit results, quality records and customer complaints.
3. Determination of steps needed to handle problems requiring preventive action.
4. Initiation of preventive actions and application of controls to ensure effectiveness.
5. Submission of relevant information on actions taken for management review.

HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

Suppliers shall establish and maintain documented procedures for handling, storage, packaging, preservation and delivery of product.

These procedures shall include:

1. Handling methods developed to protect product from damage and deterioration.
2. Secured storage areas that prevent product damage and deterioration. (Note: In order to detect deterioration, the condition of product in storage shall be assessed at appropriate intervals.)
3. Procedures to ensure security in storage with a means to control authorization of receipt and dispatch.
4. The control of packing, packaging and marking processes to the extent necessary to ensure conformance to specified requirements.
5. Procedures to ensure delivery of required documentation (material test reports, SPC charts, conformance certifications, etc.) prior to or with receipt of product. FLUKE requires documentation to be placed in an easily accessed, marked box, or delivered with product shipment and identified as a separate item on the Bill Of Lading.
6. A system to ensure that all materials shipped are labeled to FLUKE requirements.
7. Monitoring of product protection and delivery performance with a goal of 100%

on-time shipments established. When the goal of 100% delivery performance is not realized, suppliers shall perform appropriate analyses and implement corrective action to improve performance.

QUALITY RECORDS

Documented procedures shall be established and maintained for the identification, collection, access, filing, storage and disposal of quality records. Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.

All quality records shall be stored and retained in such a way that they are readily retrievable. Quality records are to be stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

RECORD RETENTION

PPAP records, tooling records, purchase orders and amendments shall be retained for the length of time the part (or part family) is active for production plus one calendar year unless otherwise specified by Fluke.

Quality performance records (e.g. Statistical Process Control records, inspection and test results) shall be retained for one calendar year after the year in which they were created.

Retention periods longer than those specified above may be specified by a supplier in their procedures. The supplier shall eventually dispose of records.

This requirement does not supersede any governmental requirements. All specified retention periods shall be considered "minimums".

INTERNAL QUALITY AUDITS

Suppliers shall establish and maintain documented procedures for performing internal quality audits to verify conformance of quality activities and to determine the effectiveness of the quality system.

Elements of the internal quality audit system shall include:

1. Suitable intervals for performing internal quality audits on the basis of the importance of the activity, results of prior audits, and magnitude and severity of non-conformances traceable to the activity or area.
2. The performance of internal quality audits by personnel independent of those having direct responsibility for the activity being audited.

3. Procedures to record audit results and reporting audit results to the personnel having responsibility for the area audited.
4. Timely corrective action taken by the management personnel responsible for the area on the deficiencies found during the audit.
5. Follow-up activities to verify and record the implementation and effectiveness of the corrective action taken.

TRAINING

Documented procedures shall be established and maintained for identifying training needs to ensure all personnel can perform their duties consistent with the quality system.

Training elements shall include:

1. Qualifying personnel on the basis of appropriate education, training and/or experience, as required. These qualification requirements shall be formally identified and documented with respect to the task to be performed.
2. Securing applicable training resources.
3. Records for individual certification and training of personnel.
4. Periodic review and evaluation of training effectiveness (e.g. pre- and post-testing, measurable results, etc.).

SERVICING

Where servicing is a specified requirement, the supplier shall establish and maintain documented procedures for performing and verifying that the servicing meets the specified requirements.

STATISTICAL TECHNIQUES

The supplier shall identify statistical techniques required for establishing, controlling and verifying process capability and product characteristics. The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified.

The selection of appropriate statistical tools for each process should be determined during advanced quality planning and shall be included in the Control Plan.

Statistical techniques should be apparent in the design and inspection elements (e.g. - Design of Experiments, Gage R&R, etc.) as well as in process control.

Basic statistical concepts should be understood throughout the supplier's organization as appropriate.

SPECIAL PROCESSES

Special processes refer to processes from which the results 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. Among others, these include electrostatic discharge, brazing, deburring, welding, heat treating, plating, and painting.

Processes used to manufacture heat treated and plated parts, particularly fasteners, require special attention and control. Likewise, the parts produced from these processes require special inspection. Therefore, it is required that a supplier of heat treated or plated parts submit the following prior to production for approval by Fluke engineering and Purchasing:

- Source
- Process
- Process Flow Chart
- Process Control Plan
- Lot Control/Traceability Plan

The following should be documented for each Special Process:

1. Definition of process parameters
2. Monitoring and Verification of compliance with these parameters
3. Qualification of personnel
4. Qualification of equipment

Changes in heat treating, plating, or other special processes must be resubmitted to Fluke Purchasing for approval. A change in sourcing of heat treating and plating is considered a process change.