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**DEFINITIONS**

1. Tyco Electronics
2. Business Unit
3. Customer
4. Customer Complaints
5. 8D Problem Solving Process
6. Product
7. Quality Operating System (QOS)
8. Safe Launch Inspection
9. Tyco Electronics Operating Advantage (TEOA)
10. Key Supplier
11. Top Management
12. OPEX (Operational Excellence) Measurement Application
13. TECHS (Tyco Electronics Complaint Handling System)
1. **SCOPE**

This global quality management system provides the basis for analyzing customer requirements, defining the processes that contribute to the achievement of a product or service that is acceptable to the customer, and provisions for keeping these processes in control. In recognition of the varying organizational structures and needs of the business units, this quality specification may be supplemented by additional detailed procedures. Such additional procedures may not be less stringent than those provided herein unless specifically required in the customer contract; records shall be kept of such contract exceptions.

Tyco Electronics – Quality Management System (QMS)

The Tyco Electronics Operating Advantage (TEOA) is the company’s enterprise wide focus on business performance and continual improvement through waste elimination and deployment of best practices. The QMS is a foundation element of TEOA. Deployment of this Quality Management System provides the comprehensive process of satisfying the customer, starting with requirements for a product or service through the delivery, and use of the item that satisfies that request. The Tyco Electronics QMS provides the attention and control that must be given to all features of a product or service to ensure total customer satisfaction. In addition to the obvious characteristics – such as form, fit, function, and reliability – the QMS involves maintainability, storability, appearance, ease of application, end use of a product, process, or service, efforts to accomplish error–free documentation and systems, and countless other aspects contributing to the overall value to the internal operations and the external customer. The Tyco Electronics QMS meets the requirements of the International Standard ISO 9001. Tyco Electronics QMS includes supplemental quality specifications that address the additional specific requirements of the various international industry standards and regulations. See Figure 1.
2. APPLICABLE DOCUMENTS

The following documents constitute a part of this specification to the extent specifically set forth herein. Unless otherwise specified, the latest edition of the document applies.

2.1. Policy / Specifications

A. 01-02 Records Management Policy
B. TEC-11-01 Tyco Electronics Corporation Quality Policy
C. TEC-1017 Global Quality Management System Cross-Reference for Policies, Specifications, and Standards

2.2. International Standards / Industry Standards (latest revision/edition applies)

A. 10 CFR 50, Appendix B Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
B. 21 CFR 820 Quality System Regulation (Medical Device Quality System Regulation)
C. AS 9100 Quality Management Systems – Aerospace – Requirements
D. ISO 9000 Quality Management Systems – Fundamentals and Vocabulary
E. ISO 9001 Quality Management Systems – Requirements
F. ISO 9004 Quality Management Systems – Guidelines for Performance Improvements
G. ISO 10012 Measurement Management Systems - Requirements for Measurement Processes and Measuring Equipment
I. ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories

2.3. Website

B. Communications Content Organization Charts http://imageserver.us.tycoelectronics.com/imageserver/Tyco/myte/CommunicationsContent/OrgCharts/SrcFiles/tyco_electronics_org_chart.pdf
3. DEFINITIONS

3.1. Tyco Electronics
An independent, publicly traded company whose common stock is listed on the New York Stock Exchange (NYSE) under the ticker symbol “TEL”.

3.2. Business Unit
A sub-organization of Tyco Electronics identified by the industry and segment to which the unit provides products and services.

3.3. Customer
The external recipient of a product or service.

3.4. Customer Complaints
Those complaints for which external customers request formal written corrective action responses.

3.5. 8D Problem Solving Process
A method used to approach and to resolve problems. This methodology incorporates all of the important aspects of problem management, such as containment of the problem, root cause analysis, problem correction, and problem prevention.

3.6. Product
The output of a team or work unit, such as connectors, cables, relays, sensors, wireless systems, components, tools, molds, dies, software, specifications, reports, or services.

3.7. Quality Operating System (QOS)
A methodology used to demonstrate that processes are meeting customer requirements and internal continual improvement goals using trend chart(s), goal(s), Pareto analysis, problem summary chart(s), and verification chart(s).

3.8. Safe Launch Inspection
Special inspection plan developed when lack of history and experience increases the consumer’s risk.

3.9. Tyco Electronics Operating Advantage (TEOA)
The Tyco Electronics Operating Advantage (TEOA) is the company’s enterprise wide focus on business performance and continual improvement through waste elimination and deployment of best practices.

3.10. Key Supplier
A business unit designated and recognized supplier that works in a cooperative and collaborative way to achieve mutual long-term competitive benefits.

3.11. Top Management
Senior corporate and/or business unit executives responsible for strategic development and direction as well as resource provision. See http://imageserver.us.tycoelectronics.com/imageserver/Tyco/myte/CommunicationsContent/OrgCharts/SrcFiles/tyco_electronics_org_chart.pdf

3.12. OPEX (Operational Excellence) Measurement Application
An internal web based application for standard global quality metrics, designed to support the management review of the quality operating system review and improvement process.

3.13. TECHS (Tyco Electronics Complaint Handling System)
A web based application for the handling of complaints, including complaint analysis and corrective action management. It is designed to enter, track, maintain, analyze, report, and respond to customer complaints, as well as manage nonconformance with suppliers and between intracompany operations.
4. QUALITY MANAGEMENT SYSTEM (QMS)

4.1. QMS – General Requirements

The Tyco Electronics model for the QMS is derived from ISO 9004. As a customer focused organization, it is the policy of Tyco Electronics that our facilities are, at a minimum, certified to the ISO 9001 Quality Management System standard. Each site maintains (or subscribes to) documented procedures to ensure adequate process controls to meet customer, regulatory, and statutory requirements and to foster continual improvement. In addition, various industry sector-specific management system certifications are maintained within business units servicing specific industries. The model is further complemented by a comprehensive Tyco Electronics Operating Advantage (TEOA) approach for business process improvement.

The goal of the Tyco Electronics QMS is delivering products and services that provide value and meet the customer’s requirements. The Quality Policy, associated metrics and goals of the QMS shall be evaluated for continued suitability as part of the business assessment process and associated management review. The ability to provide continual improvement and breakthrough improvement is a key element for growth and identifying organizational and individual achievements for recognition.

The Tyco Electronics QMS shall foster and provide guidance for the continual improvement efforts including customer satisfaction, and the quality and reliability of our products, processes and services. Specific authority shall be given to those responsible for product, process, or system quality to:

- Determine the sequence and interaction of the processes needed to maintain the QMS;
- Determine criteria and methods needed to ensure that both the operation and control of the processes are effective;
- Measure, monitor, and analyze these processes and implement actions necessary to meet goals and to drive continual improvement;
- Initiate action to prevent nonconformance;
- Initiate action to identify, record, and correct problems;
- Initiate, recommend, or provide solutions;
- Verify implementation of solutions;
- Control further processing, delivery, or installation of nonconformance;
- Use the Define, Measure, Analyze, Improve and Control (DMAIC) process to implement breakthrough improvement; and
- Represent the needs of the customer in internal functions in addressing requirements as applicable of TL 9000, ISO/TS 16949, AS 9100, 10 CFR 50, Appendix B, 21 CFR 820, and ISO 13485.

The sequence and interaction of the processes within the QMS quality system is described in Figure 2.

Tyco Electronics has responsibility for all processes that affect product conformance to requirements, regardless of whether the process is completed internally or by an external supplier.
4.2. Documentation Requirements

4.2.1. Documentation Requirements – General

This quality specification contains the statement of the Quality Policy and Quality Objectives. The Tyco Electronics QMS includes procedures required by pertinent international and industry standards and regulations. These standards and regulations include as applicable ISO 9001, TL 9000, ISO/TS 16949, AS 9100, 10 CFR 50, Appendix B, 21 CFR 820, and ISO 13485. These QMS procedures provide Tyco Electronics with the means to ensure the effective planning, operation, and control of its processes. For a list of global level quality specifications and procedures, reference Quality Specification TEC-1017, Global Quality Management System Cross-Reference for Policies, Specifications, and Standards.

Tyco Electronics ensures that personnel have access to and are aware of relevant QMS documentation.
4.2.2. Quality Manual

The quality function shall establish, implement, and maintain a documented quality system as a means of ensuring that products and services conform to specified requirements. This documented system shall include this QMS Specification supported with detailed procedures and specifications. Global level quality procedures and specifications are located on the EPS website (reference Paragraph 2.3). This specification provides a guide for design, manufacture, and marketing of Tyco Electronics products. It represents official policy and shall be used as a standard by all business units and operations of Tyco Electronics (as defined by Section 1, Scope) in developing and administering systems for continual improvement and the control of quality and reliability of products and services.

The QMS shall provide for consideration of the following activities in meeting specified requirements:

- Quality planning;
- The identification and facilitation of controls, processes, inspection, equipment, fixtures, production resources, and skills that may be needed to achieve the required quality;
- The updating, as necessary, of quality control, inspection, and testing techniques, including the development and acquisition of new instrumentation;
- The clarification and documentation of standards of acceptability for all features and requirements, including those which may contain a subjective element;
- For the entire product life cycle, ensuring the compatibility of the design, support services, production process, installation, inspection and test procedures, and the accuracy of the applicable documentation;
- The identification of suitable verification at appropriate stages of product or service development; and
- The identification, preparation, and maintenance of quality records.

4.2.3. Document and Data Control

The document control process shall provide for the review, distribution, and maintenance of documentation for policies, processes, procedures, or techniques. The process shall provide for document approval, the use of a unique identifier for each controlled document, a distribution list or an equivalent method for identifying recipients, and change control. This control applies to documents regardless of format or media.

A master list or equivalent shall identify the current revision of documents in order to preclude the use of outdated or obsolete documents. Where possible, this list shall be available on line to provide timely knowledge of, or access to, the appropriate revision of the controlling document. Records of document revisions shall be retained.

Changes shall not be permitted in data records that verify product, process, or system acceptance without adequate control and approval.

Corporate forms should be used where possible; equivalent forms may be generated electronically as long as they contain the same information.

Customer supplied documents that can influence the design, verification, validation, inspection, testing or servicing of the product shall be controlled in accordance with local business unit procedures.

4.2.3.1. Initial Issue

The initial issue of internally controlled documents shall be coordinated with and approved by the appropriate authorized personnel prior to release of the documents. Initial release of documents shall be through a documented engineering change process. When non-Tyco Electronics documents have been verified as applicable to Tyco Electronics, the revision status shall be monitored and distribution shall be controlled within the company by the chartered function.

4.2.3.2. Changes

Subsequent changes to controlled documents shall be made in accordance with documented procedures and shall be reviewed and approved by the same functions that performed the original review and approval unless specifically designated otherwise.

When changes are made to products or processes or when new processes are initiated that affect the customer drawing or product specification, identified internal and external customers shall be notified in accordance with applicable procedures.
4.2.3.3. Drawings, Standards, and Specifications
All drawings shall be prepared in accordance with Tyco Electronics drafting standards. The development/product engineering function shall be responsible for the preparation, maintenance, standardization, and obsolescence of all product drawings.
All applicable Tyco Electronics standards and specifications – such as design, material, mold, finish, quality, and packaging – shall be used. The applicable engineering function shall be responsible for the preparation, maintenance, standardization, and obsolescence of all standards and specifications.

4.2.4. Control of Quality Records
Quality records shall be collected as evidence of QMS effectiveness and to be used as a tool to improve processes, eliminate root causes, and assist in formulating corrective action strategies.
All records shall be kept in accordance with the corporate records retention schedule. Records shall be stored in a manner to prevent loss or damage and shall be readily retrievable.
If quality records are maintained by computer, it will be the responsibility of the business unit to ensure that computer records are backed up to a network resource to prevent loss or damage to records and maintain record traceability in case of disaster or computer failure.

5. MANAGEMENT RESPONSIBILITY

5.1. Management Commitment
Top Management at Tyco Electronics maintains the leadership responsibility for the QMS and TEOA. This responsibility includes:

● Ensuring the availability of resources;
● Establishing and reviewing the Quality Policy and quality objectives;
● Conducting management reviews;
● Implementing continual improvement of the QMS;
● Developing breakthrough process improvement initiatives;
● Communicating the importance of meeting customer, safety, and regulatory requirements; and
● Ensuring regulatory compliance.

5.2. Customer Focus
Tyco Electronics welcomes the opportunity to meet with customers for the purpose of establishing and maintaining mutually beneficial relationships. These meetings are intended to share expectations, understand customer perceptions, solicit and consider customer input, and ensure quality improvement with the aim of enhancing overall customer satisfaction. These meetings may involve the review of our performance as a supplier to these customers. Additionally, the opportunity to host customer representatives in our manufacturing and engineering facilities frequently results in a better mutual understanding of customer requirements and supplier capabilities.
The various organizational structures and entities, such as teams, account management, industry management, and customer service are deployed by Top Management to align our internal capabilities with the needs of our customers.

5.3. Quality Policy – Reference Global Policy TEC-11-01
It is the goal of Tyco Electronics to continually deliver safe, effective, high-quality products and services, on time, to our customers and internal operations.
Processes and controls shall be implemented such that tasks are performed properly the first time, so that products and services meet established agreed-to requirements.
Quality, customer satisfaction, continual improvement, maintaining the effectiveness of our quality management system, and compliance with customer and regulatory requirements, are the personal responsibility of every employee.
5.4. Planning

5.4.1. Quality Objectives
The Tyco Electronics QMS and related procedures and processes support the quality policy and provide for the achievement of established quality objectives and performance targets. An effective QMS assists the company in meeting the needs of our customers through the on time delivery of defect free products and services. The QMS will provide for timely and effective corrective action and provide a factual basis for continual improvement and defect prevention. Performance against the established targets will be monitored by Top Management level.

Each business unit is responsible for establishing and maintaining quality and performance objectives that are measurable and aligned with Tyco Electronics Quality Policy, objectives, and targets.

5.4.2. QMS Planning
QMS planning at the Tyco Electronics Top Management level include the implementation, updating, and maintenance of the QMS as described in this document and the supporting quality specifications. Top Management shall also establish top level quality objectives and performance targets for improving quality and customer satisfaction. Performance to these targets shall be monitored and reported.

5.5. Responsibility, Authority and Communication

5.5.1. Responsibility and Authority
The responsibilities, authorities, and interrelationships of all personnel and functions who influence product design, quality, processes, preventive and corrective action, or the quality system are defined and communicated through, but not limited to, organizational charts, job or position descriptions, skill requirements, individual performance reviews, documented quality specifications, and the functional responsibilities defined in this document.

All personnel have the authority to halt nonconforming processes and initiate, recommend, or provide corrective and preventive solutions through designated channels.

- The Tyco Electronics organizational chart is available on the [Tyco Electronics Org Chart](http://imageserver.us.tycoelectronics.com/imageserver/Tyco/myte/CommunicationsContent/OrgCharts/SrcFiles/tyco_electronics_org_chart.pdf) website.

5.5.2. Management Representative
Top Management shall appoint representatives who, regardless of other responsibilities, shall have the responsibility and authority for:

- Ensuring that the requirements of the QMS are established, implemented, and maintained;
- Ensuring compliance to pertinent industry requirements as agreed upon contractually with customers;
- Reporting the performance of the QMS as a basis for continual improvement; and
- Assisting the Top Management in promoting customer requirements, regulatory compliances, and continual improvement throughout the organization.

5.5.3. Internal Communication
Top Management shall promote awareness of the quality policy, and inform employees of the status and changes in the QMS. This promotion may include activities such as meetings of key personnel, Tyco Electronics Intranet sites, videotapes, voice message announcements, newsletters, training programs, status reports, daily interactions, group meetings, and customer contact.
5.6. Management Review

5.6.1. General
Top Management team shall review the QMS at least annually. This review identifies trends and adjusts policy and business plans, as necessary, to meet the established goals for customers, suppliers, and internal activities. The reviews shall also address, as appropriate, suitability of the quality policy, quality objectives and QMS; changing business needs, customer satisfaction, operational and performance results, quality trends, continual improvement, assessment of resources, the results of quality audits, and corrective and preventive action activities.

NOTE Business Units shall conduct management reviews annually (at a minimum) specific to their operations. Business units are responsible for local deployment and review of their quality systems.

Records of QMS reviews shall be maintained.

5.6.2. Review Input
The input to management review shall include information on:
● Audit results;
● Feedback from customers;
● Process performance and product conformity;
● Status of preventive and corrective actions;
● Follow up actions from previous management reviews;
● Changes that could affect the QMS; and
● Improvement recommendations.

5.6.3. Review Output
The output from the management review shall include any decisions and actions related to:
● Improvement of the effectiveness of the QMS and its supporting processes;
● Improvement of product related to customer requirements; and
● Resource needs.
6. RESOURCE MANAGEMENT

6.1. Provision of Resources
It is the responsibility of Top Management to ensure that the resources that are essential to the achievement of the organization’s quality objectives, including implementing, maintaining and improving the QMS and enhancing customer satisfaction, are identified during the planning processes. Resource requirements are usually planned during the budgeting process and adjusted during the year in response to sales growth, profit plans, capacity constraints, changing customer requirements, and other internal needs. Top Management shall review the adequacy of resources and adjustments shall be made based on identified business needs.

6.2. Human Resources

6.2.1. General
Adequately trained personnel shall be provided to perform the required activities of their business function. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.

6.2.2. Competence, Awareness and Training
The need for training can be identified through a comparison of job skills with the job description, changes in procedures, and nonconforming activity. When a need has been identified, training shall be scheduled and completed.
Tasks affecting product, process, or system quality shall be performed by personnel who are qualified to perform their assigned tasks in accordance with established standards. Qualification shall be based on education, experience, and/or training.

6.2.2.1. Human Resources Function
The human resources function has the responsibility for establishing, maintaining and implementing company wide training programs. Company-wide programs may be augmented with programs deployed at the local level.

6.2.2.2. Qualification Training
Job training shall be provided for personnel, including contract or agency personnel, in any new or modified job affecting product quality. Employee qualification records shall be maintained and be available to the employee and supervision.
Records of formal training, including supervisor-conducted programs, shall be maintained on file as part of the employee's personal history.
Personnel with product design responsibilities shall be qualified to achieve the design requirements and shall be skilled in applicable tools and techniques.

6.2.2.3. Training Effectiveness
The effectiveness of a training program is expected to manifest itself through improvement in job performance and/or product quality. Training program evaluations may be conducted to verify this relationship. Methods such as pre- and post-testing, assessments, employee interviews and performance appraisals may be used.

6.3. Infrastructure
Top Management shall define, provide, and maintain the buildings, workspaces, utilities, process equipment, and supporting services necessary to ensure that product conforms to established requirements.
An effective, preventive maintenance program shall be developed and implemented at a facility level that identifies key process equipment as well as, monitoring/measuring devices and provides appropriate resources for equipment maintenance. Maintenance activities are deployed to sustain process capability requirements and product quality requirements. As a minimum, the preventive maintenance program shall identify key process equipment, establish planned maintenance activities and intervals, deploy predictive methods, manage the availability of replacement parts for key manufacturing equipment, and periodically evaluate maintenance activities for program improvement opportunities.

Adequate security shall be provided to protect critical areas of the infrastructure.

6.4. Work Environment

Facilities, including workstations and associated equipment, shall be maintained in a state of order, cleanliness, and repair such that they do not adversely affect product quality or personnel performance. All work areas must comply with established safety, regulatory, and environmental standards and codes.

7. PRODUCT REALIZATION

7.1. Planning of Product Realization

It is the responsibility of the business unit to identify and plan for the product realization processes necessary for product realization. These processes should be carried out in accordance with documented procedures. The result of product realization planning shall correspond with the business unit’s operational methods.

7.1.1. New Product Introduction

The design review process is used to assure appropriate introduction of new products. Processes for the introduction of new products are detailed in Section 7.3 (Design and Development) and in related quality specifications. Safe launch inspection may be applied for a new product introduction or for significant product or process changes.

7.1.2. Disaster Recovery Planning

Business recovery plans are developed and maintained at the facility level to ensure the ability to maintain product and service continuity in the event of a disaster. These plans shall include contingencies in the event of an emergency such as utility interruptions, labor shortages, and key equipment failure and reasonably protect the customer’s supply of product.

7.2. Customer Related Processes

7.2.1. Determination of Product Related Requirements

Tyco Electronics shall launch the establishment of product requirements by:

- Determining the need for a product or service;
- Evaluating the potential for delivering a profitable product or service;
- Accurately defining the market demand and sector since doing so is important in determining the grade, quantity, price, and timing estimates for the product or service;
- Accurately determining customer requirements, including the requirements for availability, delivery and support, by a review of contract or market needs including an assessment of any unstated expectations or biases held by customers;
- Communicating all customer requirements clearly and accurately, and
- Determining regulatory requirements for a product or service.

A formal statement or outline of product requirements shall be developed which translates customer requirements and expectations into a preliminary set of specifications as the basis for subsequent design work.

Design personnel are responsible for documenting any other product requirements, including statutory and regulatory requirements into the design objectives/product specification or equivalent.
7.2.2. Review of Product Related Requirements

Records of the results of the review of customer contracts and/or purchase orders shall be maintained.

7.2.2.1. Customer Service

A business unit designated function (e.g., customer service) shall be responsible for:

- Ensuring adequate definition of customer requirements;
- Forwarding to the appropriate functions customer specifications, requests for quotes, contracts, or purchase orders in which the customer is ordering product with nonstandard requirements; and
- Honoring requests for alterations to products and services as specified in the customer documentation.

In those cases where there is an established cross-reference between the customer part number and a Tyco Electronics part number, the customer service representative shall review the order to confirm the pricing and delivery requirements. If any discrepancies are observed, the order is reconciled within the business unit and transmitted to the customer service representative. Booking the order is confirmation that there are no known discrepancies between the customer request and the ability to meet the request.

7.2.2.2. Customer Specification Review

The appropriate functions responsible for verifying that the customer request can be satisfied shall review the purchase order, request for quote, drawing, or specification. Appropriate action shall be initiated to resolve differences to ensure satisfaction of contractual requirements before acceptance of the order. This verification shall include a consideration of verbal and electronic ordering methods as well as a means to convey changes to existing order requirements. Amendments to contracts shall be reviewed and appropriate actions shall be initiated to resolve any differences. The review of customer specifications shall include as appropriate:

- Determining product compliance with the customer’s requirements and the initiation of the cross-reference process as applicable;
- Determining compliance to those quality requirements that include measurement data, performance criteria, verification requirements, customer special requirements, audit parameters, and processing customer complaints;
- Determining compliance to special labeling and packaging requirements;
- Determining compliance to the delivery requirements; and
- Contract administration and legal department review of any contract documents containing other than Tyco Electronics standard terms and conditions.

7.2.3. Customer Communication

Tyco Electronics has established primary interfaces (e.g., sales, marketing, program management, etc.) for ensuring that all customer requests for information are satisfied. In addition, there are multiple electronic systems to assist customers in obtaining product information. Customer Service is the primary function for providing responses to customer inquiries about purchase orders and delivery dates. Quality is the primary function for resolving customer complaints, including problem escalation, customer feedback, and product recall. Tyco Electronics shall effectively communicate with customers during product nonconformity issues and complaint resolution.

7.3. Design and Development

7.3.1. Design and Development Planning

Tyco Electronics uses advanced design techniques such as (Concept, Design, Optimize and Verify (CDOV), Design for Six Sigma (DFSS), Stage Gate, etc.) to assure robust designs. The design of a product typically results from thorough and careful consideration of the customer's requirements, the potential use of the product, the potential product life cycle, and the manufacturability of the product. The CDOV Six Sigma Lean Methodology should be used for new product designs. The following activities shall be the responsibility of a business unit’s design personnel. Records shall be kept of design, development, and testing activities.
7.3.1.1. Project Planning

Project plans shall be prepared that identify the responsibility, budgets, staffing and schedules for each design and development activity. The plans shall be updated and communicated to the appropriate individuals as each design evolves. The plans shall describe or reference the following activities, as applicable:

- Organizational and technical interfaces between different groups (internal and external) shall be identified and the necessary information documented, transmitted, and reviewed;
- Project roles and responsibilities;
- Project reporting requirements, including tracking and resolving open issues;
- Performance, safety, security, and other critical requirements;
- Any project specific training requirements; and
- Usage or licensing rights.

7.3.2. Design and Development Inputs

Design input requirements relating to the product requirements shall be identified, documented and reviewed by the business unit. Records of design inputs shall be maintained. Considered design inputs include (but are not limited to):

- Requirements established by the customer input;
- Functional and performance requirements;
- Design constraints;
- Requirements for certification/agency approvals;
- Overall fitness for and impact on the customer's application, including as applicable, installation ease, usability, and maintainability;
- Supplier capability and input;
- Performance characteristics such as environmental and usage conditions, including any reliability requirements;
- Ergonomic characteristics such as ease of handling and ease of use;
- Installation, configuration, or fit;
- Industry standards and safety and regulatory requirements;
- Packaging and marking;
- Quality/product assurance inspection activities;
- Verification and validation testing requirements;
- Application requirements;
- Manufacturing and procurement requirements; and
- Analysis of similar product (including competitive product) and process designs, work operations, deviations, quality records, service reports, and customer complaints to detect and eliminate potential causes of nonconformities.

7.3.2.1. Customer Input

During the development of a new product or during the extension of an existing product, customer input can be received in a variety of formal and informal methods, including:

- Customer supplied documents and prints;
- Industry standards and documents;
- Field sales proposal requests or sales logs; and
- Customer visit summaries.
7.3.3. Design and Development Outputs
The design output shall be documented and expressed in terms of requirements, calculations, and analyses and shall:
- Meet the design input requirements;
- Provide the information required for producing the product – including any purchasing information;
- Define the acceptance criteria;
- Conform to documented industry, safety, and regulatory requirements where appropriate;
- Identify those characteristics of the design that are crucial to the safe and proper functioning of the product; and
- Result from a process that makes appropriate use of the basic and advanced quality tools (such as design of experiments (DOE), failure mode and effects analysis (FMEA); statistical tolerance analysis, CDOV, etc.).

7.3.4. Design and Development Review
All product designs shall be analyzed via the design review process. Design review activities shall be held at key times during the development cycle. The purpose of design reviews shall be to determine if the product design has the ability to meet established requirements, identify problems, and propose necessary actions. Design review activities shall be documented. Records of design review activities and resulting actions shall be maintained.

7.3.5. Design and Development Verification
During design, product shall be evaluated to verify that design outputs meet input requirements. These programs shall be planned, established and conducted by appropriate functions to:
- Investigate potential failure modes and verify their effects on both the design and the production processes; and
- Demonstrate the product design capability. The design of these tests should consider electrical, mechanical, and environmental stresses as appropriate to ensure acceptable product reliability.

Records of the results of verification testing and any necessary actions shall be maintained.

7.3.6. Design and Development Validation
Following successful completion of design verification, product for sale shall be validated to ensure suitability for end use. All requests for qualification or re-qualification shall be submitted to and coordinated by Tyco Electronics. When necessary, actual testing may be performed at other qualified test facilities, but shall be under the coordination and approval of the Tyco Electronics test laboratory or facility receiving the initial test request.

7.3.7. Control of Design and Development Changes
All design changes (e.g., product, process, system, software, packaging style, packaging type, and material or component substitution) shall be identified, documented, reviewed, and approved by authorized personnel before implementation. Records of changes during the development process shall be maintained. Tyco Electronics defines the responsibilities for monitoring and ensuring that the changes do not adversely affect product quality, performance or reliability.

7.4. Purchasing

7.4.1. Purchasing Process
Purchasing, in consultation with other functions as prescribed by business units, is responsible for supplier selection. Purchasing is also responsible for on-going support, risk analysis, supply base management, technical leadership, contract definition, and ensuring that proprietary usage and licensing agreements are completed. Order releases may be done by purchasing, materials, or contract administration. To ensure that the supplier has the necessary documentation to provide what is requested, purchasing is responsible for coordinating with the appropriate function on such items as drawings, referenced specifications, packaging and labeling requirements, and quality requirements for all initial purchase orders. This documentation shall be updated by the appropriate function to include any changes on an as-needed basis and shall be transmitted to the supplier by purchasing. Records of acceptable suppliers shall be maintained. Purchased product shall comply with all governmental, safety, and environmental requirements for the country of manufacture and sale.
7.4.1.1. New Suppliers

New suppliers of production materials, components and assemblies, as well as service suppliers that could impact product quality or delivery, shall be evaluated based on their ability to supply product in accordance with Tyco Electronics' requirements prior to classification as an approved supplier. Acceptable methods include surveys (including statistical enhancement of survey results), on-site audits, first article submittal, certification by a known source, experience of our customers and any combination thereof. It is the responsibility of the purchasing and quality functions to complete such evaluations. Records of the results of evaluations and any necessary actions resulting from supplier evaluations shall be maintained.

In the event an external customer has an approved supplier list, the responsible business unit must coordinate with purchasing to make sure that those suppliers are included in the Tyco Electronics supply base. Tyco Electronics is responsible for products and services purchased from customer designated suppliers. Optionally, the business unit may work with the customer to have the Tyco Electronics supplier added to their list of approved suppliers.

The supplier shall comply with applicable legal and environmental requirements.

7.4.1.2. Supplier Performance

Quality and delivery performance ratings shall be transmitted to key suppliers based on supplier activity. Purchasing and supplier quality shall administer the evaluation of supplier performance.

The supplier’s quality system shall be subject to development by Tyco Electronics as required. Options for development may include training, supplier days, and one-on-one sessions with suppliers for corrective action review or any combination thereof.

Additional development activity can be identified using supplier reports that are sent to the supply base. Purchasing and supplier quality, in response to poor performance as identified by the reports and based on status and importance, may solicit corrective actions to foster supplier continual improvement.

7.4.2. Purchasing Information

Purchase orders placed with suppliers shall define the product or service, the revision level as applicable, and any additional quality requirements.

7.4.3. Verification of Purchased Products

It shall be the responsibility of the business unit to determine the means of verifying that suppliers meet their contractual obligations related to the quality of the procured items. Examples of ways this may be accomplished:

- Stock as received (SAR)/dock-to-stock – following receipt of the material, it can be placed directly into stores without any receiving inspection activity. Material may be designated stock as received based on supplier or part number certification as administered through purchasing or supplier quality assurance or as approved by the business unit. Purchasing/supplier quality assurance is responsible for periodic assessments of certified suppliers;

- Supplier warrants or certificate of analysis (C of A), with test results, submitted with the material;

- Incoming inspection – each lot of received material shall be inspected to confirm conformance to specifications;

- Skip lot inspection – lots of received material are inspected as defined by a skip lot plan; and

- Product is evaluated and reported as acceptable by an accredited supplier or test laboratory.

In the event that materials are needed for manufacturing commitments before receiving inspection is complete, a plan shall be developed to provide for positive identification and control of the product produced until the material is verified as acceptable.
Unless the manufacturing site or the business unit implements specific directives, material received from other locations or subsidiaries of Tyco Electronics may be processed directly into stock without receiving inspection of product characteristics. Product acceptance shall be completed in accordance with standard procedures. In all cases it is the responsibility of the supplying operation to ensure the product meets established requirements. It shall be the responsibility of incoming inspection to identify and segregate nonconforming procured items so they are not inadvertently used. Disposition of nonconforming items shall be made by the responsible engineering disciplines or designee. The supplier shall be formally advised of both the rejection and if there is a requirement to provide corrective action.

7.5. Production and Service Processes

7.5.1. Control of Production and Service Processes

Identification and planning of production and service processes that directly affect quality shall ensure that these processes are carried out under controlled conditions in accordance with documented procedures. Production functions shall ensure that:

- Product characteristics are adequately defined;
- Needed work instructions are available;
- Suitable production equipment is used;
- Calibrated and controlled monitoring and measuring devices are available (as applicable), and used; and
- Release, delivery, and post-delivery activities are implemented.

Tyco Electronics shall comply with reference standards and codes, engineering/production drawings and specifications, quality plans and other documented procedures to monitor and control suitable process parameters and product characteristics. Specific attention shall be paid to any designated special characteristics to ensure that excessive variation does not adversely affect a product’s safety, compliance with customer specified characteristics, government regulations, fit, function, appearance or the quality of subsequent manufacturing operations. Qualified operators shall carry out the processes.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

7.5.2. Validation of Production and Service Processes

Production and service processes where the resulting product cannot be verified by subsequent monitoring or measurement shall be identified and validated to demonstrate that such subject processes have the ability to produce product that meets specified requirements. Any production or service process validation shall be documented and records shall be maintained. Validation shall include, as applicable:

- Defined process approval criteria;
- Equipment approval and personnel qualifications; and
- Specific process procedures and methods.

The criteria or interval for re-validation should be established.

7.5.2.1. Process Monitoring and Operator Instructions

Documented process monitoring and work instructions shall be prepared when needed for employees having responsibilities for the operation of production and service processes. These instructions shall be accessible to employees.

7.5.2.2. Verification of Process Setups and Operational Changes

Process setups shall be verified for applicable manufacturing processes whenever a setup is performed (e.g., initial run of a job, material changeover, job change, significant time periods lapsed between runs, etc.). Verification shall include a critical inspection of the initial product produced after the setup is completed. Job instructions shall be available for setup personnel.
7.5.2.3. First Article Examination

First-article examination requirements shall indicate the amount of inspection and documentation required. This objective evidence shall verify that new or modified molds, dies, assembly machines, and other manufacturing tools and processes are capable of producing parts that conform to the engineering drawings and specifications.

7.5.3. Product Identification and Traceability

All production materials in process and in inventory shall be identifiable as to part number, and shall be traceable to revision levels, and inspection status. A comparable identification methodology shall apply to sample / prototype / preproduction parts which must meet customer requirements. Configuration control shall be maintained for product and process change control.

All product in final inventory shall be traceable to the date of manufacture. When date code identification is required, the date code shall identify the week of the manufacturing operation or inspection of the item.

Specific traceability from raw material to final item is not required, with the following exception:

Where lot traceability is required by customer contract and has been properly negotiated as to additional costs and requirements, then records shall be maintained for the unique identification of the individual product or lot.

7.5.3.1. Inspection and Test Status

All production materials in-process or in inventory shall be identifiable as acceptable for further processing or shipment. This marking shall appear on each unit container used for handling and storage. Such markings may be in the form of identification which point to electronic inspection and test records. This marking may be on cartons, reel tags, routing cards, product travelers, or any suitable location, provided there is a clear indication that prior verification operations have been performed. The verification status indication shall permit identification of the operator(s) or inspector(s) who performed the prior inspection(s) or review. Records shall be maintained of authorized identifiers.

When the status is identifiable through a machine-readable code, there shall be sufficient information provided to identify verification status when the reader is not available.

It shall be the responsibility of the materials function to receive into stock only items that are clearly identified as acceptable.

For the service and support areas of the company, an appropriate indication of approval shall be used; when verification is electronic, this identifier shall take into account computer security measures.

7.5.4. Control of Customer Supplied Product

Processes for the control of verification, storage, and maintenance of customer-supplied product, including customer-owned packaging, for incorporation into the supplies or for related activities shall be established and maintained. Any such product that is lost, damaged, or otherwise unsuitable for use shall be reported to the customer, and records shall be maintained.

7.5.5. Product Preservation

Designated distribution warehouse storage areas, general warehouse storage areas or stock rooms are used to prevent damage or deterioration of product pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. Each stocking location shall apply appropriate methods for preservation and segregation of product to ensure that material or product will remain undamaged pending use or delivery. In order to detect deterioration, each stocking area shall, at appropriate intervals, assess the condition of the product.

Inventory systems to optimize inventory turns over time, assure stock rotation, and minimize inventory levels shall be used.

Packaging, labeling and marking processes shall be controlled to the extent necessary to ensure conformance to established requirements. This shall include systems to conform to specific customer packaging and labeling requirements.
7.5.5.1. Shelf-Life

Materials that have a shelf life shall be clearly marked with an expiration date or a date of manufacture that can be used to calculate an expiration date. Materials shall not be used past the expiration date without documented engineering approval.

7.6. Control of Inspection, Measuring, and Testing Devices

Gages, measuring devices, and testing equipment used to determine the acceptability of components, assemblies, materials, and tooling affecting product quality shall be specified and/or provided by engineering, production, or quality where necessary to ensure valid results. These instruments shall be controlled and calibrated in accordance with a system that conforms to the requirements and intent of ISO 10012 and ISO 17025, or equivalent national or industry standard. Where system test and verification relies on software-controlled devices, the functionality shall be verified. General rules for controlling inspection, measurement, and test equipment are as follows:

- Process and product measurement devices that provide the required accuracy and precision shall be selected and verified before production. Measuring and monitoring devices shall be controlled to ensure that measurement capability is consistent with measurement requirements.
- All measuring devices used to verify product quality shall be uniquely identified and calibrated at prescribed intervals against certified equipment having a known relationship to a nationally or internationally recognized standard. If no standard exists, the method of calibration shall be identified and recorded.
- Processes shall be developed for calibration and record collection with adequate controls for ensuring product quality. All measuring devices shall have an indication of calibration status. If the calibration status indication is invalid, the measuring device shall not be used.
- Any inspection, measuring, and test equipment that does not require calibration shall be appropriately identified.
- A process shall be established that assesses the validity of previous inspection and test results when measuring devices are found to be out of calibration. Records of this assessment shall be maintained.
- Conditions shall be established that provide suitable environments for calibration (as applicable at sites) and use of measuring devices. These devices shall be stored and handled in a way that maintains accuracy and fitness for use.
- Methods shall be developed to safeguard measuring devices, including test hardware and software, from adjustments which would invalidate the calibration settings.
- Appropriate statistical studies of the variation present in measurement and test systems shall be completed as part of process capability analysis and as specified in customer approved control plans. As applicable, such studies shall conform to generally recognized measurement system analysis methodologies.
- All product produced with suspect measuring equipment shall be segregated and audited. Customer notification and product recall shall be considered if suspect product was shipped.
- Nonstandard measuring equipment such as pin detectors, vision systems, etc. shall be verified by the local manufacturing location by using product having known defects or other suitable means. The verification schedule and results shall be recorded.
- Should nonstandard measuring equipment be determined nonfunctional, it shall be removed from service until it is repaired and declared operational.
- Devices that are either inactive or unsuitable for use shall be visibly identified and shall not be used.
8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1. Measurement, Analysis, and Improvement - General

Monitoring, measurement, analysis, and improvement processes shall be implemented to demonstrate product conformity, ensure QMS conformity, and advance the continual improvement and effectiveness of the QMS.

8.1.1. Statistical Techniques

Quality (or other designated function) shall identify the need for and use of statistical techniques for establishing, controlling, and verifying processes that impact product characteristics and process capability. Statistical tools (as needed to assure robust processes) shall be determined during design and development or as a result of continual improvement effort (e.g., Six Sigma, Lean, QOS reviews, corrective/preventive actions, etc.). Process measurements shall be implemented and monitored at the appropriate points to ensure continual product conformance and to promote increased effectiveness of the process.

8.2. Monitoring and Measurement

8.2.1. Customer Satisfaction

Information related to customer perception as to whether Tyco Electronics has met customer requirements shall be included as a QMS performance measure.

Trends in customer satisfaction and key indicators of customer dissatisfaction shall be documented and supported by objective information. As appropriate, these trends should be compared to those of competitors or benchmarks and reviewed by Top Management.

Customer satisfaction data is received in a variety of methods, including:

- Feedback received in response to answers to customer complaints;
- Industry positioning surveys;
- Supplier “report cards”;
- Meetings with customers; and
- Ship to customer request performance.

8.2.2. Internal Assessment and Audits

QMS assessments shall be conducted at least annually to verify compliance with planned arrangements and to determine the adequacy, effectiveness, and suitability of the QMS to meet the objectives of the Tyco Electronics QMS and the pertinent international and industry related QMS standards. Results of these assessments shall be reviewed by management as feedback for continual improvement and verification of conformance to QMS requirements. Records of such assessments and reviews shall be maintained.

Each business unit shall conduct assessment of the QMS in accordance with documented procedures at regular intervals based on the status and importance of the activity. Assessment of the QMS shall be carried out by qualified personnel independent of those having direct responsibility for the area being assessed and should cover all shifts. Follow-up assessment activities shall verify and record the implementation and effectiveness of the corrective action taken.

8.2.2.1. Manufacturing Process Audits

Business units shall implement a program of manufacturing process audits to monitor the ability of manufacturing processes to achieve planned results. This program shall be established in accordance with a documented procedure and involve all Tyco Electronics production locations. These audits will ensure that product characteristic information, needed work instructions, suitable equipment and tools, and monitoring and measuring devices are available and used.
8.2.2.2. External Assessments

Tyco Electronics recognizes that it will be necessary for some customers, agencies, and third party registrars to perform quality assessments. During such customer surveys, source inspections, or quality assessments, employees shall neither demonstrate nor discuss production equipment, processes, methods, etc. which are considered to be proprietary. In those circumstances where the party performing the assessment may require additional information considered proprietary, additional consideration may be possible through the use of confidential nondisclosure agreements.

Customer and third party registrar requests to review nonproprietary manufacturing inspection data including review of SPC data, capability data, and other statistical data shall be supported. However, Tyco Electronics reserves the right to deny requests for process data below the level of the customer drawing/specification on the premise that such information is regarded as proprietary.

8.2.3. Process Monitoring and Measurement

The results of QMS assessment and production process audits, coupled with the analysis of customer satisfaction, shall be primary indicators of the effectiveness of the QMS. When assessments and audits determine an inadequacy in the implementation of the QMS, appropriate corrective action shall be taken. This corrective action could include, but is not limited to:

- Development and deployment of training to bring actual practice into alignment with documented requirements;
- Change to the documented requirements to ensure alignment with current business needs and practices; and
- Change the documented requirements to cause deployment of new practices.

The production process documentation and/or the quality inspection plan shall include measurements and control points to ensure the continued suitability and effectiveness of processes to produce conforming product.

8.2.4. Monitoring and Measurement of Product

Product characteristics shall be measured and monitored throughout the production process to ensure that the product meets the established requirements. Usually these inspection and testing activities are documented in a quality inspection plan or quality specification for the part number, product, or process. Evidence of conformity with the acceptance criteria shall be maintained and the records shall identify the individual(s) completing the inspection activities.

8.2.4.1. In-Process Inspection

In-process inspection, test, or review operations shall be clearly identified in all process documentation. Quality or its designee shall be responsible for ensuring that appropriate inspection, test, or review operations are documented. The quality function shall also ensure that adequate instructions are provided for such operations and that adequate records are maintained and properly retained. All nonconforming product at these operations shall be identified, segregated from acceptable material, and shall become the responsibility of Quality or its designee, which shall coordinate disposition and corrective action.

Where operator inspection or automatic inspection devices are used to determine product acceptance, appropriate product auditing shall be maintained to insure the integrity of the QMS.

Where in-process inspection, test, or review operations are performed by other than the quality function (such as an engineer, technician, operator, setup person, or team member), records of verification performed and results of that verification must still be provided and retained.

8.2.4.2. Final Inspection

When specified in a documented procedure, final inspection and/or testing are performed to complete the evidence of conformance of the finished product to established requirements. Records of final inspection and testing shall be maintained.

All finished goods shall have some indication of acceptability. This acceptability indication normally shall be applied during or following the final manufacturing inspection operation. However, if quality or its designee has identified the need for a final inspection or audit operation, the evidence of acceptability will be applied after product compliance is verified.
Quality or its designee shall coordinate the activity of layout inspection and functional verification at a frequency as negotiated with the customer.

Final package material audits (e.g., product integrity, packaging, labeling, documentation, quantity, marking) may be scheduled at appropriate intervals as deemed necessary by the business units.

8.3. Control of Nonconforming Product and Materials

All product (production materials, components, assemblies, final product, etc.) detected or suspected as nonconforming to requirements shall become the responsibility of Quality (in conjunction with other functions as required) for:

- Controlling further movement of the material to prevent material from unintended use or delivery;
- Documenting and reviewing material;
- Coordinating the disposition action;
- Notifying appropriate personnel;
- Initiating corrective action as necessary and verifying for effectiveness;
- Establishing and tracking a prioritized defect reduction plan; and
- Providing trend analysis input for corrective and preventive action.

Nonconforming or suspected nonconforming material (including unidentified material), shall be immediately identified as nonconforming and shall be prevented from inadvertent further processing, where practicable, by storage in an area that is visually identified and segregated for this purpose.

Nonconforming material may be sorted, reworked, returned to the supplier, scrapped, or accepted with documented engineering approval.

If the nonconforming material is dispositioned for rework or repair, rework instructions shall be provided and the material shall be re-inspected before it returns to the process. Authority to dispose of defective material shall be defined by the business unit.

Records of nonconforming material transactions, including “accepted with engineering approval”, shall be maintained.

8.4. Measurement and Analysis of Organizational Performance

The quality assurance director/manager and each business unit vice-president/director shall have the responsibility of maintaining performance data including:

- Specific industry (for example telecommunications and automotive) required metrics and trends,
- Tyco Electronics directed quality measures;
- Customer satisfaction;
- Operational performance (e.g., productivity, efficiency, effectiveness) for key products and services; and
- Regulatory compliance.

Customer satisfaction is evaluated through several tools that may include customer complaints, customer feedback responses, the QOS process, reports and information from the field, customer surveys, industry reports, etc. Trends in quality and operational performance shall be compared with progress toward objectives. Data shall be translated into actionable information to support the quality policy, business plans, and customer satisfaction. Business unit management on a periodic basis shall evaluate the measurements and goals.

All functions shall use facts, data, and quality records for improvement planning, for minimizing repetitive nonconformance situations, and for determining corrective or preventive action strategies. As appropriate, summaries of quality costs, in-process and final inspection results, quality audits, nonconformities, supplier performance, and re-qualification test activities shall be prepared by the Quality function or designate and submitted to management.
8.5. Improvement

8.5.1. Continual Improvement

The business units shall promote and manage continual improvement in quality, productivity, service, and value. Improvement projects shall include, as appropriate, external customer, corporate, supplier, safety, and regulatory requirements. Continual improvement shall be measured against goals and objectives. One or more of the following techniques may assist with achieving the goals and objectives:

- Application of statistical sciences such as the use of the engineering for quality tools, including statistical process control (SPC), design of experiments (DOE), regression analysis, and analysis of variance (ANOVA).
- LEAN: A series of tools and techniques that focus on process optimization through cycle time reduction and the elimination of waste.
- Management Methods: Self assessment and gap analysis (SAGA), ISO/TS 16949, benchmarking, suggestion systems, taskforce teams, cross functional teams, organization and leadership review (OLR), performance reviews, training, apprentice programs, bonus programs and business planning.
- Manufacturing Resource Planning (MRP): A process for integrating and controlling all business planning processes for the purpose of balancing supply and demand in the most effective and efficient way.
- QOS Review: A regular management review to demonstrate that processes are meeting customer requirements and internal continual improvement goals; utilizing trend chart(s), goal(s), Pareto analysis, problem summary chart(s), and verification chart(s).
- Six Sigma Lean: A process improvement methodology that uses a series of tools and techniques to identify, optimize, and control the key process variables that affect the key output variables.
- Best Demonstrated Practices (BDP): A total employee involvement technique focused on identifying a superior or innovative method that has proven to have contributed towards improved performance of a process in one location and implementing the method into other locations.
- The Tyco Electronics Operating Advantage (TEOA) is the company’s enterprise wide focus on business performance and continual improvement through waste elimination and deployment of best practices.

8.5.2. Corrective Action

Where a nonconformance is identified or where analysis indicates a nonconformance, the responsible function shall be notified (if deemed appropriate based on status and importance) in writing in the form of a corrective action request. A corrective action plan shall be developed by and reviewed with the function(s) responsible for implementation of the corrective action. The responsible function shall use disciplined problem solving and mistake-proofing methodologies.

The Tyco Electronics complaint handling system (TECHS) shall be used to manage all formal customer complaints unless regulatory requirements require another system. This on-line software program will assign corrective action to the owning business unit such that the issues may be resolved within time frames defined by the customer.

Where a nonconformance is identified, the business unit shall implement corrective action according to documented procedures. Unless there is a specific format required by the customer, the TECHS format shall be used for all formal customer complaints received from external customers. Consideration should be given to using the 8D problem solving process when responding to internal failures. Corrective action shall be to the degree appropriate to the magnitude of the problem and commensurate to the risks encountered. Understanding the benefits, risks, and costs is crucial in maintaining a balance in implementing the QMS. The corrective action process shall include, but not be limited to:

- The effective and timely handling of customer complaints, return of defective material, reports of product nonconformance (from internal operations and external suppliers), and internal and external audit corrective action requests;
- Identifying and investigating the root cause of nonconforming product, nonconforming processes, and systemic quality system deficiencies, and recording the results of the investigation;
- Determining the corrective action needed and applying controls to ensure corrective action is taken and root cause has been addressed;
- Implementing and recording changes in procedures resulting from corrective action; and
- Analyzing customer impact and notifying customers where necessary.

Records of the results of action taken shall be maintained and shall be included as an input for management review.

8.5.3. Preventive Action

Preventive action can take two forms. First is the elimination of potential failure modes. This technique should be deployed in the advanced quality planning stage of new product or process development. Those responsible for design should deploy these quality tools. The following tools shall be considered when designing a new product or process:

- Design FMEAs;
- Process FMEAs;
- Quality function deployment;
- Similar product / process baselining / benchmarking;
- Design of experiments; and
- Cross-functional teamwork.

The second form of preventive action is the elimination of potential failure modes when information from processes, systems, work operations, process capability studies, yield analyses, deviations, concessions, quality records, audit reports, service reports, or customer complaints suggests a nonconformity may occur. Steps shall be taken according to documented procedures to eliminate potential nonconformities. The minimum preventive action process should include, but not be limited to:

- Determining the steps needed to verify or invalidate the potential nonconformities;
- Gathering and analyzing the required data;
- Determining the effectiveness of the implemented containment actions;
- Applying controls to ensure the solution is effective in resolving the potential problem at an acceptable level corresponding to the risks encountered;
- Reviewing preventive action activities by management for trends and impact on procedures, products, processes, and systems;
- Using design reviews against customer requirements; and
- Using proposal reviews against customer requirements.

The following tools should be considered:

- Product and process audits;
- Equipment preventive maintenance; and
- Review of product and process FMEAs.

Records of preventive action shall be maintained and shall be included as an input for management review.