

**Global Quality Management System Supplement for the
Railway Industry Model, IRIS, Revision 1**

1. SCOPE

1.1. Content

This specification defines the specific railway industry quality management system requirements in accordance with IRIS, International Railway Industry Standard, Revision 1. In addition, this document is a supplement to Quality Specification, TEC-1000 in providing criteria for compliance to railway industry requirements.

Alignment to Quality Specification TEC-1000 is achieved through the ISO 9001: 2008 paragraph tables which address the each applicable IRIS, Revision 1 requirement.

1.2. Application

This specification applies to all business units of Tyco Electronics. In recognition of the varying organizational structures and needs, Business Units may develop and use supporting specifications and/or procedures. However, such supporting documentation shall not conflict with or supersede this specification.

2. APPLICABLE DOCUMENTS

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

2.1. Specifications

- A. TEC-1000 Tyco Electronics Global Quality Management System
- B. TEC-1003 Supplier Performance Reporting and Continual Improvement Process
- C. TEC-1005 Tyco Electronics Total Quality Management Requirements for Suppliers
- D. TEC-1006 Approval of Suppliers

2.2. Industry Standards

- A. IRIS International Railway Industry Standard, Revision 1
- B. ISO 9001: 2000 Quality management systems - Requirements
- C. ISO 9001: 2008 Quality management systems – Requirements
- D. ISO 10007: 2003 Quality management systems - Guidelines for configuration management
- E. EN 50126: 1999 Railway applications. The specification and demonstration of reliability, availability, maintainability and safety (RAMS)
- F. EN 50128: 2001 Railway applications. Communications, signalling and processing systems. Software for railway control and protection systems
- G. EN 50129: 2003 Railway applications. Communication, signalling and processing systems. Safety related electronic systems for signalling

3. DEFINITIONS

Definitions contained in the above mentioned Specifications and Industry standards are applicable herein.

NOTE

*On all subsequent pages, **Bold Text** in the right hand column represents Tyco Electronics commentary.*

4. QUALITY MANAGEMENT SYSTEM (QMS)

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
4.1. QMS – General Requirements	<p data-bbox="565 348 954 380">4.1. General requirements</p> <p data-bbox="695 380 1446 499">In case of transfer or outsourcing of activity within the execution of a contract a transfer procedure including: Feasibility study, risk analysis, planning, communication to customer and first article inspections to the appropriate level shall exist.</p> <p data-bbox="695 531 1451 709">Regardless of the product realization activity location, Tyco Electronics is responsible for the quality of the product delivered to the customer. Tyco Electronics will represent the needs of the customer in both internal and outsourced functions in addressing the requirements of IRIS, Revision 1.</p> <p data-bbox="695 741 1446 982">Documented procedures are established and implemented when product realization process activities are transferred and outsourced. These procedures include criteria for assigning responsibilities and authorities, an activity transfer validation process, and checklists defining customer notification, appropriate inventory builds, tooling and equipment transfers, training, and environmental and safety requirements.</p> <p data-bbox="695 1014 1398 1077">A cost management process shall be in place to address all project related costs during the whole product life cycle.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>Tyco Electronics promotes and manages 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 cost management goals and objectives:</p> <ul style="list-style-type: none"> • 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. • Tyco Electronics Operating Advantage (TEOA): Operating advantage is the umbrella for continual improvement programs that provide employees a toolset that supports improvement solutions to help achieve the company's goals and provides a common platform and standard for driving improvement throughout Tyco Electronics. It covers improvement tools, Six Sigma, Lean, Kaizen, etc.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>NOTE 1 <i>In the ISO 9001: 2000 text “process” is to be understood as “product or process”.</i></p> <p>NOTE 2 <i>Ensuring the same level of control over outsourced products, before or after transfer or outsourcing, does not absolve the organization of the responsibility of conformity to all customer requirements.</i></p>
<p>4.2. Documentation Requirements</p> <p>4.2.1. Documentation Requirements – General</p>	<p>4.2.1. General</p> <p>In addition to the ISO 9001: 2000 requirements, the business management system shall include:</p> <ul style="list-style-type: none"> f) Management system requirements imposed by the applicable regulatory authorities. g) Documented statements of a technical safety policy and safety objectives. <p>Documented regulatory requirements applicable to the Tyco Electronics Quality Management System will be controlled in accordance with established and documented procedures defining the manner of control for documents of external origin. Regulatory requirements related to product design and performance may be incorporated into Tyco Electronics product specifications which will include the applicable version of the regulatory requirement.</p> <p>Documented statements of a technical safety policy and safety objectives begin with the Tyco Electronics Environmental, Health, and Safety Policy which establishes a commitment to maintaining compliance and minimizing from the manufacture, use, and disposal of products. From established and specific safety objectives, goals are determined, communicated, measured, and reviewed by top management.</p> <p>The organization shall ensure that personnel have access to business management system documentation and are aware of relevant procedures.</p> <p>Management will implement processes and controls ensuring that all Tyco Electronics associates are aware of and have ready access to documentation pertinent to their assignments. This may be accomplished through access to electronic mediums or the controlled distribution of hard copies.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>Customer and/or regulatory authorities' representatives shall have access to the business management system documentation.</p> <p>As requested, customers and regulatory authority representatives will be granted access to relevant quality management system documentation. This documentation should be classified as non-confidential per defined Tyco Electronics policy.</p>
<p>4.2.2. Quality Manual</p>	<p>4.2.2. Quality manual</p> <p>When referencing the documented procedures, the relationship between the requirements of this document and the documented procedures should be clearly shown.</p> <p>The Tyco Electronics quality manual is established and maintained as TEC-1000, Tyco Electronics Global Quality Management System. Various industry-related supplements support and provide criteria specific to industry requirements. In addition, Quality Management System documentation includes cross-reference matrices that associate Quality Management System Standard paragraphs to applicable Tyco Electronics specifications.</p>
<p>4.2.3. Document and Data Control</p> <p>4.2.3.1. Initial Issue</p> <p>4.2.3.2. Changes</p> <p>4.2.3.3. Drawings, Standards, and Specifications</p>	<p>4.2.3. Control of documents</p> <div data-bbox="711 1010 857 1062" style="background-color: black; color: white; padding: 2px;">NOTE 1</div> <p><i>Documents of external origin can be standards, customer requirements specifications, specific customer documents, regulatory requirement, etc.</i></p> <p>The organization shall have a process to ensure the traceability of customer specification / requirements throughout the entire supply chain for design, manufacturing and field support activities.</p> <p>Customer supplied documents that can influence the design, verification, validation, inspection, testing, or servicing of the product shall be controlled in accordance with established and maintained procedures. Typically, the Design Engineering function will maintain responsibility for ensuring that the proper revision of the customer drawings and specifications and defining specific performance parameters for the product being designed are stored and made available when required. When the product is released for production, the customer document(s) that influenced the design shall be retained as design history.</p> <div data-bbox="717 1713 863 1766" style="background-color: black; color: white; padding: 2px;">NOTE 2</div> <p><i>Customer requirements can be for example RAMS/LCC, obsolescence, special process, spare parts, weight and acoustic.</i></p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
<p>4.2.4. Control of Quality Records</p>	<p>NOTE 3 <i>This process may be included as part of the organization's change management process.</i></p>
	<p>4.2.4. Control of records</p>
	<p>This documented procedure shall also include approval of results recorded before official release.</p> <p>Documented procedures are established, maintained, and implemented defining the controls needed for identification, storage, protection, retrieval, retention, and disposal of records as well as the recording of results approval prior to release.</p> <p>The organization shall maintain a record of the date and / or serial number of each change which is implemented into production.</p> <p>A record of the date on which each change is implemented in production shall be maintained.</p> <p>Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.</p> <p>As contractually required, customers and regulatory authorities shall be granted access to pertinent records.</p>
	<p>4.3. Knowledge management</p>
<p>Best practices shall be documented and regularly updated to improve the organization's process efficiency and product in quality, costs, and delivery performance.</p> <p>NOTE 1 <i>This can include but is not limited to:</i></p> <ul style="list-style-type: none"> • <i>Design standards, design rules,</i> • <i>Return of experience after a project,</i> • <i>Methods / manufacturing engineering standards,</i> • <i>Closing major NCR with standards (operating procedures, etc.), and</i> <p><i>Return of experience from the field, analysis of failure rates, etc.</i></p>	

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>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 technique that may assist with achieving the goals and objectives involves a Best Demonstrated Practices (BDP) program. This program provides 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.</p>
	<p>4.4. Management of multi sites projects</p> <p>In cases where a project involves multiple sites, an appropriate business management system (e.g. project quality plan) shall be properly documented and implemented, and shall cover as a minimum:</p> <ul style="list-style-type: none"> • Operational interfaces and responsibilities (internal and with the customer), • Communication channels within the organization and with the customer (including feedback on the results of each sites' scope of responsibility, • Work split, • Applicable procedures and records on each site, • Alignment of customer requirements, and • Assurance of IRIS compliance. <p>Cross site process efficiency shall regularly be assessed to the appropriate level (e.g. throughout audits, management reviews, process reviews, customer compliant, etc . . .) and improved where necessary.</p> <p>Project plans are prepared, documented, and implemented to manage projects involving single or multiple locations. The plans identify the interfaces, responsibilities, budgets, staffing and schedules for each project activity. The plans shall be updated and communicated to the appropriate individuals as each project progresses. The plans shall describe or reference the following activities, as applicable:</p> <ul style="list-style-type: none"> • 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; • Alignment to customer requirements; • Performance, safety, security, and other critical requirements; • Any project specific training requirements, and • Usage or licensing rights. • Assurance to IRIS requirements.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p data-bbox="695 226 1437 405">Tyco Electronics subscribes to a common and unified quality management system that links processes and procedures between multiple functions, organizations and locations. The Global Quality Management System, as defined in TEC-1000 and the supporting QMS documentation:</p> <ul data-bbox="743 409 1429 661" style="list-style-type: none"><li data-bbox="743 409 1429 472">• Supports operational interfaces and defines responsibilities across organizational boundaries,<li data-bbox="743 476 1429 539">• Facilitates both customer and internal communication,<li data-bbox="743 543 1429 606">• Provides consistency in the achievement of corporate goals,<li data-bbox="743 611 1429 642">• Facilitates best practice sharing, and<li data-bbox="743 646 1429 661">• Supports industry and regulatory compliance.

5. MANAGEMENT RESPONSIBILITY

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
<p>5.1. Management Commitment</p> <p>5.2. Customer Focus</p>	<p>5.2. Customer focus</p> <p>Company policy shall also reflect the organization’s willingness to satisfy customer needs throughout the entire project life cycle.</p> <p>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. The Sales and Marketing function are typically the representatives during these customer meetings. They will request participation from other applicable functions depending on the agenda for the meeting. 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.</p> <p>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. (TEC-1000)</p>
<p>5.3. Quality Policy</p>	<p>5.3. Quality policy</p> <p>The organization shall establish and update at least annually, a business plan covering as a minimum, the following topics:</p> <ul style="list-style-type: none"> • Railway industry activities, • Company mission and vision, • Strength, Weakness, Opportunities, Threats (SWOT) analysis and contingency plan to reduce risks, • Market and product strategy including obsolescence, • Screening of appropriate technologies, • Make or buy industrial strategy, • Company capacity (current and future), • Development plans of new product/process, and • Business objectives. <p>This plan shall be cascaded throughout the organization and supported by mid and long term action plans.</p> <p>Top management shall establish quality objectives and performance measures that address customer expectations. These quality objectives and goals shall be included in an annual Business Plan that addresses railway industry activities; the Tyco Electronics mission and vision; a SWOT analysis and plan to reduce risks; market strategy; technology review; procurement strategies; capacity; and organizational objectives.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
<p>5.4. Planning 5.4.1. Quality Objectives 5.4.2. QMS Planning</p>	<p>5.4.1. Quality objectives Business objectives should be cascaded and broken down in the organization and individual reviews organized on a regular basis.</p> <p>Business objectives should address customer expectations and be achievable within defined timescales.</p> <p>Top management shall establish quality objectives and performance measures that address customer expectations. Performance against the goals will be monitored at the top management level. These objectives shall be established, as a minimum, annually and be flowed down to an individual level.</p>
<p>5.5. Responsibility, Authority and Communication 5.5.1. Responsibility and Authority</p>	<p>5.5.1. Responsibility and authority Roles and responsibilities for all processes having an impact on customer satisfaction (including RAMS and special processes) shall be described.</p> <p>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. (TEC-1000)</p> <p>Interfaces with the customer should be identified and communication channels described and communicated.</p> <p>Customer interface and customer communication channels are defined through the various Tyco Electronics organizational structures and entities. Customer interface and communication may be deployed through account management, industry management, and customer service.</p> <p>Each employee within the organization has the responsibility to raise any issue / deviation from the requirement to his / her manager for appropriate action.</p> <p>All personnel have the authority to halt nonconforming processes and initiate, recommend, or provide corrective and preventive solutions through designated channels. (TEC-1000)</p> <p>Ownership of the business processes shall be defined. The process owner should have sufficient authority.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>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. (TEC-1000)</p>
<p>5.5.2. Management Representative</p>	<p>5.5.2. Management representative</p> <p>In addition to the ISO 9001: 2000 requirements the management representative shall have:</p> <ul style="list-style-type: none"> d) the organizational freedom to resolve matters pertaining to quality or stop development / production / delivery / field support activities if critical requirements are not met. <p>Tyco Electronics, Business Unit, and facility top management shall appoint representatives who, irrespective of other responsibilities, shall have the responsibility and authority for ensuring that the requirements of the quality management system defined in TEC-1000, and supplemented by this document, are established, implemented, and maintained. Additionally, these representatives shall be granted the freedom and authority to resolve matters pertaining to quality including identifying and resolving problems and conditions adverse to quality, verification of problem resolutions, and the authority to withhold from continued production or release for shipment, products not in conformance with acceptance criteria.</p>
<p>5.5.3. Internal Communication</p>	<p>5.5.3. Internal communication</p> <p>The organization shall establish a communication system from management to its personnel and vice versa, giving consideration to, as a minimum:</p> <ul style="list-style-type: none"> • Policy, • Mission and vision, • Organizational performance, and • Customer related issues. <p>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. (TEC-1000)</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>5.5.4. Customer relationship development</p> <p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:</p> <ul style="list-style-type: none"> a) Ensuring that processes needed to satisfy customer satisfaction and requirements are established, implemented and maintained, b) Reporting to top management on the performance of these processes and any need for improvement, and c) Ensuring the promotion of awareness of customer satisfaction throughout the organization and related training. <p>Top management shall designate individual(s) to represent the needs of the customer in internal functions. This representation shall include guaranteeing that established customer satisfaction processes are deployed, conveying to top management the performance of these processes, and promoting the importance of customer satisfaction.</p>
<p>5.6. Management Review</p> <p>5.6.1. General</p> <p>5.6.2. Review Input</p> <p>5.6.3. Review Output</p>	<p>5.6.1. General</p> <p>Planned intervals shall not exceed 12 months. Process reviews prior to the management reviews (or included therein) should be carried out and formal records maintained.</p> <p>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.</p> <p>Records of QMS reviews shall be maintained. (TEC-1000)</p> <hr/> <p>5.6.2. Review input</p> <p>In addition to the ISO 9001: 2000 requirements, the input to management review shall include:</p> <ul style="list-style-type: none"> h) Key issues from previous project reviews, and i) Analysis of actual and potential field-failures (including during the commissioning and warranty) and their impact on quality, safety or the environment. <p>The input to management review shall include information on:</p> <ul style="list-style-type: none"> • Analysis of actual and potential field failures and their impact on quality, safety or the environment, and • Design and development project summary measurements.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>As a minimum the following KPIs shall be reviewed:</p> <ul style="list-style-type: none"> • Customer on time delivery performance, and • Nonconformities raised by the customer throughout the entire product life cycle. <p>The following KPIs should also be reviewed:</p> <ul style="list-style-type: none"> • Internal and supplier nonconformities throughout the entire product life cycle, • Supplier on time delivery performance, • Customer NCR response time, and • Quality deficiency costs. <p>Management review inputs include product conformity and process performance measures on delivery performance and customer reported nonconformities. Within management review input KPIs: nonconformity costs, customer complaint response time, and supplier performance are analyzed and reported to top management.</p>
	<p>5.6.3. Review output</p> <p>In addition to the ISO 9001: 2000 requirements, the output from management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> d) Improvement plans for integration of business processes. <p>Performance data should be reviewed during management reviews in order to provide as a minimum evidence of the achievement of the business objectives specified in the business plan, and customer satisfaction with product supplied.</p> <p>Management review outputs include improvement recommendations and actions related to the results of review inputs. These recommendations will include, as applicable, business process improvements resulting from assessments, process performance, product conformity, and customer feedback.</p>

6. RESOURCE MANAGEMENT

TEC-1000		SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS	
6.1 <i>(delete vertical line)</i>	Provision of Resources	6.1.	Provision of resources A documented procedure shall be in place to ensure the appropriate capacity regarding personnel, equipment, etc . . . taking into consideration the current order book and the forecast orders on a mid- and long-term basis. Resource requirements are usually planned for the long-term during the annual budgeting process and adjusted for the mid and short-term 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. 6.2.1. 6.2.2. 6.2.2.1. 6.2.2.2. 6.2.2.3.	Human Resources General Competence, Training and Awareness Human Resources Function Qualification Training Training Effectiveness
		6.2.2.1.	Product design skills The organization shall ensure that personnel with responsibility for product design have the necessary competence to achieve design requirements and are skilled in applicable tools and techniques. Applicable tools and techniques shall be identified by the organization. Personnel with product design responsibilities shall be qualified to achieve the design requirements and shall be skilled in applicable tools and techniques. (TEC-1000)
		6.2.2.2.	Employee motivation and empowerment The organization shall motivate employees to achieve business, quality and safety objectives, to make continual improvements, and to create an environment to promote innovation. <div style="border: 1px solid black; background-color: black; color: white; padding: 2px; display: inline-block; margin-bottom: 5px;">NOTE 1</div> <i>This could include a suggestion of a scheme system deployed throughout the entire organization.</i>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>A process for motivating employees to achieve business, quality, and safety objectives, to make continual improvements and to create an environment to promote innovation shall be established. The process shall include the promotion of quality and technological awareness throughout the organization.</p>
	<p>6.2.2.3. Training</p>
	<p>The organization shall establish and maintain documented procedures for identifying and planning training needs in order to achieve the necessary competence of personnel performing activities affecting product quality and safety at all levels of the organization.</p> <p>Output of knowledge management activities (see section 4.3) shall be taken into consideration as an input to training planning.</p> <p>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. (TEC-1000)</p> <p>Personnel performing specific assigned tasks (e.g. special processes) shall be qualified, as required, with particular attention to the satisfaction of customer requirements.</p> <p>A system shall be in place to maintain and upgrade the qualifications of such personnel.</p> <p>A documented procedure shall be established and maintained for identification of training needs and achievement of competency of all personnel performing activities affecting product quality. Attention shall be given to satisfy any customer specific requirements. The training process shall include provisions for personnel to upgrade their qualifications.</p> <p>Appropriate rules shall apply for temporary workers and new comers to the organization and induction training shall be performed including as a minimum product quality and environmental and occupational health and safety.</p> <p>Job training shall be provided for personnel, including contract or agency personnel, in any new or modified job affecting product quality and environmental, health, and safety.</p>

<p>TEC-1000</p>	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>Critical activities affecting the product quality and safety shall be identified and records of skilled personnel able to undertake these activities shall be maintained and regularly updated.</p> <p>Personnel whose activities affect product quality and safety shall be qualified and periodically evaluated for continued qualification with records maintained and updated accordingly.</p> <p>Personnel whose work can affect quality and safety shall be informed about the consequences to the customer of nonconformity to quality and safety requirements.</p> <p>Personnel whose work can affect quality shall be informed about the consequences to the customer when there is a nonconformance to specified quality requirements.</p> <hr/> <p>6.2.2.4. Performance management planning</p> <p>An appraisal system shall be established to regularly set individual objectives linked with business objectives and review the individual performance.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>NOTE 1 <i>The appraisal system can also address the needs for training and development of individual people. On shop floor level, team objectives can be seen as sufficient individual objectives.</i></p> </div> <p>Each employee shall receive, as a minimum, an annual job performance review. These reviews shall assess employee performance against individually established objectives that are linked to business objectives. An output from the annual performance review may involve additional training and development.</p>
<p>6.3. Infrastructure</p>	<p>6.3.1. General</p> <p>In addition to the ISO 9001: 2000 requirements, the infrastructure includes, as applicable:</p> <ul style="list-style-type: none"> d) Planned maintenance activities, e) Packaging and preservation of equipment / tooling and measurement equipment, f) Availability of replacement parts for key manufacturing equipment, and g) Documenting, evaluating and improving maintenance objectives. <p>The organization should utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.</p>

TEC-1000	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>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. (TEC-1000)</p> <p>6.3.2. Contingency plan</p> <p>The organization shall prepare contingency plans to migrate the event of an emergency such as utility interruptions, interruptions in the supply chain, labor shortages, key equipment failure and field returns, taking into account the output of the resources analysis and including a succession plan.</p> <p>Business recovery plans are developed and maintained at a 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 emergency such as utility interruptions, labor shortages, and key equipment failure and reasonably protect the customer’s supply of product. (TEC-1000)</p>
6.4. Work Environment	6.4. Work environment
	<p>NOTE 1 <i>Factors that might affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge.</i></p> <p>An appropriate work environment shall be determined at a facility level and maintained in a state of order, cleanliness, and repair to ensure that it does not adversely affect product quality or personnel performance. All work areas must comply with established safety, regulatory and environmental standards and codes. The work environment, including facilities, workstations and associated equipment, shall be maintained accounting for factors such as temperature, humidity, lighting, cleanliness, and protection from electrostatic discharge.</p> <p>Product safety and means to minimize potential risks to employees shall be addressed by the organization, especially in the design and development process and in the production process activities.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>The established requirements, as described in the Quality Policy, include addressing of product safety and means to minimize potential risks to employees. These requirements shall especially be addressed in design, development, and manufacturing process activities.</p> <p>The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the product and production process needs.</p> <p>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. (TEC-1000)</p>

7. PRODUCT REALIZATION

TEC-1000		SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS	
7.1.	Planning of Product Realization	7.2.1.	Determination of requirements related to the product
7.1.1.	New Product Introduction		A detailed internal total cost breakdown based on the requirements shall be determined. The cost breakdown should be supported by return of experience from operation and supplier offers.
7.1.2.	Disaster Recovery Planning		A 'standard manufacturing cost' measure is determined for each saleable product based on material purchase and manufacturing histories.
7.2.	Customer Related Processes		
7.2.1.	Determination of Product Related Requirements		
7.2.2.	Review of Product Related Requirements	7.2.2.	Review of requirements related to the product
7.2.2.1.	Customer Service		Multidisciplinary approach (including suppliers when appropriate) shall be used. Project management and design / development must be appropriately represented in all requirements reviews.
7.2.2.2.	Customer Specification Review		<p>As appropriate, the review of customer specifications shall include:</p> <ul style="list-style-type: none"> • The Development / Product Engineering function shall be responsible for determining product compliance with the customer's requirements and the initiation of the cross-reference process, • The Quality function shall be responsible for determining compliance to those quality requirements that include measurement data, performance criteria, verification requirements, customer special requirements, audit parameters and processing customer complaints, • The Packaging Engineering function shall be responsible for determining compliance to special labeling and packaging requirements, • The Materials function shall be responsible for determining compliance to the delivery requirements, • The Contracts Administration function in conjunction with the Legal Department, shall be responsible for review of any contract documents containing other than Tyco Electronics standard terms and conditions. (TEC-1000)

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>The organization shall ensure that requirements identified are:</p> <ol style="list-style-type: none"> a) Individually compliant (e.g. clause by clause), b) Negotiated and updated with impact on the offer identified, c) Evaluated and taken into account, d) Properly transferred, understood, acknowledged and committed to by everybody involved, and e) Complete, clear, precise, unequivocal, verifiable, testable, maintainable and feasible. <p>NOTE 1 <i>The requirements apply explicitly for all the phases: submission of tenders, acceptance of contracts of orders, acceptance of changes to contracts.</i></p> <p>Deficiencies identified in the reviews shall be managed and migrated by the organization.</p> <p>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. (TEC-1000)</p> <p>Risks shall be identified, monitored and migrated as far as applicable. Risks shall be communicated internally and to the customer, if applicable.</p> <p>In order to avoid risks and to allow a smooth project / product realization reviews shall cover as a minimum the aspects (see also 7.4): critical product characteristics, customer & regulatory requirements, scope, time, cost, quality, resources, communication, risk, changes.</p> <p>NOTE 2 <i>These requirements are also applicable to after sales activities described in 7.10.</i></p> <p>In cases where the Tyco Electronics part number is confirmed, the customer service representative shall review the order to confirm the pricing and delivery requirements. If any risks or 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 risks or discrepancies between the customer request and the ability to meet the request.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
<p>7.2.3. Customer Communication</p>	<p>7.2.3. Customer communication</p> <p>The organization shall define and implement effective arrangements for communicating any and all information related to the delivery of the customers' contractual requirements in the value chain.</p> <p>NOTE 1 <i>This requirement may be included as part of the organization's supply chain management.</i></p> <p>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. (TEC-1000)</p>
	<p>7.2.4. Tender management</p> <p>The organization shall implement a Tender Management process.</p> <p>Prior to committing to the quotation process the organization shall use a multi-disciplinary approach (including suppliers when appropriate) to investigate customer and regulatory requirements. Also the organization shall confirm and document the feasibility of the proposed products in the tender. During the tender review the organization shall approve the offer including planning, resources and budget.</p> <p>As a minimum project / product requirements as well as risks and opportunities shall be identified, controlled and validated.</p> <p>The organization shall ensure that requirements identified during the tender are:</p> <ul style="list-style-type: none"> • Individually compliant (e.g. clause by clause), negotiated and updated with impact on the offer identified, evaluated and taken into account, and • Properly transferred, understood, acknowledged and committed to by those involved.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>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. The reconciliation process shall involve, as applicable, product/business management, development engineering, product engineering, manufacturing, and pricing. Booking the order is confirmation that there are no known discrepancies between the customer request and the ability to meet the request.</p>
<p>7.3. Design and Development</p>	<p>7.3. Design and development</p> <p>The organization shall implement a process for design and development.</p> <p>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. (TEC-1000)</p> <p>For the IRIS scope of certification No 19 (Annex 1 – signaling) the principles applied in developing high integrity systems shall be in line with the CENELEC standard or other agreed equivalent models. The software design process must explicitly implement the requirements of EN 50128 related to the safety integrity level of the intended scope of the IRIS certificate.</p> <p>Tyco Electronics will abide all product applicable national, regional, and international electro-technical standards established to remove trade barriers and minimize compliance costs.</p> <p>Documentation and training related to the application of the product is considered as integral part of the system to be designed and developed, especially in a safety critical environment. The organization must have the capability to provide this where required for safe use.</p> <div style="border: 1px solid black; background-color: black; color: white; padding: 2px; display: inline-block; margin-bottom: 5px;">NOTE 1</div> <p><i>The requirements described in this clause also apply to design and development of manufacturing equipment (e.g. for tools, jigs, fixtures, etc . . .) and new technologies.</i></p> <p>The focus is on error prevention rather than detection.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
<p>7.3.1. Design and Development Planning</p> <p>7.3.1.1. Project Planning</p>	<p>Product documentation includes product specifications, application specifications, and the necessary instructions that define the validated product capabilities, the appropriate applications and environments, and the safe use of the products.</p> <hr/> <p>7.3.1. Design and development planning</p> <p>The organization shall determine task sequence, mandatory steps, significant stages and method of configuration control.</p> <p>Where appropriate, due to complexity, the organization shall give consideration to the following activities:</p> <ul style="list-style-type: none"> • Structuring the design effort into significant elements, and • For each element, analyzing the tasks and the necessary resources for their design and development. <p>This analysis should consider an identified responsible person, design content, input data, planning constraints, and performance conditions.</p> <p>Design concepts, for example, design for safety, design for maintainability, and design for environment, should be investigated and applied where appropriate.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. (TEC-1000)
<p>7.3.2. Design and Development Inputs</p> <p>7.3.2.1. Customer Input</p>	<p>7.3.2. Design and development inputs</p> <p>The organization shall ensure new technologies / new products (designed to meet market needs) are validated before introduction into a customer project.</p> <p>This new technology / new product development shall apply the design and development requirements described in this clause.</p> <p>RAMS / LCC shall be considered as design inputs.</p>

TEC-1000	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>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. (TEC-1000)</p> <p>Consideration shall be given to RAMS (reliability, availability, maintainability, safety) and LLC (life cycle costs) as design input criteria.</p>
<p>7.3.3. Design and Development Outputs</p>	<p>7.3.3. Design and development outputs</p> <p>The production process input (design output) shall be expressed in terms that can be verified against production process design input requirements and validated.</p> <p>The production process input (design output) shall include:</p> <ul style="list-style-type: none"> • Specifications and drawings, • Information on materials, • Production process flow chart/layout, • Control plan, • Work instructions, • Process and product acceptance criteria, • Data for quality, measurement, reliability, maintainability, • Results of error-proofing activities, as appropriate, and • Methods of rapid detection and feedback of product / production process nonconformities. <p>The design output shall be documented and expressed in terms of requirements, calculations and analyses, and shall:</p> <ul style="list-style-type: none"> • Meet the design input requirements; • Provide the information required for manufacturing 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; • 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.). (TEC-1000)
<p>7.3.4. Design and Development Review</p>	<p>7.3.4. Design and development review</p> <p>In addition to the ISO 9001: 2000 requirements, systemic reviews of design and development shall be performed</p> <p>c) to authorize progression to the next stage.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>NOTE 1 <i>These design / development reviews are part or an input for the phase review (see 7.7.5).</i></p> <p>Design and development reviews shall be documented with records of activities, resulting actions, and approvals to progress to the next design and development stage maintained.</p> <p>Measurements at specified stages of design and development should be defined, analyzed and reported with summary results as an input to management / project review.</p> <p>NOTE 2 <i>These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.</i></p> <p>NOTE 3 <i>Design and development reviews are conducted on each level of detail (for example architecture, design, modular design . . .).</i></p> <p>Design reviews shall also involve other functions as appropriate to review the product characteristics (e.g. costs, RAMS and serviceability).</p> <p>Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review. These measurements shall be established as stage review criteria.</p> <p>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. (TEC-1000)</p>
<p>7.3.5. Design and Development Verification</p>	<p>7.3.5. Design and development verification</p> <p>NOTE 1 <i>Design and development verification is conducted on each level of detail (for example architecture, design, modular design . . .).</i></p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>Records of the results of verification testing and any necessary actions shall be maintained. (TEC-1000)</p>
<p>7.3.6. Design and Development Validation</p> <p>7.3.7. Control of Design and Development Changes</p>	<p>7.3.6. Design and development validation</p> <p>Design and development validation shall be demonstrated for all identified operational conditions.</p> <p>For safety critical applications the validation or verification concepts, organization and methods as mandated by applicable standards (e.g. EN 50126, EN 50128, EN 50129, . . .) shall be applied.</p> <p>A documented procedure shall be in place in the event that the tests are necessary for validation. These tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:</p> <ol style="list-style-type: none"> a) Test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria, test conditions and environmental reproducible, b) Test procedures describe the method of operation, the performance of the test, and the recording of the results, c) The correct configuration of the product is submitted for the test, d) The requirements of the test plan and the test procedures are observed, and e) The acceptance criteria are met. <p>A validation test program shall be developed that will, when completed, provide evidence of successful product testing in accordance with</p> <ul style="list-style-type: none"> • internal requirements, • customer agreed upon requirements including customer certification criteria, • government agency certification requirements, and • commercial agency requirements.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>Product design verification and validation testing is performed to an established, controlled, and documented test plan to ensure:</p> <ul style="list-style-type: none"> • A defined test scope with product descriptions, corresponding part numbers, and the latest versions of design objectives and product specifications; • Test specimens are identified and representative of normal production lots with Certificates of Conformance required for design validation/product qualification testing; • A test sequence is defined including the order of tests, examinations, and groupings; • A description of each test with defined acceptance criteria; • A description of test methods including references to applicable external requirements. <hr/> <p>7.3.8. Design approval</p> <p>For the IRIS scope of certification No 19 (Annex 1 – signaling) the organization’s system shall provide a documented procedure defining the safety case and approval in line with this standard.</p> <p>Tyco Electronics will abide by all product applicable national, regional, and international electro-technical standards established to remove trade barriers and minimize compliance costs. Signaling components developed under an IRIS certified business management system will comply with the documented safety case and approval.</p>
<p>7.4. Purchasing 7.4.1. Purchasing Process 7.4.1.1. New Suppliers 7.4.1.2. Supplier Performance</p>	<p>7.4.1. Purchasing process</p> <p>The organization shall establish, document and maintain a process for purchasing of products.</p> <p>The organization shall:</p> <ol style="list-style-type: none"> a) Maintain a register of approved suppliers which includes the scope of their approval, b) Ensure where required that both the organization and all suppliers use customer approved special processes, and c) Ensure that the function having responsibility for approving supplier quality systems has the authority to reject the use of sources. <p>Per the criteria in Global Quality Specification TEC-1006, Approval of Suppliers, suppliers are approved and identified in the Tyco Electronics Database (TED) and in the Purchasing Module of the various Tyco Electronics Enterprise Requirements Planning software such as SAP and the Purchasing On-Line Information System (POLIS).</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>A supplier’s approval scope provides a list of materials and products and limits what may be purchased from a particular supplier.</p> <p>Where customer approved special processes are a flow down requirement to suppliers, such requirements will be specified in the corresponding purchase order.</p> <p>Global Quality Specification TEC-1003, Supplier Performance Reporting and Continual Improvement Process, defines the authorities and process for supplier removal from the approved supplier list based upon unacceptable quality and delivery performance.</p> <p>The organization should:</p> <ul style="list-style-type: none"> a) Periodically review supplier performance throughout the entire supply chain; the results of these reviews should be used as a basis for establishing the level of controls to be implemented, and b) Define the necessary action to be taken when dealing with suppliers that do not meet technical and/or performance requirements. <p>The organization shall develop suppliers with the goal of improving supplier operational performance.</p> <p>Per the definitions in Global Quality Specification TEC-1003, Supplier Performance Reporting and Continual Improvement Process, the primary source for supplier performance data will be information maintained in the Tyco Electronics Database (TED). This data will be used to monitor continual improvement of a supplier’s performance and continual improvement of commodities managed by procurement. Periodic supplier performance reviews shall be conducted at a business unit, regional, and global level. At least one review shall be conducted annually for key suppliers. Performance reviews for nonstrategic suppliers will be conducted on an as-needed basis.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>NOTE 1 <i>Conformity with ISO 9001: 2000 is the first step in achieving this goal. The prioritization of suppliers for development depends upon, for example, the supplier’s quality performance and the importance of the product supplied.</i></p> </div> <p>Unless otherwise specified by the customer, suppliers to the organization should be third party registered to ISO 9001: 2000 by an accredited third-party certification body.</p> <p>The organization shall implement a system to ensure the quality of all products purchased from suppliers, including customer-designated suppliers and also of all free issue material (items provided by the customer).</p>

<p>TEC-1000</p>	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS Purchasing procedures include Global Quality Specifications TEC-1003, Supplier Performance Reporting and Continual Improvement Process, TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers, and TEC-1006, Approval of Suppliers. Collectively these procedures</p> <ul style="list-style-type: none"> • Define the manner for evaluating, selecting, and re-evaluating suppliers, • Establish the expectations and performance criteria and • Describe the methods for managing and developing suppliers.
<p>7.4.2. Purchasing Information</p>	<p>7.4.2. Purchasing information The organization shall ensure that the supplier's offer is selected only after thorough prior negotiation. The negotiation shall take into account:</p> <ul style="list-style-type: none"> • The level of compliance with the purchasing information, • The total cost requirements (including LCC), and • Previous product quality, costs and delivery performances. <p>Global Quality Specification TEC-1006, Approval of Suppliers, defines the criteria for the selection, qualification, and approval of suppliers. The supplier approval process involves the collection and review of information pertinent to capabilities, communicating performance expectations, and negotiating prices and terms.</p> <p>In addition to the ISO 9001: 2000 requirements, purchasing information shall include:</p> <ul style="list-style-type: none"> d) The name or other identification, and applicable issues of specifications, drawings, process requirements (including special ones), inspection instructions and other relevant technical data, e) Requirements for design, test, examination, inspection and related instructions for acceptance by the organization, f) Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing, <p>Purchase orders placed with suppliers shall define the product, the revision level and any additional quality assurance requirements beyond those established in Global Quality Specification TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers. (TEC-1000)</p> <ul style="list-style-type: none"> g) Requirements relative to supplier notification to the organization of nonconforming product and arrangements for the organization approval of supplier nonconforming material.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>Per the requirements of Global Quality Specification TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers, if a non-conformance is discovered by the supplier, the supplier shall be responsible for notifying the respective Tyco Electronics buyer/authorized procurement personnel of non-conforming material and any already shipped non-conforming material to ensure containment of the entire lot or order of material.</p> <p>h) Requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,</p> <p>Per the requirements of Global Quality Specification TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers, Tyco Electronics must ensure that its customers receive product that is consistent with drawings, product specifications, and inherent performance requirements. To facilitate this requirement for consistency, Tyco Electronics requires that the supplier provide prior written notice to the Procurement and/or Tyco Electronics business unit when product, process or manufacturing location changes are proposed. The responsible buyer/authorized procurement personnel must be contacted prior to any changes being implemented as the requirements vary for the different Tyco Electronics individual Business Units.</p> <p>i) Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records,</p> <p>Per the requirements of Global Quality Specification TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers, the supplier shall include right of entry provisions in subcontracts and purchase contracts, allowing the Tyco Electronics, Tyco Electronics' customers and regulatory agencies access to subcontractor work areas and records to verify the quality of work and materials and to verify conformance to contract requirements.</p> <p>j) Requirements for the supplier to cascade to its suppliers, the applicable requirements in the purchasing documents, where required, and</p> <p>k) Requirements for supply chain logistics.</p> <p>Per the requirements of Global Quality Specification TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers, the supplier shall flow down quality requirements to subcontractors to the extent necessary to ensure that characteristics not verifiable upon receipt are controlled by the sub-contractor.</p> <p>All the above purchasing information, where applicable, shall be documented separately in the contract / purchase order.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
<p>7.4.3. Verification of Purchased Products</p>	<p>7.4.3. Verification of purchased product</p> <p>Verification activities of the organization shall include:</p> <ol style="list-style-type: none"> a) Obtaining objective evidence of the quality of product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control), b) Review of the required documentation, and c) Inspection of products upon receipt. <p>The organization shall define activities accordingly in case of delegation of verification to the supplier, or supplier certification.</p> <p>Verification activities of the organization should also include inspection and audit at the supplier's premises.</p> <p>The purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under authorized customer waiver (see 8.3.2).</p> <p>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:</p> <ul style="list-style-type: none"> • 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; • Product is evaluated and reported as acceptable by an accredited supplier or test laboratory. <p>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. (TEC-1000)</p> <p>Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications.</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>The organization shall periodically verify test reports for raw material.</p> <p>A plan shall be established and administered for annual validation testing to determine a supplier’s capability to ensure the continued compliance with the requirements documented in the Tyco Electronics 100 series Material Specifications or supplier’s technical data sheets for base metals and polymeric material.</p> <p>Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.</p> <p>Product verification activities and responsibilities delegated to suppliers shall be indicated on the purchase order. These responsibilities may involve first article inspections conducted prior to full production and subsequent inspections conducted to ensure purchased product meets specified requirements.</p> <hr/> <p>7.4.4. Supply chain management</p> <p>Supplier deliveries shall be scheduled in order to meet the purchase requirements.</p> <p>Ordering shall be supported by an information system covering the whole supply chain which permits access to customer, supplier and production information at key stages of the process and which is order driven.</p> <p>The organization shall communicate regularly, a forecast to its supplier in order for them to manage their capacity accordingly.</p> <p>Supplier shortages shall be identified, communicated to the organization, controlled and actions established to recover the delivery schedule.</p> <p>Supplier inputs are acquired through the continual improvement process for the supply chain management system. Strategic suppliers are selected based on a willingness to work in a cooperative and collaborative way in order to achieve mutual long term benefits. These key suppliers participate with Tyco Electronics in cost management and performance improvements.</p>
<p>7.5. Production and Service Processes</p>	<p>7.5. Production and service provision</p> <div style="border: 1px solid black; background-color: black; color: white; padding: 5px; display: inline-block; margin: 10px 0;">NOTE 1</div> <p><i>Production in the spirit of this clause can also apply within the engineering process (Commissioning, installation).</i></p>
<p>7.5.1. Control of Production and Service Processes</p>	<p>7.5.1. Control of production and service provision</p> <p>In addition to the ISO 9001: 2000 requirements, controlled conditions shall include for all shifts:</p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>g) Accountability for all products during manufacturing (e.g. parts quantities, split orders, nonconforming product),</p> <p>h) Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized.</p> <p>Controlled manufacturing conditions shall include product accountability throughout production and documenting the completion of established manufacturing and inspection operations.</p>
	<p>7.5.1.1. Production scheduling</p> <p>Production (including test equipment) shall be scheduled (short-, mid- (MPS) and long-term (SOP) in order to meet the purchase requirements, such as just-in-time, supported by an information system that permits access to production information at key stages of the process and is order driven.</p> <p>The organization shall use customer forecasts and orders to plan, measure capacity and adjust regularly, their resources according to workload taking into account risks (e.g. extra order at the last minute, supplier failure, etc.).</p> <p>Bottlenecks in production shall be identified and an improvement action plan established.</p> <p>Production is scheduled to meet customer delivery requirements or the replenishment of appropriate inventory levels. Production scheduling is order-driven and done through the Tyco Electronics information systems which provide production order status access throughout the process. The customer forecasting process provides information on projected manufacturing workloads and the allocation of manufacturing materials and resources. Production bottlenecks are identified using production forecast and scheduling software programs with action plans established to meet customer demands.</p>
	<p>7.5.1.2. Production documentation</p> <p>Production operations shall be carried out in accordance with approved data.</p> <p>This data shall contain, as necessary:</p> <ul style="list-style-type: none"> a) Drawings, parts lists, process flow charts including inspection operations, production documents (e.g. manufacturing plans, traveller, router, work order, process cards); and inspection documents (see 8.2.4), and b) A list of tools and numerical control (NC) machine programs required and any specific instructions associated with their use.

<p>TEC-1000</p>	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>Documentation accompanying production orders shall suitably provide manufacturing operations with all the information needed to describe the product; explain the production process and use of process equipment and measuring devices; and define the verification of product acceptance. All production documentation including product drawings and specifications; manufacturing process routings and procedures; and product inspection plans shall be controlled.</p> <p>Production documentation shall include a listing of process specific equipment and tools, non-specific tools, and process equipment related software data program ms.</p>
	<p>7.5.1.3. Control of production process changes</p> <p>The organization shall establish, document and maintain a process to control production process changes. Persons authorized to approve changes to production processes shall be identified. The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with customer contracts or regulatory requirements.</p> <p>Changes affecting processes, production equipment, tools and programs shall be documented.</p> <p>The results of changes to production processes should be reviewed to confirm that the desired effect has been achieved without adverse effects to product quality.</p> <p>NOTE 1 <i>Principles to manage changes are described in clause 7.7.9 of this document.</i></p> <p>NOTE 2 <i>These activities are part of change management process.</i></p> <p>Production process changes shall be managed and controlled in a manner similar to documents. Individuals with the authority to approve production process releases and changes shall be identified and the changes shall be documented.</p> <p>Customer and regulatory agency notification and approval of production process changes shall be conducted in accordance with contract or regulatory requirements. Assigned Contract Administrators, or equivalent functions, are responsible for analyzing contracts and confirming notification requirements, informing the responsible organization, providing contract information, and conducting annual reviews of customer contracts requiring change approval.</p> <p>A change to a production process shall be confirmed through a first piece inspection of the product.</p>

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		<p>7.5.1.4. Maintenance of equipment and tools</p> <p>Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures.</p> <p>Storage requirements, including periodic preservation / condition checks, shall be established for production equipment or tolling in storage.</p> <p>Validation prior to production use shall include verification of the first article produced to the design data / specification.</p> <p>Production equipment, tooling, and process equipment related software data programs are validated prior to the initial production order of a new part number through a first article inspection.</p> <p>Production equipment, tooling, and program suitability will be validated on subsequent production orders through a product first piece or set-up inspection.</p> <p>Production tooling shall be subjected preservation/condition confirmations to ensure the tooling is properly configured and available for production. These confirmations may involve tooling component changes and examinations preceding release for production. Tooling in storage should be identified relative to its production availability status.</p>
		<p>7.5.1.5. Maintenance of product</p> <p>For the IRIS scope of certification No 19 (Annex 1 – signalling) maintainability shall be an integrated part of the design.</p> <p>In particular, procedures for the maintenance of software shall be established and recorded according to CENELEC EN 50126, 50128 or other agreed equivalent models.</p> <p>Specified product maintainability criteria is considered throughout the product design and development process as a design output, addressed through design review, and validated as conforming through design qualification.</p>
7.5.2.	Validation or Production and Service Processes Process	7.5.2. Validation of processes for production and service provision
7.5.2.1.	Monitoring and Operator Instructions	<p>These processes are frequently referred to as 'special' processes and shall be managed according to the contractual and/or internal requirements.</p> <p>The organization shall establish a process for the control of these special processes including, as applicable, qualification and approval of the process prior to use and in accordance with documented process specifications and any subsequent changes thereto.</p>
7.5.2.2.	Verification of Process Setups and Operational	

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7.5.2.3. 7.5.3. 7.5.3.1. 7.5.4	<p>Changes First Article Examination Product Identification and Traceability Inspection and Test Status Control of Customer Property</p> <p><i>(delete horizontal line)</i></p>	<p>Production and service processes where the resulting product cannot be verified by subsequent monitoring or measurement shall be identified and validated to demonstrate the subject processes have the ability to produce product that meets specified requirements. Any production or service process validation shall be documented with records of process validation maintained. Validation shall include, as applicable:</p> <ul style="list-style-type: none"> • Defined process approval criteria; • Equipment approval and personnel qualifications; • Specific process procedures and methods. <p>The criteria or interval for re-validation should be established. (TEC-1000)</p>
7.5.5. 7.5.5.1.	<p>Product Preservation Shelf-Life</p>	<p>7.5.5. Preservation of product</p> <p>Preservation of product should also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:</p> <ol style="list-style-type: none"> a) Cleaning b) Special handling for sensitive products, c) Marking and labeling, d) Shelf life control and stock rotation, and e) Special handling for hazardous materials. <p>Production processes, including the handling and storage of materials and products, shall include appropriate provisions for cleaning; foreign object prevention, detection, and removal; sensitive product handling; product marking and labeling; shelf-life control; stock rotation; and hazardous material handling.</p> <p>The organization shall ensure that product documentation required by the contract / order is present at delivery and is protected against loss and deterioration.</p> <p>When customer specified documentation is required to accompany the product through delivery, the requirement shall be effectively communicated to ensure its inclusion and shall be packaged in a manner to ensure protection from loss and deterioration.</p> <div style="border: 1px solid black; background-color: black; color: white; padding: 2px; display: inline-block; margin-top: 10px;">NOTE 1</div> <i>This also applies to products supplied to the organization including spare parts.</i>
7.6.	<p>Control of Inspection, Measuring, and Testing Equipment</p>	<p>7.6. Control of monitoring and measuring devices</p> <p>The organization shall maintain a register of these monitoring and measuring devices and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.</p>

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	<p data-bbox="695 260 834 327">NOTE 1</p> <p data-bbox="859 260 1390 506"><i>Monitoring and measuring devices include, but are not limited to: test hardware, test software, Automated Test Equipment (ATE) and plotters used to inspection data. This also includes devices that are personally owned, developed in-house, and supplied by the customer to provide evidence of product conformity.</i></p> <p data-bbox="667 531 1458 709">Each Tyco Electronics location using product inspection, measuring, and testing devices shall maintain a register of those devices to ensure that all devices used to verify product quality are uniquely identified and calibrated at prescribed intervals. The methods and acceptance criteria for performing device calibrations shall be defined.</p> <p data-bbox="667 743 1458 835">The organization shall ensure that ambient conditions are suitable for the carrying out of the calibration, inspection, measurement and testing.</p> <p data-bbox="667 898 1458 1020">Conditions shall be established that provide a suitable environment for calibration and use of measuring devices and that these devices are stored and handled in a way that maintains accuracy and fitness for use. (TEC-1000)</p> <p data-bbox="667 1083 1458 1171">In addition to the ISO 9001: 2000 requirements, measurement equipment shall be recalled in accordance with a defined process when requiring calibration.</p> <p data-bbox="667 1234 1458 1390">Procedures shall be developed for the calibration process and resulting records with adequate controls that protect 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. (TEC-1000)</p> <p data-bbox="667 1423 1458 1545">All product produced with suspect measuring equipment shall be segregated and audited. Customer notification / product recall shall be considered if suspect product was shipped. (TEC-1000)</p>
	<p data-bbox="540 1577 915 1608">7.7. Project management</p> <p data-bbox="667 1608 1458 1759">The organization shall implement a project management approach or system, or new product development process addressing the applicable areas of project management, describing roles and responsibilities, integrating all relevant functions of the organization into a multidisciplinary team.</p> <p data-bbox="695 1818 834 1885">NOTE 1</p> <p data-bbox="859 1818 1365 1906"><i>Scope of project management approach or system is from tender phase until end of warranty period.</i></p>

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	<p>NOTE 2 <i>For the IRIS scope No 19 the required SIL level has to be taken into consideration.</i></p> <p>New product development project plans shall be prepared and identify the functional responsibilities 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.</p>
	<p>7.7.1. Integration management</p> <p>An integrated project plan shall be developed reflecting the specific rules to follow whilst executing a project (e.g. multi site project, consortium) throughout the entire project life cycle, including project plan change control.</p> <p>NOTE 1 <i>A multidisciplinary team typically includes the organization’s design, manufacturing, quality, production, field support and other appropriate personnel including supplier and customer when appropriate.</i></p> <p>NOTE 2 <i>The project management or new product development process may be part of the product realization process.</i></p> <p>New product development project plans shall be prepared and clearly reflect the processes and functional responsibilities required for project completion. Project plans shall define responsibilities related to product maintenance after release to production and change control authorities.</p>
	<p>7.7.2. Scope management</p> <p>The organization shall ensure the entire scope of work is identified, subdivided in work packages, controlled and verified.</p> <p>Scope changes shall be controlled and consistently guaranteed throughout the project and reflected in the project plan.</p>

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	<div data-bbox="690 237 831 310" style="background-color: black; color: white; padding: 5px; display: inline-block;">NOTE 1</div> <div data-bbox="857 237 1339 300" style="margin-left: 10px;"><i>Scope management is detailed in clause 7.3.1, design and development.</i></div> <p data-bbox="667 380 1455 527">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.</p>
	<p data-bbox="540 594 889 625">7.7.3. Time management</p> <p data-bbox="667 625 1390 684">The organization shall ensure timely completion of the project through the identification of:</p> <ul data-bbox="716 688 1433 905" style="list-style-type: none"> • Specific activities that must be performed to produce the project deliverables, • Inter-dependencies of the work packages including those suppliers, • Activity sequences, resource requirements and duration, and • Critical path. <p data-bbox="667 940 1455 999">These integrated activities (i.e. product schedule) shall be regularly reviewed, controlled and recorded.</p> <p data-bbox="667 1035 1446 1150">In any case of an imminent deviation the organization shall identify and implement appropriate counter measures to avoid any impact on customers. The organization shall not change the delivery schedule unless authorized by the customer.</p> <p data-bbox="667 1186 1455 1302">Project plans shall be regularly reviewed and updated, and include development activities with suppliers (major milestones with suppliers) including the identification and management of long lead time items.</p> <p data-bbox="667 1337 1455 1547">Project plans shall be prepared that identify the resource requirements, activity sequences, durations, and inter-dependencies for each specific project activity. The plans shall be reviewed, updated, and communicated to the appropriate individuals as the project progresses. Plans shall include supplier interfaces including provisions for long lead time items.</p> <p data-bbox="667 1583 1373 1673">Where project plan schedule changes impact customer delivery commitments, any schedule deviations shall be authorized by the customer.</p>
	<p data-bbox="540 1738 889 1770">7.7.4. Cost management</p> <p data-bbox="667 1770 1390 1829">The organization shall have a process to ensure the project is completed within the budget approved at the tender stage.</p>

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	<p>A process shall be in place to regularly follow the cost progress on each work package and on each item of the total cost breakdown, including the identification of the estimate to completion.</p> <p>Cost savings should be identified in order to recover the budget in case of deviation.</p> <p>Projects shall be initiated only after management approval based on formal statements of business opportunities defining profit forecasts, project schedules, and costs. Project forecasts, schedules, and cost data shall be reviewed periodically to ensure that projects remain feasible and determine whether any actions are needed.</p>
	<p>7.7.5. Quality management</p> <p>The organization shall ensure a process is in place to manage project deliverables (e.g. customer deliverables, milestones, product characteristics).</p> <p>As a minimum, the following tasks shall be managed:</p> <ul style="list-style-type: none"> • Identification, clarification, fulfillment and control, • Validation and delivery on time, and • Approval by the customer (e.g. customer product acceptance points), where required. <p>Open issues shall be controlled and the appropriate resources put in place to manage the associated activities.</p> <p>Documented project reviews shall take place at regular intervals throughout the entire project life.</p> <p>These reviews shall take place at predefined project places / milestones to assess the project compliance, the availability of work package deliverables and authorize the start of the next phase.</p> <p>The organization's risk and opportunity management process shall be employed to rectify any issue / deviation arising from these reviews in order to maintain the project plan and schedule.</p> <p>Assessment of the project performance shall be established to monitor the project progress and efficiency through Performance Indicators.</p> <p>The Tyco Electronics' QMS includes documented procedures and processes developed to ensure project deliverables. Project inputs and outputs are established in accordance with documented procedures defining the identification and control of project objectives and the validation of project outputs, including delivery.</p> <p>Project reviews shall be conducted at pre-defined intervals to assess project status relative to project plans, determine resource needs, address open issues, assign actions needed to handle any project deviations, and authorize project continuance.</p>

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	<p data-bbox="539 226 1040 254">7.7.6. Human resources management</p> <p data-bbox="667 258 1377 317">Requirements described in clause 6 of this standard shall be deployed at a project team level.</p> <p data-bbox="667 350 972 378">It shall cover as minimum:</p> <ul data-bbox="716 382 1414 569" style="list-style-type: none"> <li data-bbox="716 382 1414 441">• Identification, documentation and assignment of project roles, responsibilities and reporting relationships, <li data-bbox="716 445 1414 504">• Acquisition of appropriate resources assigned to and working until project completion, and <li data-bbox="716 508 1414 569">• Development of individual and team competencies to enhance project performance. <p data-bbox="667 602 1455 779">Project plans shall be prepared that identify, document, and assign project roles, responsibilities, and reporting relationships. These resources shall be competent and qualified for their assigned responsibilities in accordance with the requirements of IRIS, Revision 1, paragraph 6.2, Human Resources.</p> <hr/> <p data-bbox="539 814 1016 842">7.7.7. Communication management</p> <p data-bbox="667 846 1455 936">The organization shall ensure that the project team determines and communicates needs of the stakeholders (e.g. communication plan).</p> <p data-bbox="667 970 1455 1029">This information, including performance information, shall be made available to project stakeholders in a timely manner.</p> <div data-bbox="695 1094 1317 1163" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p data-bbox="711 1104 813 1136">NOTE 1</p> <p data-bbox="862 1098 1317 1157"><i>This is in addition to the basic ISO 9001:2000 clause 7.2.3. requirements.</i></p> </div> <p data-bbox="667 1222 1422 1312">Project plans shall include communication tactics to ensure that information, including performance criteria, is made available to project stakeholders in a timely manner.</p> <p data-bbox="667 1367 1463 1635">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. Marketing and/or Engineering Management communicates with customers on new designs and development. Customer Service is the primary function for providing responses to customer inquiries about purchase orders and delivery dates.</p> <hr/> <p data-bbox="539 1675 1073 1703">7.7.8. Risk and opportunity management</p> <p data-bbox="667 1707 1455 1860">The organization shall ensure a process is in place to identify, analyze (quantitatively and qualitatively) and when necessary decide upon the risk response (e.g. acceptance, migration, transfer, avoidance). The process should include methods like documented risk assessment, FMEA, control of counter measures.</p> <p data-bbox="667 1894 1422 1953">The risk response or opportunity enhancement shall be recorded and reported to all stakeholders as appropriate.</p>

<p>TEC-1000</p>	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>The effectiveness of the response plan shall be assessed on a regular basis (e.g. during the project reviews).</p> <p>Output of the risk assessment shall be regularly reviewed and updated throughout the project life cycle and should be extracted and communicated for lessons learned purpose throughout the organization.</p> <p>Tyco Electronics shall establish and maintain processes for identifying hazards associated with a product, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. These processes may use one or more of the basic and advanced quality tools (such as design of experiments (DOE), failure mode and effects analysis (FMEA); statistical tolerance analysis, CDOV, etc.).</p> <p>Various processes addressing risks and opportunities are incorporated into the project review checklists. Projects also incorporate a post project analysis to determine and document 'lessons learned'.</p>
	<p>7.7.9. Change management</p> <p>The organization shall have a process to control and react to changes that impact product realization.</p> <p>The effects of any change, including those changes caused by any supplier, shall be assessed and verified. Validation and approval activities shall be defined, to ensure compliance with customer requirements before implementation.</p> <p>For proprietary designs, impact on form, fit and function (including performance and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated.</p> <p>When required by the customer, additional verification / identification requirements, such as those required for new product introduction, shall be met.</p> <p>Changes should be analyzed regarding the impact of testing and side effects.</p> <p>NOTE 1 <i>Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.</i></p> <p>NOTE 2 <i>The above requirement applies to product and production process changes (see section 7.5.1.3. herein).</i></p> <p>NOTE 3 <i>This is in addition to ISO 9001:2000 (clause 7.3.7.) requirements.</i></p>

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>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. (TEC-1000)</p> <p>Changes resulting from supplier actions are analyzed and verified to ensure compliance to documented quality, performance, and reliability requirements. Where required, changes shall be reviewed with customers to ensure all aspects of the change impact are evaluated. All changes shall be analyzed to determine whether additional verification or testing is necessary.</p>
	<p>7.8. Configuration management</p> <p>The organization shall establish, document and maintain a configuration management process appropriate to the product.</p> <p>NOTE 1 <i>The control of design and development changes may be part of Configuration Management.</i></p> <p>The organization shall:</p> <ul style="list-style-type: none"> a) At the beginning of the contract, define a list of products (safety critical products as a minimum) including their component parts, the configuration of which must be managed. This list shall be approved by the customer. b) Address change management process within the configuration management (see 7.7.9), and c) Maintain traceability during production and operations. <p>NOTE 2 <i>Guidance on configuration management is given in ISO 10007.</i></p> <p>NOTE 3 <i>In cases where a change impacts a product which is subject to configuration management, the principles described in clause 7.7.9 apply.</i></p> <p>NOTE 4 <i>For software development and production a configuration management for used tools has to be available.</i></p>

<p>TEC-1000</p>	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>The Tyco Electronics configuration management plan is established and maintained through various documented procedures where responsibilities and authorities are outlined. These responsibilities and authorities include required customer approvals. The scope of the configuration management process includes:</p> <ul style="list-style-type: none"> • Document and data control which addresses the identification, protection, approval, and availability of current issues of all pertinent product and project related documents including designs, specifications, plans, and schedules. • Design changes which require that each design change be traceable to an appropriate source and approval. • Product identification and traceability which requires that each version of a configuration item be identified by some appropriate means including component parts. • Inspection and test status which requires procedures to identify what verification steps and tests have been achieved by the product or product components at each phase in the defined life cycle. • Nonconforming product control which requires procedures to ensure that untested, defective, or incorrect versions of the product are not inadvertently used.
	<p>7.9. First article inspection (FAI)</p>
	<p>The organization's system shall provide a documented procedure defining inspection, verification, and documentation of a representative item from the first serial production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.</p> <p>FAI shall be performed subsequently to the verification of the production process.</p> <p>This FAI procedure shall also be applied to suppliers.</p> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin-bottom: 10px;"> <p>NOTE 3</p> </div> <p><i>If the product is one-off or software, FAI is meant as validation.</i></p> <p>A documented procedure is established and maintained that defines the process of inspecting a representative item from the initial production run of a new part number to assure that tooling and processes are capable of producing parts that are in conformance with the product drawing and specification requirements. This process shall include performing a new first article inspection when a change invalidates any previous first article inspection result.</p>

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	<p data-bbox="537 226 1079 254">7.10. Commissioning / Customer service</p> <p data-bbox="667 258 1404 317">Where field service is a specified requirement, processes shall provide for:</p> <ul style="list-style-type: none"> <li data-bbox="699 321 1404 407">a) Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information, <li data-bbox="699 411 1425 438">b) The control and updating of technical documentation, and <li data-bbox="699 443 1328 470">c) The approval, control, and use of repair schemes. <p data-bbox="667 506 1458 621">The organization, with supplier support when required, shall demonstrate the adequate customer support during commissioning and warranty until complete product validation and final customer acceptance.</p> <p data-bbox="667 657 1438 743">Suitable resources shall be available to provide the support to the customer in accordance with the agreed requirements, for all the after sales activities including the supply of spare parts.</p> <p data-bbox="667 779 1438 837">Maintenance contracts shall be managed with the rules defined in clause 7, "Product realization".</p> <p data-bbox="667 873 1458 1142">When applicable, procedures shall be established and maintained to ensure that contractual service agreements and product warranties are fulfilled. The procedures shall address verification that service meets customer requirements and / or expectations and that appropriate manufacturing, engineering, and design activities are aware of service concerns. When these procedures exist, problem severity, classification, resolution, training of servicing personnel and emergency service processes shall be addressed.</p> <hr/> <p data-bbox="537 1178 820 1205">7.11. RAMS / LCC</p> <p data-bbox="667 1209 1463 1388">The organization shall have a documented procedure in place to cover all the aspects of RAMS activities (e.g. calculation, documentation, data collection, improvement action plans, etc . . .). In addition the organization shall have a process in place to manage LCC. Resources shall be in place to address the RAMS / LCC requirements.</p> <p data-bbox="667 1423 1414 1514">RAMS / LCC data collection and analysis shall be supported by return of experience from operation during and after warranty period and continuously improved (see 8).</p> <div data-bbox="678 1570 1235 1629" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>NOTE 1 <i>LCC process may be part of cost management process.</i></p> </div> <div data-bbox="678 1738 1333 1797" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>NOTE 2 <i>RAMS / LCC processes have to be in line with the standard CENELEC EN 50126.</i></p> </div>

TEC-1000	<p>SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS</p>
	<p>Documented procedures are established and maintained that describe the aspects of reliability, availability, maintainability, and safety (RAMS). These procedures define the responsibilities associated with ensuring product reliability, availability, maintainability, and safety including the data collection, resulting action plans, and records associated with improving the RAMS categories. Safety shall be considered in terms of the Safety Integrity level according to EN 50129: 2003.</p> <p>Processes shall be deployed to manage product life cycle costs (LCC). Both RAMS and LLC processes shall be in accordance with EN 50126: 1999.</p>
	<p>7.12. Obsolescence management</p>
	<p>The organization shall establish a process to ensure, for the defined and agreed product life cycle, the availability of the supplied products and spare parts.</p> <p>NOTE 1 <i>This process may be part of the change management or configuration management process.</i></p> <p>NOTE 2 <i>Spare parts may be of the same product configuration or coming from alternative solutions which have been developed, validated and qualified according to the original requirements.</i></p> <p>NOTE 3 <i>Where specific requirements regarding reliability, availability, maintainability and safety with respect to the design, verification, validation and approval processes; including roles and methods; are applicable, e.g. through CENELEC EN 50126, 50128, 50129, it is expected that the processes of the company's management system are designed to fulfill these standards.</i></p> <p>A documented procedure is established and maintained that defines the process for notifying customers of proposed product discontinuances and coordinating alternative products and continued product support in accordance with contractual agreements.</p>


8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

TEC-1000		SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS	
8.1. Measurement, Analysis, and Improvement – General		8.2.2. Internal audit	
8.1.1. Statistical Techniques			<p>The organization shall audit all processes of its management system to verify compliance with all requirements (including any external requirements). The audit program shall cover all production shifts.</p> <p>Internal audits shall cover all the quality management system, activities and shifts and shall be completed in accordance with an annual plan. When nonconformities (internal and external) or customer complaints occur, the audit frequency shall be appropriately increased. Audit scopes shall include, and verify compliance to, applicable external requirements as well as the established and maintained Tyco Electronics quality management system procedures, processes, and practices.</p>
8.2. Monitoring and Measurement			
8.2.1. Customer Satisfaction			
8.2.2. Internal Assessments and Audits			
8.2.2.1 Manufacturing Process Audits			
8.2.2.2. External Assessments			
8.2.3. Process Monitoring and Measurement		8.2.3. Monitoring and measurement of processes	
			<p>Each process identified as such in these requirements should be supported by key performance indicators and targets.</p> <p>The manufacturing process documentation and / or the quality inspection plan shall include measurements and control points to ensure the continued suitability and effectiveness of the process to produce conforming product. (TEC-1000)</p>
8.4.2. Monitoring and Measurement of Product		8.2.4. Monitoring and measurement of product	
8.2.4.1. In-Process Inspection			<p>Measurement requirements for product or service acceptance shall be documented.</p> <p>This documentation may be part of the product documentation, but shall include</p> <ol style="list-style-type: none"> Criteria for acceptance and/or rejection, Where in the sequence measurement and testing operations are performed, A record of the measurement results, and Type of measurement instruments required and any specific instructions associated with their use.
8.2.4.2. Final Inspection			

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>In-process and final product inspection plans specify the following:</p> <ul style="list-style-type: none"> • Product characteristics to be verified with acceptance limits, • Measurement points in the process sequence. • The application of process control statistical techniques such as control charts, • Sampling strategies including sample sizes and skip lot criteria, and • The data to be recorded including inspector identification, production order traceability information, actual sample sizes, applicable variables data, applicable environmental conditions, and measurement devices used. <p>Test records shall show actual test results data when required by specification or acceptance test plan.</p> <p>Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.</p> <p>Product inspection and test records include:</p> <ul style="list-style-type: none"> • A product description including part number and revision status, • Information relative to the production order including dates and quantities, • The product quantity inspected or tested and any procedures defining the inspection or testing, • The person(s) performing the inspection and testing, • The specific measurement devices used to perform the inspection and testing, and • The inspection and test results.
<p>8.3. Control of Nonconforming Product and Materials</p> <p>8.4. Measurement and Analysis of Organizational Performance Improvement</p> <p>8.5. Continual Improvement</p> <p>8.5.1. Continual Improvement</p>	<p>8.3. Control of nonconforming products</p> <hr/> <p style="text-align: center;">NOTE 1 <i>Nonconformities are also considered as any deviation within the execution of a project / contract which includes also the logistics aspects.</i></p> <hr/> <p>8.3.1. Control of nonconforming processes</p> <p>In the event of business management process variation, the organization shall have a process in place to:</p> <ol style="list-style-type: none"> a) Identify and record the variation, and if the business management process is nonconforming, take appropriate action to correct the nonconforming process, b) Evaluate whether the business management process variation has resulted in product nonconformity, and c) Identify and control the nonconforming product in accordance with clause 8.3.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 1, REQUIREMENTS
	<p>Processes to monitor and assess business management process conformity are deployed to ensure that those processes remain effective and conforming. Business management process monitoring and assessments evaluate processes against established requirements and criteria and identify any observed variations. When a nonconforming business management process may result in product nonconformity, subject nonconforming product is appropriately identified and controlled.</p> <hr/> <p>8.3.2. Customer waiver</p> <p>The organization shall obtain a customer concession or deviation permit to further processing, whenever the product or production process is found to differ from that which is currently approved.</p> <p>The organization shall maintain a record of the expiration date of such a concession and/or quantity authorized.</p> <p>The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires.</p> <p>Material shipped, which is subject to such a concession, shall be clearly and appropriately identified. This applies equally to purchased product.</p> <p>The organization shall reach agreement with such a request from suppliers before submission to the customer.</p> <p>Discussions between Tyco Electronics and the customer may result in a customer concession and the issuance of a customer initiated deviation allowing for the continued manufacture of product that does not meet, or is manufactured under processes that do not meet, customer specifications. Under these circumstances, product shall not be shipped beyond the time or quantity limits documented in the deviation permit. All product shipped under such deviations shall be suitably identified.</p>
<p>8.5.2. Corrective Action 8.5.3. Preventive Action</p>	<p>8.5.2. Corrective action</p> <p>In addition to the ISO 9001: 2000 requirements, the documented procedure shall define requirements to:</p> <ul style="list-style-type: none"> g) document the effectiveness and close out of corrective action. <p>Quality management system procedures define the corrective action and verification of corrective action effectiveness as the minimum requirement for internal or external quality system, process, and product noncompliances. Systemic quality system noncompliances require a root cause analysis, corrective action and verification of effectiveness of corrective action. The results of corrective actions shall be documented and maintained as a quality record.</p>

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Bill Arbogas
Tyco Electronics Corporation
2100 Paxton Street, MS 18-11
Harrisburg, PA 17105

July 1, 2009

Dear Mr. Arbogas:

A special assessment document review was undertaken by LRQA to examine Tyco Electronics Corporation's Global Quality Management System Process (quality manual) TEC-1024. After verifying correction of non-conformances and associated revision of the document, LRQA has determined that TEC-1024 conforms to the quality manual requirements of IRIS Rev. 01.

This statement of conformance is limited, applying only to Tyco Electronics Corporation's top level quality management document and as such does not meet the requirements for a full Stage I assessment as described in ISO/IEC 17021 or LRQA assessment procedures.

Sincerely,

Michael Harder
QMS Technical Manager