Global Quality Management System Supplement for the Railway Industry Model, IRIS, Revision 2

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 2. 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 2 requirement.

1.2. Application

This specification is applicable to all organizations of TE Connectivity. In recognition of the varying organizational structures and needs, TE business organizations may develop and use support 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

- TEC-1000 TE Global Quality Management System
- TEC-1003 Supplier Performance Reporting and Continual Improvement Process
- TEC-1005 TE Total Quality Management Requirements for Suppliers
- TEC-1006 Approval of Suppliers

2.2. Industry Standards

- IRIS International Railway Industry Standard, Revision 2
- ISO 9001: 2008 Quality management systems – Requirements
- ISO 10007: 2003 Quality management systems - Guidelines for configuration management
- EN 50126: 1999 Railway applications. The specification and demonstration of reliability, availability, maintainability and safety (RAMS)
- EN 50128: 2001 Railway applications. Communications, signalling and processing systems. Software for railway control and protection systems
- 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.

| Indicates Change

4. QUALITY MANAGEMENT SYSTEM (QMS)

TEC-1000		SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS	
4.1.	**QMS – General Requirements**	4.1.	General requirements
			In the case of a transfer of processes or parts thereof, that affects product conformity to requirements within the execution of a contract, a documented procedure including feasibility study, risk analysis, planning, communication to customer and first article inspection to the appropriate level shall exist. **Regardless of the product realization activity location, TE is responsible for the quality of the product delivered to the customer. TE will represent the needs of the customer in both internal and outsourced functions in addressing the requirements of IRIS, Revision 2.** **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.**
4.2. **4.2.1.**	**Documentation Requirements** **Documentation Requirements – General**	4.2.1.	General
			In addition to the ISO 9001: 2008 requirements, the business management system shall include: e) Documented statements of a technical safety policy and safety objectives. f) Management system requirements imposed by the applicable regulatory authorities. **Documented statements of a technical safety policy and safety objectives begin with the TE Environmental, Health, and Safety Policy which establishes a commitment to maintaining compliance and enhancing the environmental, health and safety performance of our operations for the safe manufacture, use, and disposal of products. From established and specific safety objectives, goals are determined, communicated, measured, and reviewed by top management.** **Documented regulatory requirements applicable to the TE 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 TE product specifications which will include the applicable version of the regulatory requirement.**

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			The organization shall ensure that personnel have access to business management system documentation and are aware of relevant documents. **Management will implement processes and controls ensuring that all TE 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.** Customer and/or regulatory authorities' representatives shall have access to the business management system documentation. **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 TE policy.**
4.2.2.	**Quality Manual**	4.2.2.	Quality manual
			When referencing the documented procedures, the relationship between the requirements of this document and the documented procedures should be clearly shown. **The TE quality manual is established and maintained as TEC-1000, TE 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 TE specifications.**
4.2.3. **4.2.3.1.** **4.2.3.2.** **4.2.3.3.**	**Document and Data Control** **Initial Issue** **Changes** **Drawings, Standards, and Specifications**	4.2.3.	Control of documents
			The organization shall demonstrate effective management and control of all documents pertinent to the products it supplies. Names of personnel, who authorize and carry our reviews of the necessary documentation, shall be identified. **The document control process shall provide for the review, distribution, and maintenance of documentation for policies, processes, procedures, or techniques pertinent to all supplied product. The process shall provide for document approval that includes the identification of personnel authorized to review and authorize document release and revisions. This control applies to documents regardless of format or media.** Effective systems shall be in place to review impact of documents of external origin.

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			Documents of external origin are controlled in accordance with established and maintained procedures. As defined, the user of external documents is responsible for verifying the correct revision of the external document and following any agreements regarding use and distribution control. The organization shall have a process to ensure the traceability of customer documents throughout the entire supply chain; e.g. specifications, requirements. **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.** **NOTE 1** *Documents of external origin can be e.g. standards, customer documents, statutory and regulatory requirements.* **NOTE 2** *Customer requirements can be e.g. RAMS/LCC, obsolescence, special process, spare parts, weight and acoustic.* **NOTE 3** *This process may be included as part of the organization's change management process.*
4.2.4.	**Control of Quality Records**	4.2.4.	Control of records
			This documented procedure shall also include approval of results recorded before official release. **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.** Records shall be available for review and/or release by/to customers and regulatory authorities in accordance with contract or regulatory requirements. **As contractually required, customers and regulatory authorities shall be granted access to non proprietary pertinent records.**

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	4.3. Knowledge management
	Best practices shall be identified, documented, implemented and regularly updated to improve the organization's process efficiency and product in quality, costs, and delivery performance. **NOTE 1** *This can include but is not limited to:* • *Design rules (engineering standards).* • *Manufacturing practices.,* • *Procedures* **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.** The organization should define and implement a process to identify, obtain, protect, use and evaluate information, knowledge and technology. **The TE Technology organization provides a corporate resource dedicated to developing, researching and applying technology to support the business organizations. One of Technology's most important roles is to work with the business organizations to develop technology platforms that enable new products or processes.**
	4.4. Management of multi site projects
	In cases where a project involves multiple sites, an appropriate business management system shall be documented (e.g. in a project quality management plan) and implemented, and shall cover as a minimum: • Work split and operational interfaces, including alignment of customer requirements, • Authorities and responsibilities and communication channels (internal and with the customer) including feedback on the results for each site's scope of responsibility, • Applicable processes, procedures, documents and records on each site, and • Assurance of IRIS compliance.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	Efficiency of multi-site project activities should regularly be assessed to the appropriate level (e.g. throughout audits, management reviews, process reviews, analyzing customer complaints) and improved where necessary. **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:** • **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.** **TE 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:** • **Supports operational interfaces and defines responsibilities across organizational boundaries,** • **Facilitates both customer and internal communication,** • **Provides consistency in the achievement of corporate goals,** • **Facilitates best practice sharing, and** • **Supports industry and regulatory compliance.**

5. MANAGEMENT RESPONSIBILITY

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
5.1. Management Commitment **5.2. Customer Focus**	5.2. Customer focus Company policy shall reflect the organization's willingness to satisfy customer needs. **TE 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.** **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)**
5.3. Quality Policy	5.3. Quality policy The organization should define and implement a structured process for strategy and policy formation, which includes an analysis of the needs and expectations of customers along with an analysis of statutory and regulatory requirements. **Top management will develop and implement policies and business strategies based upon customer needs and expectations as well as statutory and regulatory requirements. These policies and strategies shall provide a framework for ensuring achievement of expectations, compliance to requirements, and continuing improvements.**

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	5.3.1 Business plan
	The organization shall establish and update at least annually, a business plan for the scope of their rail sector activities, covering as a minimum, the following topics: • Company mission and vision, • Plan to reduce identified risks, • Market and product strategy, including development plans of new products/processes and phase out strategies, • Impact of changes in technologies and in statutory and regulatory requirements, • Make or buy strategy, • Company capacity (current and future), and • Business objectives. This business plan should be effectively and appropriately communicated throughout the organization and supported by mid and long term action plans in accordance with the business plan vision. **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 TE mission and vision; Strength, Weakness, Opportunities, Threats (SWOT) analysis and plan to reduce risks; market and product strategy; impact of changes; technology review; procurement strategies; capacity; and organizational objectives.** A cost management process shall be in place in order to manage the finances of the organization, including rules for accounting and controlling. The organization should define and implement a process for predicting, monitoring and controlling financial resources. **The cost management process relative to product pertinent 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.** **Cost management at a TE level is defined and implemented in accordance with corporate policies and accounting rules that define the process for forecasting, monitoring, reporting, and controlling financial resources.**

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
5.4. Planning **5.4.1. Quality Objectives** **5.4.2. QMS Planning**	5.4.1. Quality objectives Business objectives should be cascaded and broken down consistently in the organization and reviews should be organized on a regular basis at each level of the organization. Business objectives should address customer expectations and be achievable within defined timescales. **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 each organizational level.** The organization should define and implement a planning process which includes consideration of changing external trends and interested party needs. **Planning at the TE Top Management level includes the implementation, updating, and maintenance of the quality management system as described in this document and supporting quality specifications. Management shall also apply the planning process to include consideration of external trends and needs. This may include soliciting customer inputs as determined through direct communication with key strategic customers and supplier inputs from strategic suppliers willing to work in a cooperative and collaborative way in order to achieve mutual long term benefits.**
5.5. Responsibility, Authority and Communication **5.5.1. Responsibility and Authority** **5.5.2. Management Representative** **5.5.3. Internal Communication**	5.5.1. Responsibility and authority Ownership, authorities and responsibilities for all processes shall be defined. **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)** Interfaces with the customer shall be identified and communication channels described and communicated.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS	
		Customer interface and customer communication channels are defined through the various TE organizational structures and entities. Customer interface and communication may be deployed through account management, industry management, and customer service. Each employee within the organization has the responsibility to raise any issue / deviation from the requirement to his / her manager for appropriate action. **All personnel have the authority to halt nonconforming processes and initiate, recommend, or provide corrective and preventive solutions through designated channels. (TEC-1000)**
	5.5.2.	Management representative
		In addition to the ISO 9001: 2008 requirements the management representative shall have: d) the organizational freedom to resolve matters pertaining to quality or stop development / production / delivery / field support activities if critical requirements are not met. **TE, 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.**
	5.5.3.	Internal communication
		The organization shall establish a communication system from management to its personnel and vice versa, giving consideration to, as a minimum: • Policy, • Mission and vision, • Organizational performance, and • Customer related issues. **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, TE Intranet sites, videotapes, voice message announcements, newsletters, training programs, status reports, daily interactions, group meetings, and customer contact. (TEC-1000)**

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS	
		The organization should define and implement a process for external and internal communication (see 7.2.3). **TE has established primary interfaces for ensuring that all employee, shareholder, customer, supplier, and all other interested party requests for information are satisfied. These include various electronic systems to assist interested parties in obtaining information.**
	5.5.4.	Customer relationship development
		Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes: 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. **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.**
5.6. Management Review **5.6.1. General** **5.6.2. Review Input** **5.6.3. Review Output**	5.6.1.	General
		Planned intervals shall not exceed 12 months. **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.** **Records of QMS reviews shall be maintained. (TEC-1000)**
	5.6.2.	Review input
		In addition to the ISO 9001: 2008 requirements, the input to management review shall include information on: h) Key issues from previous project reviews, i) Results of previous process reviews, and i) Analysis of actual and potential field-failures and their impact on quality, safety or the environment.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS	
		The input to management review shall include information on: • **Analysis of actual and potential field failures and their impact on quality, safety or the environment, and** • **Design and development project summary measurements.** • **Previous process review results.** During the management review the following KPI's shall be reviewed: • All mandatory KPI's (see annex 3), • Customer on time delivery performance, and • Nonconformities raised by the customer throughout the entire project life cycle. During the management review the following KPI's should be reviewed: • All recommended KPI's listed in annex 3, and in addition KPI's which state information about • Internal and supplier nonconformities throughout the entire project life cycle, • Supplier on time delivery performance, • Response time on nonconformities raised by customers, and • Quality deficiency costs. **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.**
	5.6.3.	Review output
		In addition to the ISO 9001: 2008 requirements, the output from management review shall include any decisions and actions related to d) Integration of business processes. e) Business objectives achievement, and f) Customer satisfaction. **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, business objective achievement, and customer satisfaction.**

6. RESOURCE MANAGEMENT

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
6.1. Provision of Resources	**NOTE** *The requirements described in this clause may be deployed at a project team level.*
	6.1. Provision of resources
	The organization should define and implement a process for the planning of resources including their identification, provision, and monitoring. 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. Human Resources **6.2.1. General** **6.3.3. Competence, Training and Awareness** **6.2.2.1. Human Resources Function** **6.2.2.2. Qualification Training** **6.2.2.3. Training Effectiveness**	6.2.1. General
	The organization should define, implement, measure, and review human resource management processes within the management system. **It is the responsibility of Top Management to ensure that the resources that are essential to the achievement of the organization's quality objectives, including implementing, maintaining and improving the management system and enhancing customer satisfaction, are identified during the planning processes. Resource requirements are usually planned during the budgeting process and adjusted during the year in response to sales growth, profit plans, capacity constraints, changing customer requirements, and other internal needs. Top Management shall review the adequacy of resources and adjustments shall be made based on identified business needs.** **Adequately trained personnel shall be provided to perform the required activities of their business function. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.**

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	6.2.2. Competencies, training, and awareness
	In addition to the ISO 9001: 2008 requirements, the organization shall: g) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the safety objectives. **Employees shall be made aware of the relevance and importance of their activities and how they contribute to the achievement of product safety objectives as well as personal workplace safety.** The organization should define and implement an appraisal process for systematically identifying training needs. **The identification of training needs will manifest itself through improvement in job performance and/or product quality. The process to evaluate the individual training needs includes testing, assessments, interviews and periodic performance appraisals.**
	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. **NOTE 1** *This could include a suggestion of a scheme system deployed throughout the entire organization.* **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.**

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	6.2.2.3. Training
	The organization shall establish and maintain documented procedures for identifying and planning training needs in order to achieve and maintain the necessary competence of personnel performing activities affecting product quality and safety at all levels of the organization. Output of knowledge management activities (see clause 4.3) shall be taken into consideration as an input to training planning. **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)** Personnel performing specific assigned tasks (e.g. special processes, engineering change activities) shall be competent and qualified, as required, with particular attention to the satisfaction of customer, local, statutory, and regulatory requirements. A system shall be in place to maintain and upgrade the qualifications of such personnel. **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, local, statutory, and regulatory specific requirements. The training process shall include provisions for personnel to upgrade their qualifications.** 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. **Personnel whose activities affect product quality and safety shall be qualified and periodically evaluated for continued qualification with records maintained and updated accordingly.** Personnel whose work can affect quality and safety shall be informed about the possible consequences to the customer if quality and safety requirements have not been met. **Personnel whose work can affect quality shall be informed about the consequences to the customer when there is a nonconformance to specified quality requirements.** Appropriate induction shall be performed for temporary workers and newcomers covering, as a minimum, product quality and safety.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	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.
	6.2.2.4. Performance management
	A system shall be established to regularly set individual objectives linked with business objectives and review the individual performance. **NOTE 1** *The system can also address the needs for training and development of individual people. On shop floor level, team objectives can be considered as sufficient individual objectives.* **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.**
6.3. Infrastructure	6.3. Infastructure
	In addition to the ISO 9001: 2008 requirements, the infrastructure includes, if applicable: d) Planned maintenance activities, e) Packaging, storage, and preservation / condition checks of equipment / tooling / fixtures and measurement equipments, f) Availability of spare parts and consumables for key manufacturing equipment, and g) Documenting, evaluating and improving maintenance objectives. The organization should utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment. The organization should periodically review the infrastructure and related processes with the future in mind.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	An effective, preventive maintenance program shall be developed and implemented at a facility level that identifies key process equipment as well as, monitoring/measuring devices and provides appropriate resources for equipment maintenance. Maintenance activities are deployed to sustain process capability requirements and product quality requirements. As a minimum, the preventive maintenance program shall identify key process equipment, establish planned maintenance activities and intervals, deploy predictive methods, manage the availability of replacement parts for key manufacturing equipment, and periodically evaluate maintenance activities for program improvement opportunities. (TEC-1000) **Reviews of the established and implemented preventive maintenance program are conducted in accordance with the internal audit process.**
6.4. Work Environment	6.4. Work environment
	The organization should define and implement processes to ensure that the work environment complies with all applicable statutory or regulatory requirements. **NOTE 1** *Factors that might affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge.* **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.** 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. **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.** The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the product and production process needs.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
6.5. Contingency Plan	6.5. Contingency plan
	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. **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)** **Resource succession plans are periodically reviewed to ensure the uninterrupted transition of personnel experience and responsibilities.**

7. PRODUCT REALIZATION

TEC-1000		SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS	
7.1.	**Planning of Product Realization**	7.1.	Planning of Product Realization
7.1.1.	**New Product Introduction**		The organization should define, implement, and manage key processes such as those related to product realization and customer satisfaction. **It is the responsibility of the business unit to identify and plan for the product realization processes necessary for product realization and customer satisfaction. These processes should be carried out in accordance with documented procedures. The result of product realization planning shall correspond with the business unit's operational methods.**
7.1.2.	**Disaster Recovery Planning**		
7.2.	**Customer Related Processes**	7.2.1.	Determination of requirements related to the product
7.2.1.	**Determination of Product Related Requirements**		A detailed internal total cost breakdown shall be determined. The cost breakdown should be supported by past experience from operation and supplier offers. **A "standard manufacturing cost" measure is determined for each saleable product based on material purchase and manufacturing histories.**
7.2.2.	**Review of Product Related Requirements**	7.2.2.	Review of requirements related to the product
7.2.2.1.	**Customer Service**		The organization should define and implement a change process which includes a change control board. A 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**		

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	As appropriate, the review of customer specifications shall include: • **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 TE standard terms and conditions. (TEC-1000)** **In combination, the participating multidisciplinary functions comprise a change control board.** The organization shall have a process to ensure that identified requirements are: a) Individually checked for compliance (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. The performance of this process should be measured by a KPI (see annex 3). This process shall also control contract variation including liaison with customers. The process shall be applied for all the phases; submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders. Deficiencies identified in the reviews shall be managed and corrected by the organization.

TEC-1000	SUPPLEMENTARY IRIS, REVISION 2, REQUIREMENTS
	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) **The customer-related product requirement review process is continually monitored for customer response time performance. This responsiveness metric is a key measurement of customer satisfaction.** In order to avoid risks and to allow a smooth project / product realization, reviews shall cover as a minimum the aspects (see clause 7.7): critical product characteristics~~,~~; customer, statutory, and regulatory requirements; scope; time; cost; quality; resources; communication; risk; changes. Reports should be issued to senior management and regular reviews should be held with them (allowing proactive activities) covering: • Actual situation vs. planned situation in terms of time, • Forecast (time to complete), • Contingency activities, migration plans, • Actualization of risk mangement, and • Follow-up of open issue list. Risks shall be identified, monitored and migrated when applicable. Risks shall be communicated internally and to the customer, if applicable. **NOTE 1** *These requirements are also applicable to after sales activities described in 7.10.* **In cases where the TE 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 organization 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.** **Customer response time is a key customer service performance metric that is established and monitored by customer service management. Not meeting established performance goals should result in corrective action initiation.**

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7.2.3. Customer Communication	7.2.3. Customer communication
	The organization shall define and implement effective arrangements for communicating any and all information related to the delivery in accordance with customer contractual requirements in the value chain. **NOTE 1** *This requirement may be included as part of the organization's supply chain management.* **NOTE 2** *Proactive communications on specific supplier management within a project may be established.* The organization should define and implement a process for external and internal communication (see clause 5.5.3). **TE 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. TE shall effectively communicate with customers during product nonconformity issues and complaint resolution. (TEC-1000)**
	7.2.4. Tender management
	In addition to the requirements related to the product (see clause 7.2.2), the organization shall have a process and should have a documented procedure to ensure that requirements identified during the tender phase are: • Individually checked for compliance (e.g. clause by clause), • Negotiated and updated with impact on the offer identified, • Evaluated and taken into account, • Properly transferred, understood, acknowledged and committed to by everybody involved, and • Complete, clear, precise, unequivocal, verifiable, testable, maintainable, and feasible. The performance of this process shall be measured by a KPI (see annex 3).

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			Prior to the submission of the quotation, the organization shall use a multidisciplinary approach (including suppliers when appropriate) to investigate customer and statutory 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 pricing. As a minimum, project /product requirements, as well as risks and opportunities, shall be identified, controlled, and validated. **In those cases where there is an established cross-reference between the customer part number and a TE 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 organization and transmitted to the customer service representative. The reconciliation process shall involve, as applicable, product/business management, development engineering, suppliers, product engineering, manufacturing, and pricing. The process will take into account product compliance to all applicable customer, statutory, and regulatory requirements and confirm feasibility in a precise and verifiable manner. Booking the order is confirmation that there are no known discrepancies between the customer request and the ability to meet the request.** **All business opportunities will be evaluated using a multidisciplinary approach to identify, control, and validate any potential business, project, and/or product related risks and opportunities.** **The performance of the product proposal process shall be defined, measured, tracked, and reported as a key performance indicator in measuring progress toward organizational goals.**
7.3.	**Design and Development**	7.3.	Design and development
			The organization shall establish and maintain a process for design and development and should document it in a procedure. The performance of this process shall be measured by a KPI (see annex 3). The organization should define and implement an innovation process for new products and processes which is able to identify changes in the organization's business environment and to plan innovation. Every new technology / new product shall fulfill the design and development requirements described in clause 7.3.

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	TE 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) The principles applied in developing high integrity systems shall be in line with the IEC (CENELEC) standards or other agreed equivalent models. The software design process shall explicitly implement the appropriate requirements (e.g. IEC 62279 (EN 50128)) related to the safety integrity level of the intended IRIS scope of certification. **TE will abide by all product applicable national, regional, and international electro-technical standards established to remove trade barriers and minimize compliance costs.** Documentation and training related to the application of the product shall be 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. **NOTE 1** *The focus is on error prevention rather than detection.* **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. Design criteria are established in the development phase to meet the appropriate standards.**

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7.3.1.	**Design and Development Planning**	7.3.1.	Design and development planning
7.3.1.1.	**Project Planning**		The organization should define and implement a collaboration process and indicators to measure its efficiency. The organization shall determine task sequence, mandatory steps, significant stages and method of configuration control. Where appropriate, due to complexity, the organization shall give consideration to the following activities: • Structuring the design effort into significant elements, and • For each element, analyzing the tasks and the necessary resources for their design and development. This analysis should consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Design concepts, for example, design for safety, design for maintainability, and design for environment, should be investigated and applied where appropriate. **Project plans shall be prepared that identify the responsibility, budgets, staffing and schedules for each design and development activity. The plans shall be updated and communicated to the appropriate individuals as each design evolves. The plans shall describe or reference the following activities, as applicable:** • **Organizational and technical interfaces between different groups (internal and external) shall be identified and the necessary information documented, transmitted, and reviewed;** • **Project roles and responsibilities;** • **Project reporting requirements, including tracking and resolving open issues;** • **Performance, safety, security, and other critical requirements;** • **Any project specific training requirements, and** • **Usage or licensing rights.** **(TEC-1000)**
7.3.2.	**Design and Development Inputs**	7.3.2.	Design and development inputs
7.3.2.1.	**Customer Input**		The organization shall ensure new technologies / new products (designed to meet market needs) are validated before introduction into a customer project. RAMS / LCC shall be considered as design inputs. End of life of products should be considered as design input.

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	NOTE 1 *In particular, customers are expected to collect by the end users all the information needed and demanded by the supplier in order to enable the supplier to have complete and reliable design inputs.* **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 TE. When necessary, actual testing may be performed at other qualified test facilities, but shall be under the coordination and approval of the TE test laboratory or facility receiving the initial test request. (TEC-1000)** **Consideration shall be given to RAMS (reliability, availability, maintainability, safety) and LLC (life cycle costs) as design input criteria.**
7.3.3. Design and Development Outputs	7.3.3. Design and development outputs The organization should define and implement a process, which ensures that approval is carried out by sufficient competent staff (e.g. gate reviews process). The design and development output shall be expressed in terms that can be verified against production process input requirements. **NOTE 1** *The design and development includes e.g. (see clause 7.5):* • *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 prevention activities (e.g. FMEA), as appropriate, and* • *Methods of rapid detection and feedback of product / production process nonconformities.* **Product requirements will be reviewed at suitable stages of the development process, by a design team, to assure that design outputs meet the all design inputs. Project gates will not be passed without team approval.**

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		The design output shall be documented and expressed in terms of requirements, calculations and analyses, and shall: • **Meet the design input requirements;** • **Provide the information required for 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)**
7.3.4.	**Design and Development Review**	7.3.4. Design and development review In addition to the ISO 9001: 2008 requirements, systematical reviews of design and development shall be performed c) to authorize progression to the next stage. **NOTE 1** *These design / development reviews are part or an input for the phase review (see 7.7.5).* The organization shall define and implement a design review process. **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.** Measurements at specified stages of design and development should be defined, analyzed and reported with summary results as an input to management / project review. **NOTE 2** *These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.* **NOTE 3** *Design and development reviews are conducted on each level of detail (e.g. architecture, design, modular design).* Reviews shall also involve other functions as appropriate to review the product characteristics (e.g. costs, RAMS and serviceability).

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			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. **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)**
7.3.5.	**Design and Development Verification**	7.3.5.	Design and development verification
			NOTE 1 *Design and development verification is conducted on each level of detail (e.g. architecture, design, modular design).* **During design, product shall be evaluated to verify that design outputs meet input requirements. These programs shall be planned, established and conducted by appropriate functions to:** • **Investigate potential failure modes and verify their effects on both the design and the production processes; and** • **Demonstrate the product design capability. The design of these tests should consider electrical, mechanical, and environmental stresses as appropriate to ensure acceptable product reliability.** **Records of the results of verification testing and any necessary actions shall be maintained. (TEC-1000)**
7.3.6.	**Design and Development Validation**	7.3.6.	Design and development validation
			Design and development validation shall be demonstrated for all identified operational conditions. The organization shall apply the validation concepts, organization and methods as mandated by applicable standards (e.g. IEC 62278 (EN 50126), IEC 62279 (EN 50128), IEC 62475 (EN 50129)).

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	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: 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 reproducible environmental, 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. **A validation test program shall be developed that will, when completed, provide evidence of successful product testing in accordance with** • **internal requirements,** • **customer agreed upon requirements including customer certification criteria,** • **government agency certification requirements, and** • **commercial agency requirements.** **Product design verification and validation testing is performed to an established, controlled, and documented test plan to ensure:** • **A defined test scope with product descriptions, corresponding part numbers, and the latest versions of design objectives; product specifications; and applicable standards;** • **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.**
7.3.7. Control of Design and Development Changes	7.3.7. Control of design and development changes
	The organization should define and implement a design and development change process. The organization shall have a process to control deferred and abnormal work in design and development.

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	NOTE 1 *The control of design and development changes may be part of configuration management.* **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. TE defines the responsibilities for monitoring and ensuring that the changes do not adversely affect product quality, performance or reliability. (TEC-1000)** **Changes to design during the development process will follow established controls. Changes to the project itself must also be controlled (e.g. abnormal work requirements that are required to be completed in order to attain product acceptance).**
	7.3.8. Design approval
	In the case that IEC 62279 (EN 50128) in conjunction with a safety integrity level is required, the organization shall provide a documented procedure defining the safety case and approval in line with this standard. **TE 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.**
7.4. Purchasing **7.4.1. Purchasing Process** **7.4.1.1. New Suppliers** **7.4.1.2. Supplier Performance**	7.4.1. Purchasing process
	In addition to ISO 9001: 2008, the organization shall ensure that a process for purchasing products is in place. The organization should define and implement a process to select, evaluate, re-evaluate and rank suppliers. The performance of this process shall be measured by a KPI (see annex 3). The organization shall provide a documented procedure covering purchasing process activities that affect product conformity to requirements. The organization shall implement a system to ensure the quality of all • Products purchased from suppliers, • Products purchased from customer designated suppliers.

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	The organization shall: a) Maintain a register of approved suppliers which includes the scope of their approval, b) Ensure that customer requirements are cascaded down through the supply chain and especially that both the organization and its suppliers use customer approved special processes, where required, c) Ensure that the function having responsibility for approving supplier quality systems has the authority to reject the use of sources, and d) Assess and manage the risks for supply of critical products throughout the supply chain. **Per the criteria in Global Quality Specification TEC-1006, Approval of Suppliers, suppliers are approved and identified in the TE Database (TED) and in the Purchasing Module of the various TE Enterprise Requirements Planning software such as SAP and the Purchasing On-Line Information System (POLIS). Suppliers are evaluated for conformity to requirements.** **A supplier's approval scope provides a list of materials and products and limits what may be purchased from a particular supplier.** **Where customer approved special processes are a flow down requirement to suppliers, such requirements will be specified in the corresponding purchase order.** **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.** **Risks are accessed and managed through supplier selection, defining the supplier requirements, and monitoring the supplier performance.** The organization should: 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 targets. The organization shall develop suppliers with the goal of improving supplier operational performance. The organization should define and implement a relationship process to develop key suppliers.

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	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 TE 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 organization, 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. Unless otherwise specified by the customer, suppliers to the organization should be third party registered to ISO 9001: 2008 by an accredited third-party certification body. **NOTE 1** *Conformity with ISO 9001: 2008 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.* **Purchasing procedures include Global Quality Specifications TEC-1003, Supplier Performance Reporting and Continual Improvement Process, TEC-1005, TE Total Quality Management Requirements for Suppliers, and TEC-1006, Approval of Suppliers. Collectively these procedures** • **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.**
7.4.2. Purchasing Information	7.4.2. Purchasing information In addition to the ISO 9001: 2008 requirements, purchasing information regarding the product shall include, where appropriate: d) The name or other identification, and applicable issues of specifications, drawings, process requirements (including special ones), inspection instructions, appropriate details from the organization's quality plan 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, **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, TE Total Quality Management Requirements for Suppliers. (TEC-1000)**

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	g) Requirements relative to supplier notification to the organization of nonconforming product and arrangements for the organization approval of supplier nonconforming material. **Per the requirements of Global Quality Specification TEC-1005, TE Total Quality Management Requirements for Suppliers, if a non-conformance is discovered by the supplier, the supplier shall be responsible for notifying the respective TE 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.** h) Requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval, **Per the requirements of Global Quality Specification TEC-1005, TE Total Quality Management Requirements for Suppliers, TE must ensure that its customers receive product that is consistent with drawings, product specifications, and inherent performance requirements. To facilitate this requirement for consistency, TE requires that the supplier provide prior written notice to the Procurement and/or TE business organizations 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 TE individual business organizations.** i) Right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, **Per the requirements of Global Quality Specification TEC-1005, TE Total Quality Management Requirements for Suppliers, the supplier shall include right of entry provisions in subcontracts and purchase contracts, allowing the TE, TE 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.** j) Requirements for the supplier to cascade to its suppliers, the applicable requirements in the purchasing documents, where required, k) Requirements for supply chain logistics, and l) Requirements for all deliverables associated to the product. **Per the requirements of Global Quality Specification TEC-1005, TE 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.**

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		The organization shall ensure that the supplier's offer is selected only after thorough analysis prior to negotiation. The negotiation shall take into account: • The level of compliance with the purchasing information, • The total cost requirements (including LCC), and • Previous product quality, costs and delivery performances. **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.**
7.4.3.	**Verification of Purchased Products**	7.4.3. Verification of purchased product The organization should define and implement a process for verification activities, like inspection or audit at supplier's premises, which is supported by checklists and templates. Verification activities of the organization shall include: 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. Verification activities of the organization should also include inspection and audit at the supplier's premises. The purchased product shall not be used or processed until it has been verified as conforming to specified requirements or unless it is released under authorized customer concession (see 8.3.2).

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	It shall be the responsibility of the business organization to determine the means of verifying that suppliers meet their contractual obligations related to the quality of the procured items. Examples of ways this may be accomplished: • **Stock as received (SAR)/dock-to-stock – following receipt of the material, it can be placed directly into stores without any receiving inspection activity. Material may be designated stock as received based on supplier or part number certification as administered through purchasing or supplier quality assurance or as approved by the business unit. Purchasing/supplier quality assurance is responsible for periodic assessments of certified suppliers;** • **Supplier warrants or certificate of analysis (C of A), with test results, submitted with the material;** • **Incoming inspection – each lot of received material shall be inspected to confirm conformance to specifications;** • **Skip lot inspection – lots of received material are inspected as defined by a skip lot plan;** • **Product is evaluated and reported as acceptable by an accredited supplier or test laboratory.** **In the event that materials are needed for manufacturing commitments before receiving inspection is complete, a plan shall be developed to provide for positive identification and control of the product produced until the material is verified as acceptable. (TEC-1000)** Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically verify test reports for raw material. **A plan shall be established and administered for periodic validation testing to determine a supplier's capability to ensure the continued compliance with the requirements documented in the TE 100 series Material Specifications or supplier's technical data sheets for base metals and polymeric material.** The organization shall define activities accordingly in case of delegation of verification to the supplier or suppler certification. Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

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	NOTE 1 *In the case of change of the product or design or production process, these requirements for delegation may be reviewed accordingly.* **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.**
	7.4.4. Supply chain management
	Supplier deliveries shall be scheduled in order to meet the purchase requirements. Ordering shall be supported by an information system which: • Covers the supply, • Permits access to customer, supplier, and production information at key stages of the purchasing process, and • Is order driven. The organization shall communicate regularly, a forecast to its supplier in order for them to manage their capacity accordingly. Supplier shortages shall be identified, communicated to the organization, controlled and actions shall be established to recover the delivery schedule. **NOTE 1** *Identification of potential supplier shortages is part of risk management according to clause 7.7.8.* **NOTE 2** *Identified supplier shortages are dealt within the contingency plan according to clause 6.5.* **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 TE in cost management and performance improvements. Regular communication is maintained with suppliers to identify quality or delivery issues.**

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7.5.	**Production and Service Processes**	7.5.	Production and service provision
			NOTE 1 *Production in the spirit of this clause can also apply within the engineering process (commissioning, installation).* The organization shall insure that the production process inputs are expressed in terms that can be verified against design and development output requirements, including: • Specifications and drawings. • Information on materials, • Production process flow chart / layout, • Control plan, • Work instructions, • Process and product approval acceptance criteria, • Data for quality, measurement, reliability, maintainability, • Results of error prevention activities (e.g. FMEA), as appropriate, and • Methods of rapid detection and feedback of product / production process nonconformities. **The output of a design project includes all information relative to product requirements, specification of components and materials, the defined process including work instructions, inspection requirements, and expected production capability. FMEA's are a required deliverable on design projects.**
7.5.1.	**Control of Production and Service Processes**	7.5.1.	Control of production and service provision
			In addition to the ISO 9001: 2008 requirements, controlled conditions shall include for all shifts: g) Accountability for all products during manufacturing (e.g. parts quantities, split orders, nonconforming product), h) Evidence that all manufacturing and inspection operations have been authorized and completed as planned in the production schedule or as otherwise documented. **Controlled manufacturing conditions shall include product accountability throughout production and documenting the completion of established manufacturing and inspection operations.**

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	7.5.1.1. Production scheduling
	Production (including test equipment) shall be: • Scheduled (short-, mid- (MPS = Master Production Schedule) and long-term (SOP = Sales and Operation Plan)) in order to meet the customer purchase requirements, • Supported by an information system that permits access to production information at key stages of the process, and • Order driven. The organization shall use customer forecasts and orders to plan, measure capacity and adjust regularly it's resources according to workload taking into account risks (e.g. extra order at the last minute, supplier failure). Bottlenecks in production shall be identified and an improvement action plan established. **Production is scheduled to meet customer delivery requirements or the replenishment of appropriate inventory levels. Production scheduling is order-driven and done through the TE 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.**
	7.5.1.2. Production documentation
	Production operations shall be carried out in accordance with approved data. This data shall contain, when necessary: 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 clause 8.2.4), and b) A list of tools and numerical control (NC) machine programs required and any specific instructions associated with their use. **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.**

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	Production documentation shall include a listing of process specific equipment and tools, non-specific tools, and process equipment related software data programs.
	7.5.1.3. Control of production process changes
	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 and/or statutory and regulatory requirements. Changes affecting processes, production equipment, tools and programs (software) shall be documented. 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. The organization shall maintain a record of the date and/or serial number of each change which is implemented in production. **NOTE 1** *Clause 7.5.1.3 refers to the change management process which is described in clause 7.13 of this document.* **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.** **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.** **Production documentation identifies the date on which a change is made. A change to a production process shall be confirmed through a first piece inspection of the product.**
	7.5.1.4. Control of equipment and tools
	The organization shall have a documented procedure for providing adequate manufacturing equipment and tools to produce products according to the design output. The organization should apply the design and development process (see clause 7.3) for manufacturing equipment (e.g. tools, jigs, fixtures).

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	NOTE 1 The validation of the manufacturing equipment is included in clause 7.9. **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.** **Production equipment, tooling, and program suitability will be validated on subsequent production orders through a product first piece or set-up inspection.** **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.**
7.5.2. Validation or Production and Service Processes **7.5.2.1. Process Monitoring and Operator** **7.5.2.2. Instructions Verification of Process Setups and Operational** **7.5.2.3. Changes First Article** **7.5.3. Examination Product Identification and** **7.5.3.1. Traceability Inspection and** **7.5.4. Test Status Control of Customer Property**	7.5.2. Validation of processes for production and service provision The organization should define and implement a process for validation of processes for production and service provision. Special processes shall be managed according to the contractual and/or internal requirements. The organization shall establish a process for the control of special processes including, qualification and approval of the special processes prior to use and in accordance with documented specifications and any subsequent changes thereto. All personnel performing special processes shall be identified, trained, and authorized. **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:** • **Defined process approval criteria;** • **Equipment approval and personnel qualifications;** • **Specific process procedures and methods.** **The criteria or interval for re-validation should be established. (TEC-1000)**
7.5.5. Product Preservation **7.5.5.1. Shelf-Life**	7.5.5. Preservation of product Preservation of product should also include, in accordance with product specifications and/or applicable regulations, provisions for: a) Cleaning b) Special handling for sensitive products,

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		c) Marking and labeling, d) Shelf life control and stock rotation, and e) Special handling for hazardous materials. **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.** The organization shall ensure that product documentation required by the contract / order is present at delivery and is protected against loss and deterioration. **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.** **NOTE 1** *This also applies to products supplied to the organization including spare parts.*
7.6.	**Control of Inspection, Measuring, and Testing Equipment**	7.6. Control of monitoring and measuring equipment In addition to the ISO 9001: 2008, measurement equipment shall (f) be recalled in accordance with a defined method when requiring calibration. The organization should define and implement a process, how to react when monitoring and measuring equipment is found not to conform to requirements. The organization shall maintain a register of this monitoring and measuring equipment and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. **NOTE 1** *Monitoring and measuring equipment includes, but is not limited to: test hardware, test software, Automated Test Equipment (ATE) and plotters used to produce inspection data. This also includes equipment that is personally owned, developed in-house, and supplied by the customer to provide evidence of product conformity.* **Each TE location using product inspection, measuring, and testing equipment shall maintain a register to ensure that all equipment used to verify product quality is uniquely identified and calibrated at prescribed intervals.**

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		A defined method for measurement equipment recall shall be employed to ensure equipment requiring calibration is available for verification in accordance with defined requirements. The process shall include a reaction plan when monitoring and measuring equipment is found out of calibration. **The methods and acceptance criteria for performing device calibrations shall be defined.** The organization shall ensure that ambient conditions are suitable for the carrying out of the calibration, inspection, measurement and testing. **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)** **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)** **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)**
	7.7.	Project management
		The organization shall implement a project management process 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. The performance of this process shall be measured by a KPI (see annex 3). **NOTE 1** *The scope of project management process is from tender phase until the end of warranty period (project life cycle).* **NOTE 2** *If applicable in the project, the required SIL level has to be taken into consideration.*

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		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. **Project management is considered a process that is subject to management review and is to be measured by a KPI.**
	7.7.1.	Integration management
		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. **NOTE 1** *A multidisciplinary team typically includes the organization's design, manufacturing, quality, production, field support and other appropriate personnel including supplier and customer when appropriate.* **NOTE 2** *It is to be understood that project management, as well as new product development process can be part of overall product realization process.* **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.**
	7.7.2.	Scope management
		The organization shall ensure the entire scope of work is identified, subdivided in work packages, controlled and verified. Scope changes shall be controlled and consistently guaranteed throughout the project and reflected in the project plan.

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	NOTE 1 *Scope management in design and development is detailed in clause 7.3.1.* **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.**
	7.7.3. Time management
	The organization shall ensure timely completion of the project through the identification of: • Specific activities to produce the project deliverables, • Inter-dependencies of the work packages including those of suppliers, • Activity sequences, resource requirements and duration, and • The critical path. These integrated activities (i.e. product schedule) shall be regularly reviewed, controlled and recorded. 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. Project schedules shall be regularly reviewed and updated with regard to development activities with suppliers (major milestones with suppliers) and the identification and management of long lead time items. **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.** **Where project plan schedule changes impact customer delivery commitments, any schedule deviations shall be authorized by the customer.**

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	7.7.4. Cost management
	A cost management process shall be in place: • To plan all project related costs during the whole project life cycle, • 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 of completion. The performance of this process shall be measured by a KPI (see annex 3). Cost savings should be identified in order to recover the budget in case of deviation. **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.** **Cost management is considered a process that is subject to management review and is to be measured by a KPI.**
	7.7.5. Quality management
	The organization shall ensure a process is in place to manage project deliverables. As a minimum, the project deliverables shall be managed with regard to: • Identification, clarification, fulfillment and control, • Validation and delivery on time, • Approval by the customer (e.g. customer product acceptance points), where required, and • Management of the suppliers within the project (e.g. listing, criticality, innovation, actions, sites). Open issues shall be controlled and the appropriate resources put in place to manage the associated activities. Documented project reviews shall take place at regular intervals throughout the entire project life. Phase reviews shall take place at predefined project phases / milestones to assess the project compliance, the availability of work package deliverables and to authorize the start of the next phase. 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.

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		Assessment of the project performance shall be established to monitor the project progress and efficiency through performance indicators. **The TE 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.** **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. Subcontractor or supplier activities relative to the project are subject to review throughout the product realization process.**
	7.7.6.	Human resources managtement
		Requirements described in clause 6.2 of this standard with regard to competence, awareness, training, motivation, empowerment, and performance management shall be deployed at a project team level. It shall cover as minimum: • Identification, documentation and assignment of project roles, responsibilities and reporting relationships, • Acquisition of appropriate resources assigned to and working until project completion, and • Development of individual and team competencies to enhance project performance. **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 2, paragraph 6.2, Human Resources. Team awareness, motivation, empowerment and performance management will also be deployed in team formation.**
	7.7.7.	Communication management
		The organization shall ensure that the project team determines and communicates needs of the stakeholders (e.g. communication plan). This information, including performance information, product specific requirements, defect reporting, and rail industry risks shall be made available to project stakeholders in an adequate timely manner.

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	NOTE 1 *This is in addition to the basic ISO 9001:2008 clause 7.2.3. requirements.* **Project plans shall include communication tactics to ensure that information, including performance criteria, is made available to project stakeholders in a timely manner.** **TE 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.**
	7.7.8. Risk and opportunity management
	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 be documented in a procedure and should include methods like documented risk assessment, FMEA, and control of counter measures. The risk response or opportunity enhancement shall be recorded and reported to all stakeholders as appropriate. The effectiveness of the response plan shall be assessed on a regular basis (e.g. during the project reviews). The output of the risk assessment shall be regularly reviewed and updated throughout the project life cycle and should be extracted and communicated for the purpose of lessons to be learnt throughout the organization. The organization shall demonstrate • Appropriate awareness of the criticality of the product and the function and risks of a product within the system / vehicle of which it forms a part, • Assurance of appropriate production control procedures to implement risk mitigation. **TE 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.).**

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	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'.
	7.8. Configuration management
	The organization shall establish, document and maintain a configuration management process appropriate to the product. The organization should have a documented procedure for configuration management. The organization shall: a) At the beginning of the contract, define a list of products – at least safety critical ones - including their component parts, which shall be managed with regard to their configuration. This list shall be approved by the customer. b) Address the change management process within the configuration management process (see clause 7.13), and c) Maintain traceability during production and operations. **NOTE 1** *Guidance on configuration management is given in ISO 10007.* **NOTE 2** *In cases where a change impacts a product which is subject to configuration management, the principles described in clause 7.13 apply.* **NOTE 3** *For software development and production a configuration management for applied tools has to be available.* **The TE 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:** • **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.**

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	• **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.**
	7.9. First article inspection (FAI)
	The organization shall provide a documented procedure covering the inspection, verification, documentation, and update of records with results of a representative item from the first series production run of a new product or major upgrade of an existing product following: • The verification of the production process or • A change that invalidates the previous first article inspection result. The organization shall ensure that a process is in place to plan, initiate and conduct first article inspection. The performance of this process should be measured by a KPI (see annex 3). This FAI procedure shall also be applied to suppliers according to defined and agreed criteria. **NOTE 1** *If the product is a one-off , FAI is meant as validation.* **NOTE 2** *FAI is not applicable for organizations having activities in design only.* **NOTE 3** *If the product is a software only, FAI is meant as validation according to applicable IEC Standards.* **NOTE 4** *FAI is a key milestone of the organization's production process.* **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.**

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	7.10. Commissioning / Customer service
	Where commissioning / customer service is a contractual requirement, a process shall be in place. This process shall include a) Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information, b) The control and updating of technical documentation and its publication, c) The approval, control, and use of repair schemes. and d) The management of consignment stock. The organization shall demonstrate that adequate customer support is provided during commissioning ▪ Until product validation is complete, ▪ During warranty ▪ Until final customer acceptance. Suitable resources shall be available to provide customer support in accordance with the agreed requirements, for all the after sales activities including the supply of spare parts. Maintenance contracts shall be managed with the requirements defined in clause 7, “Product realization”. **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.**
	7.11. RAMS / LCC
	Maintainability of the product shall be an integrated part of the design and development process. Standardized routines for the maintenance of software shall be established and recorded according to IEC 62278 (EN 50126), IEC 62279 (EN 50128), IEC 62245 (EN 50129) or other agreed equivalent models in accordance with the design and development process. The organization shall have a documented procedure in place to cover all the aspects of RAMS activities including • Calculation and documentation, • Data collection, analysis, and improvement action plan set up, and • Implementation of defined tasks of the action plan. The organization shall have a process in place to manage LCC and should document it in a procedure.

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	Resources shall be in place to address the RAMS / LCC requirements. RAMS / LCC data collection and analysis shall be supported by past experience from operation during and after warranty period and continuously improved (see clause 8.5.1). **NOTE 1** *It is expected that the organization demands and collects all data needed for the product.* **NOTE 2** *LCC process may be part of cost management process (see clause 7.7.4).* **NOTE 3** *It is recommended that RAMS / LCC are in line with the applicable Standards (e.g. IEC 62278 (EN 50126)).* **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.** **RAMS / LCC data collection and analysis will also be incorporated into software design in accordance with the customer requirements for design and development.** **Processes shall be defined and deployed to manage product life cycle costs (LCC). Both RAMS and LLC processes shall be in accordance with EN 50126: 1999.**
	7.12. Obsolescence management
	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. **NOTE 1** *This process may be part of the change management or configuration management process.*

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	NOTE 2 *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.* **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.**
	7.13 Control of changes
	The organization shall establish a process and a documented procedure to implement, execute, control and react to changes that impact product realization, including the definition of which changes need to be referred back to the customer for authorization in line with local and customer requirements. The effects of any change, including those changes caused by any supplier (e.g. changes of subcontractor, location, production process, standard) and by customers (e.g. for new product introduction) shall be assessed and verified. Validation and approval activities shall be defined to ensure compliance with customer requirements before implementation. Changes should be analyzed regarding the impact of testing and side effects. The organization shall have controls in place which prevent changes from external origin being implemented without prior authorization from all appropriate stakeholders. The impact of change on form, fit and function of proprietary designs (including performance and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated. **NOTE 1** *Any product realization changes and their possible constraints affecting customer requirements require notification to and agreement from the customer.* **NOTE 2** *The above requirement applies to design and development changes (see clause 7.3.7) as well as production process changes (see clause 7.5.1.3).* **NOTE 3** *This is in addition to ISO 9001: 2008 clause 7.3.7 requirements.*

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	TE quality management system procedures define the processes for initiation, approval, implementation, and validation of product design, specification, supplier, manufacturing location, and manufacturing process change control. These procedures include provisions for contractually required customer notification, review, and approval.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

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8.1.	**Measurement, Analysis, and Improvement – General**	8.1	General
			In addition to ISO 9001: 2008, the organization shall ensure that a process for measurement, analysis, and improvement is in place.
8.1.1.	**Statistical Techniques**		**TE maintains implemented processes for measurement, analysis, and improvement demonstrating product conformity, ensuring QMS conformity, and advancing continual improvement and QMS effectiveness.**
8.2.	**Monitoring and Measurement**	8.2.1	Customer satisfaction
8.2.1.	**Customer Satisfaction**		The organization should define and implement a monitoring process which is performed in a systematic and planned way and includes cross checks with external data sources. The organization should define and implement processes for tracking statutory and regulatory requirements. The organization shall implement a process for obtaining and evaluating customer satisfaction data. The performance of this process should be measured by a KPI (see annex 3). Root cause analysis of the main issues should be done with special emphasis on customer related issues. **NOTE 1** *Also refer to clause 8.4.e)* **The defined and implemented TE customer satisfaction process includes direct customer contact with the purpose of sharing expectations, understanding customer perceptions, soliciting customer inputs, and ensuring improvement with the aim of enhancing overall customer satisfaction. Customer satisfaction data is also obtained through customer provided report cards and internally gathered data on complaints, returns, and delivery performance. Any resulting corrective action benefits from a disciplined corrective action process.**

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8.2.2.	**Internal Assessments and Audits**	8.2.2. Internal audit
8.2.2.1.	**Manufacturing Process Audits**	The organization should define and implement a process for data gathering (see clause 8.4). Internal auditors of relevant functions shall be qualified to ensure that rules of auditor behavior are applied and IRIS requirements of relevant chapters are understood. 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, if applicable. **Internal audits shall cover all the quality management system, activities and shifts and shall be completed in accordance with an annual plan by qualified auditors who understand the IRIS requirements. 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 TE quality management system procedures, processes, and practices.**
8.2.2.2.	**External Assessments**	
8.2.3.	**Process Monitoring And Measurement**	8.2.3. Monitoring and measurement of processes Mandatory and recommended KPI's shall be established as listed in annex 3 to measure and monitor processes. **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)** **Mandatory and applicable recommended KPI's are used to determine the effectiveness of the quality system.**
8.2.4.	**Monitoring and Measurement of Product**	8.2.4. Monitoring and measurement of product Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the product documentation, but shall include a) Criteria for acceptance and/or rejection, b) Where in the sequence measurement and testing operations are performed, c) A record of the measurement results, and d) The type of measurement instruments required and any specific instructions associated with their use.
8.2.4.1.	**In-Process Inspection**	
8.2.4.2.	**Final Inspection**	

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	Test records shall show actual test results data when required by specification or acceptance plan. **In-process and final product inspection plans specify the following:** • **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.** **Product inspection and test records include:** • **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 including data as required.**
8.3. Control of Nonconforming Product and Materials	8.3. Control of nonconforming products **NOTE 1** *Any deviation within the execution of a project / contract is considered as nonconformity (e.g. logistics aspects, documentation)*

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	8.3.1. Control of nonconforming process
	The organization shall establish, document, and maintain a process to manage business management process variation, which includes: a) Identification, recording, and analyzing of the root causes of the variation and if the business management process is nonconforming, taking appropriate action to correct the nonconforming process. b) Evaluation whether the business management process variation has resulted in product nonconformity, and c) Identification and control of the nonconforming product in accordance with clause 8.3. **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.**
	8.3.2. Customer concession
	The organization shall obtain a customer concession or deviation permit prior to further processing, whenever the product or production process differs from what has been approved. Penaties due to concessions and deviation permits should be collected, analyzed and assigned to causers. **NOTE 1** *Penalties due to concessions and deviation permits may be considered as part of Quality Deficiency Cost.* The organization shall maintain a record of the expiration date of such a concession and/or quantity authorized. The organization shall also ensure compliance with the original or superseded specification when the authorization of the customer concession expires. Material shipped, which is subject to such a concession, shall be appropriately identified. This applies equally to purchased products.

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			The organizaiton should define and implement a customer concession process. The organization shall ensure that concessions requested by an supplier are agreed before submission to the customer. **Discussions between TE 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 or prior to required customer approvals. All product shipped under such deviations shall be suitably identified. Penalties due to concessions are to be tracked to evaluate the impact of the concession and to assign the costs relative to the responsible party.**
8.4.	**Measurement and Analysis of Organizational Performace**	8.4.	Analysts of data
			In addition to ISO 9001: 2008, the organizaiton should ensure that a process for the analysis of data is in place (see clause 8.2.2.) and the performance of this process should be meausred by a KPI (see annex 3). In addition to ISO 9001: 2008, the analysis of data shall provide information relating to external incident reports associated with the organization's products and product safety. **Data analysis of internal and external incidences is incorporated into various TE quality management system processes and activities. A KPI for data analysis is recommended.** **All functions shall use facts, data, and quality records for improvement planning, for minimizing repetitive nonconformance situations, and for determining corrective or preventive action strategies. (TEC-1000)**
8.5. **8.5.1.**	**Improvement** **Continual Improvement**	8.5.1.	Continual Improvement
			The organization should define and implement improvement processes, based on corrective and preventive actions (see clause 8.5.2 and 8.5.3).

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	TE 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. (TEC-1000)**
8.5.2. Corrective Action	8.5.2. Corrective action
	In addition to the ISO 9001: 2008 requirements, the documented procedure shall define requirements to: g) document the effectiveness and close out of corrective action. The organization should define and implement a corrective action process, which is regularly reviewed in a multidisciplinary assessment (see clause 8.5.1). **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. The corrective action process is reviewed as part of a multidisciplinary review process**
8.5.3. Preventive Action	8.5.3.
	The organization should define and implement a preventive action process, which is regularly reviewed in a multidisciplinary assessment (see clause 8.5.1). **Quality management system procedures define the preventive action process. The results of preventive actions shall be documented and maintained as a quality record. The Preventive action processes are reviewed as part of a multidisciplinary review process.**

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