Total Quality Management Requirements for Suppliers

1. INTRODUCTION

This document has been developed to help suppliers understand the quality requirements necessary to ensure a successful relationship with TE Connectivity. Communication and cooperation are key elements in achieving these high standards.

TE expects suppliers to have the following basic business principles: The supplier shall:

- Ensure that materials and services are produced in conformance to the required standards, and TE will receive defect-free product, on time, at the agreed upon terms.
- Manage facilities, processes, quality systems and personnel to consistently and cost-effectively manufacture products and furnish services that meet the needs of TE and its customers.
- Be committed to continual process improvement by emphasizing reduction of part to part variation and the elimination of all waste.
- Conduct operations in conformance with, or exceeding, all applicable environmental laws and regulations of the jurisdictions in which the supplier does business.
- Ensure all products and materials supplied meet applicable product environmental compliance requirements.
- Embrace and comply with socially important values, principles and guidelines defined in Quality Specification TEC-1015.

2. SCOPE

This specification defines the minimum quality management system requirements for suppliers of production materials, components, and assemblies and service suppliers (test labs, calibration service, tooling, warehousing/logistics) that have an impact on product quality, product environmental compliance, or delivery.

NOTE
Additional requirements are included in this specification for those suppliers providing materials that are used for Automotive and Aerospace Industry customers. (Reference Appendices B and C). These additional requirements will be noted on the purchase order or other appropriate documents when applicable.

NOTE
Additional requirements are included in this specification for those suppliers providing materials or services to a TE Medical facility. (Reference Appendix E).

2.1. Revision of this Specification

TE reserves the right to make changes to this specification and specifications referenced herein. Hard copies of this specification may not be updated. The latest version of this document is available on the TE web site at https://supplier.te.com/web/supplier-portal/home. Suppliers are responsible for ensuring that they are using the current version of this document. Suppliers shall specify any exceptions to the requirements of this document. Exceptions shall be in writing and must be approved by either a TE business unit Purchasing Manager or Global Commodity Manager.

3. APPLICABLE DOCUMENTS AND FORMS

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

| Indicates Change

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

• ISO 13485	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
• ISO 9001	Quality Management Systems Requirements
• ISO 10012	Measurement Management Systems - Requirements for Measurement Processes and Measuring Equipment
• ISO 14001	Environmental Management Systems - Requirements with Guidance for Use
• ISO/IEC 17025	General Requirements for the Competence of Testing and Calibration Laboratories
• ISO/ IATF 16949	Quality Management Systems - Requirements for the Application of ISO 9001 for Automotive Production and Relevant Service Part Organizations
• IECQ 80000	IEC Quality Assessment System for Electronic Components (IECQ
• TL 9000	Quality System Requirements for Telecommunications Industry
• BS EN 9100	Aerospace Series - Quality Management Systems
• SAE AS 9100	Quality Management Systems - Requirements for Aviation, Space and Defense Organizations
• ISO/TS 22163: 2017	Railway applications -- Quality management system -- Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector

3.2. AIAG Reference Manuals

- Advanced Product Quality and Control Plan Manual (APQP)
- Failure Mode and Effects Analysis Manual (FMEA)
- Statistical Process Control Manual (SPC)
- Measurement System Analysis (MSA)
- Production Part Approval Process Manual (PPAP)
- CQI-9 Special Process Heat Treat System Assessment
- CQI-11 Special Process Plating System Assessment
- CQI-12 Special Process Coating System Assessment

3.3. Documents

TEC-1015 TE Connectivity Guide to Supplier Social Responsibility

3.4. Website

https://supplier.te.com/web/supplier-portal/home

3.5. Reference Documents

TEC-138-702 Supplier Requirements for Product Environmental Compliance

4. DEFINITIONS

4.1. Certificate of Analysis (C of A)

A document provided by a supplier that reports and certifies the actual results of the tests performed on a shipment of products or materials.

4.2. Certificate of Conformance (C of C)

A certificate provided by a Supplier's Quality Assurance department to TE confirming that all material conforms to all applicable specifications.

4.3. Key Product Characteristics (KPC)

Those product features whose reasonably anticipated variation affect subsequent operations, product function or customer satisfaction. KPCs are established by the engineering control organization (ECO), using input from a review of product and process FMEAs and discussions with the customer and product management.

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6. SUPPLIER QUALITY MANAGEMENT SYSTEM REQUIREMENTS

6.1. Supplier Evaluation

Suppliers are encouraged to earn third party registration to ISO 9001, TL 9000, ISO/ IATF 16949 , SAE AS 9100, ISO 13485, BS EN 9100, ISO 17025, ISO 14001, ISO/TS 22163: 2017, IECQ 80000 or equivalent national standards.

6.2. Supplier Responsibilities

A. Requirements for Quoting

Requests for quotation shall be provided by the TE buyer/authorized purchasing personnel. Suppliers are to respond to the request for quote within the allocated time to the appropriate buyer/authorized purchasing personnel. All requests for exceptions to the requirements shall be documented; otherwise, full compliance with these requirements is expected.

B. Purchase Order Conditions

The supplier must agree to the terms and conditions set forth with the Purchase Order or applicable contract conditions.

C. Confidentiality

The supplier understands and agrees to hold in strict confidence all confidential information derived from TE. Suppliers may be required to sign a Confidential Disclosure Agreement (CDA), Non-disclosure Agreement (NDA), or Mutual Confidentiality Agreement (MCA). When requested by an authorized representative of TE, the supplier shall return all documents provided by TE.

D. Specification and Document Review

1. Prior to acceptance of the purchase order, the supplier shall review all engineering drawings and specifications to ascertain that they are to the engineering revision level specified on the purchase order. The supplier shall notify the appropriate buyer/authorized purchasing personnel of any errors or omissions. TE will either correct the error or arrange for a temporary deviation until correction can be made. The supplier shall not implement changes to any TE document without prior approval having been issued in writing by the TE buyer/authorized purchasing personnel.
2. The supplier is responsible for verifying that they are using the most current revision level of all documents referenced on the engineering drawings and specifications called out on the purchase order.
3. The supplier will establish a process to ensure the timely review, distribution and implementation of authorized drawing and document changes.
4. Instructions for accessing engineering drawings and specifications are available on the TE web site at https://supplier.te.com/web/supplier-portal/home.

NOTE
The Supplier Secure Document Access (SDA) application is available for suppliers to quickly search for and retrieve key documents such as Engineering Drawings and specifications. SDA has enhanced usability features, multi-language support, wild card search, watermarks, and Engineering Change Order subscription capabilities. Suppliers must have a Confidentiality Disclosure Agreement (CDA) with TE to use SDA. Your Purchasing contact will work with you to set up a CDA if you do not already have one.

NOTE
This does not apply to suppliers to the TE Medical facilities. Specifications/ Engineering drawings are issued to the supplier by the applicable TE Medical facility.

E. Suppliers are required to provide product environmental compliance documentation upon request. This documentation may include but is not limited to: surveys to gather compliance status to

legislation or customer requirements, material, content disclosure, test results to verify compliance, and disclosure of systems and procedures used to ensure compliant products.

F. Suppliers are required to purchase raw materials from authorized agents or re-sellers.

6.3. Handling and Storage Requirements

A. The supplier is responsible for the proper handling and storage of all raw material, components, and tooling supplied or consigned from TE. Any special handling, packaging, and storage requirements requested by TE will be documented on the purchase order or other appropriate documents when applicable.

B. Prior to processing, the supplier is responsible for the visual inspection of TE supplied material and verification of the correct quantity. If TE supplies nonconforming material to the supplier, the supplier shall be responsible for notifying the respective TE buyer/authorized purchasing personnel of the receipt of nonconforming material. TE buyer/authorized purchasing personnel shall provide specific instructions regarding the disposition or use of supplied nonconforming material.

6.4. Process Controls

A. The supplier is responsible for the quality of any process that affects the configuration, assembly, heat treatment, plating, and/or metallurgical properties of TE consigned or stocked material.

B. The supplier is responsible for adopting the necessary techniques and controls during all phases of manufacturing to ensure that the quality of the product being produced is both known and controlled. As a measure of continual process improvement, a capability study shall be conducted on key product characteristics with target Cpk requirements as agreed to by TE and the supplier. The supplier shall submit data or evidence of performance when requested by TE purchasing or quality personnel. Established key processes that affect the form, fit, or function of our product may not be modified by a supplier without written agreement from the TE buyer/authorized purchasing personnel.

6.5. Notification of Product or Process Changes and Product Discontinuance (obsolescence)

A. A process change is defined as any significant change to the manufacturing process, equipment modifications or replacements, changes to process parameters, the purchasing of materials from new sources, and process changes of subcontractors that could adversely affect form, fit, or function (including any change that will alter product content and/or environmental compliance status to the requirements listed in TE Hazardous Substance List, Table 2 of TEC-138-702) of the purchased material that has been accepted/approved by TE and/or our customer.

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 provides prior written notice to the buyer/ authorized purchasing personnel when product, process (that could adversely impact form, fit, function) (including any change that will alter product content and/or environmental compliance status to the requirements listed in TE Hazardous Substance List, Table 2 of TEC-138-702), or manufacturing location changes are proposed. The responsible buyer/authorized purchasing personnel must be contacted at least one hundred eighty **(180) calendar days** prior to any changes being implemented unless there is a different requirement per Business Unit in the appendixes below. The planning and strategy of any agreed changes will be done in strict co-ordination with the TE buyer/authorized purchasing personnel. Changes to product content or process should not be implemented until TE approval is given.

A discontinued product is a product (assembly, component, or material) that suppliers to TE will no longer manufacture or sell. It is important that TE is notified in writing, **360 days** prior to any planned product discontinuance so that appropriate action can be implemented to find an qualify a replacement product or source.

NOTE
Section 6.5 does not apply to suppliers to the TE Medical facilities. Refer to Appendix E for the notification of change requirements for suppliers to the TE Medical facilities

6.6. Subcontract Jobs

The supplier is not to subcontract any work related to any given purchase order without notification and written permission from TE purchasing.

The supplier shall not place any TE tooling with subcontractors without notification and written permission from TE purchasing.

6.7. Packaging and Labeling

A. The supplier shall maintain unit container traceability and identification of all lots of material (trace number, date code, etc.).

B. Packaging shall conform to all packaging and labeling requirements documented on the purchase order, product drawings, TE Packaging and Marking requirements or material specifications. When not specified, packaging and labeling are the responsibility of the supplier and shall be adequate to prevent damage or deterioration during shipment. All shipments shall be labeled as a minimum with;

1. Purchase order number
2. TE part number
3. Product/material revision level
4. Quantity
5. Country of Origin

6.8. Base Metal Material Supplies

The supplier shall have responsibility for:

A. Maintaining and providing unit container traceability and identification of all lots of material supplied by the original manufacturer (e.g. heat, master coil, delivery note, trace number, etc.).

B. Ensuring that the base metal is properly identified with the following minimum information:

1. TE purchase order number is required on the packing list and on the unit container.
2. TE raw material part number per the purchase order is required on the packing list and on the unit container label.

6.9. Polymeric Material Supplies

The supplier shall have responsibility for:

A. Maintaining and providing unit container traceability and identification of all lots of material supplied by the original manufacturer (i.e., batch, lot, etc.).

B. Ensuring that the polymeric material is properly identified on the shipping packing list and/or unit container label/marking with the following minimum information:

1. TE purchase order number is required on the packing list and on the unit container label.
2. TE raw material part number per the purchase order is required on the unit container label.
3. TE material specification number and current revision level on the packing list or C of C / C of A when applicable.
4. Manufacturer’s name (If not on the original manufacturers unit container).
5. Manufacturer’s designation/description (e.g., Valox 420 SEO).
6. Trade/generic name on the unit container label/marking, when applicable.
7. Color name/code (i.e., industry or manufacturer’s designation).

6.10. Unit Count Accuracy

Unless otherwise specified, unit count accuracy of supplied materials shall be within the following limits:

1. Reeled Material +1.0%/-0.0%

2.	Weigh Count	+0.2%/-0.0%
3.	Machine Count Bulk	+0.5%/-0.0%
4.	(Tube/Tray) Packaging	±0.0%
5.	Base Metals	± 2% (Qty. Shipped vs. Qty. Received)
6.	Resins	±2% (Qty. Shipped vs. Qty. Received)

6.11. Inspection

A. When indicated on the purchase order or other appropriate document when applicable, first article inspection data approval shall be obtained from the supplier and approved by TE prior to initiation of full production. The supplier is responsible for notifying Purchasing when first article samples and inspection data are available. Purchasing will make arrangements with the supplier to review the first article data and samples. TE first article approval does not relieve the supplier of the responsibility of assuring that subsequent production is in accordance with documented requirements.

B. When specified on the TE purchase order, one copy of a C of A or C of C shall be submitted by the supplier to the designated location.

C. The C of C and/or C of A shall certify and provide evidence (as appropriate) that the material meets all specified requirements of quality including conformance to applicable product environmental specifications.

6.12. Calibration System

A. Responsibility for the supply, maintenance, and calibration of standard measurement and test equipment, such as pin gages, thread gages, micrometers, comparators, multimeters, etc. rests with the supplier.

B. Provision for special measurement and test equipment, unique to a specific purchase order or product, shall be negotiated at time of order placement. Calibration and maintenance of such special equipment rests with the supplier, unless otherwise specified in the purchase order.

C. Gages, measuring devices, and testing equipment used to determine the acceptability of materials and tooling used in production shall be controlled and calibrated in accordance with the current revision of ISO 10012 or equivalent national standard.

6.13. Verification of Quality

A. TE and its customers reserve the right to perform any testing or inspection that may be necessary to determine that the purchase order requirements have been met, including verification at the supplier’s location if required. The supplier may be required to submit test or inspection data along with gage Repeatability and Reproducibility (R&R) study corresponding to the lot(s) being tested or inspected for comparison or correlation purposes.

B. The supplier shall permit access by representatives of TE, TE customers, and applicable regulatory agencies to the supplier’s premises (and the premises of Supplier’s subcontractors and supplier(s)) for the purpose of evaluating Supplier’s facilities, processes, goods, quality system and records.

C. C. Product accepted at receiving inspection may be found to be nonconforming during the manufacturing process. The supplier is liable for such product regardless of when a non-conformance is found.

6.14. Product/Material Non-conformance

A. The supplier shall notify the respective TE buyer/authorized purchasing personnel if nonconforming material, including failure to meet product environmental compliance requirements, has been shipped to TE. The TE buyer/authorized purchasing personnel shall coordinate the containment and disposition of suspect nonconforming material with Quality and Materials department personnel.

B. If a supplier responsible non-conformance is found at TE, its customer, or an agent of TE, upon communication of the details of the non-conformance the supplier is responsible for determining the necessary actions to establish an effective containment plan. The supplier is responsible for immediately initiating containment of any suspect product within their facility or in the supply pipeline. This shall include the present lot, or any lots currently being inventoried. The supplier shall also notify the TE buyer/authorized purchasing personnel of any suspect material that is in transit. Suppliers are required to communicate details of containment action to the TE buyer/authorized purchasing personnel or Supplier Quality Engineer within 24 hours of receiving the initial non-conformance notification or as specified by the business unit purchasing department. The communication shall be via 8-D Corrective Action Plan or Customer specified Form.

C. Suppliers may be charged back for all expenses incurred by TE as a result of delivery or quality problems attributed to that supplier. Charge backs may be transacted as a debit against open invoices. A supplier will have 60 days from the issue of defective material notification to contest the charge back and provide evidence that the non-conformance was not caused by the supplier or agents of the supplier. Hourly rates to be charged will be negotiated with the supplier and the buyer/authorized purchasing personnel.

6.15. Request for Deviation

A. The supplier is responsible for meeting all the requirements of the purchase order, drawings, and TE specifications or industry standards and Specifications (e.g., EIA, ASTM, etc.) when specified or applicable. Material that does not conform to these requirements shall not be shipped to TE, its customers or other suppliers without prior written approval having been given in the form of an approved deviation request for known non-conformance.

B. Request for deviation from requirements shall be brought to the attention of the TE buyer/authorized purchasing personnel. Approval or disapproval of supplier deviation requests will be documented and communicated to the supplier.

C. Each request for deviation shall include a statement of corrective action, person responsible for the corrective action, and estimated date of implementation of corrective action to prevent recurrence of the non-conformance.

D. Supplier shall identify, store, and ship approved deviated nonconforming material in such a manner as to keep it separate from conforming material. Where applicable, the deviation number shall be noted on the packing slip, and when requested, on all shipping containers.

6.16. Corrective Action

When requested, the supplier will submit an 8-D corrective action plan that provides the details of how the nonconformity will be resolved. TE expects a supplier to investigate the root cause(s) and respond to the TE buyer/authorized purchasing personnel or Supplier Quality Engineer with a corrective action plan within ten business days or as specified by the business unit purchasing department. The details of the investigation, corrective action plan, verification of the effectiveness of the corrective action and preventive actions shall be documented. Should the corrective action be ineffective, untimely, or performance not be restored, TE may exercise all rights available under contracts or purchase orders.

6.17. Quality Records

The supplier is responsible for maintaining the following records for each production part number manufactured or provided, as applicable:

A. Inspection records

1. First article inspection results
2. Incoming inspection
3. Set up inspection records
4. In process inspection records
5. Final inspection records

6. Dock audit results

B. Certificates of analysis

C. Certificates of compliance

D. Laboratory analysis test results

E. SPC data (if applicable)

F. Purchase orders

G. Change orders

H. Approved deviations

I. Calibration records

J. Nonconforming material records

K. Corrective action responses

L. Shipping records

M. PPAP (if applicable)

N. Environmental record

O. IMDS registration number (if applicable)

P. Production record

Q. Tool maintenance/repairing record

These records shall be maintained for a minimum of ten years or as specified by the business unit purchasing department.

6.18. Continual Improvement

TE expects that each of its suppliers support continual quality and delivery improvement by formulating and implementing continual quality and deliver improvement plans.

6.19. Business Recovery Plans

TE expects that each of its suppliers will have a documented business recovery plan. These plans shall include the following items.

A. Summary of critical business processes

B. Defined business recovery options

C. Summary of information resources necessary for business recovery

D. Summary of physical resources needed for business recovery

E. Recovery goals for critical business processes

F. List of Emergency Management Team Members

APPENDIX A – SPECIFIC REQUIREMENTS FOR SUPPLIERS OF TOOLING

Suppliers providing tools (dies, molds and their spares) are not required to be certified to ISO 9001 but are expected to implement a basic documented quality system for the scope of their manufacturing. This appendix outlines the requirements for suppliers providing tooling and where there is a conflict in this appendix to other sections within this document then this appendix takes precedence. This requirement is necessary to promote consistency and conformance of this critical commodity. The quality system shall address, as a minimum, the following elements:

Scope	Element	Description
Tool Build Only	System for Quoting	Supplier's quoting system must be well organized and reliable in regards to getting accurate quotes on time to their customers, and should include a method to track their quoting performance and work to improve it.
	Corrective Action	Supplier must have a formal system for tracking and reducing non-conformances – both internal and external.
	Quality / Inspection	Supplier must have a formal system to ensure that defects will be detected early in the fabrication process and that no defective product will get through to the customer.
	Material Control	Supplier must have a system for controlling and identifying raw materials and in-process materials. All nonconforming material must be clear identified and segregated and a clear process must be defined for dispositioning nonconforming material.
	Document Control	Supplier must have a clear process for managing and controlling various controlled documents, such as drawings, specifications and engineering changes.
	Continuous Improvement	The supplier must have a formal system for monitoring its performance in key areas (key performance indicators) and for seeking continuous improvement.
	Fabrication Scheduling, Loading and Tracking	The supplier must have a formal process for developing a reliable routing and schedule for each job and tracking the order through to completion.
	Subcontractor Controls	The supplier must have a system for maintaining and managing relationships with subcontractors.
	Equipment Maintenance Practices	Supplier must have a system for maintaining their tool room equipment in order to be effective and efficient.
Design, Build, and Condition	Design Review	The supplier must have a formal and complete system for performing design reviews for new tools which includes a review of the product design as well as the tool design.
	Tooling Conditioning	The supplier must have documented procedures for conditioning (i.e. debugging, grooming, qualifying) new tools.
	Project Management	The supplier must have a system for managing and tracking new tool project tasks and schedules.

APPENDIX B – ADDITIONAL REQUIREMENTS FOR MATERIALS SOLD TO THE AUTOMOTIVE BUSINESS SITE

1. INTRODUCTION

There are specific requirements that suppliers to TE Global Automotive Business and any TE site that is selling products to the Automotive Industry must meet and agree. This appendix outlines these requirements and where there is a conflict in this appendix to other sections within this document then this appendix takes precedence.

All the manufacturing units of TE global automotive are certified to ISO/ IATF 16949 which is the technical specification outlining the particular requirements for the application of ISO 9001 for automotive production and relevant service part organizations.

Communication between TE and the supply base is essential for the development of a successful long term relationship. To facilitate this communication TE has set up a supplier resources web page. All suppliers are expected to sign up and gain access to this web page. The web page and instruction for sign up can be accessed at https://supplier.te.com/web/supplier-portal/home

2. BUSINESS/QUALITY SYSTEM REQUIREMENTS

2.1. Quality System Requirements

Suppliers to TE Global Automotive Business Unit are required, as a minimum to be certified to ISO 9001 by an accredited 3rd party certification body. The scope of the registration must include the product, materials or services supplied to TE global automotive. Suppliers also agree to participate in a supplier development program which has the goal of achieving conformity to the ISO/ IATF 16949 technical specification.

Suppliers are expected to have readily available, and be fully familiar with the requirements of, the current revision of the following Automotive Industry Action Group (AIAG) publications, or national equivalent:

a) Advanced Product Quality and Control Plan Manual (APQP)
b) Statistical Process Control Manual (SPC)
c) Measurement System Analysis (MSA)
d) Failure Mode and Effects Analysis Manual (FMEA)
e) Production Part Approval Process Manual (PPAP)

The supplier shall notify TE buyer/authorized purchasing personnel within 5 working days should their ISO 9001 or ISO/ IATF 16949 certificate be suspended or withdrawn.

2.2. Business System Requirements

Electronic Data Interchange (EDI)

All suppliers of production parts, assemblies, components and production materials to TE plants are required to have capabilities for the exchange of purchasing documents via electronic methods. For additional information on EDI, Internet Data Exchange, or Internet Labeling contact your TE buyer/authorized purchasing personnel.

3. ADVANCED QUALITY – PRODUCT PROCESS LAUNCH

3.1. Advanced Product Quality Planning (APQP)

Suppliers are expected to implement Advanced Product Quality Planning (APQP) activities to communicate and ensure timely, high-quality product development. APQP must be consistent with the "Advanced Product

Quality Planning and Control Plan – APQP" requirements published by AIAG.

The supplier shall carry out the relevant APQP activities on all new materials, products and components supplied to TE Global Automotive. The supplier is responsible for appointing an individual to organize and manage the APQP process. Updates of the APQP status shall be provided to the TE buyer/authorized purchasing personnel on a frequency agreed to by the buyer/authorized purchasing personnel. The supplier may be required to participate in the TE' product development process and attend Product Development Team meetings. The supplier is expected to attend any meetings requested of them by the buyer/authorized purchasing personnel/ Supplier Quality Engineer.

Suppliers to TE shall have personnel trained on FMEA techniques and Statistical process control. It is expected that the current version of Statistical Process Control (SPC) and Failure Mode and Effects Analysis (FMEA) manuals published by AIAG will be used as guidance when implementing these techniques.

3.2. Measurement System Analysis (MSA)

The analysis of measuring systems is an integral part of the APQP process. TE expects suppliers to conduct measuring systems analysis evaluation on all measuring and test equipment referenced on the Control Plan.

The process is to be conducted per the latest version of Measurement System Analysis (MSA) manual published by the AIAG

3.3. Production Part Approval Process (PPAP)

The submission and approval of production parts (initial sample approval) is an integral part of the automotive supply chain. Production part approval is always required prior to the first production shipment of goods. The supplier shall follow the AIAG published PPAP procedure for each PPAP submission and all PPAP submissions are to be to AIAG Level 3 requirements unless otherwise authorized in writing by the TE buyer/authorized purchasing personnel. The actual PPAP documentation shall be submitted following the sections defined in the AIAG published PPAP manual. All reports, accreditations, and certifications must be less than one year old at the time of PPAP submission. The AIAG published PPAP manual defines the circumstances which a PPAP is required to be submitted but if the supplier requires any clarification the TE buyer/authorized purchasing personnel is to be contacted prior to the shipment of production parts.

PPAPs submitted to TE' customers are required to contain data which is less than 1 year old. Some of this data is provided by TE' suppliers. The supplier is therefore expected upon request to update any previously submitted PPAP information.

3.4. External Laboratory Accreditation

Any testing, inspection, or measurement performed by a laboratory external to the suppliers' organization shall be accredited through a 3rd party firm to ISO/IEC 17025 or national equivalent and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); **the certificate of calibration or test report shall include the mark of a national accreditation body; or there shall be evidence that the external laboratory is acceptable to the customer.**

4. PRODUCTION REQUIREMENTS

4.1. Notification/Approval of Product or Process Changes

Once the PPAP has been reviewed and approved the supplier is not authorized to make any changes to the product, raw material, the manufacturing process or the manufacturing location without the written permission of the TE buyer/authorized purchasing personnel. The process to request changes is initiated by the completion of TE form. This form is available from the buyer/authorized purchasing personnel.

The supplier shall notify TE in writing of all proposed changes prior to the implementation of any change. The planning and strategy of any agreed changes will be done in strict co-ordination with the TE buyer/authorized purchasing personnel.

PPAP will be required to be submitted per AIAG published PPAP manual before production start.

4.2. Non-conformance

If a non-conformance of purchased products/materials or services is discovered at TE, TE' customer or agent of TE the details of the non-conformance will be formally communicated by a Reject Report. To expedite the communication process, the initial notification may be by telephone or email.

The supplier is responsible for immediately initiating containment of any suspect product within their facility or in the supply pipeline.

Suppliers are required to communicate details of containment action to the TE buyer/authorized purchasing personnel or Supplier Quality Engineer within 24 hours of receiving the initial non-conformance notification. The communication shall be via 8-D Corrective Action Plan or Customer specified Form.

4.3. Containment

Suppliers are expected to implement effective containment to isolate nonconforming product/material or services. The supplier is responsible for determining the necessary actions to establish an effective containment program.

TE reserves the right to mandate, at the supplier's expense, increased levels of containment based on the nature or severity of the non-conformance.

4.3.1. Level I Containment

Level I containment is a redundant inspection process, away from the normal processing area, performed by the supplier to ensure that the defect(s) being inspected for are contained at the supplier's facility.

The supplier will be notified by letter from TE that level I containment has been mandated. The letter will document the reasons for the Level I containment, the reporting expectations from the supplier and the criteria the supplier will be required to meet to exit the level I containment. TE Buyer/authorized purchasing personnel will follow up by telephone with the supplier to ensure that the letter mandating Level 1 containment has been received by the supplier.

4.3.2. Level II Containment

Level II containment is the same as Level I except that the redundant inspection is performed by a third party representing the interests with respect to the containment of TE.

The third party is selected by the supplier, approved by TE and paid for by the supplier.

The supplier will be notified by letter from TE that level II containment has been mandated. The letter will document the reasons for the Level II containment, the reporting expectations from the supplier and the criteria the supplier will be required to meet to exit the level II containment. TE Buyer/authorized purchasing personnel will follow up by telephone with the supplier to ensure that the letter mandating Level II containment has been received by the supplier.

4.4. Corrective Action

When an incidence of non-conformance is reported to a supplier the initial step is containment. A concurrent action must be to establish the root cause of the issue and implement corrective action. TE expects a supplier to investigate the root cause(s) and respond to the TE buyer/authorized purchasing personnel with a corrective action plan within 10 business days. The details of the investigation and the corrective action plan shall be documented using TE suppliers network management system (SNMS) application program.

4.5. Chargeback

Suppliers may be charged back for all expenses incurred by TE as a result of delivery or quality problems attributed to that supplier. Charge backs will be transacted as a debit against open invoices. A supplier will have 30 days from the issue of the IRR to contest the charge back and provide evidence that the non-conformance was not caused by the supplier or agents of the supplier. Hourly rates to be charged will be negotiated with the supplier and the buyer/authorized purchasing personnel.

4.5.1. Chargeback Guidelines

a. Administrative Charges. – Each Incoming Rejection Report (IRR) will be subjected to a 2-hour minimum charge to cover the collection of data and documentation of the incident.
b. Sorting and/or Reworking – Time spent by TE personnel sorting or reworking supplier product will be charged back to the supplier based on the time spent conducting the sort/rework. If TE uses temporary or contracted services personnel to complete the rework/sort, then the fee charged by the service will be charged back to the supplier. Suppliers sorting and/or reworking at a TE location using their own resources will be charged back for administrative time spent by TE personnel related to the sort.
c. Downtime – Any and all line stoppages caused by supplier issues will be charged back based on both man hour and machine idle time. Charges will be determined by TE accounting department.
d. Customer Chargeback – All chargeback from the customers' of TE related to supplier issues will be passed on the supplier.

5. PERFORMANCE MEASURES

5.1. Supplier Performance

TE monitors the performance of their suppliers.

The supplier rating is based on Delivery and Quality metrics.

The Delivery section of the supplier performance rating is calculated on performance to Scheduled deliveries and Requested Deliveries.

The Quality section of the supplier performance rating is calculated based on rejection PPM, percentage of lots accepted, percentage of on time corrective action responses, and number of supplier responsible complaints.

5.2. Continual Improvement

Suppliers are expected to develop methods of measuring and improving their own internal performance. The preferred methodology of monitoring is the techniques used in Quality Operating System (QOS). QOS is a tool to define, track and measure, continual improvement activities.

5.3. Incoming Quality Meetings (IQ)

Suppliers who do not meet TE' performance expectations may be selected to attend an IQ Meeting. IQ Meetings are meetings designed to drive suppliers to identify the systemic/management issues that need to be addressed in order to put effective closure to an issue(s).

The planned outcome of the IQ Meeting is a mutually, agreed action plan with realistic goals and targets against which the supplier is monitored to effective closure of the issue. The personnel required to attend an IQ meeting will be decided by TE on a case by case basis.

5.4. Special Processes

Suppliers that provide products that are either zinc plated, heat treated, or coated shall comply with the applicable AIAG Publication, or national equivalent:

- CQI-9 Special Process Heat Treat System Assessment
- CQI-11 Special Process Plating System Assessment
- CQI-12 Special Process Coating System Assessment

Suppliers that provide products that are either welded or soldered shall comply with the applicable AIAG Publication, or national equivalent.

- CQI-15 Special Process Welding System Assessment
- CQI-17 Special Processes Soldering System Assessment

APPENDIX C – ADDITIONAL REQUIREMENTS FOR MATERIALS SOLD TO THE AEROSPACE, DEFENSE, AND MARINE BUSINESS SITES

There are specific requirements that suppliers to TE Global Aerospace, Defense, and Marine business unit and any TE sites that is selling products to the Aerospace, Defense, and Marine Industry must meet and agree. This appendix outlines these requirements and where there is a conflict in this appendix to other sections within this document then this appendix takes precedence.

The supplier acknowledges that the items supplied may have an end use in products for the aerospace industry. In this regard, supplier operations must be in compliance with Federal Aviation Regulations as applicable for manufacturers (Ref. FAR Part 21). The supplier will assume the responsibility for the quality of parts and/or services supplied by sub-contractors, including TE designated sources. The supplier agrees that they will not deny any responsibility for quality of their products either on the grounds that TE has approved any specification, drawing or other documentation prepared by the supplier, or on the grounds that TE accepted the items upon initial inspection, if the product is found to be unsuitable for use in subsequent operations.

Suppliers to ADM Business Units shall employ a Quality System with the goal of conformity to the latest revision level of ISO 9001 or AS-9100, or national equivalent.

Suppliers are also encouraged to maintain environmentally friendly operations and are required to notify TE in the event that products supplied are on the EPA list of regulated chemicals or if the products could have been contaminated with mercury in processing.

PURCHASING REQUIREMENTS

The supplier will maintain a listing of approved material sources with scope of approval defined and will document the process for approving, monitoring and, if necessary, disapproving those sources. The company functions with responsibility to approve material source quality systems shall also have the authority to disapprove the source.

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.

The supplier shall include right of entry provisions in subcontracts and purchase contracts, allowing the supplier, 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.

VERIFICATION OF PURCHASED PRODUCT

The supplier shall define the requirements for delegating verification of purchased parts / services to subcontractors.

The supplier shall check material test reports against specification requirements. When incoming product has been accepted on the basis of certification or test reports, periodic scheduled checks shall be made of samples of product. The frequency of checks shall be based on historical performance and other objective data concerning the subcontractor.

COUNTERFEIT MATERIALS AND PARTS

Supplier shall establish, implement and maintain a documented Counterfeit Materials and Part Prevention system in accordance with Industry Standard AS-5553.

PRODUCTION DOCUMENTATION

The supplier will maintain approved production data adequate to define production and inspection operations and the tools necessary to accomplish those operations. The production data will include

manufacturing plans that contain clear, concise and complete instructions for work that affects product quality.

NOTIFICATION AND APPROVAL OF CHANGES

Changes to production processes will be properly evaluated to confirm that desired results are achieved without adverse effects to product quality. TE Global Aerospace, Defense, and Marine Business Unit shall be notified in writing 90 days prior to any changes being made to a manufacturing process and/or a manufacturing location change that may affect the form, fit, or function of purchased product. Form, fit, and function are those characteristics and requirements defined by TE that are given to suppliers in the normal course of establishing purchasing contracts or placing Purchase Orders on the TE Supply Base. The TE Global Aerospace, Defense, and Marine Business Unit reserves the right to approve or disapprove changes to manufacturing processes and/or a manufacturing location change for purchased products.

PRODUCT DISCONTINUANCE (OBSOLESCENCE)

A discontinued product is a product (assembly, component, or material) that suppliers to TE will no longer manufacture or sell. It is important that the TE Global Aerospace, Defense, and Marine Business Unit has sufficient notice of any proposed discontinuance so that appropriate action can be implemented to find and qualify a replacement product or source. The following statement applies to all suppliers who currently provide products or have provided products to TE Global Aerospace, Defense, and Marine Business Unit in the last five years.

As a supplier to TE Global Aerospace, Defense, and Marine Business Unit, that by acceptance of Purchase Orders, I/We agree that no product manufacture or delivery will be discontinued without prior notification, in writing, 90 days prior to any planned product discontinuance.

INSPECTION REQUIREMENTS

All parts supplied to TE Aerospace Business Sites must have traceability to inspection reports and material certifications from receipt of materials through processing and delivery. This traceability shall include accountability for all product and evidence that all manufacturing operations have been completed as planned or as otherwise documented and authorized.

Supplier shall verify that inspections have been completed on products prepared for delivery. When sampling is used as the means of product acceptance, the sampling plan shall be statistically valid and appropriate and shall not allow acceptance of lots whose samples have known nonconformities.

Supplier data submittals utilized for lot acceptance in lieu of receiving inspections shall be statistically valid. The data submittal shall denote the statistically valid sampling plan or a statement shall be included on or with the data that describes the statistically valid sampling plan that was used to evaluate the product.

Documentation for inspection or test will indicate where in the sequence of operations the measurement or testing is to take place, the criteria for acceptance or rejection and any specific measurement instruments to be used. Results of the inspections or tests will be recorded. Authorities for acceptance must be defined and controlled.

For product manufactured to TE specifications a First Article Inspection Report (FAIR) may be required.

FAI approval must be granted by TE before shipment of product and in accordance with the latest revision level of AS9102 Aerospace First Article Inspection Requirement. When directed by TE, Supplier shall document FAIs within the licensed Net-Inspect software.

Partial or Re-accomplishment of a First Article Inspection shall also be done in accordance with the latest revision level of AS9102 Aerospace First Article Inspection Requirement, section 5.3.

First article data must include verification of materials and all specifications and tolerances on the prints, the actual reading of each dimension, a numbered print to correlate to the recorded data and

must include the print revision level. Where physical testing is required, test results must also be documented on the FAIR. If the FAI sample is accepted, the remainder of the lot will be inspected in accordance with the supplier's final inspection plan.

All out of tolerance conditions will be listed and corrected or reported to TE Quality Assurance prior to delivery of the supplies.

Suppliers shall conduct periodic First Article Inspection for Aerospace Products. Tooling shall be approved and periodically verified through FAI. Tools out of service shall be properly stored and periodically checked.

When specified on the purchase order all products shipped to TE Aerospace sites shall be accompanied by a certificate of compliance (C of C) stating that the materials provided conform to the order requirements. This C of C shall include the TE part number and revision level, purchase order number, quantity of parts in the shipment, date and the release authority's signature or stamp. Material analysis reports should accompany all raw material or contact material shipments. Supplier shall supply current Material Safety Data Sheets (MSDS) for raw materials and chemical compounds. Shipments not accompanied by the required documentation are subject to rejection.

NONCONFORMING PRODUCT

The supplier shall notify TE buyer/authorized purchasing personnel promptly (not to exceed 24 hours or the next business day) when a nonconformity is discovered that may affect product already delivered.

Suppliers shall respond to parts non-conformance reports and corrective action requests within the due dates indicated on the request. If an extension is necessary, the supplier must request one from the originator.

Procedures for corrective action shall provide for flow down of these requirements when the root cause has been determined to be the responsibility of a subcontractor.

Product disposition as "scrap" shall be conspicuously marked until physically rendered useless for original purpose.

The supplier shall establish written procedures and implement provisions for the prevention, detection, and removal of foreign objects from products supplied to the TE Aerospace, Defense, and Marine business unit. Employees shall be trained on these procedures.

Non-conformance If a non-conformance of purchased products/materials or services is discovered at TE, TE' customer or agent of TE the details of the non-conformance will be formally communicated by a Reject Report. To expedite the communication process, the initial notification may be by telephone or email.

The supplier is responsible for immediately initiating containment of any suspect product within their facility or in the supply pipeline.

Suppliers are required to communicate details of containment action to the TE buyer/authorized purchasing personnel or Supplier Quality Engineer within 24 hours of receiving the initial non-conformance notification. The communication shall be via 8-D Corrective Action Plan or Customer specified Form.

Containment

Suppliers are expected to implement effective containment to isolate nonconforming product/material or services. The supplier is responsible for determining the necessary actions to establish an effective containment program.

TE reserves the right to mandate, at the supplier's expense, increased levels of containment based on the nature or severity of the non-conformance.

Level I Containment (Yellow Status)

Level I containment is an increased inspection process, separate from the normal process, performed by the supplier to ensure that the defect(s) being inspected for are contained at the supplier's facility. The defect concern for part number of concern shall be 100% inspected with documented inspection results. Supplier must submit the data results with each lot. Each Level 1 Containment lot must be uniquely identified (i.e.; "green dot") on outside of container / packaging signifying Level 1 Containment lot. When (3) consecutive lots are received without a reject concern the Level 1 Containment (Yellow Status) will no longer be required.

The supplier will be notified by letter from TE that Level I Containment (Yellow Status) has been mandated. The letter will document the reasons for the Level I Containment, the reporting expectations from the supplier and the criteria the supplier will be required to meet to exit the Level I Containment. TE Buyer/authorized purchasing personnel will follow up by telephone with the supplier to ensure that the letter mandating Level 1 Containment has been received by the supplier.

Level II Containment (Red Status)

Level II Containment (Red Status) is implemented when the same supplier has had a second rejected lot for any part number in the same fiscal year. The inspection requirements are the same as Level I except that the redundant inspection is performed by a third party representing the interests with respect to the containment of TE.

The third party is selected by the TE, approved by TE, and placed at the receiving inspection function of the TE receiving facility and paid for by the supplier.

The supplier will be notified by letter from TE that Level II Containment (Red Status) has been mandated. The letter will document the reasons for the Level II Containment, the increased expectations from the supplier and the criteria the supplier will be required to meet to exit the Level II Containment. TE Buyer/authorized purchasing personnel will follow up by telephone with the supplier to ensure that the letter mandating Level II Containment has been received by the supplier.

Corrective Action

When an incidence of non-conformance is reported to a supplier the initial step is containment. A concurrent action must be to establish the root cause of the issue and implement corrective action.

TE expects a supplier to investigate the root cause(s) and respond to the TE buyer/authorized purchasing personnel with a corrective action plan within 10 business days. The details of the investigation and the corrective action plan shall be documented using TE suppliers network management system (SNMS) application program.

Chargeback

Suppliers may be charged back for all expenses incurred by TE as a result of delivery or quality problems attributed to that supplier. Charge backs will be transacted as a debit against open invoices. A supplier will have 30 days from the issue of the IRR to contest the charge back and provide evidence that the non-conformance was not caused by the supplier or agents of the supplier. Hourly rates to be charged will be negotiated with the supplier and the buyer/authorized purchasing personnel.

Chargeback Guidelines

a. Administrative Charges. – Each Incoming Rejection Report (IRR) will be subjected to a 2-hour minimum charge to cover the collection of data and documentation of the incident.

b. Sorting and/or Reworking – Time spent by TE personnel sorting or reworking supplier product will be charged back to the supplier based on the time spent conducting the sort/rework. If TE uses temporary or contracted services personnel to complete the rework/sort, then the fee charged by the service will be charged back to the supplier. Suppliers sorting and/or reworking at a TE location using their own resources will be charged back for administrative time spent by TE personnel related to the sort.
c. Downtime – Any and all line stoppages caused by supplier issues will be charged back based on both man hour and machine idle time. Charges will be determined by TE accounting department.
d. Customer Chargeback – All chargeback from the customers' of TE related to supplier issues will be passed on the supplier.

PERFORMANCE MEASURES

Supplier Performance

TE monitors the performance of their suppliers.

The supplier rating is based on Delivery and Quality metrics.

The Delivery section of the supplier performance rating is calculated on performance to Scheduled deliveries and Requested Deliveries.

The Quality section of the supplier performance rating is calculated based on DLPM- percentage of lots accepted, number of lots rejected, and number of supplier responsible customer complaints.

Continual Improvement

Suppliers are expected to develop methods of measuring and improving their own internal performance. The preferred methodology of monitoring is the techniques used in Quality Operating System (QOS). QOS is a tool to define, track and measure, continual improvement activities.

Focus Review Meetings

Suppliers who do not meet TE' performance expectations may be selected to attend a supplier Focus Review Meeting. These meetings are designed to drive suppliers to identify the systemic/management issues that need to be addressed in order to put effective closure to an issue(s) in place along with a step down plan to achieve goals.

The planned outcome of the Focus Review Meeting is a mutually, agreed to step down plan with realistic goals and targets against which the supplier is monitored to effective closure of the issue. The personnel required to attend a Focus Review Meeting will be decided by TE on a case by case basis.

APPENDIX D – ADDITIONAL REQUIREMENTS FOR MATERIALS SOLD TO THE RAIL AND MASS TRANSPORTATION

There are specific requirements that suppliers to TE Rail and Mass Transportation business unit and any TE sites are selling products to the Rail and Mass Transportation Industry must meet and agree. This appendix outlines these requirements and where there is a conflict in this appendix to other sections within this document then this appendix takes precedence.

The supplier acknowledges that the items supplied may have an end use in products for the Rail and Mass Transportation industry. The supplier will assume the responsibility for the quality of parts and/or services supplied by sub-contractors, including TE designated sources. The supplier agrees that they will not deny any responsibility for quality of their products either on the grounds that TE has approved any specification, drawing or other documentation prepared by the supplier, or on the grounds that TE accepted the items upon initial inspection, if the product is found to be unsuitable for use in subsequent operations.

Suppliers to Rail and Mass transportation shall employ a Quality Management System (QMS) that complies with ISO 9001 at least and adopt ISO/TS 22163: 2017 requirements defined further where applicable.

Suppliers are expected to have readily available, and be fully familiar with the requirements of, the current revision of the following Automotive Industry Action Group (AIAG) publications, or national equivalent:

- Advanced Product Quality and Control Plan Manual (APQP)
- Statistical Process Control Manual (SPC)
- Measurement System Analysis (MSA)
- Failure Mode and Effects Analysis Manual (FMEA)
- Production Part Approval Process Manual (PPAP)

The supplier shall notify TE buyer/authorized purchasing personnel within 5 working days should their ISO 9001 or any other QMS certificate be suspended or withdrawn.

The supplier shall include right of entry provisions in subcontracts and purchase contracts, allowing the supplier, 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.

PURCHASING REQUIREMENTS

The supplier will maintain a listing of approved suppliers with scope of approval defined and will document the process for approving, monitoring and, if necessary, disapproving those sources.
Ensure that the function having responsibility for approving supplier quality systems has the authority to reject the use of source.
Ensure that customer requirements are cascaded down through the supply chain and especially that both, the supplier and possibly its sub-contractor use customer approved special processes where required. Assess and manage risks for supply of critical products through the supply chain.

VERIFICATION OF PURCHASED PRODUCT

The supplier shall define the requirements for delegating verification of purchased parts / services to subcontractors.
The supplier shall check material test reports against specification requirements. When incoming product has been accepted on the basis of certification or test reports, periodic scheduled checks shall be made of samples of product. The frequency of checks shall be based on historical performance and other objective data concerning the subcontractor.

CONTINGENCY PLAN

The organization shall prepare contingency plans to mitigate the event of an emergency such as utility interruptions, interruptions in the supply chain, labour shortages, key equipment failure and field returns taking into account the output of the resource analysis including a succession plan

REVIEW OF REQUIREMENTS TO THE PRODUCT

The organization shall have a process to ensure that identified requirements 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 ● complete, clear, precise, unequivocal, verifiable, testable, maintainable and feasible

TENDER MANAGEMENT

Organization shall ensure that requirements identified during tender phase are processed as defined above in paragraph „REVIEW OF REQUIREMENTS TO THE PRODUCT“.
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. Organization shall confirm and document the feasibility of the proposed Product in the tender. During the tender review the organization shall approve offer including planning, resources and pricing.
As a minimum, Project / Product requirements as well as risks and opportunities shall be identified, controlled and validated.

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 including scope management, time management, cost management, quality management, human resources management, communication management, risk and opportunity management and configuration management.

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.

DESIGN AND DEVELOPMENT INPUTS

Reliability, Availability, Maintenance and Safety (RAMS) and Life Cycle Costs (LCC) shall be considered as design inputs (where applicable).
End of life of product should be considered as design input (where applicable).

EXTERNAL LABORATORY ACCREDITATION

Any testing or measurement performed by a laboratory external to the suppliers’ organization shall be accredited through a 3rd party firm to ISO/IEC 17025 or national equivalent.

CONTROL OF NONCONFORMING PROCESS

The organization shall establish, document and maintain a process to manage business management process variation, which includes:

- identification, recording and analysis of the root causes of the variation and if the business management process is non conform, taking appropriate action to correct the nonconforming process
- evaluation whether the business management process variation has resulted in product nonconformity
- identification and control of the nonconforming product if business management process resulted to the nonconforming product

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

SPECIAL PROCESS MANAGEMENT

ISO/TS 22163: 2017 identified following special processes relevant for rail sector, however further processes may be considered by the organization depending on rail products.

- Bonding and sealing
- Casting/Molding
- Crimping
- Force fitting or shrink fitting
- Forging
- Heat treatment
- Laminating (composites,…)
- Riveting
- Surface treatment (painting, shot peening, coating, corrosion protection)
- Torque tightening
- Welding (including soldering and brazing)

Special process shall be managed according to the contractual and/or internal requirements.

The supplier 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.

APPENDIX E – ADDITIONAL REQUIREMENTS FOR MATERIALS OR SERVICES PROVIDED TO A TE MEDICAL (TEM) FACILITY.

E.1 INTRODUCTION

A. There are specific requirements that suppliers to TE Medical Business and any TE site that is selling products to the TE Medical Business must meet and agree. This appendix outlines these requirements and where there is a conflict in this appendix to other sections within this document then this appendix takes precedence.

B. Supplier may be supplying to TEM certain components, raw materials, labels, and/or packaging, for TEM's use in connection with the design and manufacture of medical devices via a confirmed Purchase Order. In consideration of the foregoing, supplier agrees to comply with the obligations set forth in this document.

C. Supplier of services may be performing for a testing, calibration, or other services to TEM which may be used in connection with the design and manufacture of medical devices via a confirmed Purchase Order. In consideration of the foregoing, supplier agrees to comply with the obligations set forth in this document.

E.2 CHANGE NOTIFICATION

A. Unless otherwise covered in an applicable specification, no temporary or permanent changes to supplier's process, manufacturing, specification, product marking, vendor, equipment, inspection and test methods, facility, packaging, labeling, shipping, software or materials which have the potential to affect TEM quality, specifications, documentation, traceability, manufacturing, form, fit, function, performance, life, reliability, sterility, safety, environmental compatibility or chemical characteristics of products (collectively "Changes") shall be made or incorporated in Products without the prior written approval of TEM, including such Changes resulting from the implementation of corrective and preventive actions. Supplier's prior written notice of a proposed Change to TEM shall include the details regarding such proposed Change, samples of the affected Product, and such other appropriate information as may be requested by TEM. Without limiting the foregoing, all such proposed Changes shall be submitted to TEM at least one hundred and twenty (120) days prior to supplier's proposed date of implementation for such Change unless the parties mutually agree otherwise. Supplier shall not implement any such Change without TEM's prior written approval. Notwithstanding the foregoing, if events requiring such Change are beyond the reasonable control of Supplier, Supplier shall notify TEM in writing within two business days of awareness by Supplier of such events.

B. In addition to the foregoing, if supplier desires to make any change in supplier's location of manufacturing, supplier shall provide prior written notice to TEM, including the details regarding such proposed change, and such other information requested by TEM. Without limiting the foregoing, all such changes shall be submitted in writing to TEM at least twenty-four (24) months prior to supplier's proposed date of implementation for such change, unless the parties mutually agree otherwise. Supplier shall not implement any change in the location of manufacturing of any product without TEM's prior written approval. Notwithstanding the foregoing, if events requiring such change are beyond the reasonable control of supplier, supplier shall notify TEM in writing within two (2) business days of awareness by Supplier of such events.

C. Supplier shall immediately notify TEM in writing as soon as supplier becomes aware of regulatory or ISO inspections and/or other communications with regulatory or ISO authorities related to product or that would in any way impact the product or Supplier's performance of its responsibilities hereunder.

E.3 FAILURE ANALYSIS AND CORRECTIVE ACTION

A. As needed, TEM may require supplier to assist with complaint investigations to investigate the cause of any complaints and determine any required corrective actions if the product is deemed to be out of compliance with the specifications. Within thirty (30) days after Supplier's receipt of a request from TEM to perform a complaint investigation (or any longer time period to which TEM agrees), Supplier shall perform such complaint investigation and provide to TEM a written report of such complaint investigation, including a complete investigation that contains a root cause analysis and corrective action recommendations. In connection with a complaint investigation, TEM may request formal corrective action in addition to the complaint handling process described above, in which case, supplier shall: (i) respond to such request with a containment and remediation plan within two business days (unless TEM specifies a later deadline); (ii)

obtain TEM's written approval prior to implementing any corrective action, (iii) complete all corrective actions approved by TEM within ninety (90) days after TEM's approval of such action or any other mutually agreed upon deadline, and (iv) if requested by TEM, provide written certification of such completion and evidence of effectiveness.

E.4 INSPECTION AND ACCESS

A. Subject to the restrictions on disclosure of information contained in any signed Confidentiality Disclosure Agreement, if applicable, supplier shall provide TEM and its representatives with such documentation, information and reasonable access to facilities and personnel (including TEM's right to audit supplier and its operations during normal business hours with at least two business days' prior notice for a "for cause" inspection, or at least fifteen (15) business days for a routine inspection) as TEM may reasonably request. This includes copies of all requested documentation related to the product design, manufacturing processes, material/device history records, specifications, compliance with raw material and component suppliers, proof of manufacturability (including packaging and labeling), regulatory approvals, regulatory or ISO inspections, and other communications with regulatory or ISO authorities that may be generally or specifically related to the products. Supplier shall promptly take action as required by TEM to correct any deficiencies identified by TEM or its representatives relating to the production of any product. Supplier shall reasonably assist TEM in arranging visits and inspection of the plants at which supplier's vendors manufacture any raw material, component, or sub-assembly or perform any contract service for any product.

E.5 SUPPLIER'S VENDORS

A. Supplier shall establish and maintain appropriate controls for its vendors of any contract services, materials, components, and sub-assemblies incorporated into products, including periodically evaluating their performance. At TEM's request, supplier shall perform a quality system assessment of the vendors who provide supplier with raw materials, components, sub-assemblies or contract services for any products.

E.6 RECORDS

A. For a period of seven (7) years after delivery to TEM of each product, supplier shall: (a) maintain traceability records for each product, including the manufacture date and lot number of each unit of product and each component and material comprising product; and (b) promptly provide TEM a copy of such records without charge upon TEM's request. Upon request for urgent matters, supplier shall provide requested quality records to TEM within two business days.

E.7. TEST LABORATORIES/CALIBRATION PROVIDERS ONLY

A. Without prior written approval of TEM, Laboratory/Calibration Provider shall not subcontract, with the exception of subcontractors accredited to ISO17025 and where the scope of that accreditation explicitly covers the specific test/service being outsourced, outsource or permit any third party to perform any service relating to the Testing/Calibration Services. Any subcontractors shall agree to comply with the obligations of the Laboratory/Calibration Provider contained in this Agreement.