Quality Assurance Manual

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1. Purpose & Scope
   1.1. Purpose
      1.1.1. ZENTECH Manufacturing, Inc. is an Electronic Manufacturing Services (EMS) provider for all types of assemblies for the consumer, commercial, defense, aerospace and medical industries.
   1.2. Scope
      1.2.1. Contract Design, development, assembly and qualification of electrical and mechanical systems, electronic circuit cards, cable and wiring harnesses, electromechanical enclosures, RF electronics, control systems, and system integration for; government, aerospace, avionics, defense, medical, commercial, consumer product, and original equipment manufacturers.
   1.3. Exclusions
      1.3.1. The following are exclusions to the ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes as the organization does not currently have the necessary facilities.
         1.3.1.1. 7.5.1.3 Requirements for sterile medical devices.
         1.3.1.2. 7.5.2.2 Requirements for sterile medical devices.
         1.3.1.3. 7.5.3.2.2 Requirements for active Implantable medical devices.
2. Applicable Documents
   2.1. Prerequisite Documents
      2.1.1. ISO 9001:2008 Quality Management System – Requirements
      2.1.2. ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for regulatory purposes
      2.1.3. AS 9100:2009 Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
   2.2. Statutory and Regulatory Documents
      2.2.1. OSHA Standard 29 CFR 1910 (General Industry)
      2.2.2. ANSI/ESD S20.20 - Protection of Electrical and Electronic Parts Electrostatic Discharge Control
      2.2.3. IPC-A-610 - Acceptability of Electronic Assemblies
      2.2.4. IPC-A-600 – Acceptability of Printed Boards
      2.2.5. IPC-A-620 – Requirements and Acceptance for Cable & Wire
      2.2.6. J-STD-001 – Requirements for Soldered Assemblies
      2.2.7. J-STD-020 - Moisture/Reflow Sensitivity Classification for Surface Mount Devices
      2.2.8. J-STD-033 - Standard for Handling, Packing, Shipping and Use of Moisture Sensitive Devices
   2.3. Peer Documents
      2.3.1. 4.2.3 Control of Documents Procedure
      2.3.2. 4.2.4 Control of Records Procedure
      2.3.3. 5.3 Zentech Quality Policy
   2.4. Subordinate Documents
      2.4.1. 6.2.2 Competence, Training and Awareness Procedure
      2.4.2. 6.4.3 Electrostatic Discharge (ESD) Controls Procedure

2.4.3. 6.4.4 Unique Work Environment Procedure
2.4.4. 7.1.2 Risk Management Procedure
2.4.5. 7.1.3 Configuration Management Procedure
2.4.6. 7.2.1 Product Requirements Determination Procedure
2.4.7. 7.3.1 Design and Development Control Procedure
2.4.8. 7.3.2 Design and Development Inputs Procedure
2.4.9. 7.3.3 Engineering Design and Development Outputs Procedure
2.4.10. 7.3.4 Engineering Design and Development Review Procedure
2.4.11. 7.3.5 Design and Development Verification Procedure
2.4.12. 7.3.6 Engineering Design and Development Validation Procedure
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2.4.19. 7.5.1 Control of Production and Service Procedure
2.4.20. 7.5.2 Validation of Processes Procedure
2.4.21. 7.5.3 Identification and Traceability Procedure
2.4.22. 7.5.4 Customer Property Procedure
2.4.23. 7.5.5 Preservation of Product Procedure
2.4.24. 7.6 Control of Monitoring and Measuring Equipment Procedure
2.4.25. 8.2.1 Customer Satisfaction Procedure
2.4.26. 8.2.2 Internal Audits Procedure
2.4.27. 8.2.4 Product Inspection and Acceptance Instruction
2.4.28. 8.3 Control of Nonconforming Material Procedure
2.4.29. 8.4 Analysis of Data Procedure
2.4.30. 8.5.1.2 Quality Alert Procedure
2.4.31. 8.5.1.4 Adverse Events Advisory Notice Procedure
2.4.32. 8.5.2 Corrective Action Procedure
2.4.33. 8.5.3 Preventive Action Procedure

2.5. Terms and Definitions

2.5.1. Unless otherwise specified herein, the terms and definitions included in the Prerequisite documents (above) apply.

3. Responsibility

3.1. The Management Representatives Office, assigned by the General Manager's Office, is responsible for the implementation, maintenance and execution of this Quality Assurance Manual, the Quality Management System, and to define the processes required to document, establish and maintain the Quality Management System.

3.2. All other management offices within the organization shall support the Management Representatives Office in the design, documentation, implementation and maintenance of this Quality Assurance Manual and the Quality Management System.

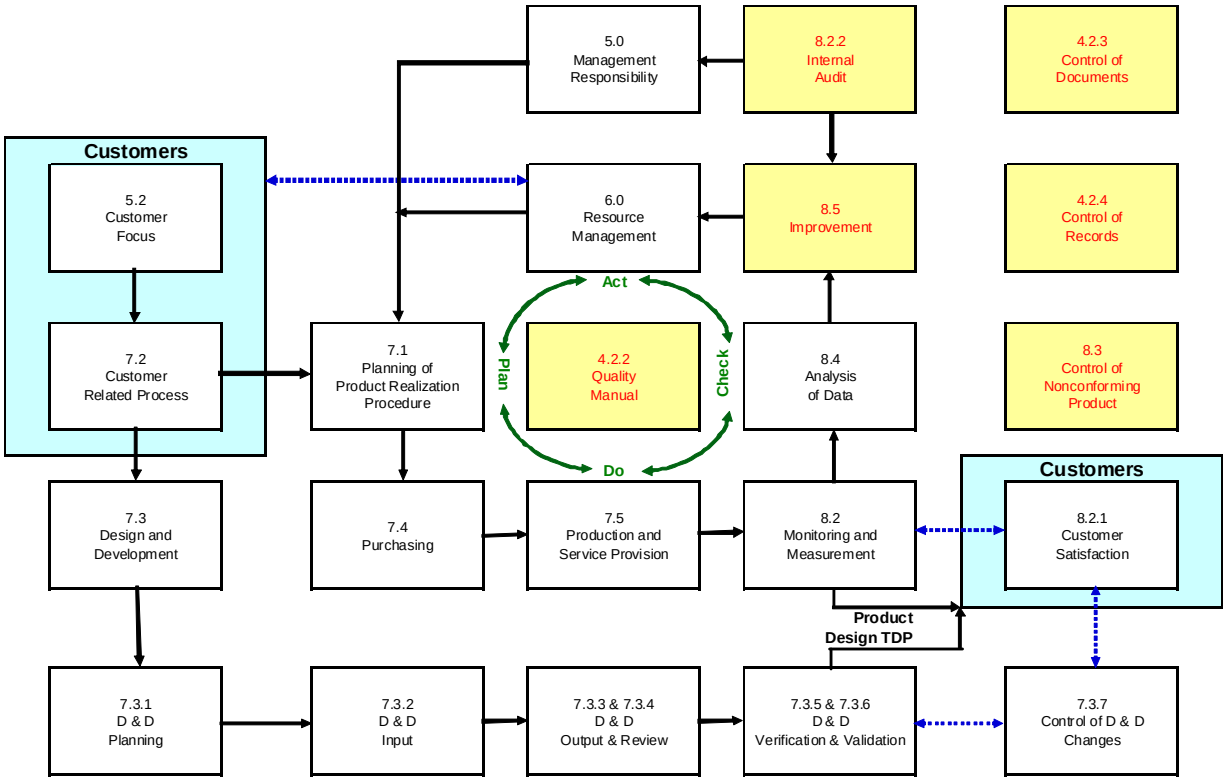
4. Quality Management System
   4.1. General Requirements
      4.1.1. The organization has established, documented, implemented and maintains a quality management system and maintains and continually improves its effectiveness according to this Quality Assurance Manual, and the applicable documents established for the quality management system including customer and applicable statutory and regulatory quality management system requirements indicated (see 2.0, Applicable Documents) herein.
      4.1.2. The General Manager's Office has appointed a member of the organization's management (Management Representative) who, irrespective of other responsibilities, has been delegated the responsibility and authority to ensure processes needed for the quality management system are established, implemented and maintained. The organization's General Manager reviews the organization's quality management system, at planned intervals (see 5.6, Management Review), to ensure its continuing suitability, adequacy and effectiveness.
         4.1.2.1. The Manufacturing Management Office maintains the Manufacturing Engineering activity to ensure the availability of information necessary to support the operation of the identified processes.
         4.1.2.2. The Product Assurance Office maintains the Quality Engineering activity to ensure the effective monitoring of the identified processes.
         4.1.2.3. The Human Resources Office ensures the availability of qualified personnel necessary to support the operation and monitoring of the identified processes.
         4.1.2.4. The Operations Management Office ensures the availability of adequate environment and infrastructure necessary to support the operation and monitoring of the identified processes.
         4.1.2.5. Key Operating Indicators, depicting the effectiveness of the identified processes from measurement data collected and analyzed are implemented, maintained and reported to the General Manager's Office at planned intervals (see 5.6, Management Review).

4.1.3. Primary processes within the organization are depicted below. The sequence of interaction begins with defined requirements established by the Program Management Office and passed on to the Subcontract and Procurement Office, and the Manufacturing Management Office. Raw material flows from receiving into Product Realization Processes. Semi-finished product flows into the Quality and Test functions. Completed product is processed through Packaging and Shipping to the Customer. Shipping/Receiving processes provide data to the Finance and Accounting Office for accounting purposes.

4.1.3.1. Each of the identified processes are assigned to an appropriate management office who shall ensure the outcomes satisfy the interested parties and that corrective, preventive and/or improvement actions, as required, are carried out.

4.1.3.2. Outsourcing of processes and/or product shall be controlled and verified to conform to all requirements outlined in the Quality Management System. Conformance verification may take place in the form of Certificates of Conformance, on-site inspection and/or receiving inspection processes.

4.1.4. Primary Processes Flow/Block Diagram



4.2. Documentation Requirements

4.2.1. General Documentation Requirements

4.2.1.1. The quality management system documentation includes a documented quality policy (see 5.3 Quality Policy), statements of quality objectives (see 5.4.1 Quality Objectives), this quality manual (Ref; 4.2.2 Quality Assurance Manual), documented procedures, documents determined by the organization to be necessary and any other documentation specified by national or regional regulations (see 2.0 Applicable Documents) and records (see 4.2.4 Control of Records) required by the management system to ensure the effective planning, operation and control of its processes.

4.2.1.2. The organization ensures that personnel have access to, and are aware of, relevant quality management system documentation and changes by making the pertinent information readily available on the organizations data management system and information flow-down through management interaction.

4.2.2. Quality Manual

4.2.2.1. The organization has established and maintains this quality manual (Ref; 4.2.2 Quality Assurance Manual) that includes the scope of the management system and the details of any exclusions (see 1.2 Scope).

4.2.2.2. Procedures and other documents required by the quality management system are included in, or referenced in this quality manual (see 2.0 Applicable Documents).

4.2.3. Control of Documents

4.2.3.1. The Document Control Office is responsible for the control of documents required by the Quality Management System according to the 4.2.3 Control of Documents Procedure.

4.2.4. Control of Records

4.2.4.1. The Document Control Office is responsible for the control of records required by the Quality Management System according to the 4.2.4 Control of Records Procedure.

5. Management Responsibility
   5.1. Management Commitment
      5.1.1. The top management of Zentech Manufacturing, Inc. demonstrates its commitment to the development, implementation, maintenance and continual improvement of the quality management system represented by this Quality Assurance Manual, and the applicable documentation referenced herein, as the only management system employed by the enterprise.
      5.1.2. The General Manager's Office demonstrates and maintains the effectiveness of this management system by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements throughout this management system, periodic reviews (see 5.6, Management Review), establishing the Quality Policy (see 5.3, Quality Policy, below, and the policy; 5.3 Zentech Quality Policy), ensuring objectives are established (see 5.4.1, Quality Objectives, below), conducting periodic management reviews (see 5.6, Management Review, below), and ensuring the availability of necessary resources (see 6.0, Resource Management, below).
   5.2. Customer Focus
      5.2.1. The Program Management Office is responsible to ensure that customer requirements are determined and are met according to 7.2 Customer Related Processes (below).
      5.2.2. The Product Assurance Office is responsible to ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved according to 8.2 Monitoring and Measurement (below).
   5.3. Quality Policy
      5.3.1. The quality policy is maintained as 5.3 Zentech Quality Policy, a controlled document included as an integral element of the management system (see 2.0 Applicable Documents, above).
      5.3.2. The Management Representative Office, assigned by the General Manager's Office, is responsible for the implementation and maintenance of the policy.
      5.3.3. This policy is reviewed annually for continuing suitability by top management, as an element of management reviews (see 5.6, Management Review, below), to ensure the policy; is appropriate to the purpose of the organization, includes a commitment to comply with the requirements and maintain the effectiveness of the quality management system, provides a framework for establishing and reviewing quality objectives, and is communicated and understood within the organization.

5.4. Planning

5.4.1. Quality Objectives

5.4.1.1. The Management Representative Office, assigned by the General Manager's Office, is responsible to ensure that objectives, including those needed to meet requirements for product (see 7.1, Planning of Product Realization, below), are established at relevant functions and levels within the organization.

5.4.1.2. The objectives shall be measurable and consistent with the quality policy.

5.4.1.3. Objectives are established annually as an element of management reviews (see 5.6, Management Review, below).

5.4.1.4. At minimum, objectives are established for each of the organizations primary processes (see 4.1.4, Primary Processes Flow/Block Diagram, above).

5.4.1.4.1. Each established objective is assigned to one or more management office(s) to ensure the objective is defined to include specific, measurable, attainable, required and time-bound elements that are consistent with the organizations quality policy and guiding goals.

5.4.1.4.2. The assigned management office shall ensure the defined objective is reviewed and approved by the General Manager's Office.

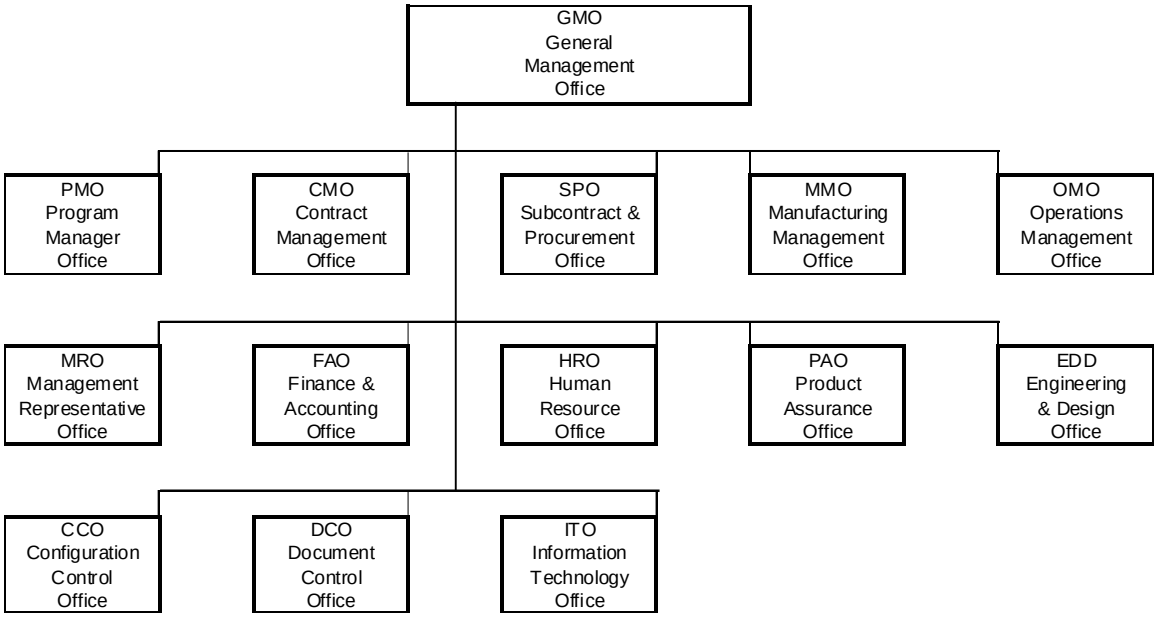
5.4.1.4.3. The Product Assurance Office shall maintain metrics, progress reporting, and objective documentation (see 8.5 Improvement, below).

5.4.2. Quality Management System Planning

5.4.2.1. The Management Representative Office, assigned by the General Manager's Office, is responsible to ensure that the planning of the quality management system is carried out in order to meet requirements (see 4.1, QMS General Requirements, above), as well as the quality objectives (see 5.4.1, Quality Objectives, above), and the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.4.2.1.1. The Management Representative Office and/or the Product Assurance Office shall ensure the effect of proposed changes on the management system is considered prior to the implementation of changes, and shall review the actual effect of changes, following any change implementation (see 8.5, Improvement, below).

5.5. Responsibility, Authority and Communication



5.5.1. Responsibility and Authority

5.5.1.1. The General Manager's Office has established a series of management offices (see diagram above) and defined responsibilities and authorities including all elements and sub-elements of the management system.

5.5.1.2. The Management Representatives Office annually communicates to the organization; the persons assigned to each management office in an Annual Responsibilities and Authorities Memo, published to all employees following the annual management review (see 5.6, Management Review, below).

5.5.1.3. Management office responsibilities and authorities are defined within this quality assurance manual (Ref; 4.2.2 Quality Assurance Manual) including applicable documents (see 2.0 Applicable Documents, above).

5.5.1.4. Established management offices perform and verify work affecting quality, have the independence and authority necessary to perform these tasks, and participate equally as team members to ensure customer, statutory and regulatory requirements are met.

5.5.1.5. Established Management Offices

5.5.1.5.1. MRO, Management Representative Office is responsible for all activities defined by the management system including those specifically defined within 5.5.2, Management Representative, below.

5.5.1.5.2. PMO, Program Management Office is responsible for all activities defined by the management system including; Project Management, Integrated Product Development, Product Lifecycle & Logistics, and Customer Care & Support.

5.5.1.5.3. FAO, Finance and Accounting Office is responsible for all activities defined by the management system including; Accounts Receivable, Accounts Payable, Payroll Accounting, and Employee Benefits.

5.5.1.5.4. CMO, Contract Management Office is responsible for all activities defined by the management system including; Marketing, Sales, Contract Administration, and Project Controls.

5.5.1.5.5. HRO, Human Resource Office is responsible for all activities defined by the management system including; Recruiting, Performance Appraisal, Succession Planning, and Salary Administration.

5.5.1.5.6. SPO, Subcontract and Procurement Office is responsible for all activities defined by the management system including; Subcontract Management, Commodity Procurement, Pack & Ship, and Inventory Control.

5.5.1.5.7. PAO, Product Assurance Office is responsible for all activities defined by the management system including; Quality Engineering, Quality Control, Test Engineering, and Production Test.

5.5.1.5.8. MMO, Manufacturing Management Office is responsible for all activities defined by the management system including; Product Realization, Process Engineering, Preventive Maintenance, and Production Control.

5.5.1.5.9. EDD, Engineering Design and Development is responsible for all activities defined by the management system including; Component, Systems, Electronics, Ergonomics, Mechanical, and Software Engineering.

5.5.1.5.10. OMO, Operations Management Office is responsible for all activities defined by the management system including; Environmental Health & Safety, Facility Maintenance, and Disaster Preparedness & Recovery.

5.5.1.5.11. CCO, Configuration Control Office is responsible to implement and maintain the configuration management process including planning, identification, change control and configuration status.

5.5.1.5.12. DCO, Document Control Office is responsible to control documents required by the management system including approval, identification, change control and distribution control.

5.5.1.5.13. ITO, Information Technology Office is responsible to maintain the organizations communication and information infrastructure.

5.5.1.5.14. MPO, Manufacturing Planning Office is responsible to plan, implement and maintain the organizations requirements planning subsystem.

5.5.2. Management Representative

5.5.2.1. The General Manager's Office appoints a member of the organization's management who, irrespective of other responsibilities, has the responsibility and authority that includes; ensuring that processes needed for the quality management system are established, implemented and maintained, reporting to top management on the performance of the quality management system and any need for improvement, ensuring the promotion of awareness of statutory, regulatory and customer requirements throughout the organization, and the organizational freedom and unrestricted access to top management to resolve quality management issues.

5.5.2.1.1. The person appointed as Management Representative is included in the Annual Responsibilities and Authorities Memo, published to all employees following the annual management review (see 5.6, Management Review, below).

5.5.3. Internal Communication

5.5.3.1. The General Manager's Office ensures that appropriate communication is flowed to the established management offices that ensure necessary information is flowed to all employees within the organization including communication regarding the effectiveness of the quality management system.

5.5.3.1.1. Necessary information flow down may be in any form or type of medium, including verbal communication.

5.6. Management Review

5.6.1. General

5.6.1.1. The person with the responsibility and authority for the General Manager's Office and the Management Representatives Office annually review the organization's management system to maintain its continuing suitability, adequacy and effectiveness.

5.6.1.1.1. The review shall include, at minimum, assessing opportunities for improvement and the need for changes to the management system, including the quality policy and quality objectives.

5.6.1.1.2. Other members of the organization may be invited, requested or directed to participate in the management review by the General Manager's Office.

5.6.2. Review Input

5.6.2.1. The management review is prepared, scheduled and conducted by the Management Representatives Office, and includes, at minimum: opportunities for improvement, proposed changes (if any) to the management system, proposed changes (if any) to the quality policy, proposed changes (if any) to the quality objectives, results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, identified resource needs, follow-up objectives from previous management reviews, and new or revised regulatory requirements.

5.6.3. Review Output

5.6.3.1. Records of the management review are maintained by the Management Representatives Office according to the 4.2.4 Control of Records Procedure, and include at minimum; any decisions and actions related to; improvement of the effectiveness of the management system and its processes, improvements needed to maintain the effectiveness of the quality management system and its processes, improvement of product related to customer requirements, resource needs, and the review and acceptance of the Quality Policy, Quality Objectives, and approved Annual Responsibilities and Authorities Memo.

6. Resource Management
   6.1. Provision of Resources
      6.1.1. The General Manager's Office shall determine and provide the resources needed to implement and maintain the management system, maintain and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer and regulatory requirements.
      6.1.2. Each responsible management office within the organization holds the responsibility to identify resource needs, and to include in the management review (see 5.6 Management Review, above) the justification for such needs.
         6.1.2.1. Additional resource requirements, once approved, are assigned to the appropriate management office(s) for implementation.
   6.2. Human Resources
      6.2.1. General
         6.2.1.1. The Human Resources Office is responsible for maintaining sufficient human resources required by the organization.
         6.2.1.2. Each responsible management office within the organization holds the responsibility to identify human resource needs, and to include in the management review (see 5.6 Management Review, above) the justification for such needs.
      6.2.2. Competence, training and awareness
         6.2.2.1. Each responsible management office within the organization is responsible to ensure personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.
         6.2.2.2. The responsible management office shall determine necessary competence for its personnel, provide training as required to achieve necessary competence, evaluate the effectiveness of necessary training, and ensure that its personnel are aware of the relevance and importance of their activities and contributions to achieving quality objectives.
         6.2.2.3. This information, along with any training renewal and/or expiration information, is conveyed to the human resources office as the basis for employee competence and training records.
            6.2.2.3.1. The Human Resources Office is responsible for maintaining employee records according to the 4.2.4 Control of Records Procedure.

6.3. Infrastructure

6.3.1. The Operations Management Office is responsible for maintaining sufficient infrastructure resources required by the organization.

6.3.2. Each responsible management office within the organization holds the responsibility to identify infrastructure resources needed to achieve product conformity, and to include in the management review the justification for such needs.

6.3.2.1. Infrastructure requirements may include buildings, workplace and associated utilities, process equipment, and supporting services.

6.3.3. Buildings, workplace and associated utilities are maintained by third party contractors, managed by the Operations Management Office, including conditioning of the air and providing lights and power necessary for control of production processes.

6.3.4. Processing equipment is maintained, including preventive maintenance, according to the maintenance schedule and log sustained by the Operations Management Office.

6.3.4.1. The maintenance log is a quality record maintained by the Operations Management Office according to the 4.2.4 Control of Records Procedure.

6.3.5. Supporting services, such as transport of goods, are contracted to a third party as necessary.

6.3.6. The Subcontract and Procurement Office (Information Technology Activities) is responsible for supporting services, such as communication and information services including the maintenance and availability of data processing tools, equipment and database availability including records.

6.3.6.1. The organization's data network is the repository for data processing programs and any necessary database, including records.

6.3.6.2. A duplicate image of the data network is compiled and down-loaded to a secure, off-site, location on a daily basis.

6.3.6.3. The cache of duplicate images may be used to recover necessary records and/or recover the entire network in the event of inadvertent loss or damage.

6.4. Work Environment

6.4.1. The Operations Management Office is responsible for maintaining the work environment required by the organization to achieve conformity to product requirements.

6.4.2. Each responsible management office within the organization holds the responsibility to identify work environment resources needed to achieve product conformity, and to include in the management review the justification for such needs.

6.4.2.1. Work environment relates to those conditions under which work is performed including physical, environmental and other factors including temperature, humidity, lighting and weather.

6.4.3. The physical environment including; temperature, humidity, lighting and protection from weather is controlled. All product realization processes are performed in buildings appropriately implemented and maintained according to 6.3 Infrastructure (above).

6.4.3.1. Temperature and humidity are maintained at levels that are comfortable and compliant with IPC specifications for control of solderability and damage to electrostatic sensitive devices.

6.4.3.2. Electrostatic sensitive devices are protected according to the 6.4.3 Electrostatic Discharge (ESD) Controls Procedure.

6.4.3.3. Work areas and tools are designed for ease of use and avoidance of stress due to repeated use. Safety guards and emergency stops are included where necessary.

6.4.3.4. The facility is compliant with applicable statutory or regulatory specifications. Material Safety Data Sheets (MSDS) are readily available for applicable chemicals and compounds.

6.4.4. The Manufacturing Management Office is responsible for unique work environments, such as clean rooms, where required by customer, statutory or regulatory specification according to the 6.4.4 Unique Work Environment Procedure.

7. Product Realization
   7.1. Planning of Product Realization
      7.1.1. Project Management
         7.1.1.1. The Program Management Office is responsible to ensure product realization processes are executed in a structured and controlled manner to meet requirements at acceptable risk within resource and schedule constraints according to the 7.2.1 Product Requirements Determination Procedure.
      7.1.2. Risk Management
         7.1.2.1. The Program Management Office is responsible for the identification, assessment, and mitigation of risk according to the 7.1.2 Risk Management Procedure.
      7.1.3. Configuration Management
         7.1.3.1. The Configuration Management Office is responsible for configuration management according to the 7.1.3 Configuration Management Procedure.
      7.1.4. Control of Work Transfers
         7.1.4.1. The Subcontract and Procurement Office is responsible to plan and control the temporary or permanent transfer of work; from one organization facility to another, from the organization to a supplier, from one supplier to another supplier, and to verify the conformity of the work to requirements according to the; 7.4.1 Purchasing Process, 7.4.2 Purchasing Information Procedure, and/or the 7.4.3 Purchased Products Verification Procedure.

7.2. Customer Related Processes

7.2.1. Determination of Requirements related to the Product

7.2.1.1. The Program Management Office is responsible for the determination of requirements related to the product including; product requirements specified by the customer, product requirements not specified by the customer, statutory and regulatory requirements, and the organization's product requirements according to the 7.2.1 Product Requirements Determination Procedure.

7.2.2. Review of Requirements related to the Product

7.2.2.1. The Program Management Office is responsible for the review of requirements related to the product including; conducting the review, timing of the review, maintaining records of product requirement reviews, handling undocumented statements of requirements and changes to product requirements.

7.2.2.2. Upon receipt of a sales order the Program Management Office reviews requirements stated by the customer to ensure that product requirements are defined and that the organization has the ability to meet defined requirements.

7.2.2.2.1. The Program Management Office resolves any issues related to the order with the customer, and then arranges a review meeting to include necessary subject matter experts from within the organization.

7.2.2.2.2. A record of the review and any assigned action items are recorded according to the 7.2.1 Product Requirements Determination Procedure.

7.2.3. Customer Communication

7.2.3.1. The Program Management Office is responsible for customer communication including; providing product information, inquiries, contracts and orders and contract amendments.

7.2.3.1.1. The Program Management Office is responsible for customer feedback according to the 8.2.1 Customer Satisfaction Procedure.

7.2.3.1.2. The Program Management Office is responsible to coordinate response to customer complaints including, where applicable, the initiation of corrective actions according to the 8.5.2 Corrective Action Procedure.

7.2.3.1.3. The Program Management Office is responsible to communicate any product quality concerns including, where applicable, the coordination of a quality alert and/or advisory notice according to the 8.5.1.2 Quality Alert Procedure and/or the 8.5.1.4 Adverse Events Advisory Notice Procedure.

7.3. Design and Development

7.3.1. Design and Development Planning

7.3.1.1. The Engineering Design and Development Office (Engineering) is responsible for the planning and control of design and development including managing the organizational interfaces, ensuring plans are updated as the design progresses, determining the stages of design, planning review/verification/validation activities, and determining responsibilities and authority for design and development activities according to the 7.3.1 Design and Development Control Procedure.

7.3.2. Design and Development Inputs

7.3.2.1. Engineering is responsible for the design & development inputs including determining and recording design inputs, and review of design input requirements according to the 7.3.2 Design and Development Inputs Procedure.

7.3.3. Design and Development Outputs

7.3.3.1. Engineering is responsible for the design & development outputs including documenting the design and development output, and approval of design outputs according to the 7.3.3 Design and Development Outputs Procedure.

7.3.4. Design and Development Review

7.3.4.1. Engineering is responsible for the design & development review including planning design reviews, design review participants, and design records according to the 7.3.4 Design and Development Review Procedure.

7.3.5. Design and Development Verification

7.3.5.1. Engineering is responsible for the design & development verification including performing design verification, and recording design verification results according to the 7.3.5 Design and Development Verification Procedure.

7.3.6. Design and Development Validation

7.3.6.1. Engineering is responsible for the design & development validation including performing validation, timing of validation, and recording validation results according to the 7.3.6 Design and Development Validation Procedure.

7.3.7. Control of the Design and Development Changes

7.3.7.1. Engineering is responsible for the design & development changes including identification and recording of design changes, review and evaluation of changes, and verification and validation of design changes according to the 7.3.7 Design and Development Changes Procedure.

7.4. Purchasing

7.4.1. Purchasing Process

7.4.1.1. The Subcontract and Procurement Office shall sustain the purchasing processes including ensuring purchased product conforms to specified requirements, control of suppliers and evaluation and selection of suppliers including results of supplier evaluation, in accordance with the 7.4.1 Purchasing Process.

7.4.2. Purchasing Information

7.4.2.1. The Subcontract and Procurement Office shall sustain purchasing information including describing products to be purchased and adequacy of purchasing requirements in accordance with the 7.4.2 Purchasing Information Procedure.

7.4.3. Verification of Purchased Product

7.4.3.1. The Product Assurance Office shall sustain purchased products verification including ensuring purchased product meets requirements and verification on supplier premises, in accordance with the 7.4.3 Purchased Products Verification Procedure.

7.4.4. Counterfeit Component Mitigation

7.4.4.1. The Subcontract and Procurement Office shall prevent the introduction of counterfeit electronic components into customer products according to the 7.4.4 Counterfeit Component Mitigation Procedure.

7.5. Production and Service Provision

7.5.1. Control of Production and Service Provision

7.5.1.1. The Manufacturing Management Office is responsible to plan and carry out production and service provision under controlled conditions according to the 7.5.1 Control of Production and Service Procedure.

7.5.2. Validation of Processes for Production and Service Provision

7.5.2.1. The Manufacturing Management Office is responsible to validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement according to the 7.5.2 Validation of Processes Procedure.

7.5.3. Identification and Traceability

7.5.3.1. The Manufacturing Management Office is responsible to, where appropriate, identify the product by suitable means throughout product realization according to the 7.5.3 Identification and Traceability Procedure

7.5.4. Customer Property

7.5.4.1. The Manufacturing Management Office is to responsible to exercise care with customer property while it is under the organization's control according to the 7.5.4 Customer Property Procedure

7.5.5. Preservation of Product

7.5.5.1. The Manufacturing Management Office is responsible for preserving the conformity of product during internal processing and delivery to the intended destination according to the 7.5.5 Preservation of Product Procedure

7.6. Control of Monitoring and Measuring Equipment

7.6.1. The Product Assurance Office is responsible for the control of monitoring and measuring equipment according to the 7.6 Control of Monitoring and Measuring Equipment Procedure.

8. Measurement, Analysis and Improvement
   8.1. General
      8.1.1. The Product Assurance Office is responsible to plan and implement monitoring, measurement, analysis and improvement processes needed to demonstrate product conformity, ensure conformity of the management system, and to maintain and continuously improve the effectiveness of the management system.
         8.1.1.1. Product conformity to requirements is demonstrated according to 8.2.4 Monitoring and Measurement of Product, below.
         8.1.1.2. Conformity, maintenance and continuous improvement of the effectiveness of the management system is ensured through the effective utilization of document control according to 4.2.3 Control of Documents, above, and internal audits according to 8.2.2 Internal Audits, below.
   8.2. Monitoring and Measurement
      8.2.1. Customer Satisfaction
         8.2.1.1. The Program Management Office is responsible for monitoring information relating to the customer's perception of the organization's ability to meet requirements according to the 8.2.1 Customer Satisfaction Procedure.
      8.2.2. Internal Audit
         8.2.2.1. The Product Assurance Office is responsible to conduct internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements (see 7.1), to the requirements of the prerequisite standards (see 1.1), to the quality management system requirements established by the organization, and is effectively implemented and maintained according to the 8.2.2 Internal Audits Procedure.

8.2.3. Monitoring and Measurement of Process

8.2.3.1. The Product Assurance Office is responsible for monitoring and measuring the effectiveness of primary processes (see 4.1.4 Primary Processes Flow/Block Diagram, above) and product realization processes to demonstrate the ability of these processes to achieve planned results.

8.2.3.2. Where applicable, pertinent performance data for each of the indicated processes is collected, analyzed and reported to the organization.

8.2.3.3. Reporting metrics include objectives to be achieved and leading indicators of improvement opportunities.

8.2.3.4. Corrective, preventive and/or improvement actions are initiated, where necessary, according to 8.5 Improvement (below).

8.2.4. Monitoring and Measurement of Product

8.2.4.1. The Product Assurance Office is responsible to monitor and measure product characteristics to demonstrate product conformity.

8.2.4.2. Procured component parts, assemblies, and customer supplied material is inspected according to the 7.4.3 Verification of Purchased Product Procedure.

8.2.4.3. Products are inspected to acceptance criteria following each product realization process according to the 8.2.4 Product Inspection and Acceptance Instruction.

8.2.4.4. Acceptance and/or specific discrepancies are recorded in the organizations defect tracking system.

8.2.4.5. Where applicable, pertinent performance data for each product is collected, analyzed and reported to the organization.

8.2.4.6. Corrective, preventive and/or improvement actions are initiated, where necessary, according to 8.5 Improvement (below).

8.3. Control of Nonconforming Product

8.3.1. The Product Assurance Office is responsible to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery according to the 8.3 Control of Nonconforming Material Procedure.

8.4. Analysis of Data

8.4.1. The Product Assurance Office is responsible for analysis of data necessary to demonstrate the suitability and effectiveness of the management system according to the 8.4 Analysis of Data Procedure.

8.5. Improvement

8.5.1. Continual Improvement

8.5.1.1. The Management Representatives Office is responsible to identify and initiate any changes necessary to ensure and maintain the continued suitability, improvement and effectiveness of the quality management system.

8.5.1.1.1. The key operating indicators and quality objectives are monitored to identify opportunities for improvement.

8.5.1.1.2. The management review, including quality policy and quality management system reviews contribute to improvement opportunities.

8.5.1.1.3. Audit results and data analysis may contribute improvement opportunities.

8.5.1.1.4. Improvement activities are initiated, monitored and evaluated by the organization's senior management to ensure the effectiveness of results.

8.5.1.1.4.1. Staff notes reporting progress of improvement activities are retained by the Management Representatives Office according to the 4.2.4 Control of Records Procedure.

8.5.1.2. The Product Assurance Office is responsible for advisory notices to the organization according to the 8.5.1.2 Quality Alert Procedure.

8.5.1.3. The Product Assurance Office is responsible for processing customer complaints according to the 8.5.2 Corrective Action Procedure.

8.5.1.4. Where national or regional reporting of adverse events are required by contract or regulation, the Product Assurance Office is responsible for processing such reports according to the 8.5.1.4 Adverse Events Advisory Notice Procedure.

8.5.2. Corrective Action

8.5.2.1. The Product Assurance Office is responsible to initiate action to eliminate the cause of nonconformities in order to prevent recurrence and requires the actions to be appropriate to the effects of the nonconformities encountered according to the 8.5.2 Corrective Action Procedure.

8.5.3. Preventive Action

8.5.3.1. The Product Assurance Office is responsible for the implementation and maintenance of preventive action processes according to the 8.5.3 Preventive Action Procedure.