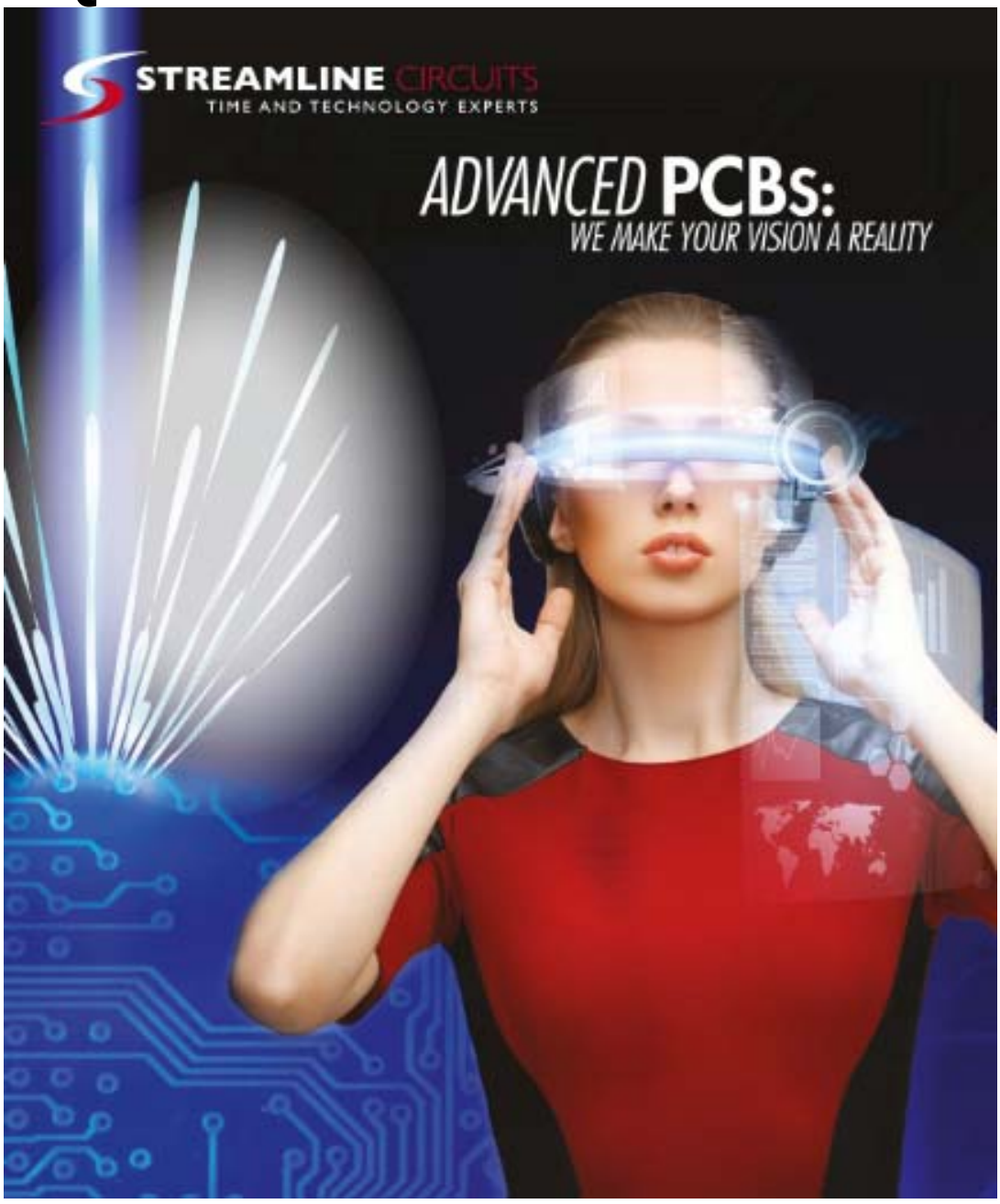
QUALITY SYSTEMS MANUAL



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Introduction

Streamline Circuits is a leading provider of high quality printed circuit boards. We are committed to providing our customers the most advanced technology, quality and engineering support available. Customers take advantage of these resources to develop cost effective products in a time sensitive manner. This is critical for today's customers who want and need to get their quality products first to market.

Streamline Circuits acquired Excel Circuits in September 2003. Excel Circuits was established in 1982 to meet an ever-increasing demand for complex printed circuit boards.

Streamline Circuits management team has over 300 cumulative years of PCB experience, ***Streamline Circuits*** is led by CEO Chuck Dimick, who is widely recognized throughout the industry, for advanced technology leadership and superior quality.

Streamline Circuits is register with International Traffic in Arms Regulations (ITAR Part 122) as a manufacture and exporter (Registration Code M18448).

Streamline Circuits has developed and implemented a QMS (Quality Management System) to document the company's best business practices, better satisfy the requirements and expectations of its customers, and improve the overall management of the company.

This quality manual outlines the policies, procedures and requirements of the QMS. The **system is structured to comply** with the conditions set forth in the International Standard ISO 9001:2015, AS9100C, ISO 13485:2016, MIL-PRF-55110, MIL-PRF-31032, NADCAP and ITAR. Registration to these standards is maintained through the registration program of UL DQS, qualifying activity, Nadcap and the Office of Defense Trade Controls Compliance and Registration Division (CRD).

This manual is divided into five sections that best correlate with the QMS sections of the ISO 9001:2015, ISO 13485:2016 and AS9100C format. This manual is used internally to guide the company's employees through the various requirements of the ISO 9001: 2015, ISO 13485: 2016 and AS9100C standards that must be met and maintained in order to ensure customer satisfaction, continuous improvement, and provide the necessary instructions that create an empowered workforce.

This manual is used externally to introduce our QMS to our customers and other external organizations. This manual is used to familiarize those individuals with the controls ***Streamline Circuits*** has implemented. It also assures them that the integrity of the QMS is maintained and that we are focused on customer satisfaction and continuous improvement.

Scope of Registration

Streamline Circuits interactions are limited since we are a contract manufacturer. Of double-sided, multilayer rigid, rigid flex and flex, MCM-L, HDI, embedded passive devices and microwave printed circuit boards. For industrial, commercial, aerospace, defense, and medical applications.

Statement of Commitment

- Management will provide our customers with products and services that meet or exceed expectations
- Management will provide leadership and actively participate in the quality process and above all, will make improvements the focal point of our company
- We will promote the spirit of continuous improvement and provide consistent direction in all aspects of our business
- We will invest in our employees in order for them to become educated in total quality improvement process
- The quality team, representing management of ***Streamline Circuits*** is the approval authority for the Quality System/Plan operating throughout ***Streamline Circuits***.

Mission Statement

- To provide our customers with products and services that meet or exceed expectations
- To provide a safe working environment that promotes honest communication, loyalty, ownership, employee advancement and the protection of the earth's environment
- To develop partnerships with ***suppliers*** and ***customers*** to accelerate product and service advancement

Quality Policy

We the employees of ***Streamline Circuits*** make the commitment to first understand our customer's expectations, to meet or exceed our commitment to those expectations by;

- *Provide a framework for establishing, reviewing, understanding and* ***communicate*** *quality objectives,*
- *Ensuring that we comply, with all applicable internal & external* ***requirements****,*
- *Ensuring continuous* ***improvement*** *with the intent to improve processes, product and our customer's total experience*
- *Maintain the* ***effectiveness*** *of our Quality Management Systems.*

Quality Objectives refer to QS-PL-007

Environmental Policy

Streamline Circuits recognizes that the privilege of conducting business in our communities demands excellence in our environmental, health and safety performance.

Streamline Circuits is committed to the safe operation of our facility, the welfare of our employees and community, and the protection of the earth's environment. Accordingly,

Streamline Circuits will:

- comply fully with the requirements of all applicable laws and regulations, and follow relevant industry standards for safety, engineering, and principles of risk management;
- operate our facilities in a manner that continuously improves employee and public safety and environmental protection;
- require, as a condition of employment, that all employees accept personal responsibility and accountability for safe work behavior, and
- provide effective employee environmental, health, and safety training.

Absence of REACH Substances of Very High Concern Policy

As supplied, there are no substances intended to be released from our products as defined by article 7 (1) under normal or reasonably foreseeable conditions of use.

Streamline Circuits committed to comply in every respect to the requirements of REACH and relevant amendments. At present we **do not** expect any anticipated Substances of Very High Concern to be in our products requiring reporting to the supply chain.

Right of Access

Streamline Circuits grants the right of access to our customer to inspect any or all materials included in their purchase order.

Counterfeit Electronic Parts, Avoidance, Detection, Mitigation and Disposition

Streamline Circuits has a documented "Counterfeit Material Avoidance Plan" (QS-PL-005), and we are a active member Government - Industry Data Exchange Program (GIDEP).

Conflict Mineral Policy

There has been increased awareness of violence and human rights violations in the mining of certain minerals from a location described as the “Conflict Region”, which is situated in the eastern portion of the Democratic Republic of the Congo (DRC) and surrounding countries. Companies around the globe have been requested to practice reasonable due diligence with their supply chain to assure that specified metals are not being sourced from mines in the Conflict Region, which is controlled by non-government military groups, or unlawful military factions.

Streamline Circuits supports this initiative and has either obtained, or is in the process of obtaining, information from our current metal suppliers concerning the origin of the metals that are used in the manufacture of ***Streamline Circuits*** products. Based upon information provided by our suppliers, ***Streamline Circuits*** does not knowingly use metals derived from the Conflict Region in our products.

Suppliers of metals used in the manufacture of ***Streamline Circuits*** products (specifically gold and tin) must demonstrate that they understand the conflict minerals laws and will not knowingly procure specified metals that originate from the Conflict Region.

Suppliers must review and agree in writing to the following conflict minerals contractual language:

Supplier represents and warrants that it is in full compliance with conflict minerals laws, including, without limitation, Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 as it may be amended from time to time and any regulations, rules, decisions or orders relating thereto adopted by the Securities and Exchange Commission or successor governmental agency responsible for adopting regulations relating thereto (collectively, (“Dodd-Frank Section 1502”).

- Supplier must cooperate with ***Streamline Circuits*** to make available to ***Streamline Circuits*** and/or its agents, full material declarations that identify the sources of and amount of all substances contained in the Products. Unless ***Streamline Circuits*** specifically agrees in writing that a particular Product may contain a particular material, Supplier will also provide a statement that the Products do not contain various materials at issue in applicable laws and regulations.

- Supplier must declare each Product’s compliance to all applicable hazardous material legislation and identify any substances that are banned or must be declared under applicable laws. In addition, Supplier will make available any documentation that supports the declaration. Without limiting the generality of the foregoing, Supplier agrees to disclose to ***Streamline Circuits***, upon ***Streamline Circuits*** request, to the extent known or discoverable by Supplier following inquiry, the original source of all minerals contained in the Product.

- If Supplier does not know the original source of the minerals, Supplier agrees to cooperate with ***Streamline Circuits***, including disclosing from whom Supplier purchased the minerals and urging others to disclose such information, so that the original source of minerals can be accurately determined and reported. Supplier shall comply with all laws regarding the sourcing of minerals, including, without limitation, laws prohibiting the sourcing of minerals from mines controlled by combatants and Dodd-Frank Section 1502.

- Without any further consideration, Supplier shall provide such further cooperation as ***Streamline Circuits*** may reasonably require in order to meet any obligations it may have under conflict minerals laws, including, without limitation, under Dodd-Frank Section 1502.

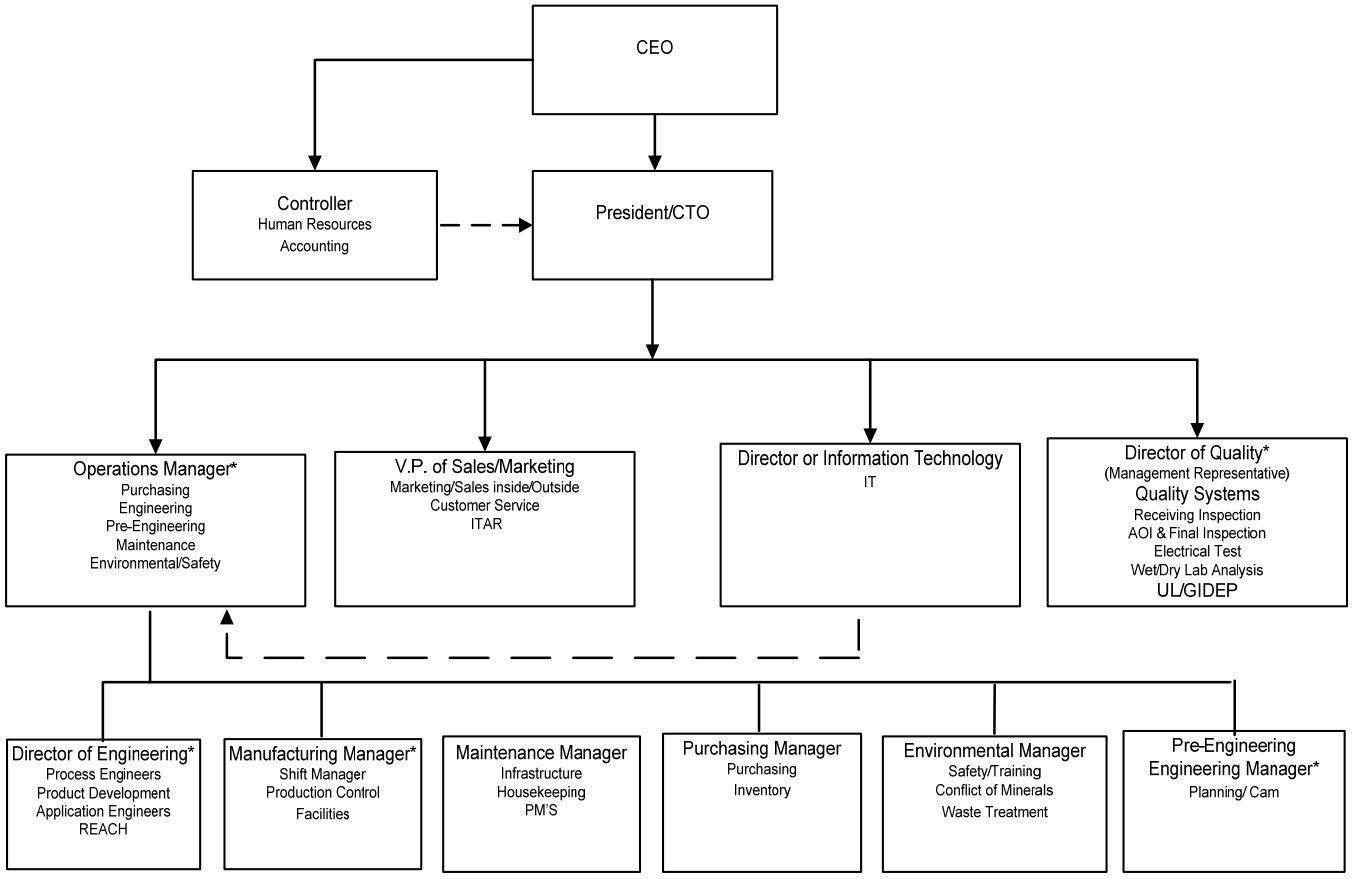
As a leading global company in the manufacturing of printed wiring boards, ***Streamline Circuits*** is committed to ensuring the safety, health and protection of people and the environment worldwide. We promote these principles in our global business practices and our code of conduct.

Quality Manual Distribution & Approvals

The Quality Manual shall be distributed to the following:

Chief Executive Officer,
President/CTO,
Senior Vice President of Marketing/Sales,
Vice President of Operations Manager,
Manufacturing Manager,
Director of Quality/Management Representative,
Director of Engineering,
Front-End Manager,
Purchasing Manager,
Sales Manager,
Customer Service Manager,
Information Systems Manager,
Human Resources

Organizational Structure and Technical Review Board



Roles are documented within their job descriptions (refer to section 5.5.1 in this manual).

TRB Members are identified by an asterisk (*) refer to "MIL-PRF-31032 "Quality Management Plan"

Section 1: Scope

1.1 General

Streamline Circuits is a manufacturer of rigid and flex, high speed, signal integrity printed circuit boards for commercial, aerospace, microwave, medical and military applications. The scope of the QMS includes all processes that produce the products and/or services. Our QMS is our means of assuring the printed boards we manufacture meet applicable aviation, space, defense, medical, industry, customer and applicable regulatory requirements for safety and performance. ***Streamline Circuits*** follows all required City, State and Federal statutory and regulatory guidelines and UL regulatory support when applicable.

The special requirements and needs of ***Streamline Circuits*** customers (external and internal) require a special emphasis on pre-production engineering and quality review. Customer data is verified using design rule software, which ensures manufacturability. Quick turn volumes are produced with production ready tooling, which ensures consistency from prototyping to production volumes. The special needs of customers are documented in customer and part number specific quality plans. The quality plan identifies the processes and controls required to meet these special requirements and needs. We are a contract manufacturer life-cycles of products we build at ***Streamline Circuits*** are controlled by our customer. The quality plan identifies the processes and controls required to meet these special requirements and needs.

The product is manufactured and certified to meet the performance specifications and class, as specified by the customer. If a **class is not specified** ***Streamline Circuits*** will **default** to IPC Class 2. ***Streamline Circuits*** considers information shared confidential and proprietary.

1.2 Application

Streamline Circuits QMS meets the requirements of the AS9100, ISO 9001:2015 and ISO 13485:2016. The following table identifies ISO 9001:2015 and ISO 13485:2016 requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS:

These sub-clauses may or may not align with the clause numbering scheme

Clause or Sub-Clause	Exclusion	Justification
ISO 13485:2016 4.2.3	Medical device files	***Streamline Circuits*** products **do not** require installation or servicing activities.
ISO 13485:2016 6.4.2	For sterile medical devices	***Streamline Circuits*** products **do not** require sterilization.
AS9100 - ISO 9001:2015 – 7.3 ISO 13485:2016 – 7.3 ISO 9001:2015 - 8.3	Design and Development	***Streamline Circuits*** **does not** participate in design or development.
ISO 13485:2016 7.5.2 7.5.3 7.5.4 7.5.5 7.5.9.2	Control of Production and Service Provision – Cleanliness of product and contamination control a), b) and c) Installation activities Servicing activities Particular requirements for sterile medical devices Particular requirements for validation of processes for sterilization and sterile barrier systems Particular requirements for implantable medical devices	***Streamline Circuits*** products **do not** require sterilization, installation or servicing activities.

Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/AS 9001/ASQ Q9000 latest revision, Quality Management Systems – Fundamentals and Vocabulary
- American National Standard ANSI/AS 9001/ASQ Q9001latest revision, Quality Management Systems – Requirements
- American National Standard ANSI/AS 9001/ASQ Q9004 latest revision, Quality Management Systems – Guidelines for performance Improvements
- SAE Aerospace SAE AS9100 latest revision - Quality Management Systems – Requirements
- MIL-PRF-31032 latest revision - Certification and Qualification Information for Manufacturers
- International Standard ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

Section 3: Definitions

3.0 Quality Management System Definitions

This section is for definitions unique to ***Streamline Circuits***.

- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Product – The end item result of meeting all contracts (terms and conditions).
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.
- Key Characteristics – An attribute or features whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.
- Risk - An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
- Special requirements - Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved thus, requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity.
- Critical items - Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed.
- Advisory notices – Organizations often issue advisory notices after their medical devices have been delivered. These advisory notices provide supplementary information about the device or specify actions that should be taken. ***Streamline Circuits*** is a contract manufacturer we build to customer drawing. We do not issue advisory notices. This would be the responsibility of the customer.
- QM Plan – Is the documentation used to describe the QM program implementation. It is a controlled document with, at a minimum, a separate section for each element noted in paragraph A.3.2.1 of MIL-PRF-31032.
- Technical Review Board (TRB) – Is a cross-functional team made up of responsible individuals selected from different areas covered by the QM program.
- *Self-Validation – Is the manufacturer's means of determining compliance to MIL-PRF-31032 and the QM program*
- *Use-As-Is – Means "in accordance with specifications and/or customer requirements".*

Refer to additional terms and definitions

Section 4: Quality Management System

4.1 General Requirements

Streamline Circuits has determine external and internal issues that are relevant to purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS.

Streamline Circuits has established documented and implemented Quality Management System (QMS) in accordance with the requirements of AS9100, ISO 9001:2015, ISO 13485:2016 and MIL-PRF-31032 latest revisions. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

To design and implement the QMS ***Streamline Circuits*** has:

- determine the inputs required and the outputs expected from the processes needed for the QMS and their application throughout the organization. Documented on the “Interaction of Process Diagram” at the end of this section page 14;
- apply a risk based approach to the control of the appropriate processes needed for the QMS;
- determined the sequence and interaction of these processes. Documented on the “Interaction of Process Diagram” at the end of this section page 14;
- determined criteria and methods needed to ensure that the operation and control of the processes are effective, these are documented in quality plans and/or work instructions;
- ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes;
- assign the responsibilities and authorities for these processes;
- established systems to monitor, measure where applicable and analyze these processes;
- established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes, and
- establish and maintain records needed to demonstrate conformance to the standards and compliance with applicable regulatory requirements.

Printed Circuits Board Process Flow Charts are available upon request. Charts may not necessarily depict all steps needed dependent upon the complexity of the products technology. Additional flow are available upon request (MF-PL-003, MF-PL-004, MF-PL-005 and MF-PL-006).

Streamline Circuits manages the quality management system processes in accordance with the requirements of the standards and applicable regulatory requirements. Changes to be made to these processes shall be:

- evaluated for their impact on the QMS, and
- evaluated for their impact on product produced under this QMS.

Outsource processes are managed by ***Streamline Circuits*** it does not absolve us of the responsibility of conformity to all customer, statutory and regulatory requirements. Regulatory requirements are met by meeting customers’ requirements. The controls shall be proportionate to the risk involved and the ability of the external part to meet the requirements in section 7.4 in this manual. Our controls included flow-down requirements.

Streamline Circuits has documents procedures for validation of the application of computer software used in the QMS. Such software applications are validated prior to initial use and as appropriate, after changes to such software. The specific approach and activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software. Records of such activities are maintained.

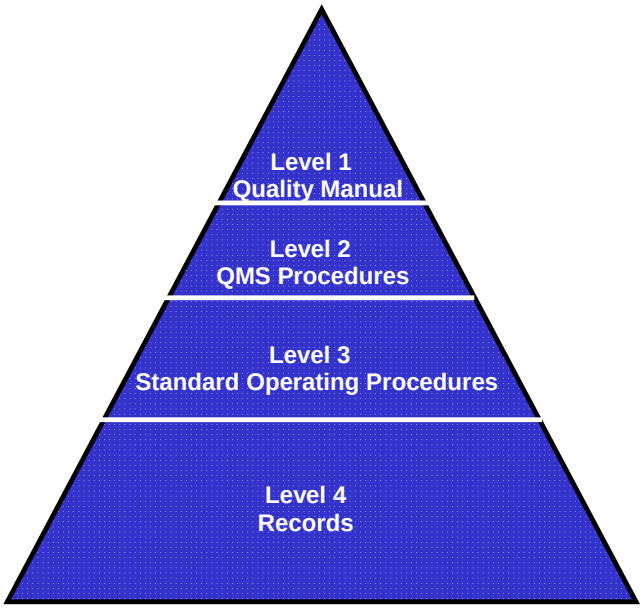
4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- a documented quality policy and quality objectives;
- this quality manual;
- documented procedures and records required by the standards;
- documents, including records determined by ***Streamline Circuits*** to be necessary to ensure the effective planning, operation and control of our processes;
- a description of the interaction between the processes of the QMS and
- other documentation specified by national or regional regulations.

Streamline Circuits ensures that personnel have access to, and are aware of, relevant QMS documentation and changes. We also provide customer or statutory and regulatory authorities' access to QMS documentation.



4.2.2 Quality Manual

This Quality Manual has been prepared to describe ***Streamline Circuits*** QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The QMS Systems Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

4.2.3 Control of Documents

We are a contract manufacturer Medical device files are maintained within our configuration management (QS-PR-039). Tool file is created with a unique identifier assigned to single customer part number, revision and /or process change to said part number.

Documents required by the QMS shall be controlled according to the "Document Control Procedure" (QS-PR-001). Records are special type of document (see 4.2.4) and shall be controlled according "Control Quality Records Procedure" (QS-PR-002). This procedure defines the process for:

- reviewing and approving documents for adequacy prior to issue;
- reviewing and updating as necessary and re-approving documents;
- ensuring that changes and current revision status of documents are identified;
- ensuring that relevant versions of applicable documents are available at points of use;
- ensuring that documents remain legible and readily identifiable;
- ensuring that documents of external origin determined by ***Streamline Circuits*** to be necessary for the planning and operation of the QMS are identified and their distribution controlled;
- prevent deterioration or loss of documents;
- preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose, and
- obtaining customers and/or regulatory agency approvals when required by contract or statutory and regulatory requirements. Regulatory requirements are met by meeting customers' requirements.

Streamline Circuits ensures that changes to documents are reviewed and approved either by the original approving function or another designated function.

Documents are maintained is Q-Pulse QMS database within document module. Obsolete documents are retained indefinitely and only the document administrator as access to these documents.

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the QMS are controlled. The records, including certification information of QML product and those created by or maintained according to the "Control of Quality Records Procedure" (QS-PR-002). The procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. Records remain legible, readily identifiable and retrievable.

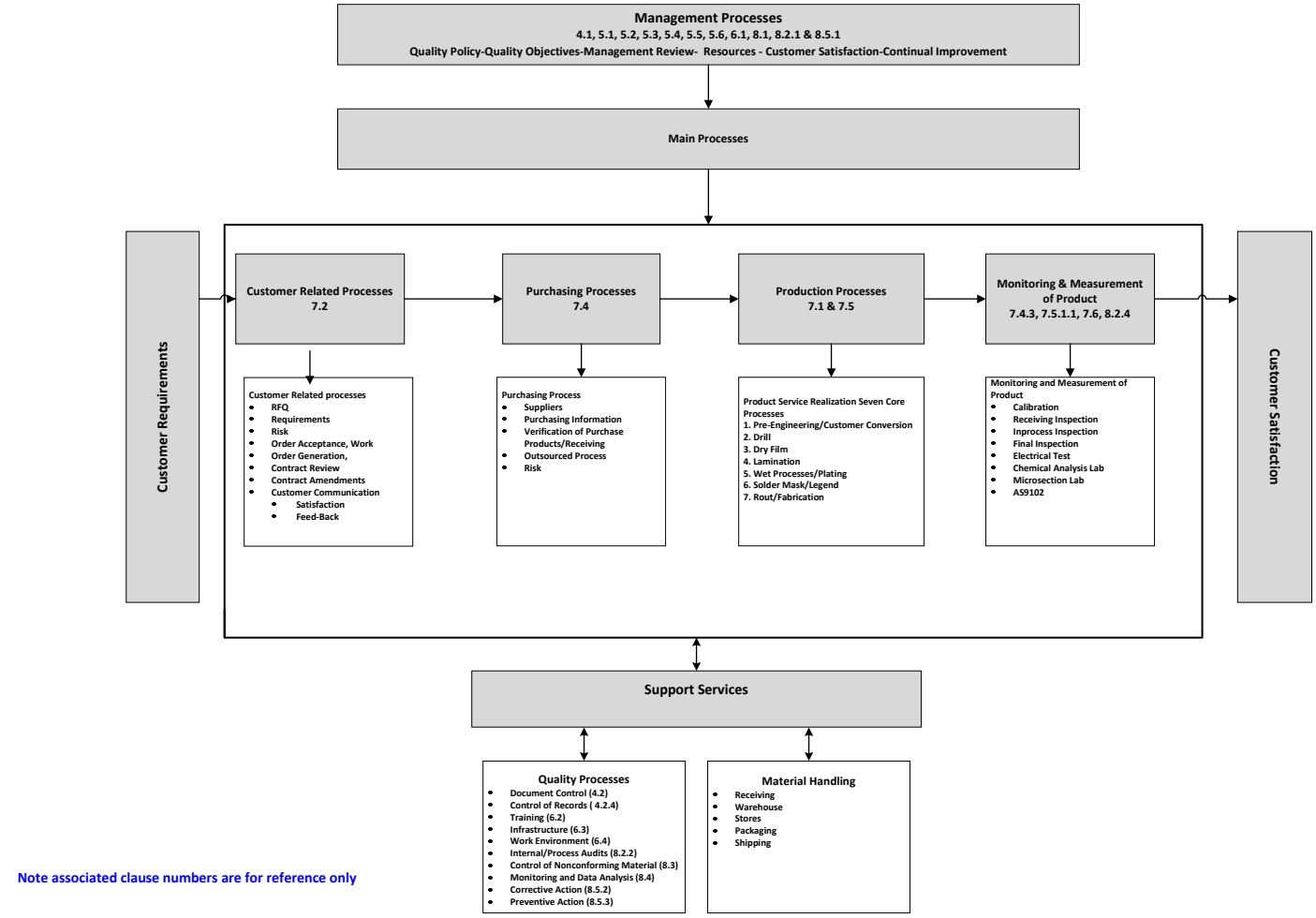
Streamline Circuits is a contract manufacturer record retention is based upon industry standards and/or customer requirements documented in "Records Table" (QS-ML-001).

Records are made available to customers / regulatory agencies when required by contract or statutory and regulatory requirements. Regulatory requirements are met by meeting customers' requirements.

Related Procedures

Document Control Procedure	QS-PR-001
Control Quality Records Procedure	QS-PR-002
Quality Objectives	QS-PL-007
Records Table	QS-ML-001
Flex Type 1 & 2 Printed Circuit Board Process Flow Chart	MF-PL-003
Flex Type 3 & 4 Printed Circuit Board Process Flow Chart	MF-PL-004
Rigid Type 1 & 2 Printed Circuit Board Process Flow Chart	MF-PL-005
Rigid Type 3 & 4 Printed Circuit Board Process Flow Chart	MF-PL-006

"Streamline Circuits QMS Processes and Interactions"



Section 5: Management Responsibility

5.1 Management Commitment

Streamline Circuits top management has been actively involved in implementing the Quality Management System (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, ***Streamline Circuits*** management will do the following:

- taking accountability for effectiveness of the QSM;

- ensuring that the quality policy and quality objectives are established for the QMS. They are compatible with the context and strategic direction of ***Streamline Circuits;***
- ensuring the integration of the quality management system requirements into ***Streamline Circuits*** *business processes;*
- promotes the use of the process approach and risk-based thinking;
- ensure the availability of resources
- communicating the importance of effective QMS and of conforming to QMS requirements;
- ensuring that the QMS achieves its intended results;
- engaging, directing and supporting employees to contribute to the effectiveness of the QMS;
- promoting improvement;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility;
- communicating to the organization the importance of meeting customer, statutory and regulatory requirements, and
- conduct annual management reviews.

5.2 Customer Focus

Streamline Circuits strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures that customer requirements are understood and consistently met. The risks and opportunities that can affect conformity of products and ability to enhance customer satisfaction are determined, addressed and communicated to the appropriate people in our organization. They 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

5.3 Quality Policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. The “Quality Policy” (QS-PC-001) is posted in prominent places throughout our facility to maintain high standards within our organization. The “Quality Policy” is also located on page 5 of this manual.

Management reviews the quality policy requirements at each management review meeting to determine the policy’s continuing suitability for our organization. It provides the framework for establishing and reviewing our quality objectives.

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established to support our organizations efforts in achieving our quality policy and reviewed annually for suitability.

Objectives are established at relevant functions and levels within the organization. Quality objectives are consistent with the quality policy, measurable, take into account applicable requirements, relevant to conformity of products to enhancement of customer satisfaction, monitored, communicated and updated as required refer to “Quality Objective” (QS-PL-007).

5.4.2 Quality Management System Planning

Our quality system has been planned and implemented to meet our quality objectives and requirement of the ISO 9001:2015, AS9100, ISO 13485:2016 and MIL-PRF-31032. We determine the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended results(s) and enhance desirable affects. Quality planning takes place, as changes that affect the quality system are planned and implemented. To prevent, or reduce, undesirable effects and achieve improvement. Refer to “MIL-PRF-31032 Quality Management Plan Procedure” (QS-PR-041).

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The Chief Executive Officer (CEO) and President sets direction and ensures the success of ***Streamline Circuits***. An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available to help employees understand responsibilities and authorities. Refer to "Organizational Structure and Technical Review Board" (QS-CH-001) and page 8 of this manual.

Top Management: Members of top management are ultimately responsible for the quality of ***Streamline Circuits*** products and services since they control the systems and processes by which work is accomplished. Top management is responsible for strategic planning, development and communication of our quality policy, QMS Planning, including the establishment and deployment of corporate level objectives, and the provision of resources needed to implement and improve the quality system.

Management: All officers, managers, engineers and floor supervisors are responsible for execution of the strategic plan and implementation of the policies, processes and systems described in this manual. They are responsible for planning and controlling quality system processes within their area(s) of responsibility, including the establishment and deployment of operational level objectives, and the provision of resources needed to implement and improve these processes. Managers also conduct employee performance reviews as needed.

Employees: All employees are responsible for the quality of their work and implementation of the policies and procedures applicable to processes they perform. Employees also identify and report any know or potential problems and recommend related solutions through the internal audit and/or corrective/preventive action processes.

The President shall appoint members to the Technical Review Board. The members in total shall have the experience and knowledge to make decisions regarding printed circuit board acceptability and certification. Refer to "Organizational Structure and Technical Review Board" (QS-CH-001) and page 8 of this manual.

5.5.2 Management Representative

The Director of Quality has been appointed by top management as our management representative. As Management Representative, he/she has the following responsibility and authority:

- ensure that processes needed for the QMS are established and implemented;
- report to top management on the performance of the QMS, and note needed improvements;
- promote awareness of customer requirements throughout the organization;
- act as a liaison with external parties such as customers or auditors on matters relating to the QMS
- Resolve matters pertaining to quality issues;
- organizational freedom and unrestricted access to top management to top management to resolve to quality management issues and
- ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.

5.5.3 Internal Communication

Streamline Circuits ensures communication within the organization between its various levels and functions regarding the effectiveness of the QMS. Methods of communicating the effectiveness of the QMS include, but are not limited to training, organizational meetings, internal audits, and management reviews and other routine business communication.

The Quality group may post information throughout the facility to convey information regarding customer requirements and the status and importance of quality activities. The Environmental group may post information on safety throughout the facility to convey information regarding the status of the Safety and Environmental Management Program, and related statutory/regulatory requirements. Regulatory requirements are met by meeting customers' requirements.

5.6 Management Review

5.6.1 General

Streamline Circuits top management reviews the QMS annually at Management Review meetings (or more frequently, as is determined by top management). This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement, and as-needed changes. Records are maintained for each management review meeting (see 4.2.4).

Streamline Circuits Technical Review Board shall meet quarterly (or more frequently, as is determined by TRB) to evaluate the status of the QM program.

5.6.2 Review Input

Assessment of the QMS is based on a review of information inputs to Management Review. These inputs include the following:

- results of audits;
- customer feedback this includes complaint handling;
- process performance and product conformity;
- status of preventive and corrective actions;
- follow-up actions from previous management reviews;
- changes that could affect the QMS;
- recommendations for improvement and
- new or revised regulatory requirements are met by meeting customers' requirements.

5.6.3 Review Output

During our review meetings, ***Streamline Circuits*** management will identify appropriate actions to be taken regarding the following issues:

- improvement on the effectiveness of the QMS and its processes;
- Improvement of products related to our customer requirements,
- changes needed to respond to applicable new or revised regulatory requirements and
- resource needs.

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during our management review process actions are assigned, and their due dates are recorded in the minutes of management review. Refer to "Management Responsibility Procedure" (QS-PR-006).

Related Procedures:

Quality Policy	QS-PC-001
Management Responsibility Procedure	QS-PR-006
Organizational Structure and Technical Review Board	QS-CH-001
Quality Objectives	QS-PL-007
MIL-PRF-31032 Quality Management Plan	QS-PR-041

Section 6: Resource Management

6.1 Provision of Resources

Streamline Circuits has implemented a QMS that complies with ISO 9001:2015, AS9100, ISO 13485:2016 and MIL-PRF-31032. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, ***Streamline Circuits*** management determines and provides necessary resources, to enhance customer satisfaction by meeting regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience. To ensure competence of our personnel, job descriptions have been prepared by identifying the qualifications required for each position. We believe that our employees are our most valuable asset and we do our best to help them achieve their full potential through continuous education and training.

6.2.2 Competence, Training, and Awareness

Qualifications are reviewed upon hire, when an employee changes positions, or the requirements for a position change. Human Resources or Training Coordinator maintains the records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action will be taken to provide the employee with the necessary competence for the job.

- determine the necessary competence for personnel performing work affecting conformity to product requirements;
- where applicable, provide training or take other actions to achieve the necessary competence;
- evaluate the effectiveness of the actions taken;
- ensure that our personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- maintain appropriate records of education, training, skills and experience (see 4.2.4).

The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.

All ***Streamline Circuits*** employees are trained on the relevance and importance of their activities including how they contribute to the achievement of the quality objectives. This is achieved through daily communication with internal customers, supervisors, engineers and management. Refer to "Competence, Training, and Awareness Procedure" (QS-PR-007).

6.3 Infrastructure

To meet quality objectives and product requirements ***Streamline Circuits*** has determined the infrastructure needed. The CEO and President have overall responsibility for identifying, providing and maintaining the resources needed to achieve product conformance, prevent product mix-up, ensure orderly handling of product (refer to Preservation of Product QS-PR-017) including workspace, associated facilities, equipment, hardware and software, and supporting services. The Systems Administrator has overall responsibility for establishing and maintaining our information management systems. The Maintenance Manger has the overall responsibility of maintaining the preventative maintenance activities.

The infrastructure has been provided, and includes:

- buildings, workspace and associated utilities;
- process equipment, both hardware and software, and
- supporting services such as transport or communication, as applicable

As new infrastructure requirements arise, they will be documented. Existing infrastructure is maintained to ensure product conformity. Maintenance activities are documented including their frequency; records are maintained (see 4.2.4). Refer to "Infrastructure Procedure" (QS-PR-020).

6.4 Work Environment

Work Environment suitable for achieving product conformance is maintained by ***Streamline Circuits*** management team. The work environment is managed for continuing suitability and providing the elimination of FOD (Foreign Object Damage/Debris) refer to "Foreign Object Elimination (FOE) Plan" (QS-GL-002). Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Requirements are determined during quality planning and documented in the Quality Plan:

- established documented requirements for health, cleanliness and clothing of personnel in contact between such personnel and the product or work environment could adversely affect the quality of the product;
- established documented requirements for work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions;
- ensure that all personnel who are required to work temporary under special environmental conditions within the work environmental are appropriately trained or supervised by trained person and
- if appropriate, special arrangements shall be established and documented for the control of contaminated product in order to prevent contamination of other product the work environment or personnel.

Related Documents

Competence, Awareness and Training Procedure	QS-PR-007
Preservation of Product Procedure	QS-PR-017
Infrastructure Procedure	QS-PR-020
"Foreign Object Elimination (FOE) Plan"	QS-GL-002
Hazard Communication Program Training Manual	ES-MN-002
Injury and Illness Prevention Program for High Hazard Employers Manual	ES-MN-003

Section 7: Product Realization

7.1 Planning of Product Realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the "Planning of Product Realization Procedure" (QS-PR-037). During this planning, management or assigned personnel identify:

- the quality objectives and requirements for the product;
- the need to establish processes, and documents and to provide resources specific to the product;
- required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

- records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4);
- configuration management appropriate to the product, and
- the identification of resources to support the use and maintenance of the product

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

7.1.1 Project Management

Streamline Circuits plans and manages product realization in a structured and controlled manner to meet the requirements at acceptable risk, within resource and schedule constraints.

7.1.2 Risk Management

Streamline Circuits has established, implemented and maintains a process for maintaining risk to the achievement of applicable requirements that includes as appropriate to the organization and the product. Refer to “Risk Management Procedure” (QS-PR-038) and “Customer Related Processes” (QS-PR-009).

- assignment of responsibilities for risk management;
- definition of risk criteria (e.g. likelihood, consequences, risk acceptance);
- identification, assessment and communication of risks throughout product realization;
- identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria;
- acceptance of risks remaining after implementation of mitigating actions and
- records arising from risk management shall be maintained (see 4.2.4)

7.1.3 Configuration Management

Streamline Circuits has established, implemented and maintains a configuration management process that includes, as appropriate to the product Refer to “Configuration Management Procedure” (QS- PR-039).

The plan defines the process for:

- configuration management planning;
- configuration identification;
- change control;
- configuration status accounting, and
- configuration audit.

7.1.4 Control of Work Transfers

Streamline Circuits has established, implemented and maintains a process to plan and control the temporary or permanent transfer of work (e.g. from one facility to another facility) and to verify the conformity of the work to requirements. Any outside processing steps to be completed are also listed on the traveler.

When products are sent out to be processed utilizing an approved service registered on ***Streamline Circuits*** AVL listing, a purchase order with flow-down requirements is generated and provide to outside service. When product is returned from the outside service, an evaluation is performed and recorded on the traveler.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Streamline Circuits determines customer requirements before acceptance of an order.

Customer requirements include those:

- requested by the customer;
- required for delivery and post-delivery activities;
- not stated by the customer but necessary for specified use or known and intended use;

- statutory and regulatory requirements are met by meeting customers' requirements that are applicable to the product;
- any user training needed to ensure specified performance and safe use of the medical device, and
- any additional requirements considered necessary by *Streamline Circuits*

Customer requirements are determined according to the "Customer Related Processes Procedure" (QS-PR-009) and "International Traffic Arms Regulation Policy "ITAR" Procedure" (QS-PR-033)

7.2.2 Review of Requirements Related to the Product

Streamline Circuits has a process in place for the review of requirements related to the product Quote Preparation. The review is conducted before the order is accepted. The process ensures that:

- product requirements are defined and documented;
- contract or order requirements differing from those previously expressed are resolved;
- applicable regulatory requirements are met;
- any user training identified in accordance with 7.2.1 is available or planned to be available;
- have the ability to meet the defined requirements;
- special requirements of the product are determined;
- risks design guidelines and manufacturing capabilities shall be utilizes to mitigate risk during the quoting process. This is based on technology (Standard = No/Low Risk, Advanced = Medium Risk and Emerging = High Risk);
- where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance, and
- when product requirements are changed, ***Streamline Circuits*** communicates changes to relevant personnel and amends relevant documents.

Records are maintained showing the results of the review and any actions arising from the review, (see 4.2.4)

7.2.3 Customer Communication

Streamline Circuits has implemented an effective procedure, "Customer Related Processes Procedure" (QS-PR-009) for communicating with customers in relation to;

- Product information,
- Enquiries, contracts and order handling, including amendments, and
- Customer feedback, including customer complaints
- Advisory notices (not applicable refer to section 8.5.1)

7.3 Design and Development

This Quality System Element ***exclusion applies***. This sub-clause is included to align the clause numbering scheme with that of ISO 9001:2015, AS9100 and ISO 13485:2016. ***Streamline Circuits*** does not participate in design or development therefore it is not applicable to the operations at this site.

7.4 Purchasing

7.4.1 Purchasing Process

"Purchasing Procedure" (QS-PR-012) is followed to ensure that purchased product conforms to the specified purchase requirements.

The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the Purchasing Procedure. Responsibilities and

criteria for selection, evaluation and re-evaluation, status and status change and risk analysis are documented in the procedure. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the evaluation and any necessary actions are maintained as quality records (see 4.2.4). The organization is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

Streamline Circuits:

- maintains a register of its suppliers that includes approved status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);
- periodically review supplier performance; the results of these reviews shall be used as a basis for establishing the level of controls to be implemented,
- define the necessary actions to be taken when dealing with suppliers that do not meet requirements;
- ensure where required that both the organization and all suppliers use customer-approved special process sources,
- define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and
- determine and manage the risk when selecting and using suppliers (refer to 7.1.2)

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate:

- requirements for approval of product, processes and equipment;
- requirements for qualification of personnel;
- QMS requirements outlined in the Purchasing Procedure;
- the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data;
- requirements for test, inspection, verification (including production process verification (including production process verification, use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics;
- requirements for test specimens (e.g. production method, number, storage conditions) for inspection, investigation or auditing;
- requirements regarding the need for supplier to:
  - notify ***Streamline Circuits*** of nonconforming product;
  - obtain ***Streamline Circuits*** approval for nonconforming product disposition;
  - notify ***Streamline Circuits*** of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and where required, obtain ***Streamline Circuits*** approval, and
  - flow down to the supply chain the applicable requirements including customer requirements;
- record retention requirements (see 4.2.4), and
- right of access by the organization, their customer, and regulatory authorities to the applicable area of all facilities, at any level of the supply chain, involved in the order and to all applicable records

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of Purchased Product

Purchasing Procedure describes the process used to verify that purchased product meets specified purchase requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

Verification activities can include:

- obtaining objective evidence of the conformity of the product from suppliers (e.g. accompanying documentation, certificate of conformity, test reports, statistical records, process control);
- inspection and audit at supplier's premises;
- review of the required documentation;
- inspection of products upon receipt;
- avoidance, detection, mitigation, and disposition of counterfeit parts/material/chemistry refer to "Counterfeit Material Avoidance Plan" (QS-PL-005), and
- delegation of verification to the supplier, or supplier certification.

Where purchased product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

When ***Streamline Circuits*** becomes aware of any changes to the purchased product, we shall determine whether these changes affect the product realization process.

If ***Streamline Circuits*** or the customer intends to perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Verification by the customer shall not be used by ***Streamline Circuits*** as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer. Records of the verification shall be maintained (see 4.2.4)

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Streamline Circuits plans and carries out production and service provision under controlled conditions

Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product. Resulting in the conversion of customer requirements (e.g. purchase order, master drawing, electronic data files, etc.) and assure customer's needs are met;
- the availability of standard operating procedures, work instructions (e.g., manufacturing plans, travelers and inspection documents), as necessary;
- qualification of infrastructure;
- the availability and use of monitoring and measuring equipment;
- the implementation of monitoring and measurement;
- the implementation of product release, delivery and post-delivery activities:
- accountability for all product during production (e.g., parts quantities, split orders, nonconforming product);
- evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- provision for the prevention, detection, and removal of foreign objects;
- monitoring and control of utilities and supplies (e.g., water, compressed air, electricity and chemical products) to the extent they affect conformity to product requirements;
- criteria for workmanship, specified in the clearest practical manner (e.g., written standards, representative samples, illustrations);
- the implementation of defined operations for labeling and packaging, and
- Implementation of product release, delivery and post-delivery activities.

Planning considers, as appropriate:

- establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified;

- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stage of realization, and
- special processes

Cleanliness of product:

Streamline Circuits has documents requirements in regards to cleanliness of product and/or contamination control in regards to the product we manufacture.

- product is supplied to be used non-sterile, and its cleanliness is of significance in use, and
- process agents are to be removed from product during manufacturing

Outsourced processes:

Streamline Circuits shall ensure that externally provided processes, products and services conform to requirements. Outsourced processes include mass lamination, hot air leveling. Refer to "Outsource Processes" (QS-PR-040);

- outsourcing is controlled through the purchasing process. Purchase orders for outsourcing clearly describe or reference the work to be done and any needed specifications;
- confirmation that the requirements have been met is by review of any required documentation and any required additional testing or inspection;
- product outsourcing is defined on the traveler;
- incoming verification results are recorded on the traveler, and
- validation results (Certificates of Conformance, Inspection Reports, etc.) are filed and become part of the traveler record.

7.5.1.1 Production Process Verification

Streamline Circuits uses a representative item from the first production run (first article) of a new part to verify that the production processes, production documentation and tooling are capable of producing conforming parts that meet requirements. This verification shall be repeated when changes occur that invalidates the original results (e.g., engineering changes orders, manufacturing process changes, tooling changes).

7.5.1.2 Control of Production Process Changes:

Personnel authorized changes to production processes are identified "Engineering Change Notice (ECN) Form" (PE-FM-005). ***Streamline Circuits*** identifies and obtains acceptance of changes that require customer or regulatory authority approval in accordance with contract or regulatory requirements. Regulatory requirements are met by meeting customers' requirements.

Streamline Circuits, controls and documents changes affecting processes, production equipment, tools or software programs. The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control/monitor product realization processes are validated prior to release for production and maintained. Storage requirements, including periodic preservation/condition checks, have been be defined for production equipment or tooling in storage.

7.5.1.4 Post-Delivery Support

Post-delivery support shall provide as applicable for the:

- collection and analysis of in-service data;
- actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or statutory and regulatory requirements. Regulatory requirements are met by meeting customers' requirements;
- control and updating of technical documentation;
- approval, control, and use of repair schemes, and

- controls required for off-site work (e.g. organization's work undertaken at the customer's facilities).

7.5.2 Validation of Processes for Production and Service Provision

Streamline Circuits validates any processes for production and service provision where the resulting output can not be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Streamline Circuits has documented the process for validation including:

- defined criteria for review and approval of the processes;
- approval of equipment and qualification of personnel;
- use of specific methods and procedures;
- requirements for records (see 4.2.4), and
- revalidation

7.5.3 Identification and Traceability

Streamline Circuits identifies the product throughout product realization according to the "Identification and Traceability Procedure" (QS-PR-015) includes unique identification as required per customer or applicable regulatory requirements.

Streamline Circuits has established documented procedure to ensure that product(s) returned to the organization are identified and distinguished from conforming product "Return Material Authorization (RMA) Work Instruction" (QC-WI-010).

Streamline Circuits maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration "Configuration Management Procedure" (QS-PR-039). Product is identified with respect to monitoring and measurement requirements. Throughout production and storage to ensure the only product that has passed the required inspections and test. When acceptance authority media such as stamps, electronic signatures or passwords are used.

Streamline Circuits establishes and documents controls for the media. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

Streamline Circuits system provides for:

- identification to be maintained throughout the product life;
- the ability to trace all products manufactured from the same batch of raw material or from the same manufacturing batch, to the destination (delivery, scrap), and
- for a product, a sequential record of its production (manufacture and inspection/verification) to be retrieved.

7.5.4 Customer Property

Streamline Circuits exercises care with customer property while it is under the organization's control or being used. The "Customer Property Procedure" (QS-PR-016) outlines the identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, ***Streamline Circuits*** will report this to the customer and maintain records (see 4.2.4). Customer property can include intellectual property, and personal data.

7.5.5 Preservation of Product

Streamline Circuits preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Refer to "Preservation of Product Procedure" (QS-PR-017). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and applicable statutory and regulations requirements, provisions for:

- cleaning;

- prevention, detection and removal of foreign objects “Foreign Object Elimination (FOE) Plan” (QS-GL-002);
- special handling for sensitive products;
- suitable packaging and shipping containers
- marking and labeling including safety warnings;
- self-life control and stock rotation;
- special handling for hazardous materials, and
- establish documented procedures or documented work instruction for the control of product with limited shelf-life, requiring special storage conditions or special conditions needed if packaging alone cannot provide preservation. Such special storage conditions shall be controlled and recorded (see 4.2.4)

7.6 Control of Monitoring and Measuring Equipment

Streamline Circuits has determined the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. “Control of Monitoring and Measuring Equipment Procedure” (QS-PR-018) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements;

- be calibrated or verified , or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);

- be adjusted or re-adjusted as necessary;
- have identification in order to determine its calibration status;
- be safeguarded from adjustments that would invalidate the measurement result, and
- be protected from damage and deterioration during handling, maintenance and storage.

Streamline Circuits has established, implemented and maintains a process for the recalled of monitoring and measuring equipment requiring calibration or verification.

In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. ***Streamline Circuits*** takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained (see 4.2.4)

Streamline Circuits maintains a register of the monitoring and measuring equipment. The process used for their calibration/verification are defined in procedures, work instructions, equipment manuals, includes details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

When used in the Monitoring and Measurement of specified requirements, the ability of computer software to satisfy the intended application is used for confirmation. This is undertaken prior to initial use and reconfirmed as necessary.

Streamline Circuits ensures that environmental conditions suitable for the calibrations, inspections, measurements, and testing are being carried out.

Related Documents

Planning of Product Realization Procedure	QS-PR-037
Risk Management Procedure	QS-PR-038
Configuration Management Procedure	QS-PR-039
Customer Related Processes Procedure	QS-PR-009

International Traffic Arms Regulation Policy “ITAR” Procedure	QS-PR-033
Purchasing Procedure	QS-PR-012
Engineering Change Notice (ECN) Form	PE-FM-005
Identification and Traceability Procedure	QS-PR-015
Control of Customer Property Procedure	QS-PR-016
Preservation of Product Procedure	QS-PR-017
Foreign Object Elimination (FOE) Plan	QS-GL-002
Control of Monitoring and Measuring Equipment Procedure	QS-PR-018
Return Material Authorization (RMA) Work Instruction	QC-WI-010
Outsource Processes	QS-PR-040
Counterfeit Material Avoidance Plan	QS-PL-005

Section 8: Measurement, Analysis and Improvement

8.1 General

Streamline Circuits plans and implements the monitoring, measurement, analysis and improvement processes as needed:

- to demonstrate conformity to product requirements;
- to ensure conformity of the QMS, and
- to continually improve the effectiveness of the QMS.

Processes are identified in documented and include determination of applicable methods, including statistical techniques, and the extent of their use.

According to the nature of the product built and depending on the specified requirements, statistical techniques can be used to support:

- process control;
  - selection and inspection of key characteristics;
  - process capability measurements;
  - statistical process control;
- inspection, and
- failure mode, effect and critically analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, ***Streamline Circuits*** monitors information relating to customer perception/feedback as to whether the organization has fulfilled customer requirements.

Feedback

Information to be gather and used for the evaluation of customer satisfaction includes, but is not limited to, product conformity, on-time delivery performance, customer complaints/compliments and corrective action requests. The method for obtaining and using this information is identified in the “Customer Satisfaction Procedure” (QS-PR-023).

Feedback should come from production and post-production activities. The information shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

Complaint Handling

Streamline Circuits has a documented procedure for timely complaint handling in accordance with applicable regulatory requirements:

Procedure includes at a minimum requirements and responsibilities for:

- receiving and recording information;
- evaluating information to determine if the feedback constitutes a complaint;
- investigating complaints;
- determining the need to report the information to the appropriate regulatory authorities;
- handling of complaint-related product, and
- determining the need to initiate corrective actions.

When complaint is not investigated, justification is documented, any correction or action resulting from compliant handling process is documented. If an investigation determines activities outside the company contributed to the complaint, relevant information shall be exchanged between the organization and the external party involved. Refer to “Return Material Authorization (RMA) and Complaint Handling” (QC-WI-010).

Records of complaint handling are maintained (see 4.2.4)

Reporting to Regulatory Authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events. ***Streamline Circuits*** shall document procedures for proving notification to the appropriate regulatory authorities. Refer "Notification Process for Recalling Product and Reporting to Regulatory Authorities" (MF-WI-001).

8.2.2 Internal Audit

Streamline Circuits conducts internal audits at planned intervals to determine whether the QMS:

- conforms to the planned arrangements (refer to 7.1), to the requirements of International Standard, customer contractual requirements and to the QMS requirements established by the ***Streamline Circuits,*** and
- is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The selection of auditor(s) and conduct of audits shall ensure objectivity and impartiality of the audit process. The criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the "Internal Audit Procedure" (QS-PR-024).

The management responsible for the area being audited is responsible for ensuring that any necessary corrections and corrective actions are taken. Without undue delay and to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results. Records of the audits and their results are maintained (see 4.2.4).

8.2.3 Monitoring and Measurement of Processes

Streamline Circuits applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, we follow the "Nonconforming Material Control and Review Procedure" (QS-PR-029):

- takes appropriate action to correct the nonconforming process;
- evaluates whether the process nonconformity has resulted in product nonconformity;
- determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- identify and controls the nonconforming product (refer to 8.3).

The process for identifying and carrying out the required Monitoring and Measuring of Processes is documented in the "Statistical Techniques Procedure" (QS-PR-022).

8.2.4 Monitoring and Measurement of Product

Streamline Circuits monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes. Evidence of conformity with the acceptance criteria is maintained. Refer to "Receiving Inspection Procedure" (QS-PR-025), "In-Process Inspection Procedure" (QS-PR-026) and "Final Inspection Procedure" (QS-PR-027).

Measurement requirements for product acceptance are documented and includes:

- criteria for acceptance and/or rejection;
- where in the sequence measurement and testing operations are performed;
- required records of the measurement results (at a minimum, indication of acceptance or rejection and identity of personnel performing any inspection or testing);
- any specific measurement instruments required and any specific instructions associated with their use, and
- identity of the person authorizing release of product

When critical items, including key characteristics have been identified ***Streamline Circuit*** ensures we controlled and monitored in accordance with the established processes. When we use sampling inspection as a means of product acceptance, the plan is justified on the basis of recognized statistical principles and appropriate for use (e.g., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

The release of product to the customer shall not proceed until the planned arrangements (refer to 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable by the customer. ***Streamline Circuits*** ensures that all documents required to accompany product are present at delivery.

Records indicate the person authorizing release of product, and provide evidence that the product meets requirements (see 4.2.4).

8.3 Control of Nonconforming Product

Streamline Circuits ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product. Refer to "Nonconforming Material Control and Review Procedure" (QS-PR-029).

The term "nonconforming product" includes nonconforming product returned by a customer.

Where applicable ***Streamline Circuits*** deals with nonconforming product by one or more of the following ways:

- by taking action to eliminate the detected nonconformity;
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- by taking action to preclude its original intended use or application, and
- by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has stated.

Streamline Circuits ensures nonconforming product control process shall provide for timely reporting of delivered nonconforming product. By taking actions necessary action:

- taking action to eliminate the detected nonconformity;
- taking action to preclude its original intended use or application, and
- authorizing its use, release or acceptance under concession/ and/or (AABUS).

Streamline Circuits has incorporated the use of **"use-as-is"** which refers to **"in accordance with specifications".** The allowance of and the requirements for repair of bare printed circuits boards shall be As Agreed Between User and Supplier (AABUS). ***Streamline Circuits*** **does not** perform repair on medical, military, space or military avionics product.

If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization an approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. Product disposition for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

When nonconforming product is detected after delivery or use has started, ***Streamline Circuits*** shall take action appropriate to the effects, or potential effects, of the nonconformity. Process steps are defined in "Return Material

Authorization (RMA) and Complaint Handling" (QC-WI-010) and "Notification Process for Recalling Product and Reporting to Regulatory Authorities" (MF-WI-001).

Records of the nature of nonconformities and any subsequent actions taken, including any concessions obtained, are documented and maintained (see 4.2.4).

8.4 Analysis of Data

Streamline Circuits determines collects and analysis appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made. The process for determining, collecting and analyzing this data is defined in "Management Responsibility Procedure" (QS-PR-006) and "MIL-PRF-31032 Quality Management Plan" (QS-PR-041).

Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources. Analysis is performed using "Statistical Techniques Procedure" (QS-PR-022).

The analysis of data provides information relating to:

- customer satisfaction/feedback;
- conformance to product requirements;
- characteristics and trends of processes and products including opportunities for preventive action;
- suppliers:
- audits, and
- service reports, as appropriate

If the analysis of data shows that the QMS is not suitable, adequate or effective, ***Streamline Circuits*** will use this analysis as input for improvement as required in (see 8.5). Records of the results of the analysis of data shall be maintained (see 4.2.4)

8.5 Improvement

8.5.1 Continual Improvement

Streamline Circuits continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Management monitors the implementation of improvement activities and evaluates the effectiveness of results. Refer to "Continuous Advancement of Product and Services (CAPS)" (QS-MN-002).

The organization shall establish documented procedures for issue. These procedures shall be capable of being implemented at any time. Implementations of advisory notices are not applicable. ***Streamline Circuits*** is a contract manufacturer we build to customer drawing. We do not issue advisory notices. This would be the responsibility of the customer.

Records of customer complaints investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.2.4).

If any customer complaint is not followed by corrective action and/or preventive action the reason shall be authorized and recoded (see 4.2.4).

If national or regional require notification of adverse events that meet specified reporting criteria the organization shall establish documented procedures to such notification to regulatory authorities.

8.5.2 Corrective Action

Streamline Circuits takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. "Corrective Action Procedure" (QS-PR-031) defines requirements for:

- reviewing nonconformities (including customer complaints);
- determining the causes of nonconformities;
- evaluating the need for action to ensure that nonconformities do not recur;

- determining and implementing action needed;
- reviewing the effectiveness of the corrective action taken;
- flowing down corrective action requirements to a supplier, when it is determined that the supplier is responsible for the nonconformity;
- specific actions where timely and/or effective corrective actions are not achieved;
- determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required;
- verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product, and
- records of the results of action taken (see 4.2.4).

8.5.3 Preventive Action

Streamline Circuits determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. “Preventive Action Procedure” (QS-PR-035) defines requirements for:

- determining potential nonconformities and their causes;
- evaluating the need for action to prevent occurrence of nonconformities;
- determining and implementing action needed;
- verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product;
- reviewing the effectiveness of the preventive action taken, and
- records of results of action taken (see 4.2.4).

Related Documents

Customer Satisfaction Procedure	QS-PR-023
Internal Audit Procedure	QS-PR-024
Receiving Inspection Procedure	QS-PR-025
In-Process Inspection Procedure	QS-PR-026
Final Inspection Procedure	QS-PR-027
Nonconforming Material Control and Review Procedure	QS-PR-029
Management Responsibility Procedure	QS-PR-006
MIL-PRF-31032 Quality Management Plan	QS-PR-041
Statistical Techniques Procedure	QS-PR-022
Corrective Action Procedure	QS-PR-031
Preventive Action Procedure	QS-PR-035
Notification Process for Recalling Product and Reporting to Regulatory Authorities	MF-WI-001
Return Material Authorization (RMA) and Complaint Handling	QC-WI-010
Continuous Advancement of Product and Services (CAPS)	QS-MN-002

Appendix A

Master List of Key QMS Documents

Document Number	Document Title
QS-CH-001	Organizational Structure and Technical Review Board
QS-GL-002	Foreign Object Elimination (FOE) Plan
QS-ML-001	Records Table
QS-ML-005	Preventive Action Organizer Worksheet
QS-MN-001	Quality Systems Manual
QS-MN-002	Continuous Advancement of Product and Services (CAPS) Manual
QS-PC-001	Quality Policy
QS-PL-002	Quality Plan & Process Control Checkpoints
QS-PL-004	Calibration Process Plan
QS-PL-005	Counterfeit Material Avoidance Plan
QS-PL-007	Quality Objectives
QS-PR-001	Document Control
QS-PR-002	Control of Quality Records
QS-PR-006	Management Responsibility
QS-PR-007	Competence Awareness and Training
QS-PR-009	Customer Related Processes
QS-PR-012	Purchasing
QS-PR-015	Product Identification and Traceability
QS-PR-016	Control of Customer Property
QS-PR-017	Preservation of Product
QS-PR-018	Control of Monitoring and Measuring Devices
QS-PR-020	Infrastructure
QS-PR-022	Statistical Techniques
QS-PR-023	Customer Satisfaction
QS-PR-024	Internal Audits
QS-PR-025	Receiving Inspection
QS-PR-026	In-Process Inspection
QS-PR-027	Final Inspection
QS-PR-029	Nonconforming Material Control and Review
QS-PR-031	Corrective Action Procedure
QS-PR-033	International Traffic Arms Regulation Policy “ITAR”
QS-PR-035	Preventive Action
QS-PR-036	Gage R & R Procedure
QS-PR-037	Planning of Product Realization
QS-PR-038	Risk Management
QS-PR-039	Configuration Management
QS-PR-040	Outsourced Processes
QS-PR-041	MIL-PRF-31032 Quality Management Plan
MF-WI-001	Notification Process for Recalling Product and Reporting to Regulatory Authorities
QC-WI-010	Return Material Authorization (RMA) and Complaint Handling
PE-FM-005	Engineering Change Notice (ECN) Form
ES-MN-002	Hazard Communication Program Training Manual
ES-MN-003	Injury and Illness Prevention Program for High Hazard Employers Manual
XX-WI-XXX	Work Instructions
XX-PC-XXX	Pictorials
XX-PL-XXX	Quality Plans
XX-GL-XXX	Guidelines
XX-FM-XXX	Forms
XX-LG-XXX	Logs

QUALITY SYSTEM MANUAL REVISIONS

REV.	SECTION	SUB-SEC.	COMMENTS	DATE	AUTHORIZED BY
A	All	ALL	New	10/01/03	Lorraine Hook
B	6.2	6.2.1	Add Job Descriptions	03/31/05	Lorraine Hook
C	All	All	Upgrade to AS9100 & MIL-PRF-31032	09/15/06	Lorraine Hook
D	All	All	Minor Changes Spelling Errors	01/15/08	Lorraine Hook
E	5.3, 5.4 8.5	5.4.1 8.5.2 8.5.3	Updated due to Obsolete or Title Changes of Related Procedures	07/13/08	Lorraine Hook
F	All	All	Updates to add AS9000 Rev C Changes, Grammar and Spelling Errors	11/01/2010	Lorraine Hook
G	1.2, 2.0 4.1, 5.3, 7.1, 7.3, 8.2.4	7.1.1,	Update to 1.2 added justification for exclusion, 2.0 & 4.1 removed revisions and changed to latest revision. 4.1 added last bullet on outsource. 7.3 added justification for exclusion. 7.5.2 Removed as exclusion and added. 8.2.3 & 8.2.4 removed QS-PR-040. 8.2.4 added QS-PR-025, 026 & 027 updated related documents. Change work program management to project	11/01/2011	Lorraine Hook
H	All	All	Updates added information on MIL-PRF-31032, added ISO 13485:2003. New lay-out added Environmental, Conflict Mineral Policy, and Absence of REACH Substances of Very High Concern Policy, Exclusion Table and Appendix A Master List of Key QMS Documents.	08/31/2013	Lorraine Hook
I	1, 3, 4, 5, 7 & 8	1.1, 1.2, 3.0, 4.1,4.2.3, 4.2.4, 5.1, 5.5.3, 5.6.2, 7.1.4, 7.2.1, 7.2.3, 7.5.1, 7.5.1.2, 7.5.1.4, 8.3,, 8.5.1,	Added scope of registration, updated Quality Policy, exclusions 7.5.1.2.1, 7.5.1.2 .2, 7.5.1.2.3, 7.5.3.2.2, added note to Advisory notices page 11, updated policy on regulatory requirements on page 12,13 , 17, 19, 23, 26, 27 added Outsourced Processes page 26, added repair statement page 31 and updated appendix 4	11/26/13	Lorraine Hook
J	4	4.2.2	Updated page 14 adding Core Processes at Build Requirements. Also removed ISO off title	01/29/2015	Lorraine Hook
K	All	Cover, pages 5, 8, 9 & sections 1.1, 1.2 2.0, 3.0, 4.1, 4.2.1, 4.2.3, 4.2.4, 5.1, 5.2, 5.4.1, 5.4.2, 5.5.1, 5.6.2, 5.6.3, 6.6.2, 6.3, 6.4, 7.1.4, 7.2.1, 7.2.2, 7.4.1, 7.4.2, 7.4.3, 7.5.1, 7.5.3, 7.5.5, 8.2.1, 8.2.4, 8.3, 8.4, 8.5.2., 8.5.3 & page 35	Update to align with changes in ISO 13485:2016 and ISO 9001:2015 cover, added Right to Access, Counterfeit Electronics Parts, Avoidance, Detection, Mitigation and Disposition, Organizational Structure and Technical Board. Added Use-As-Is, added document diagram, updated related documents and appendix A. Changes are in blue on master copy.	06/05/2016	Lorraine Hook
L	4	4.2.2	Updated page (Org Chart), 12, 15 (Interaction of Process Diagram), 19, 31 & 35 typo errors	11/15/2016	Lorraine Hook
M	4		Updated page 15 Interaction of Process Diagram and Rev page typo error page 15	12/01/2016	Lorraine Hook