



**ISO 9001 Quality
Policy Manual**

Quality Policies Manual

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Quality Policies Manual
Formal Policies

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Quality Assurance Manager

(Note: Update Distribution List at each revision change)

Title: **Purpose and Scope**

1. Scope

The purpose of the Quality Policies Manual is to document the Quality Management System used by **AEROTRONICS** to:

- a) assure the quality of its products and services *consistently meets customer and applicable statutory and regulatory requirements.*
- b) *enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.*

2. Normative references

The scope of the Quality Management System includes only the activities and materials of **AEROTRONICS** operations under the requirements of ISO 9001: 2015

Title: **Terms and Definitions****3.0 Quality Systems Definitions**

- 3.1 **Approved Supplier List** – A listing or record of suppliers that have been approved to provide materials, parts, products and/or services.
- 3.2 **Audit** – A systematic and independent examination of activities to determine whether they comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve documented objectives.
- 3.3 **Calibration** – The process by which measurement and test equipment is checked for accuracy by comparison to known standards.
- 3.4 **Conformance** – The state of meeting the specified requirement(s).
- 3.5 **Continuous Improvement** – The systematic and continuous elimination of wasted capital, materials, labor and time accomplished by the identification and resolution of problems, (root causes) and the reduction of variation.
- 3.6 **Contract** – Requirements agreed to between a supplier and a customer, transmitted by any means.
- 3.7 **Context** – Combination of internal and external issues that can have an effect on an organization's approach to developing and achieving objectives.
- 3.8 **Corrective Action Report (CAR)** - Used for internal corrective actions.
- 3.9 **Customer** – The recipient of a product or service provided by a supplier.
- 3.10 **Customer Complaint** – Any reported allegation, written or verbal, from a customer of deficiencies related to the identity, quality, durability, reliability safety or performance of a product or service.
- 3.11 **Cybersecurity** – Measures taken to protect a computer or computer system (as on the internet) against unauthorized access or attack.
- 3.12 **Design** – The process of translating customer requirements into quantifiable and measurable specifications which, when achieved, assure the output will meet those requirements.
- 3.13 **Design Change** – A formal revision to specifications/configurations requiring review and approval by responsible function(s).
- 3.14 **Design Verification** – The process of proving design by testing.
- 3.15 **Document** – To write requirements prior to an event; or a drawing, specification, procedure, etc., that contains written requirements.
- 3.16 **External Provider** – See Supplier

Title: **Terms and Definitions**

- 3.17 **Finding** – Objective evidence that a system/product requirement or specification is missing or is not being implemented with complete reliability.
- 3.18 **FOD** – Foreign Object Debris
- 3.19 **Interested parties** – Person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.
- 3.20 **Label** – All written, printed or graphic matter:
a) On a product or any of its containers or wrappers; or
b) Accompanying a product; relating to identification, technical description and use of the product but excluding shipping documents.
- 3.21 **Labeling** – The process of combining labels with products.
- 3.22 **Nonconformance** – A deficiency of a characteristic or a failure to adhere to documented procedures, which may render the quality of a product or service unacceptable.
- 3.23 **NCMR** – Nonconformance Material Report - Used for supplier rejects.
- 3.24 **Observation** – Objective evidence that a system/product requirement or specification is not being implemented with complete reliability but is not repetitive or missing. An observation may also include an audit element, which is not contrary to documented requirements, but warrants further qualification or improvement.
- 3.25 **Organization** – Person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives.
- 3.26 **Procedure** – A document that describes specifically how an activity is to be performed. It may include methods to be used, equipment to be used and sequence of operations.
- 3.27 **Process** – A set of interrelated activities that uses inputs and deliver and intended result.
- 3.28 **Process Control** – Operational procedures designed to monitor a process with built in feedback and adjustment steps required to maintain the outcome (product or service) in conformance with requirements.
- 3.29 **Product** – The physical good or service *intended for, or required by, a customer* that is the output of a process.
- 3.30 **Qualified Auditor** – An individual trained and experienced in designated audit procedures who is independent of the system or activity to be audited.
- 3.31 **Quality** – The totality of characteristics of a product or service that bear on its ability to satisfy stated and implied requirements or needs.

Title: Terms and Definitions

- 3.32 **Quality Assurance** – The activity of providing the evidence needed to establish confidence among all concerned that the quality function is being effectively performed. Dynamic planned quality systems designed with emphasis on prevention. Quality Assurance depends on tangible evidence of adequacy of such characteristics as capability, availability, reliability, operability, maintainability, durability, safety and cost.
- 3.33 **Quality Policies Manual** – An approved quality manual that describes the methods and controls for conformance of the products and services provided.
- 3.34 **Quality Control** – Inspection, test or examination techniques used to ensure that materials, products or services conform to specified requirements.
- 3.35 **Quality System** – The organizational structure, responsibilities, procedures, processes and resources necessary to effectively manage the quality function.
- 3.36 **Record** – Retrievable information / data.
- 3.37 **Requirement** – All stated and implied criteria, which must be met to satisfy market demands.
- 3.38 **Review** – An examination to evaluate conformance, which shall be indicated by signature, initials, stamps, flags/indicators, etc.
- 3.39 **Rework** – Restoring a nonconformance to conformance of original specifications.
- 3.40 **Risk & Opportunities** – That need to be addressed to a) give assurance that the QMS can achieve its intended results; b) enhance desirable effects; c) prevent, or reduce, undesirable effects; d) achieve improvement.
- 3.41 **RMA** – Returned Material Authorization - Used for customer rejects, corrective and preventative actions.
- 3.42 **Sample** – In acceptance sampling, one or more units of product (or a quantity of material) drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot.
- 3.43 **Sample size** – (n) The number of units in a sample.
- 3.44 **Scorecard** – A scorecard is an evaluation device, usually in the form of questionnaire, that specifies the criteria customers will use to rate your business's performance in satisfying their requirements.
- 3.45 **Specifications** – A document that states the requirements to which a given product or service must conform.

Title: **Terms and Definitions**

- 3.46 **Standard** – The metric, specification, gage, statement, category, segment, grouping, behavior, event or physical product sample against which the outputs of a process are compared and declared acceptable or unacceptable.
- 3.47 **Standard deviation** – A computed measure of variability indicating the spread of the data set around a mean.
- 3.48 **Statistical Process control (SPC)** – The application of statistical techniques to control a process.
- 3.49 **Statutory and Regulatory Requirements** – *Legal requirements.*
- 3.50 **Supplier** – A source of materials, service or information input provided process.
- 3.51 **Top Management** – Person or group of people who direct and control an organization at the highest level.
- 3.52 **Survey** – The act of examining a process or of questioning a selected sample of individuals to obtain data about a process, product or service.
- 3.53 **Tolerance** – The maximum and minimum limit values a product may have and still meet customer requirements.
- 3.54 **Total Quality** – A strategic integration system for achieving customer satisfaction that involves all managers and employees and uses quantitative methods to continuously improve an organization's process.
- 3.55 **Trend** – The graphical representation of a variable's tendency, over time, to increase, decrease or remain unchanged.
- 3.56 **Unit** – An object on which a measurement or observation can be made. Commonly used in the sense of a "unit of product," the entity of product inspected in order to determine whether it is defective or non-defective.
- 3.57 **Validation** – The act of confirming a product or service meets the requirements for which it was intended.
- 3.58 **Value added process** – Activities that transform input into a customer usable output. The customer can be internal or external to the organization.
- 3.59 **Variation** – A change in data, characteristic or function caused by one of four factors: special causes, common causes, tampering or structural variation.
- 3.60 **Verification** – The act of determining whether products and services conform to specific requirements.
- 3.61 **Waste** – An activity that consumes resources and produces no added value to the product or service a customer receives.

Title: **Context of the Organization**

4.1 Understanding the organization and its context

AEROTRONICS shall determine external and internal issues that are relevant to its purpose and its strategic direction and that may affect its ability to achieve the intended results of the Quality Management System.

AEROTRONICS shall monitor and review information about these external and internal issues.

Internal issues may be related to values, culture, knowledge, and performance of the organization.

External issues can arise from legal, technological, competition, market, cultural, social and economic environments, whether international, national, regional or local.

Issues can include positive and negative factors or conditions for consideration.

4.2 Understanding the Needs and Expectations of Interested Parties

ISO9001:2017 definition of “interested parties” - “person or organization that can affect, be affected by, or perceive itself to be effected by a decision or activity.”

Examples of interested parties include customer, owners, people in the organization, providers, bankers, competitors, etc.

The scope of ISO9001 is to provide products and services that meet customer, statutory, and regulatory requirements. **AEROTRONICS** will address only those applicable interested parties that effect its ability to provide products or services that meet the Quality Management System requirements.

4.3 Determining the Scope of the Quality Management System

The scope of **AEROTRONICS** Quality Management System is:

“The design, manufacture, and distribution of precision screw machine components, pins, sockets, and bodies for electrical connectors and precision medical components”.

The industries supplied by these components and services include:

- Military
- Aerospace
- Medical
- Commercial

Title: **Context of the Organization****4.4 Quality Management System and its Processes**

AEROTRONICS has implemented a Quality Management System that is continuously maintained and its processes improved for effectiveness in accordance with the requirements of ISO 9001:2015.

AEROTRONICS will use a process approach as outlined in the model below to continually improve the Quality Management System.

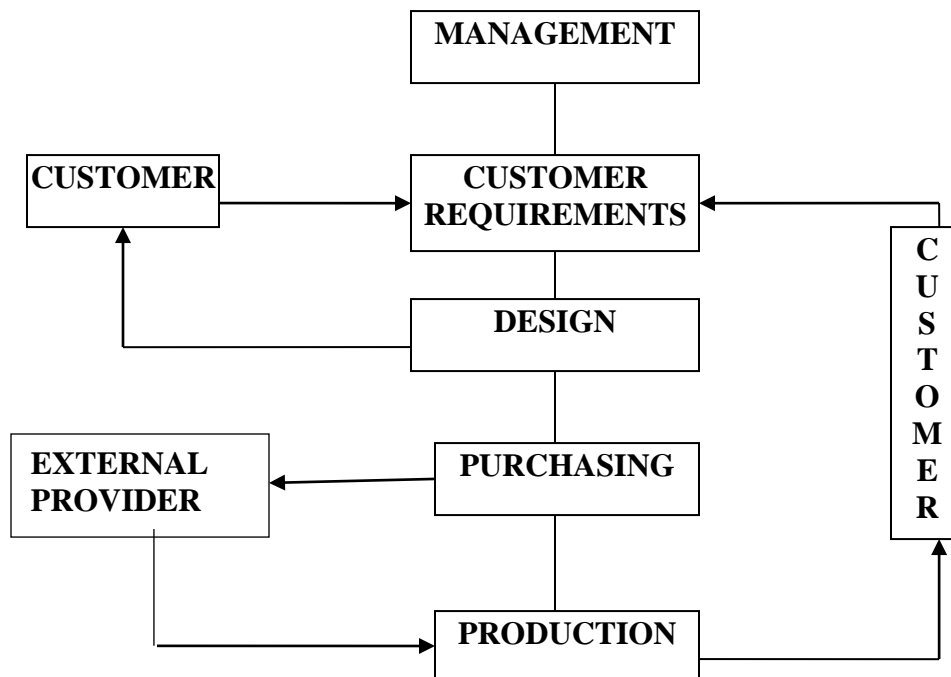


Figure 1: Model of Aerotronics Process Based Quality Management System

4.4.1 **AEROTRONICS** will determine the processes needed for the Quality Management System and their application throughout the organization, and shall:

- Determine the inputs required and the outputs expected from the processes;
- Determine the sequence and interaction of these processes;
- Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

Title: Context of the Organization

- d) Determine resources needed for these processes and ensure their availability;
- e) Assign the responsibilities and authorities for these processes;
- f) Address the risks and opportunities as determined in accordance with requirements of 6.1;
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) Improve the processes and the Quality Management system.

4.4.2 To the extent necessary, **AEROTRONICS** shall:

- a) Maintain documented information to support the operation of its processes;
- b) Retain documented information to have confidence that the processes are being carried out as planned.

Title: **Leadership**

5.1 Leadership and Commitment

5.1.1 **AEROTRONICS** top management shall demonstrate leadership and commitment with respect to the Quality Management System by:

- a) Taking accountability for the effectiveness of the Quality Management System;
- b) Ensuring that the Quality Policy and Quality Objectives are established for the Quality Management System and are compatible with the context and strategic direction of the organization;
- c) Ensuring the integration of the Quality Management System requirements into the organization's business processes;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring that the resources needed for the Quality Management System are available;
- f) Communicating the importance of effective quality management and of conforming to the Quality Management System requirements;
- g) Ensuring that the Quality Management System achieves its intended results;
- h) Engaging, directing, and supporting persons to contribute to the effectiveness of the Quality Management System;
- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer Focus

AEROTRONICS establishes, implements, and maintains documented procedures for contract review and for the coordination of related activities.

It is the responsibility of the Order Service Department to review all tenders and contract offerings.

Customer quotations, inquiries, orders, and contracts are reviewed to ensure customer requirements are adequately defined and documented.

Risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are assessed during all processes of the Quality Management System.

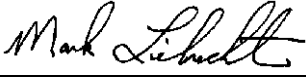
Any changes or amendments to the contract are reviewed according to the procedures established.

Title: **Leadership****5.2 Policy****5.2.1 Establishing the Quality Policy**

AEROTRONICS defines and documents its Policy for Quality, which provides the overall objectives for an effective Quality Management System. Top Management continually reviews the Quality Policy to ensure that it is relevant to **AEROTRONICS** goals and customer expectations. **AEROTRONICS** is a provider of professional services and products with sales in various world markets. Our **AEROTRONICS** Policy is:

***AEROTRONICS** is committed to the design and manufacture of connector products that exceed customer expectations, have high reliability, and are delivered on time at a competitive price. It is our policy to develop an employee base that is committed to comply with, and continually improve the effectiveness of, the quality management system. Each employee must be committed to a work ethic that prevents defects, reduces variability and promotes the theme of:*

“Do it right the first Time”.

Approved: 
President: Mark Liebrecht

5.2.2 Communicating the Quality Policy

AEROTRONICS employees and management are instructed in and have an understanding of our Quality Policy. The Quality Policy is also conspicuously displayed in various areas of the company and provides a constant reminder.

5.3 Organizational Roles, Responsibilities, and Authorities

It is the responsibility of the Quality Manager to ensure that the Quality Management System conforms to the requirements of ISO901:2015 Standard. This includes ensuring that the integrity of the Quality Management System is maintained when changes are planned and implemented.

It is the responsibility of the Internal Audit team to ensure that the processes conform to the Quality Management System and report any non-conformances.

It is the responsibility of the Quality manager to report on the performance of the Quality Management System and on opportunities for improvement to top management at the quarterly management reviews.

It is top managements responsibility to ensure that customer focus is promoted throughout the organization.

Title: **Planning****6.1 Actions to Address Risks and Opportunities**

6.1.1 **AEROTRONICS** will access risks and opportunities related to of Internal and External issues that may affect interested parties such as:

- Customers – Customer loyalty – Quality – On time delivery – Technology – Market share – Social and economic environment – Transportation
- Suppliers – Quality -Lead times - On-time delivery – Sole source vs alternate supplier – Capacity – Technical capabilities – economic environment (exchange rates)
- Competition – Strengths/Weaknesses - Size of organization – Price structure – Capacity – Short orders vs high quantities.
- Employees – Knowledge – Loyalty – Environment – Values – Culture

6.1.2 **AEROTRONICS** will plan actions to address these risks and opportunities. These actions will be implemented into the Quality Management System processes and monitored to evaluate the effectiveness of these actions.

6.2 Quality Objectives and Planning to achieve them

6.2.1 The primary objective of **AEROTRONICS** is to achieve customer satisfaction for both products and services. This is accomplished by implementing and maintaining the following:

- The quality system and procedures as outlined in this manual.
- Participative management focused on achieving continuous quality improvement.
- Training designated employees in job skills and quality.
- Establishing internal performance standards to meet and exceed customer requirements.

6.2.2 **AEROTRONICS** top management are responsible for planning how to achieve its quality objectives. This will be carried out by determining:

- What will be done;
- What resources will be required;
- Who will be responsible;
- When will it be completed;
- How the results will be evaluated.

Title: **Planning****6.3 Planning of changes**

When AEROTRONICS determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The following shall be considered:

- What is the purpose of the changes and their potential consequences;
- It must not affect the integrity of the Quality Management System;
- Are their enough resources available to make the change;
- Is it necessary to allocate or reallocate the responsibility and authority?

Title: **Support**

7.1 Resources

7.1.2 General

AEROTRONICS establishes, implements and maintains documented procedures for identifying training needs and for ensuring that personnel performing activities affecting quality are adequately trained, qualified and certified per established requirements or standards.

7.1.2 People

AEROTRONICS Senior Staff are responsible for determining the appropriate resource requirements and providing adequate resources for the organization. This includes, assigning trained personnel to implement and maintain the Quality Management System and continually improve its effectiveness in regard to customer satisfaction and customer requirements.

7.1.3 Infrastructure

AEROTRONICS establishes and maintains the facilities, utilities and all associated process equipment, both hardware and software, along with supporting services needed to achieve conformity to product requirements.

7.1.4 Environment for the operation of processes

AEROTRONICS establishes and maintains the appropriate work environment needed to achieve conformity to product requirements.

7.1.5 Monitoring and measurement resources

7.1.5.1 General

AEROTRONICS determines the monitoring and measurement resources needed to ensure valid and reliable results when monitoring and measuring is used to verify the conformity of products or services to the requirements.

The resources shall be:

- a) Suitable for the specific type of monitoring and measurement activities being undertaken
- b) Maintained to ensure their continuing fitness for their purpose.

Appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources will be retained.

Title: **Support****7.1.5.2 Measurement traceability**

AEROTRONICS together with its suppliers determines the monitoring and measurement requirements and establishes, implements and maintains documented procedures to control, and maintain inspection, measuring and test equipment used to demonstrate the conformance of product to the specified requirements.

Where necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified 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
- b) Be adjusted or re-adjusted as necessary
- c) Be identified to enable the calibration status to be determined
- d) Be safeguarded from adjustment that would invalidate the measurement result
- e) Be protected from damage and deterioration during handling, maintenance, and storage

AEROTRONICS implements and maintains documented calibration systems to ensure adequate control of inspection, measuring and test equipment and to assess the validity of previous results when the equipment is found not to conform to requirements. Calibration records are maintained for each item of inspection, measuring and test equipment to provide a documented calibration history.

7.1.6 Organizational knowledge

AEROTRONICS shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, **AEROTRONICS** shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

Organizational knowledge can be based on:

- a) Internal sources such as:
 - Intellectual property;
 - Knowledge gained from experience;
 - Lessons learned from failures and successful projects;
 - Capturing and sharing undocumented knowledge and experience;
 - The results of improvements in processes, products, and services.
- b) External sources such as:
 - Standards;
 - Academia;
 - Conferences;
 - Gathering knowledge from customer or external providers.

Title: **Support**

7.2 Competence

Department Managers are responsible for:

- a) Determining the necessary competency for personnel performing work affecting conformity to product requirements.
- b) Providing training or take other actions to achieve the necessary competence where applicable.
- c) Evaluate the effectiveness of the actions taken.
- d) Maintaining appropriate records of education, training, skills, and experience.

7.3 Awareness

Department Managers shall ensure that the persons doing the work are aware of:

- a) The quality policy;
- b) All relevant quality objectives;
- c) Their contribution to the effectiveness of the quality management system, including the benefits of improved quality;
- d) The implications of not conforming with the quality management system requirements.

7.4 Communication

AEROTRONCS shall determine the internal and external communications relevant to the quality management system, including:

- a) On what will be communicated;
- b) When to communicate;
- c) With whom to communicate;
- d) How to communicate;
- e) Who communicates.

7.5 Documented information

7.5.1 General

The Quality System Documentation consists of five levels; the Quality Policy (level one), the Quality Policies Manual (level two), Quality Procedures (level three), Work Instructions (level four) and Records (level five).

LEVEL I Quality Policy – A documented Policy Statement *and Quality Objectives*.

LEVEL II Quality Policies Manual – The Quality Policies Manual establishes requirements and guidelines for the overall Quality System objectives. These requirements and guidelines are applicable to the operations at **AEROTRONICS**.

Title: **Support**

LEVEL III Quality Procedures – The Quality Procedures Manual is a collection of Standard Operating Procedures (SOP's), which are documented in conformance with, and support of the Quality Policies Manual's requirements and guidelines. The Quality Procedures Manual details the implementation of requirements and guidelines for the operation.

LEVEL IV Work Instructions – Work Instructions are documented as necessary to support applicable Quality Procedure. They detail **specific** quality or inspection information and **specific instructions** for performance of individual tasks. (Work Instructions are placed as hard copies at relevant workstations).

LEVEL V Records – Completed Forms provide the objective evidence of compliance.

7.5.2 Creating and updating

When creating and updating documented information, AEROTRONICS shall ensure appropriate:

- a) Identification and description (e.g. a title, date, author, or reference number);
- b) Format (e.g. language, software version, graphics) and media (e.g. paper, electronic).
Wherever appropriate AEROTRONICS will make documents available on the network for viewing, but paper copies of relevant documents will be made available in the production area.
- c) Review and approval for suitability and adequacy.

7.5.3 Control of documented information

AEROTRONICS establishes implements and maintains documented procedures to control all documentation and data that relate to Quality System requirements, to include documents of external origin such as standards and customer drawings.

It is the responsibility of the Quality Assurance Manager and the assigned holders of Quality System Documents to maintain Quality System Documentation.

Documents and data are reviewed and approved for adequacy by the Quality Assurance Manager and the appropriate Department Supervisors as per the documented procedures. These controls ensure that:

- a) All documents, instructions and procedures are adequate for their intended purpose.
- b) Documents are reviewed, updated as necessary and re-approved.
- c) The changes and the current revision status of documents are identified.
- d) Correct documents, instructions and procedures are available at effected work locations and/or accessible to appropriate personnel.
- e) Documents remain legible and readily identifiable.
- f) Documents of external origin necessary for the planning and operation of the quality management system are identified and controlled.
- g) Obsolete Quality documents are promptly removed from all points of issue or use where appropriate. Obsolete drawings may be kept in closed customer and Supplier PO files as this

Title: **Support**

reflects the parts shipped. Obsolete drawing in open files must have a RED line drawn through them.

- h) Changes affecting form, fit, or function of product must be approved by the customer in accordance with contract or regulatory requirements.

Document Revisions are subject to:

- a) Approval – Revisions to documents are reviewed and approved by the same approval process and/or authority as the original.
- b) Revision Identification – Revised documents reflect the nature of revisions, where practical.
- c) Record of Revisions – Records of revisions are maintained by the issuing function where appropriate.

Title: **Operation**

8.1 Operational planning and control

AEROTRONICS develops the processes needed to meet the requirements for the provision of products and services by:

- a) Determining the requirements for the products and services;
- b) Establishing criteria for 1) the process; 2) the acceptance of products or services;
- c) Determining the resources needed to achieve conformity to the product and service requirements;
- d) Implementing control of the processes in accordance with the criteria;
- e) Determining, maintaining, and retaining documented information to the extent necessary:
 - To have confidence that the processes have been carried out as planned
 - To demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for AEROTRONIC'S operations.

AEROTRONICS shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

AEROTRONICS shall ensure that outsourced processes are controlled as addressed in section 8.4.

8.2 Requirements for products and services

8.2.1 Customer communication

AEROTRONICS develops and implements effective methods of communicating with customers in relation to:

- a) Providing information relating to products and services;
- b) Handling enquiries, contracts, or orders, including changes;
- c) Obtaining customer feedback relating to products and services, including customer complaints;
- d) Handling and controlling customer property;
- e) Establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services

AEROTRONICS determines the following:

- a) The requirements specified by the customer, including the requirements for delivery and post-delivery activities
- b) The requirements not stated by the customer but necessary for specified or intended use, where known
- c) Statutory and regulatory requirements applicable to the product
- d) Any additional requirements considered necessary by the organization

Title: **Operation**

8.2.3 Review of the requirements for products and services

8.2.3.1 **AEROTRONICS** reviews the requirements related to the product prior to commitment to supply product to the customer and ensures that:

- a) Product requirements are defined
- b) Contract or order requirements differing from those previously expressed are resolved
- c) The defined requirements can be achieved
- d) Risks (e.g. new technology, short delivery time scale) have been evaluated.

AEROTRONICS confirms product requirements with the customer when no documented statement is provided and ensures that relevant documents are amended and relevant personnel are notified of any changes or modifications.

8.2.3.2 **AEROTRONICS** maintains records of the results of reviews and actions arising from the review.

8.2.4 Changes to requirements for products and services

AEROTRONICS shall ensure that relevant documented information is amended, and the relevant persons are made aware of the changed requirements, when the requirements for products or services are changed.

8.3 Design and development of products and services

8.3.1 General

AEROTRONICS shall establish, implement, and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

AEROTRONICS plans and controls the design and development of product and manages the interfaces between different groups involved to ensure communication by determining:

- a) The nature, duration, and complexity of the design and development activities;
- b) The design and development stages – in respect of organization, task sequence, mandatory steps, significant stages, and method of configuration control
- c) The review, verification and validation that are appropriate to each design and development stage;
- d) The responsibilities and authorities for design and development;
- e) The internal and external resource needs for the for the design and development;
- f) The need for involvement of customers and users in the design and development process;
- g) The level of control expected by customers and other relevant parties;
- h) The documented information needed to demonstrate that design and development requirements have been met.

Title: **Operation**

8.3.3 Design and development inputs

AEROTRONICS determines and records inputs relating to product design and development to include:

- a) Functional and performance requirements;
- b) Applicable statutory and regulatory requirements;
- c) Where applicable, information derived from previous similar designs;
- d) Standards or codes of practice that **AEROTRONICS** has committed to implement;
- e) Potential consequences of failure due to the nature of the products or services.

These inputs are reviewed for adequacy and are complete, unambiguous and do not conflict with each other.

8.3.4 Design and development controls

AEROTRONICS shall apply controls to the design and development process to ensure that:

- a) The results to be achieved are defined;
- b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) Validation activities are conducted to ensure that the resulting products or services meet the requirements for the specified application and intended use;
- e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) Documented information of these activities is retained.

8.3.5 Design and development outputs

AEROTRONICS provides the outputs in a part drawing that enables verification against the design and development input, which are approved prior to release. The outputs are updated, as appropriate, as the design and development progresses.

These design and development outputs shall:

- a) Meet the input requirements for design and development
- b) Provide appropriate information for purchasing, production and for service provision
- c) Contain or reference product acceptance criteria
- d) Specify the characteristics of the product that are essential for its safe and proper use
- e) Identify key characteristics in accordance with design or contract requirements

8.3.6 Control of Design and Development Changes

AEROTRONICS identifies design and development changes and records are maintained. The changes are reviewed, verified, and validated, as appropriate and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and products already delivered.

Title: **Operation****8.4 Control of externally provided process, products, and services****8.4.1 General**

AEROTRONICS has developed, documented and implemented procedures and systems to ensure that material, products and services purchased from suppliers conform to specified purchase requirements.

The Purchasing Manager is responsible for Purchasing procedures and all relevant Quality System documentation, such as records of orders placed.

The Quality Assurance Manager is responsible for maintaining records on suppliers that are on the Approved Vendors List and has the authority to approve and disapprove suppliers after reviewing their quality and delivery performance.

8.4.2 Type and extent of control

AEROTRONICS shall ensure that externally provided processes, products, and services do not adversely affect **AEROTRONICS** ability to consistently deliver conforming products and services to our customers.

This will be achieved by:

- a) Making sure that externally provided processes remain within the control of **AEROTRONICS** quality management system;
- b) Defining both the controls that will be applied to an external provider and those that apply to the resulting output;
- c) Taking in consideration:
 - 1) The potential impact of the externally provided processes, products, and services on **AEROTRONICS** ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) The effectiveness of the control applied by the external provider;
- d) Determining the verification activities necessary to ensure that the externally provided processes, products, and services meet requirements.

8.4.3 Information for external providers

AEROTRONICS ensures that specified purchase requirements are adequate prior to being communicated to the supplier and that they describe the product, to include where appropriate:

- a) Requirements for approval of product, procedures, processes, and equipment. This information is communicated in applicable drawings and relevant specifications on the purchase order, drawings, or attachments.
- b) Requirements for qualification of personnel.
- b) Quality Management System requirements.

Title: **Operation**

8.5 Production and service provision

8.5.1 Control of production and service provision

AEROTRONICS establishes and maintains production and service provision under controlled conditions to include the following:

- a) The availability of information that describes the characteristics of the product
- b) The availability of work instructions, as necessary
- c) The use of suitable equipment
- d) The availability of monitoring and measuring equipment
- e) The implementation of monitoring and measurement
- f) The implementation of release, delivery and post-delivery activities
- g) Accountability for all products during manufacturing (e.g., quantities, nonconforming, etc)
- h) Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized
- i) Provision for the prevention, detection, and removal of foreign objects
- j) Criteria for workmanship, which shall be stipulated in the clearest manner

8.5.2 Identification and traceability

AEROTRONICS establishes, implements and maintains the appropriate documented procedures for Product Identification and Traceability, during all stages of product realization.

The Production Supervisor is responsible for Product Identification and Traceability. Products are identified during all stages of production.

Traceability is provided to meet internal and external requirements and/or contract specifications. Traceability records are maintained for items requiring traceability.

8.5.3 Property belonging to customers or external providers

AEROTRONICS shall clearly identify, record, and exercise care of customer or external supplier supplied property while being used or stored at **AEROTRONICS**.

Customer property that will be used by an **AEROTRONICS** external supplier will be recorded and tracked until they are returned to the customer.

8.5.4 Preservation

AEROTRONICS establishes, implements, and maintains documented procedures for the preservation of product to include: identification, handling, storage, packaging, protection and delivery of materials and products.

Title: **Operation**

The Production Supervisor is responsible for identification, handling, storage, packaging, protection and delivery of products. General methods are developed and maintained to protect materials and products from damage and/or deterioration during handling and shipping.

General procedures for packing and marking are implemented to ensure protection and identification. Where appropriate, special packing and/or marking instructions are documented.

8.5.5 Post-delivery activities

AEROTRONICS shall meet requirements for post-delivery activities associated with supplied product or services.

To determine the extent of post-delivery activities that are required, the following shall be considered:

- a) Statutory and regulatory requirements;
- b) Customer requirements;
- c) Any potential undesired consequences associated with products or services, including procedures to recall products if deemed necessary;
- d) Preservation and shelf life of product
- e) Customer feedback on product or service performance.

8.5.6 Control of changes

AEROTRONICS shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

AEROTRONICS shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Any planned change that may affect form, fit, or function of the product or service will be communicated to the customer for their approval.

8.6 Release of products and services

Product cannot be released to a customer without a certificate of conformance being signed by a quality representative who will check that evidence of conformity with the acceptance criteria has been satisfactorily completed for all stages of the production processes.

AEROTRONICS will retain documented information on the release of products and services for a minimum of seven years or longer if contractually required. The documented information shall include:

- a) Evidence of conformity with the acceptance criteria;
- b) Traceability to the person (s) authorizing the release.

Title: **Operation****8.7 Control of nonconforming outputs**

8.7.1 AEROTRONICS establishes, implements and maintains documented procedures to ensure that nonconforming materials, parts or products are prevented from inadvertent use and/or additional processing without review and disposition from authorized personnel.

The Quality Manager is responsible for the Control of Nonconforming Product. Nonconforming materials, parts or products are reviewed in accordance with documented procedures.

Nonconforming product is dealt with by one or more of the following ways:

- a) Action taken to eliminate the detected nonconformity.
- b) Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.
- c) Taking action to preclude its original intended use or application.
- d) Taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use as started.

Reworked/repared items are re-inspected in accordance with the same documented procedures as conforming products to ensure conformance.

Records of the nature of nonconformities and any subsequent actions taken including concessions obtained, is maintained according to quality procedures.

8.7.2 AEROTRONICS shall retain documented information that:

- a) Describes the nonconformity;
- b) Describes the actions taken;
- c) Describes and concessions obtained;
- d) Identifies the authority deciding the action in respect to the nonconformity

Title: **Performance evaluation**

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

AEROTRONICS implements and maintains comprehensive methods for monitoring and measuring the characteristics of product to verify that product requirements are achieved throughout all phases of product realization in accordance with quality procedures.

Evidence of conformity with the acceptance criteria is maintained in the records and indicates the person authorizing the release. Product release and delivery is dependent upon compliance with the appropriate quality procedures set forth.

9.1.2 Customer satisfaction

AEROTRONICS determines methods for monitoring, measuring and improving customer satisfaction. Information relating to customer perception as to whether their requirements are being met will also be monitored. This measurement of process performance shall include the analysis of customer complaints and on-time delivery.

9.1.3 Analysis and evaluation

AEROTRONICS utilizes statistical techniques and methods for the analysis of appropriate data collected from various relevant sources to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement can be made.

Methods used to generate relevant data are reviewed periodically to ensure the information provided relates to:

- a) Customer satisfaction;
- b) Conformity to product and services;
- c) The performance and effectiveness of the quality management system;
- d) The performance of external providers;
- e) If planning has been implemented effectively;
- f) The effectiveness of actions taken to address risks and opportunities
- g) The need for improvements to the quality management system

9.2 Internal audits

AEROTRONICS establishes, implements and maintains documented procedures for a comprehensive system of internal audits at planned intervals to verify the effectiveness of the Quality Management System.

The Quality Assurance Manager is responsible for administering the Internal Audit system per documented procedures. The Quality Assurance Manager develops a schedule for internal audits according to Quality Management System requirements and conducts unscheduled audits (internal and external) when reasons for such audits exist.

Title: **Performance evaluation**

Audits are conducted utilizing documented checklists and/or audit plans. Audit results are documented in audit reports per established procedures. Copies of all audit reports including completed corrective action requests are forwarded to management of the audited area and maintained by the Quality Assurance Manager.

Where practical, personnel who are independent of the area or activity, perform internal audits.

Management personnel responsible for the audited area determine and implement timely corrective actions for any reported nonconformance and follow-up activities include verification of the corrective actions taken and reporting of the results.

9.3 Management reviews

9.3.1 General

AEROTRONICS top management shall review the quality management system quarterly or as required, to assess its continued suitability, effectiveness, and alignment with the strategic direction of our organization.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- c) Information on the performance and effectiveness of the quality management system, including trends in:
 - 1) Customer satisfaction and feedback from relevant interested parties;
 - 2) The extent to which quality objectives have been met;
 - 3) Process performance and conformity of products and services;
 - 4) Nonconformities and corrective actions;
 - 5) Monitoring and measurement results;
 - 6) Audit results;
 - 7) The performance of external providers;
- d) The adequacy of resources;
- e) The effectiveness of actions taken to address risks and opportunities
- f) Opportunities for improvement.

9.3.3 Management review outputs

The output of the management review shall include decisions and actions related to:

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system;
- c) Resources needed.

Records of Management Reviews – The Quality Assurance Manager records/documents a summary, (minutes), of each management review.

Title: **Improvement**

10.1 General

AEROTRONICS shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

- a) Improving products and services to meet requirements as well as to address future needs and expectations;
- b) Correcting, preventing, or reducing undesired effects;
- c) Improving the performance and effectiveness of the quality management system.

10.2 Nonconformity and corrective action

AEROTRONICS establishes, implements and maintains documented procedures to initiate corrective and preventive actions for conditions adverse to quality.

Corrective Action Procedures define the requirements for:

- a) Reviewing nonconformities (including customer complaints)
- b) Determining causes of nonconformities
- c) Evaluating the need for action to ensure that nonconformities do not recur
- d) Determining and implementing the action needed
- e) Records of the results of action taken
- f) Review the effectiveness of corrective action taken
- g) Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause.
- h) Specific actions where timely and/or effective corrective actions are not achieved.

The Quality Assurance Manager is responsible for Corrective Actions and a feedback system is used to provide early warning of quality problems and for input into the corrective action system.

10.3 Continual improvement

AEROTRONICS continually improves the effectiveness of its Quality Management System through the use of the Quality Policy, quality objectives, audit results, analysis of data, corrective and continual improvement actions and management reviews.



ISO 9001 Quality Policy Manual

Quality Policies Manual

Title: Quality Policies Manual - General

Revision History:

Rev.	Date	Description
1	06/21/02	original
2	08/22/02	Revised section 7.4.1
3	05/08/03	Revised section 4.2.2
4	07/07/03	Revised section 3 (Added terms & definitions)
5	07/22/03	Revised section 5.6.1 (Changed annually to quarterly)
6	11/25/03	Revised section 4.2.3 (Handling of Obsolete drawings)
7	12/12/03	Revised section 7.5.3 (Traceability is provided to meet.)
8	04/20/05	Revised section 4.2.1 (Level III & IV) 4.2.2 (Controlled)
9	08/17/06	Revised section 5.4.2 (Replace President with Senior Staff)
10	09/06/06	Revised section 5.3 (Changed Quality Policy) & section 6.2.2
11	02/23/07	Revised section 7.5 by adding new 7.5.4 to match ISO standards
12	04/27/07	Revised section 4.2.2 by changing President to CEO
13	08/15/07	Revised section 5.5, & 6.1 by changing President to Senior Mg. or CEO
14	12/20/07	Revised section 7.4.1 & 7.4.3 to add Quality Authority for purchasing
15	04/17/08	Revised sections 7.5.1, 7.5.2, 8.2.2, 8.2.3, 8.3, 8.5.2 & 8.5.3 for AS9100
16	05/12/08	Added section 5.5.3 Internal Communication and added (e) to 4.2.3 and a new 4.3 for Configuration Management to meet AS9100
17	09/23/08	Change Quality Policy in Section 5 to add design and manufacture
18	12/20/08	Changed 7.1, 7.2, & 7.3 to meet AS9100
19	09/10/09	Changes sections 2, 4, 5, and 6 to bring in line with ISO 9001:2008
20	12/20-09	Changed sections 7.1,7.2,7.3, and 7.4 to meet with ISO 9001:2008
21	04/27-10	Changed section 8.2.1, 8.3, 8.4, 8.5.2, & 8.5.3 to meet ISO 9001:2008
22	09/10/10	Change sections 4.1 to add Process Model, and Section 5.3 updated Quality Policy to include "commitment to comply" to meet ISO 9001:2008
23	09/22/10	Changed Process Model in section 4.1
24	10/25/12	Updated section 4.2.3 and 7.5.4
25	09/24/13	Added NCMR, RMA, CAR to Section 3 Definitions
26	06/01/17	Major revision of all sections to bring it line with ISO9001:2015
27	07/08/19	Changed 10.3 from preventive action to continual improvement action
28	08/10/21	Added Risk & Opportunities, Cybersecurity, FOD to Terms and Definitions