

<b>Quality Management System Manual</b>	Quality Management System Manual QSM-1	<b>Revision Level</b>	<b>G</b>
<b>Subject:</b>	Quality Management System		
<b>Category:</b>	AS9100 Quality Management System		

# Quality Management System Manual



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## Revisions

REV LEVEL	REV DATE	DETAILS		DESCRIPTION OF CHANGE
		SEC.	PARA.	
N/C	08-25-97	All	All	Original release ISO
A	02-28-00	N/A	N/A	Change per Moorhill audit
B	07-09-01	N/A	N/A	Wording change by steering committee
C	06-28-02	All	All	Update to AS9100 revision A
D	11-12-03	N/A	N/A	Pro Inc corrective action responses
E	02-01-05	N/A	N/A	Update to AS9100 revision B
F	05-01-05	N/A	N/A	Honeywell corrective action responses
G	10/12/2006	All	All	Update to reflect audit finding's formatting

### APPROVED BY

CEO

Division President WEDM

Division President Rubber

Operations Manager

Quality Manager

*Mike Nosek*

*Approval signatures on file*

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## General

Micro-Tronics has developed and implemented a quality management system to better satisfy the needs of our customers and to improve management system and processes of the company. The quality system complies with the International Aerospace Standard AS9100.

## Process Approach

Micro-Tronics has adopted the process approach to quality management. Figure 1 is a conceptual illustration of the process approach at Micro-Tronics. Another purpose of this manual is to define and describe the quality system, to define the authorities and responsibilities of the management personnel affected by the system.

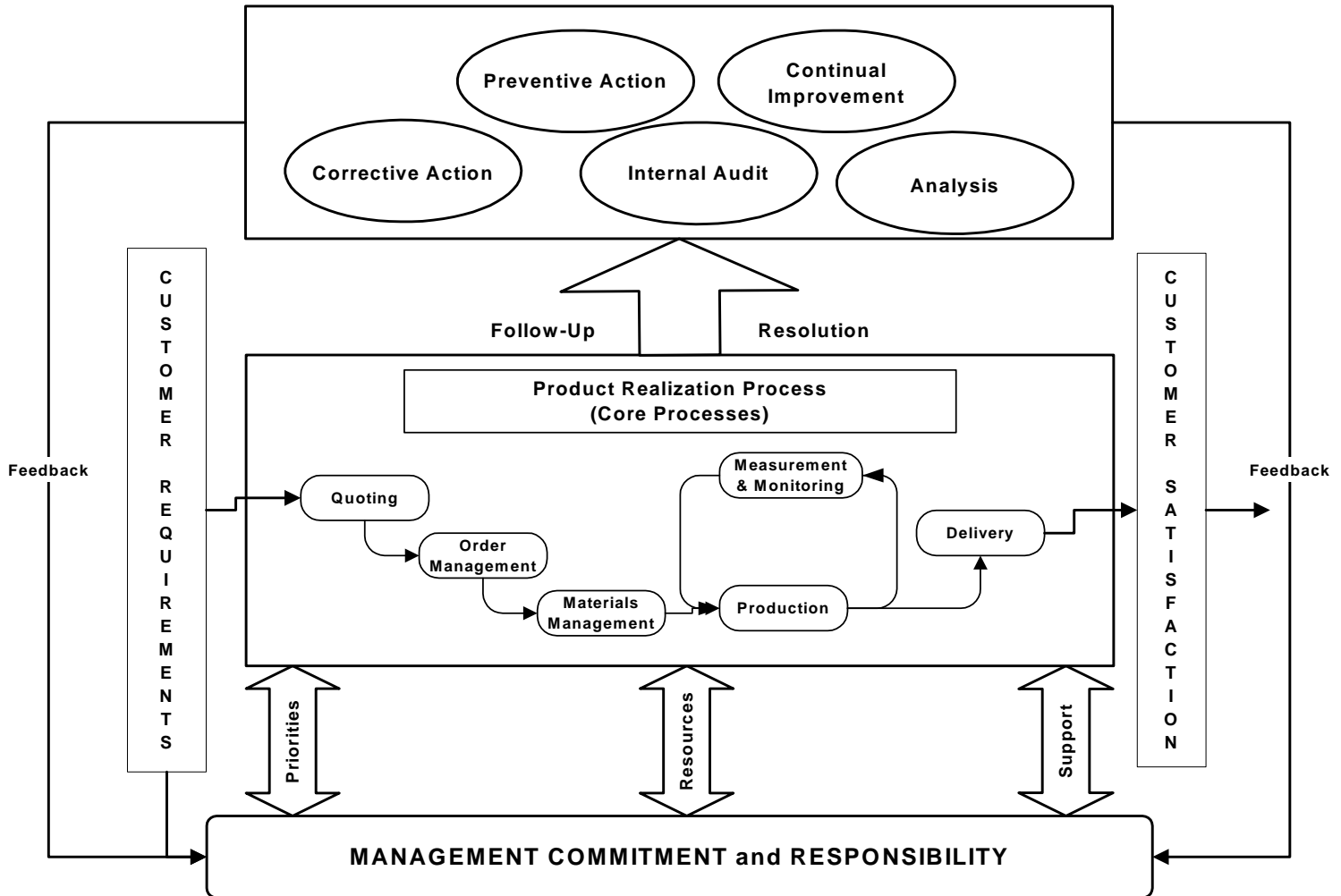


Fig: 1 Process Approach

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## Quality Policy

Micro-Tronics Inc. will provide its customers with precision machining and compression molded products, on time, cost competitive, and shall meet and/or exceed customer expectations.

## Company Mission Statement

To maintain the highest quality standards through continual improvements

## Profile

This quality manual presents an overview of Micro-Tronics Inc. quality system used in production of its products. It addresses the requirements as set forth by ANSI/ASQC ISO 9001:2000 and AS9100b standards. Policies have been developed to support the applicable clauses of 9001:2000 and AS9100b. Micro-Tronics Inc. has developed and implemented the key processes and procedures in order to support these policies. This quality management system is effective across all disciplines and at all levels within Micro-Tronics.

This program is designed to provide quality control over all phases of production through delivery, and to ensure that a top quality product is consistently produced. Micro-Tronics Inc. stands behind and is proud of its proven reputation of quality and customer satisfaction.

Products provided by Micro-Tronics Inc. shall conform to the requirements specified. Employees are responsible for input to the procurement, production, support, delivery or management provided.

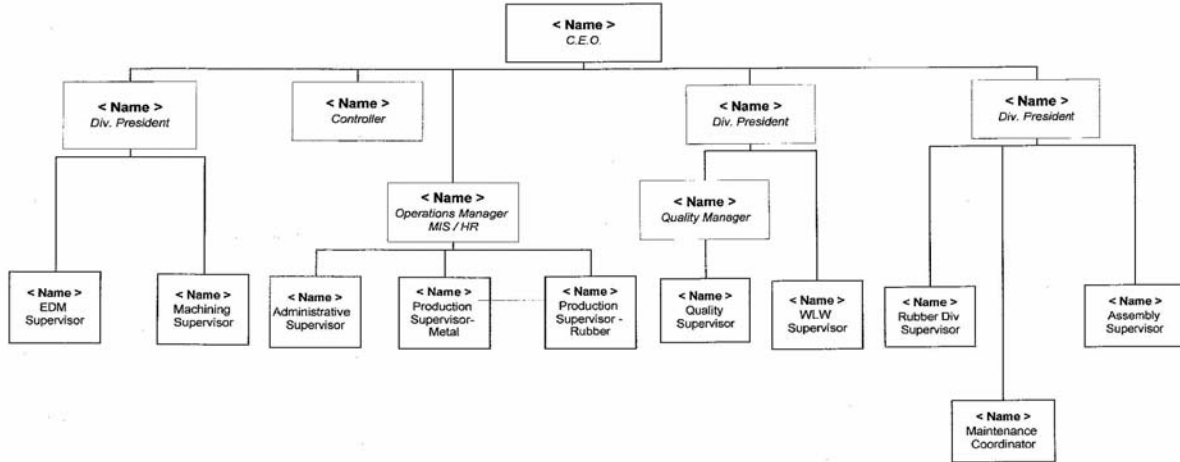
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## Organizational Chart



MTIorgchart.toc  
6/21/06

### Scope:

This quality manual applies to all activities and personnel within Micro-Tronics Inc.

This quality manual does not address the post delivery service contracts and design for they are not applicable to Micro-Tronics, and takes exclusions to any clauses in reference to service and design.

This Quality Manual addresses AS9100 standards.

Micro-Tronics, Inc. 2905 S. Potter drive, Tempe, AZ. 85282 and manufactures detailed component rubber parts, precision machined parts and EDM.

Changes in the marketplace, advancing technology and competitive pressures will make it necessary, from time to time, to revise the quality manual. Revisions are not made to this manual except those processed through the Quality Manager. After management reviews, the revisions are approved by the Micro-Tronics management staff.

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## Purpose:

The primary purpose of this quality manual is to describe and document the quality program currently in practice at Micro-Tronics, Inc.

The quality manual provides comprehensive evidence to all customers, suppliers, and employees that Micro-Tronics is committed to establishing and maintaining acceptable levels of measurable quality in its processes and products.

## Authority

The manual is issued under the authority of Micro-Tronics management staff. The quality system is maintained and enforced by Quality Manager

## Responsibilities:

Organization consists of three primary groups, Administrative, Production, and Quality. Implementation of this document is the responsibility of all Micro-Tronics inc. employees. The Quality Manager has the responsibility to monitor and oversee this activity. The responsibilities at Micro-Tronics is demonstrated in the process and organization flow charts.

The C.E.O has the responsible for engineering, financial management, policy formation, and general management through organizational assignments and delegation. The C.E.O is responsible for overall operations, including adequate facilities and activities relative to product integrity and ensuring personnel are adequately trained in the performance of their assigned tasks.

Division Presidents shall be responsible for engineering, financial management, policy formation, and general management for specific divisional assignments. Responsible for divisional operations, including adequate facilities, activities relative to product integrity and ensuring personnel are adequately trained in the performance of their assigned tasks.

Micro-Tronics Management Representative is responsible for the AS9100 activities and coordinators. Reports results of the Quality Management System back to management staff during management review meet. For appointment see Micro-Tronics organization chart.

Quality Manager responsibilities include directing, planning, detailed layout of inspection standards, inspection methods, work instructions interruption of customer specification requirements. Initiating actions for any control processes, delivery, and nonconforming product. Direct and plan the actions to prevent recurrence of quality problems and delegated quality assurance activities.

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Production Engineer/Planning are responsible to the C.E.O and Division Presidents for direction of the overall product flow through the facility, timely scheduling, and work order maintenance.

Operations/Administration responsibilities include the purchasing function, accounting, and financial reporting activities

## Exclusions

7.3 Design and Development. Micro-Tronics does not perform design for this department; therefore this clause does not apply.

7.5.1.5 Control of Service Operations Micro-Tronics does not perform servicing therefore this clause does not apply.

## Reference Documents

### 1.1 Standards

- ◆ ISO 9000:2000 Quality Management Systems-Fundamentals and Vocabulary
- ◆ ISO 9001:2000 Quality Management Systems- Vocabulary
- ◆ ISO 9004:2000 Quality Management Systems- Guidelines for Performance Improvements
- ◆ ISO 10007 Quality Management –Guidelines for Configuration Management
- ◆ SAE AS9100:2004-01 Aerospace Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
- ◆ SAE AS9102:2000 Aerospace First Article Inspection Requirement

## Terms and Definitions

The terms and definitions listed below are frequently used to describe our quality system.

1. SOP: Quality Operational Procedure.
2. WI: Quality Work Instruction.
3. QF: Quality Form
4. Customer: Any organization or person that receives product from Micro-Tronics
5. Nonconformity: Situation where a requirement was not fulfilled.
6. Process: Set of interrelated or interacting activities, which transforms inputs (information, materials, etc.) into outputs.
7. QMS: Quality Management System.
8. Supplier/Vendor: Any organization or person that provides a product or service to Micro-Tronics

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## 4. Quality Management System

### 4.1 General Requirements

Micro-Tronics has established, documented, and has implemented a quality management system to requirements of AS9100b standard. Management has the committed in maintaining the quality management system and to ensure that it continually improves its effectiveness and shall:

- a) Identify the processes needed for the quality management system and their application throughout the organization.
- b) Determine criteria and/or methods needed for the operation and/or control of these processes.
- c) Ensure availability of Micro-Tronics resources and information necessary to support the operation with the monitoring of these processes.
- d) Monitor, measure and analyze these processes.
- e) Implement actions necessary to achieve planned results and/or continual improvement of Micro-Tronics processes.
- f) Determine the sequence and interaction of these processes.

**4.1.2** When outsourcing is necessary for process that affects product conformity Micro-Tronics ensures the control over the process. The control of Micro-Tronics outside process is identified within the quality management system.

### 4.2 Documentation Requirements

**4.2.1** General Micro-Tronics quality management system documentation includes:

- a.) Documented quality policy and quality objectives.
- b.) Quality manual
- c.) Procedures that are required by the international Aerospace standard. AS9100
- d.) Documents required by the organization to ensure the effective planning, operation and control of the processes.
- e.) Records required by A9100 and quality system requirements imposed by the applicable regulatory authorities.

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	<b>Objective of Document</b>	<b>Explanation/Examples</b>
<b>Quality Manual</b>	<b>The goal ( What to achieve)</b>	<b>Defines the policy for each requirement</b>
<b>Quality Procedures ( SOP's )</b>	<b>What to do to achieve the goal</b>	<b>Defines responsibility and describes the general process to be used</b>
<b>Work Instructions ( WI )</b>	<b>How to do the job</b>	<b>Describes the steps by step processes</b>
<b>Forms and Records</b>	<b>Proof that documented process are followed</b>	<b>Forms, checklist, data sheets, logs, flowcharts, etc.</b>

**Note: Documents/data can be in the form of either hard copy or electronic.**

This quality manual also includes the quality system requirements imposed by the applicable regulatory authorities. Micro-Tronics personnel have access to all quality management documentation. Customer and any regulatory representatives shall have access to Micro-Tronics quality management system documentation with the assists of Micro-Tronics authorized personnel upon request.

#### **4.2.2 Quality Manual**

Micro-Tronics, Inc. established and maintains a quality manual that includes:

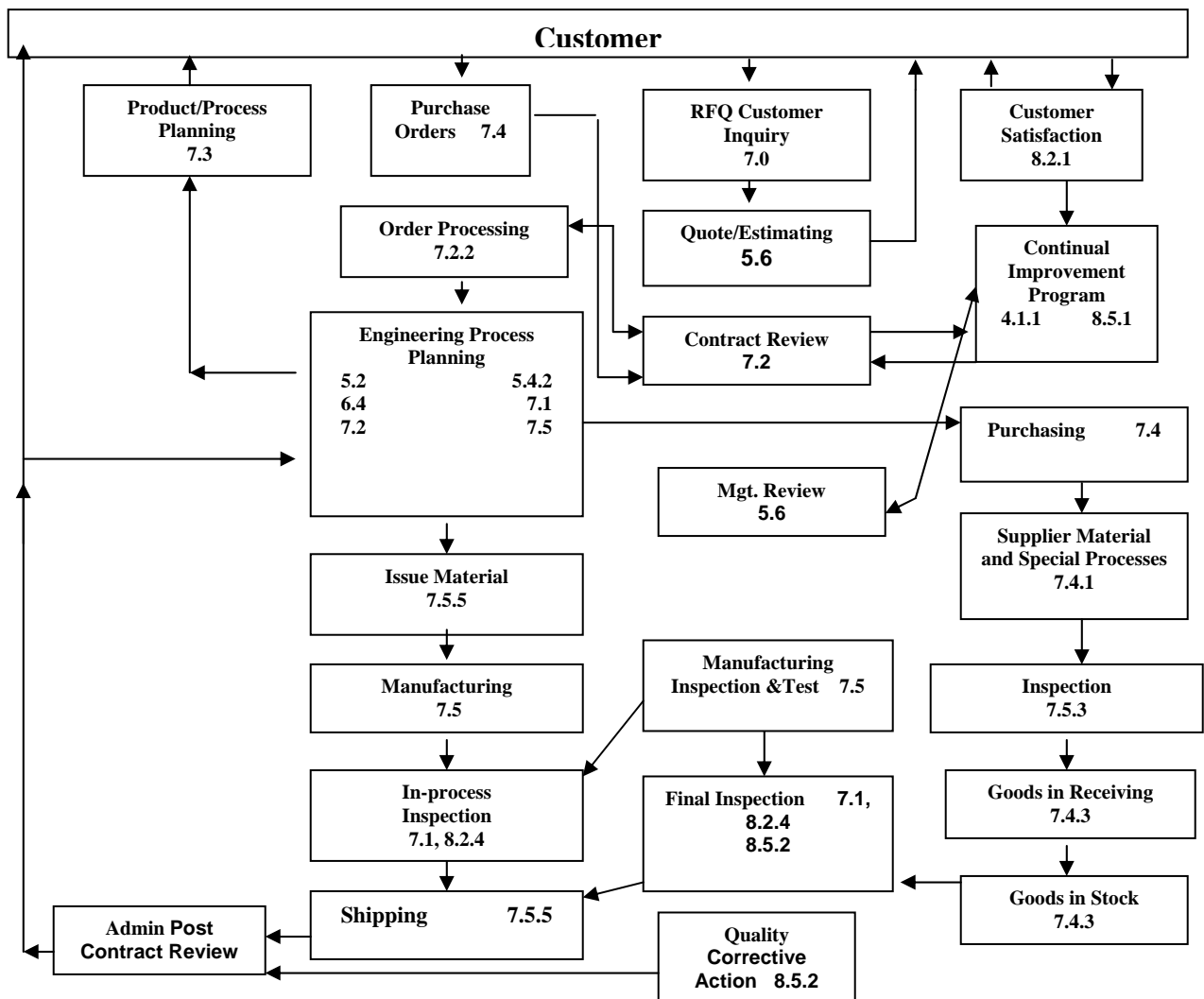
- a.) The scope of Micro-Tronics quality management system, including details of the justification for any exclusion's.
- b.) Documented procedures established for the quality management system or reference to them.
- c.) Description and Micro-Tronics interaction between the processes of the quality management system.
- d.) The interaction between processes and the quality management system described within these procedures. Subordinate to the procedures are WI's and forms. See fig: 2
- e.) Independent verification of compliance to the quality management system is accomplished per [SOP-8.2.2 Internal Auditing](#).

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**Fig: 2 Interactions Between Processes**

When required by customers and/or regulatory authorities they are notified of changes to the quality management system. Notifications list the change form revision and the change to revision along with description of the change.

**4.2.3 Control of Documents**

**4.2.3.1** Documentation used to support the quality management system are being controlled per [SOP-4.2.3 Document Control](#). Furthermore, Micro-Tonics coordinates document changes with customer and/or regulatory authorities in accordance with contract or regulatory requirements and has a documented procedure to define the controls needed to ensure:

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- a.) Approve documents for adequacy prior to issue.
- b.) Review and update as necessary and re-approve documents.
- c.) Changes and/or the current revision status of documents are identified.
- d.) Relevant versions of applicable documents are available. at points of use.
- e.) Documents remain legible and readily identifiable.
- f.) Documents of external origin are identified their distribution is controlled.
- g.) The prevention and/or unintended use of obsolete document, and to apply suitable identification to them it they are retained for any purpose.

Micro-Tronics coordinates Quality Management System document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

Micro-Tronics external documents are identified and/or controlled by [SOP 4.2.3 Document Control](#)

#### 4.2.4 Control of Records

Records are established, maintained at Micro-Tronics to demonstrate the effective operation of the quality management system and to provide evidence of its conformance to specified requirements. Controls needed to identify, store, and/or retrieve records are defined in [SOP- 4.2.4 Control of Quality Records](#), as well as the retention time and disposition of records. Records that support quality management system shall be legible, stored and easily retrievable, and maintained to minimize deterioration and to prevent loss.

Micro-Tronics has a procedure that defines the method for controlling records that are created by and/or retained by suppliers and is defined in [SOP- 4.2.4 Control of Quality Records](#).

Micro-Tronics has records available for review by customers and/or regulatory authorities in accordance with contract or regulatory requirements.

#### 4.3 Configuration Management

Configuration information in the form of drawings, product specification, and other documents related to the product given by the customers are maintained and/or controlled internally as part of document control process per [SOP 4.2.3 Document Control](#).

#### Related Documentation

SOP-4.0 Quality Management System	<a href="#">SOP-4.0</a>
Control of Documents	<a href="#">SOP-4.2.3</a>
<b>Control of Records</b>	<a href="#">SOP-4.2.4</a>

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## 5. Management Responsibility

### 5.1 Management Commitment

Management is committed to the development and implementation of quality management system and in the continual improvement of its effectiveness by:

- a.) Communicating to organization the importance of meeting customer as well as statutory and regulatory requirements.
- b.) Establishing the quality policy.
- c.) Ensure that quality objectives are met and understood.
- d.) Conducting management reviews.
- e.) Ensuring the availability of resources.

Quality management system and policies are continuously reviewed to ensure quality policy requirements are current and suitable for continuing business.

### 5.2 Customer Focus

The Micro-Tronics management shall ensure that customer requirements are clearly defined, understood, documented, and/or can be met. Customer satisfaction is a quality objectives and is enhanced by continual measurement with a closed loop corrective action.

### 5.3 Quality Policy

Micro-Tronics Inc. provides customers with precision machining and compression molded products, on time, cost competitive, and will meet or exceed customer expectations.

Micro-Tronics quality policy is appropriate for our business and is aligned with the requirements of our customers. The elements of this quality policy are reflected in our quality objectives and performance the objectives is measured and acted on to ensure continuous improvement and ensure the quality policy is:

- a.) Include commitment to comply with requirements and continually improve effectiveness of the quality management system.
- b.) Ensuring the availability of resources.
- c.) Is appropriate to the purpose of the organization.
- d.) Provides a framework for establishing and reviewing quality objectives.
- e.) Is communicated and understood within the organization.
- f.) Is reviewed for continuing suitability.

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## 5.4 Planning

### 5.4.1 Quality Objectives

Quality objectives are defined, reviewed and redefined during the Management review meeting. Objectives have been established for the following

- a. On time delivery to be greater than 90%.
- b. Maintain a PPM below 1000
- c. Maintain self release score greater than 100
- d. Nonconformance's to be below 8 a month
- e. CAR aging to be below 90 days
- f. CAR's to be below 6 a month

Theses quality objectives are measurable, and reviewed against performance at each management review.

### 5.4.2 Quality Management System Planning

Micro-Tronics management review meeting ensures that the planning of the quality management system is carried out to meet the requirements of clause 4.1 of AS9100 standard. Changes to the system and quality objectives are reviewed as well to validate the integrity of the system.

## 5.5 Responsibility, Authority, and Communication

### 5.5.1 Responsibility and Authority

Responsibility and authority are defined and communicated through documents as in the quality manual, job description, and organizational chart.

### 5.5.2 Management Representative

The management staff has appointed the management representative who has the authority for:

- a.) Ensure quality management system has been established, implemented and maintained in accordance with AS9100.
- b.) Reports on the performance of the quality management to management team for review as a basis for improvement.
- c.) Ensures promotion of the awareness of customer requirements throughout the organization.
- d.) Has organizational freedom to resolve matters pertaining to quality.

### 5.5.3 Internal Communication

Management fosters a culture of a open communications that assures effective quality management system. Communication is accomplished through regular all hands meeting, internal audits, management review meeting, newsletter, the use of e-mail, bulletin board.

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The Management Representative conducts the annual management review meeting as described in 5.6 below. Monthly supervisors meeting are held to commutate internal audit results, our performance to quality objective with newsletter's and etc posted on bulletin boards at each facility.

## 5.6 Management Review

Management review meeting is held at least annual to evaluate continual suitability the adequacy and effectiveness of the quality management system. This meeting is chaired by the management representative and is comprised of Micro-Tronics management staff as appropriate.

Micro-Tronics quality management review looks for changes to the quality management system and for improvement opportunities. Quality policy and the quality objectives are reviewed as well to make sure that they are current and do not need any modification or improvement. The notes from this meeting are maintained as a record to show evidence of adherence to this policy.

### 5.6.2 Review Input

Management review agenda items include, but are not limited to, the following:

- a.) Results of audits
- b.) Customer satisfaction and feedback.
- c.) Process performance and product conformity.
- d.) Status of preventive and corrective actions.
- e.) Follow-up actions from previous management reviews.
- f.) Changes that could affect the quality management system.
- g.) Recommendations for improvement

### 5.6.3 Review Output

Micro-Tronics output from the management review shall include any decisions and actions related to:

- a.) Improvement of the effectiveness of the quality management system and its processes.
- b.) Improvement of product related to customer requirements.
- c.) Resources needed.

Decisions and/or actions taken are documented in the meeting minutes and published to all members. Actions relating to customer products or satisfaction will be handled through the corrective or preventive action process. Other actions and/or improvement ideas will be prioritized and assigned based on resource availability and cost benefit.

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### Related Documentation

SOP-5.0 Quality Management System	<a href="#">SOP-5.0</a>
Control of Documents	<a href="#">SOP-4.2.3</a>
<b>Control of Records</b>	<a href="#">SOP-4.2.4</a>

## 6.0 Resource Management

### 6.1 Provision of Resources

Micro-Tronics provides the needed resources to maintain our business, quality systems, human resources, facilities and equipment capabilities. Micro-Tronics is continually reviewing and/or adjusting to improve our effectiveness (as measured by performance to our quality objectives) and to enhance customer satisfaction by meeting their requirements.

### 6.2 Human Resources

#### 6.2.1 General

The personnel performing work affecting product quality have been and will continue to be competent on the basis of appropriate education, training, skills and experience. All personnel have been assessed to be competent for the job they are performing. Initial assessment occurs during the hiring process, and review of education and relative experiences. Continuing assessments occur at regular intervals as job conditions change and/or career opportunities arise. Applications, resumes, certificates, etc. are kept as records.

#### 6.2.2 Competence, Awareness and Training

- a.) Micro-Tronics has determined the necessary competence and/or needs for personnel performing work effecting product quality.
- b.) Micro-Tronics Job descriptions will determine the necessary competencies and required skills for an individual to perform their job function(s) and maintained on a competence matrix.
- c.) Training opportunities will be reviewed by department supervisors and the human resource representative on an annual basis ensures that training requirements are being completed.
- d.) Effectiveness of this informal internal training and/or the on-the-job training is measured by means of hands-on demonstration to the trainer or the lead/supervisor/manager. Certificate for the completion of the training shall be signed by the trainer or lead/supervisor/manager and will be kept in the employee file as training record.

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- e.) Participant's receive an evaluation by the trainer. Training record's for formal training are found in the form of a quiz paper and/or certificate. The human resource representative will assess and make arrangement for external training. Training conducted external the use of certificates, grades shall be the verification of completion. Internal audits also measure the effectiveness of any training.
- f.) Training is given on the Micro-Tronics quality policies. Emphasis is placed on the responsibility they have for ensuring quality in their personal work. Where an employee has been assigned a position, the appropriate work instructions and/or quality procedures will be reviewed. Quality focus continues during periodic shift meetings, written notification on bulletin boards and visual communication

### 6.3 Infrastructure

Micro-Tronics has determined, provided, and maintained the infrastructure to conformity to product requirements. Evidence of this infrastructure can be seen in the innovative use of current technology by trained and competent employees, buildings, facilities, information systems with required equipment made available.

Buildings and/or facilities have been provided and are maintained as safe secure work environments, appropriately equipped to produce quality products and services, in accordance with all regulatory requirements.

Micro-Tronics established relationships with suppliers. Supplier partnerships are fostered daily to create an extension of our internal capabilities.

Preventive maintenance programs exist to provide continuous operation and minimize unplanned downtime. Programs are based on the manufacturer's guidelines. Computer information systems are maintained and backed up to provide access secure information on demand.

Micro-Tronics internal and/or external communication systems exist to meet ongoing business requirements, which include electronic communications, supplier's approval list/performance and internal database management performance reporting.

### 6.4 Work Environment

Micro-Tronics is committed in providing a safe effective work environments needed to achieve conformity to product requirements. Employee health, safety awareness is included in new employee orientation. It is the responsibility of every employee to maintain a safe workplace and conduct themselves in a safe manner at all times.

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Supplier(s) are notified per Micro-Tronics flow down to maintain environmental requirements to achieve conformance to product requirements, statutory, and regulatory requirements.

Work environmental control requirements include adequate lighting; heating, cooling, humidity control, and clean work area maintenance.

### Related Documentation

SOP-6.0 Resource Management	<a href="#">SOP-6.0</a>
Control of Documents	<a href="#">SOP-4.2.3</a>
<b>Control of Records</b>	<a href="#">SOP-4.2.4</a>

## 7.0 Product Realization

### 7.1 Planning of Product Realization

Business practices include the understanding of our customer's requirements and fiscal responsibilities. Policies, procedures, process controls with process monitoring providing the basis for our product realization. Quality objectives described in this manual measure our business performance and customer satisfaction.

The Micro-Tronics process for establishing quality requirements for the product is documented under the process control documents, and product-specific resources set forth throughout product realization. Required verification, validation, monitoring, and inspection/test activities specific to Micro-Tronics, the criteria for product acceptance are covered under sections 7&8 of this quality manual.

Records needed to provide evidence that the realization process and resulting product meet requirements are covered under sections 7&8 of this document. Micro-Tronics resources needed to support operation and maintenance of the product is identified in the quoting stage. The outputs of this planning can be a router, manufacturing plan, manufacturing outline, quality plan/control plan, and/or other form that is suitable to Micro-Tronics method of operations.

### 7.2 Customer Related Processes

#### 7.2.1 Determination of Requirements Related to the Product

Micro-Tronics determines:

- a.) Requirements specified by the customer, and including the requirements for delivery, post-delivery activities.
- b.) Requirements not stated by the customer documents but necessary for specified or intended use, were known.

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- c.) Statutory and regulatory requirements related to the product.
- d.) Additional requirements determined by Micro-Tronics review.

### 7.2.2 Review of Requirements Related to the Product

Management conducts a contract review of all products they manufacture. The contract review is conducted prior to making a commitment the following shall be ensured:

- a.) Product requirements are defined and fulfilled.
- b.) Contract and older requirements differing from those previously expressed are resolved.
- c.) Micro-Tronics has the ability to meet all the defined requirements.
- d.) Risks of new technology short delivery time scale and other risks have been evaluated.

When the customer provides no documented statement of requirements, the customer requirements are confirmed and documented by Contract Review prior to review and acceptance.

Where product requirements have been changed, Contract review ensures that relevant and/or required documents are amended and the personnel are made aware of the change requirements.

Records of the results of the review and actions arising from the review are maintained per [SOP-4.2.4 Control of Quality Records](#).

### 7.2.3 Customer Communication

Micro-Tronics has determined and implements the effective arrangements for communicating with the customers in relation to the following:

- a.) Product information.
- b.) Inquiries, contracts or order handling, including amendments.
- c.) Customer feedback and complaints are recorded in "customer feedback" or complaint database.

### 7.3 Design (Does not apply)

### 7.4 Purchasing

#### 7.4.1 Purchasing Process

Micro-Tronics has ensured that any product purchased conforms to specified purchase requirements. The type, extent of control applied to the supplier and any purchased product shall be dependent upon the effect of the purchased product and/or on subsequent product realization or final product.

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Micro-Tronics evaluated and/or select suppliers based on their ability to supply purchased product in accordance with the organizations requirements.

The criteria for selection, evaluation and re-evaluation shall be established. Records of the results and necessary actions arising from the evaluation are maintained and shall:

- a.) Maintain an approved supplier List (ASL) that includes the scope of the approval.
- b.) Periodically review supplier performance, records of these reviews is used as a basis for establishing the level of controls to be implemented.
- c.) Define the necessary actions to take when dealing with suppliers that do not meet requirements.
- d.) Purchasing ensures, as required that approved special process suppliers are used and by sub tier suppliers.
- e.) Quality has the authority to disapprove the use of sources.

#### **7.4.2 Purchasing Information**

Purchased materials required for manufacturing of products shall be procured with written purchase orders. Micro-Tronics purchase order shall clearly describe the following necessary requirements as applicable:

- a.) The requirements for any approval of product, procedures, processes, and equipment.
- b.) The requirements for qualification of personnel.
- c.) The quality management system requirements.
- d.) The name and/or positive identification with the applicable issues of specifications, drawings, any process requirements, including inspection instructions and other relevant technical data.
- e.) The requirements for the design, test, examination, inspection instructions for acceptance.
- f.) The requirements for test specimens and the method for the testing, test number, storage conditions for design approval, inspection, investigation or auditing.
- g.) Requirements relative to supplier notification of nonconforming product and arrangements for approval of supplier nonconforming material.
- h.) The requirements for the supplier to notify the organization of changes in product and/or process definition and where required obtain organization approval.
- i.) Right of access by Micro-Tronics, customer and/or regulatory authorities to all facilities involved in the order and records.

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- j.) Micro-Tronics ensures flow down to sub-tier suppliers the requirements in the purchasing documents, and shall include any key characteristics where required.

Personnel who are responsible for generating purchase orders ensure adequacy of the specified purchase requirements prior to sending their communication to the supplier.

### 7.4.3 Verification of Purchased Product

Micro-Tronics has established, implemented the inspection and other activities to ensure that purchased products meet specified purchase requirements. Verification activities may include one or more of the following:

- a.) Obtaining objective evidence of the product from suppliers.
- b.) Inspection and audit at supplier's premises.
- c.) Review of the required documents.
- d.) Inspection of products upon receipt.
- e.) Delegation of verification to the supplier, or supplier certification.

Purchased products are not to be used and/or processed until verified as conforming to specified requirements. Under emergency release, product used prior to verification shall be released under positive recall instructions.

When test reports are utilized to verify purchased product, the data in the reports shall be acceptable per applicable specifications. Raw material is periodically validated by a 3<sup>rd</sup> party testing lab.

Micro-Tronics work's with sub-tier suppliers to establish protocols to eliminate the need for incoming inspection. If verification activities are delegated to the supplier, the requirements for delegation is defined, register of delegations is maintained.

When verification at the supplier's location is required, Micro-Tronics, and the customer when required will state the intended verification arrangements and method of product release in our purchase order.

When specified in the contract, that verification shall be performed at the supplier's location the customer or the customer's representative are afforded the right to verify at the supplier's premises that product conforms to specified requirements.

Micro-Tronics and sub-tier suppliers will not use verification by the customer as evidence of effective control of quality. Verification by the customer does not absolve the supplier the responsibility to provide acceptable product and/or to preclude subsequent rejection by the customer.

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## 7.5 Production and Service Provision

### 7.5.1 Control of Production Provision

Micro-Tronics, planning considers, as applicable:

- a.) Establishment of process control and the development of control plan(s) where key characteristics have been identified.
- b.) The identification in process verification points when adequate verification of conformance cannot be performed at any later stage.
- c.) Tooling is considered so the use of variable measurements can be taken, particularly for key characteristics and special processes.
- d.) Micro-Tronics plans and carries out production process provisions under controlled conditions. Controlled conditions shall include, as applicable:

Process planning and/or production provision are carried out under controlled conditions. The controlled conditions include, as applicable.

- a) Availability of information that describes the characteristics of the product.
- b) Availability of work instructions, as necessary.
- c) The use and availability of suitable equipment, monitoring and measuring devices.
- d) The implementation and/or use monitoring and measurement.
- e) The implementation of release, delivery and post delivery activities.
- f) Accountability for product during manufacture.
- g) The evidence that manufacturing and inspection operations are completed as planned, or as otherwise documented and authorized
- h) Provision for the prevention, detection, and removal of foreign objects.
- i) Monitoring and/or control of utilities and supplies to the extent they affect product quality.
- j) Criteria for workmanship, which is stipulated in the clearest and practical manner.

#### 7.5.1.1 Production Documentation

Production operations are carried out in accordance with required approved data. As necessary, the data shall contain:

- a) Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents.
- b) A list, of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.

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### 7.5.1.2 Control of Production Process

Micro-Tronics person's authorized to approve changes to production processes shall be identified..

Identified and obtain acceptance of changes that require customer and/or any regulatory authority approval in accordance with the contract and/or regulatory requirements.

Changes affecting processes, production equipment, tooling, and/or programs shall be documented. Procedures are available to control their implementation.

Results of the changes to production processes are assessed to confirm that the desired effects are achieved without adverse effects to product quality.

### 7.5.1.3 Control of Production Equipment:

Micro-Tronics ensures production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to Micro-Tronics documented procedures. Validation prior to production use includes verification of the first article produced to the design specifications.

Micro-Tronics performs periodic preservation/condition checks for production equipment or tooling in storage.

Product temporarily transferred outside Micro-Tronics Manufacturing facility shall be controlled through purchase order agreements and defines the process control and quality of work is validated.

Any changes driven by continual improvement to current process controls are documented, reviewed, and approved per [SOP 4.2.3 Document Control](#).

### 7.5.1.3 Control of Service Operations

Exclusion has been taken to this clause since Micro-Tonics does not sell our own products.

## 7.5.2 Validation of Processes for Production

Any special processes which resulting output cannot be verified by subsequent monitoring and measurement without destroying the part shall be validated by methods suitable to the process (e.g. lot samples or test coupons). Internal weld joint, for example, is validated by inspecting a coupon cut in half to verify the weld joint. These coupons and inspection reports are kept as records per [SOP 4.2.4 Control of Quality Records](#).

Validation shall demonstrate the ability of these processes to achieve planned results.

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Micro-Tronics shall establish arrangements for these processes including as applicable.

- a) Defined criteria for review and approval of the processes, with qualification and approval of special processes prior to use.
- b) Processes (including equipment and personnel must be qualified and approved prior to use. Therefore the review and/or approval criteria must be clearly defined.
- c) Operations and process parameters are controlled in accordance with documented procedures including changes to it.
- d) Records needed for the evidence that process will achieve planned results and the re-validation of the process.

### 7.5.3 Identification and Traceability

Micro-Tronics identifies the product by suitable means throughout the product realization process.

Configuration of the product is identified through the use customer drawings, specification, purchase order, and other necessary document.

Documents are included in the job packet ensuring actual configuration meets the agreed configuration.

Micro-Tronics has identified the product status with the respect to monitoring and measurement requirements.

When acceptance media is used Micro-Tronics has documented procedure for the control of acceptance authority media.

Where traceability is a requirement, Micro-Tronics shall control and record the unique identification of the product.

According to the level of traceability required by a contract and/or regulatory or other established requirements, Micro-Tronics provides for:

- a) Identification to be maintained for the life of the product.
- b) Products manufactured from same batch of raw material are traced, as well as their destination. Components at all levels are identified.
- c) For a given product records are maintained of inspection and sequential production of the products by means of the traveler.

### 7.5.4 Customer Property

Possession and care of customer product is controlled. Customer product may be customer supplied raw materials, product returned for additional work to be performed (modifications), and drawings, specifications or intellectual property. When raw materials are received from the customer, they are inspected and deemed fit for use and stored into separate areas.

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Nonconformance Report is generated by production or receiving Inspection for any parts unfit for use and will be reviewed and disposition per customer review board. The customer will be sent a copy of the NCR to notify them regarding the material's condition. The NCR is also retained as quality record.

Modifications are evaluated and negotiated through contract review prior to completing work. Customer's documents are controlled and released on as needed basis and are destroyed by shredding. Intellectual property is controlled by the use of confidentiality and non-disclosure agreements with our employees and suppliers, or with written permission from the customer.

### 7.5.5 Preservation of Product

Micro-Tronics preserves the conformity of product during internal processing, delivery to the intended destination. This preservation includes identification, handling, packaging, storage and the protection. The following provisions are made when product specifications and/or regulations require them:

- a) Cleaning
- b) Prevention, detection, and removal of Foreign objects (FOD).
- c) Special handling for sensitive products.
- d) Marking and labeling including safety warnings.
- e) Shelf life control and stock rotation.
- f) Special handling for hazardous materials.

Documents required by the contract/order to accompany product are present at delivery and are protected against loss or deterioration.

### 7.6 Control of Monitoring and Measuring Devices

Micro-Tronics determine the monitoring and/or measurement to be undertaken and/or the monitoring/measuring devices needed to provide evidence of conformity of product to determined requirements.

Micro-Tronics maintains a register of monitoring/measuring devices and define the process employed for their calibration including:

- a) Equipment type with unique identification.
- b) Location.
- c) Frequency of checks and check method.
- d) Acceptance criteria.

Procedure has been established to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

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Micro-Tronics ensures that the environmental conditions are suitable for the calibrations inspections, measurements and tests being carried out.

Where necessary to ensure valid results measuring equipment shall:

- a) Measuring devices are calibrated and/or verified at specified intervals, or prior to use, against standards traceable to international and/or national measurement standards. When standards do not exist, the basis used for calibration or verification are recorded.
- b) Monitoring and/or any testing devices are adjusted and/or re-adjusted as necessary, identified to enable the calibration status to be determined.
- c) Monitoring and testing devices shall be safeguarded from adjustments that would invalidate the measurement results.
- d) Inspection devices are protected from damage and deterioration during handing, maintenance and storage. Inspection devices are recalled to a defined method when requiring calibration.
- e) Measuring devices/equipment used to buy-off products shall be calibrated to ensure that it will yield valid results. When devices/equipment has been found to be nonconforming Micro-Tronics assesses and records the validity of the devices/equipment previous results. Micro-Tronics takes appropriate action on the devices/equipment product affected. Records of calibration and verification are maintained per [SOP 4.2.2 Control of Quality Records](#).
- f) Computer software used in the monitoring and measurement of specified requirements, and its ability to satisfy the intended application is confirmed prior to initial use and reconfirmed as necessary.
- g) Quality identifies and selects the monitoring and measuring devices that are capable of the necessary accuracy and precision needed. Inspection sign-off (either by quality stamp and/or initial) on traveler and/or MOT ensures that monitoring and measurement of product are carried out at appropriate stages of production as planned.

### Related Documentation

SOP-7.0 Product Realization	<a href="#">SOP-7.0</a>
Control of Documents	<a href="#">SOP-4.2.3</a>
Control of Records	<a href="#">SOP-4.2.4</a>
Internal Audits	<a href="#">SOP-8.2.2</a>
Control of Nonconforming Product	<a href="#">SOP-8.3</a>
Corrective Action	<a href="#">SOP-8.5.2</a>
Preventive Action	<a href="#">SOP-8.5.3</a>

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## 8.0 Measurement, Analysis, and Improvement

### 8.1 General

Micro-Tronics shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a. To demonstrate conformity of the product
- b. To ensure conformity of the quality management system, and
- c. To continually improve the effectiveness of the quality management system.

According to the nature of the product and depending on the specified requirements, Micro-Tronics may use statistical techniques.

### 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

As one of the measures of the performance of the Quality Management System Micro-Tronics has established, maintains a method for obtaining and using information relating to customer perception to determine whether it has met customer requirements.

#### 8.2.2 Internal Audits

MTI has established and maintains an internal audit system at planned intervals to determine whether the Quality Management System:

- a. Conforms to planned arrangements,
- b. Meets the requirements of AS9100 and to the quality management system requirements established by MTI.
- c. Effectively implemented and maintained.

The following has been implemented:

1. Audit planning, taking into consideration the status and importance of processes and the areas being audited, and the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of auditors shall ensure objectivity and impartiality of the audit process.
2. Auditors shall not audit their own work,
3. Documented procedures, including responsibilities for the planning, conducting, reporting and maintaining records.
4. Response to corrective actions should be taken without delay, and follow up activities shall include the verification of the actions taken and the reporting of verification results.

Micro-Tronics ensures that internal audits meet contractual and regulatory requirements.

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Detailed tools and techniques shall be developed such as check sheet's, process flow -charts or any similar method to support audit of the Quality Management System requirements. Per [SOP-8.2.2 Internal Audits](#)

### 8.2.3 Monitoring and Measurement of Processes

Micro-Tronics has applied, where applicable, measurement of the Quality Management System processes.

In the event of process nonconformity Micro-Tronics:

- a. Take appropriate action to correct the nonconforming process,
- b. Evaluate whether the process nonconformity has resulted in product nonconformity, and
- c. Identify and control the nonconforming product in accordance with clause 8.3.

### 8.2.4 Monitoring and Measurement of Product

Micro-Tronics monitor's and measure the characteristics of the product to ensure that product requirements are met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Where key characteristics have been identified, they shall be monitored and controlled.

Where sampling inspection is used, Micro-Tronics does use statistically valid plan appropriate for use. The plan shall preclude acceptance of lots whose samples include known nonconformities. When required, the plan shall be available for customer approval.

Evidence of conformity with the acceptance criteria shall be maintained.

Product release shall not proceed until all the planned arrangements have been satisfactorily completed unless otherwise approved by a relevant authority and, where applicable, by the customer.

#### 8.2.4.1 Inspection Documentation:

Micro-Tronics ensures those measurement requirements for product or service is documented. The documentation shall include:

- a. Criteria for acceptance and/or rejection,
- b. Where in the sequence measurement and/or testing are performed, record of the measurement results has been recorded.

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- c. Type of measurement instruments required and any specification or acceptance plan.

When required to demonstrate product qualifications, Micro-Tronics shall ensure records provide evidence that the product meets the defined requirement.

#### **8.2.4.2 First Article Inspection:**

Micro-Tronics has provided the process for the inspection, verification, documentation of a representative sample from the first production run of a new part, and/or following any subsequent change that invalidates the previous first article inspection result.

### **8.3 Control of Nonconforming Product**

Micro-Tronics established and maintains documented procedures that ensure that product which does not conform to the product requirements is identified and controlled to prevent unintended use or delivery.

Nonconforming product shall be dealt with in one of the following ways:

- a. by taking action to eliminate the defective nonconformity;
- b. by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c. by taking action to preclude its original intended use or application.

Micro-Tronics shall not use dispositions of use-as-is, unless specifically authorized by the customer, if

- The product is produced to customer design, or
- The nonconformity results in the departure from the contract requirements.

Unless restricted by contract, Micro-Tronics designed product which is controlled via a customer specification may be dispositioned as use-as-is or repair provided the nonconformity will not depart from customer-specified requirements.

Records of the nature of the nonconformities and any actions taken, including concessions obtained, shall be maintained.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, MTI shall take action appropriate to the effects, potential effects, of the nonconformity.

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Micro-Tronics shall provide timely reporting of delivered nonconforming product that may affect safety – in addition to any contract or regulatory authority reporting requirements. Parties requiring notification may include suppliers, internal organizations, customers, distributors, and regulatory authorities this is per [SOP 8.3 Control of Nonconforming Product](#)

#### 8.4 Analysis of Data

Micro-Tronics determines, collect, and analyze appropriate data to demonstrate the suitability and the effectiveness of the Quality Management System and to evaluate where improvement can be made in the system. The data comes from a number of sources such as internal audits, management reviews, product verification and/or continual improvements activities.

Analysis of data shall include:

- a. Customer satisfaction
- b. Conformity of product requirements
- c. Characteristics and trends of processes and products including opportunities for preventive action, and
- d. Supplier's performance.

#### 8.5 Improvement

##### 8.5.1 Continual Improvement:

Micro-Tronics continually improve the effectiveness of the Quality Management System through the use of the Quality Policy, Quality Objectives, Audit results, Analysis of data, Corrective and Preventive Actions and Management Review.

##### 8.5.2: Corrective Action

Micro-Tronics established and maintains a corrective action system to eliminate the cause nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effect of the nonconformity encountered.

A documented procedure has been established to define requirements for:

[SOP-8.5.2 Corrective Action](#)

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

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### 8.5.3 Preventive Action

Micro-Tronics established and maintains a preventive action system to eliminate the causes of potential nonconformities. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure has been established to define requirements for:

[SOP-8.5.3 Preventive Action](#)

- a. Determining potential nonconformities and their causes,
- b. Evaluating need for action to prevent occurrence of nonconformities,
- c. Records of action taken,
- d. Reviewing preventive action taken.

### Related Documentation

SOP-8.0 Measurement Analysis and Improvement	<a href="#">MTI SOP-8.0</a>
Control of Documents	<a href="#">SOP-4.2.3</a>
<b>Control of Records</b>	<a href="#">SOP-4.2.4</a>
<b>Internal Audits</b>	<a href="#">SOP-8.2.2</a>
<b>Control of Nonconforming Product</b>	<a href="#">SOP-8.3</a>
<b>Corrective Action</b>	<a href="#">SOP-8.5.2</a>
<b>Preventive Action</b>	<a href="#">SOP-8.5.3</a>

**CHECK CURRENT REVISION AFTER: 12/21/07**

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