

TITLE <b>Merit Electronics Corp.</b>			PROCEDURE NUMBER <b>4.2.2-0001P</b>
INITIATOR	DATE	EFFECTIVE DATE <b>4/12/04</b>	REVISION LETTER <b>A</b>
APPROVED	DATE	CURRENT DATE <b>4/12/04</b>	ISO SECTION REFERENCE <b>4.2.2</b>
APPROVED	DATE	REVISION REASON A: Release	



# QUALITY MANUAL

March 16, 2004

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# 1 Scope

## 1.1 General

This Quality Manual outlines the Quality Management System for Merit Electronics. It is intended to meet the requirements of the ISO 9001: 2000 standard. It is also intended to provide Merit Electronics' employees with the necessary information to demonstrate the ability to provide product that meets customer and applicable regulatory requirements.

This Quality Management System is set up to provide Merit Electronics employees, customers and suppliers with processes for continually improving the system and enhancing customer satisfaction.

## 1.2 Application

This Quality Manual covers all sections of the ISO 9001: 2000 standard. Merit Electronics is a stocking distributor of electronic components. There is no design or development of products currently being done at this site.

# 2 Normative reference

ISO 9001: 2000 Quality Management Systems - Requirements

# 3 Terms and definitions

CAPA            Corrective Action Preventive Action

MRB            Material Review Board

QMS            Quality Management System

RFQ            Request for Quote

# 4 Quality Management System

## 4.1 General Requirements

Merit Electronics has created, documented, implemented and maintains a QMS that is set up to continually improve the processes developed. Where appropriate, procedures and measurements for processes have been established. Top Management assures that there are ample resources and information to support these processes.

## **4.2 Documentation Requirements**

### **4.2.1 General**

Merit Electronics documentation is setup as follows. The Quality Manual, which is structured after the ISO 9001: 2000 standard and includes the quality policy and objectives for the company. This manual may include policies in regards to each of the sections of the ISO standard, which may further be defined in procedures. The procedures are set up to be numbered with reference to a particular section of the Quality Manual. Procedures are generally the business processes. Work Instructions are the next level of documentation and generally are for the process details. Records, Forms and Reports are outputs to the processes.

### **4.2.2 Quality Manual**

The Quality Manual is a guide to the QMS for Merit Electronics. This Quality Manual includes information for exclusions. It has been set up to follow the format of the ISO 9001: 2000 standard. Exclusions can be found in section 1.2 of this manual and in each section an exclusion has been made with the statement of explanation. Procedures are controlled documents and are referred to through out this manual. A description of the QMS processes and their interaction can be seen in section 4.1 of this Quality Manual.

### **4.2.3 Control of Documents**

Documents required by the QMS are controlled documents. Procedures are controlled as stated in the Control of Documents procedure # 4.2.3-0001P.

### **4.2.4 Control of Records**

All records that are created by the QMS are handled in conformance with the procedure for Control of Records procedure # 4.2.4-0001P.

## **5 Management Responsibility**

### **5.1 Management Commitment**

Top management is committed to the QMS and to continual improvement of its effectiveness. Management communicates, where appropriate, to the rest of the organization on the importance of customer satisfaction as well as any regulatory or statutory requirements. The quality policy and objectives have been developed and can be found in section 5.3 and 5.4.1 of this Quality Manual. The Quality Council holds reviews of the QMS per section 5.6 of this manual. Resources are evaluated as required.

## 5.2 Customer Focus

Merit Electronics is committed to its customers and has set up this quality manual and supporting procedures to ensure that customer requirements are met with the aim of enhancing customer satisfaction. Through this QMS system, Merit Electronics strives to identify and meet the requirements for understanding and meeting the needs and expectations of its customers, employees, and suppliers. The processes in this QMS system are set up to focus on continuous improvement and to communicate the results of these processes throughout the company.

## 5.3 Quality Policy

The quality policy is defined and approved by the executive management of Merit Electronics. The management of Merit Electronics is responsible for ensuring that this policy is communicated and understood by all employees as it pertains to their job.

*Merit Electronics will deliver quality products efficiently, in a professional and flexible environment, on time and at the right cost to our customers, leveraging continuous improvement to become a world-class organization.*

The quality policy is reviewed on a regular basis through the Quality Council meetings per section 5.6 of this Quality Manual.

## 5.4 Planning

### 5.4.1 Quality Objectives

The Quality objectives are determined by the executive management of Merit Electronics and are listed below:

- On-time delivery: goal of 100%
- Final inspection defects: goal of zero
- Customer complaints: goal of zero

### 5.4.2 Quality Management System Planning

Quality plans define and document how the requirements for quality are met. The requirements for Quality Plans are contained in the procedures for any new controls, processes, equipment, fixtures, resources and skills at the appropriate stage of each process. The Quality Council, per section 5.6 of this manual, reviews changes to the QMS.

## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

An Organizational Chart is reviewed annually, or when there is a change in the executive members, which shows the senior management level of the company. This chart is maintained and controlled by the President of Merit Electronics.

- Employees have the organizational freedom and authority to:
- Initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system.
- Identify and record any problems relating to the product, process and quality system.
- Initiate, recommend or provide solutions through designated channels.
- Verify the implementation of solutions.
- Control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

Job descriptions are maintained for all positions in the company. The job descriptions describe the general duties, authority, qualifications and training requirements for each job.

### **5.5.2 Management Representative**

The president of Merit Electronics appoints the ISO Management Representative for the QMS. This will be indicated on the Organizational Chart for the company. This representative is responsible for establishing, implementing, maintaining, and reporting of the processes for the QMS.

### **5.5.3 Internal Communication**

Top management will communicate to the organization QMS. This will include but is not limited to meetings, e-mail, and wall charts as appropriate.

## **5.6 Management Review**

### **5.6.1 General**

The Quality Council reviews the QMS a minimum of once a quarter. The Quality Council reviews the system for suitability, adequacy and effectiveness in satisfying the requirements of the ISO 9001: 2000 standard and the company's stated quality policy and objectives. The reviews will also cover areas for improvement and changes that may be needed to the QMS. Minutes of the review will be taken and maintained by the ISO Management Representative per section 4.2.4 of this manual.

## **5.6.2 Review Input**

Input to the management reviews will include, but are not limited to:

- Audit results (internal and external)
- Customer feedback
- Process performance and product conformity
- The status of Corrective and Preventive Action
- Follow-up on management reviews
- Planned changes and effects on the QMS
- Recommendations for improvement

## **5.6.3 Review Output**

Output from the management reviews will include (as applicable) but are not limited to:

- Improvement of the effectiveness of the QMS and its processes
- Improvement of Product
- Resource needs

# **6 Resource Management**

## **6.1 Provision of Resources**

The president is responsible for identifying and providing the resources necessary to implement and maintain the QMS. Management is also responsible for ensuring that customer satisfaction is met by meeting customer requirements.

Each manager is responsible for identifying the resource requirements and providing adequate resources, including the assignment of trained employees, performance of work, and verification activities including internal quality audits and continuous improvement of the processes that make up the QMS.

Resource requirements are also considered as part of the job acceptance process

## **6.2 Human Resources**

### **6.2.1 General**

Employees performing work that affects product quality shall be competent on the basis of appropriate education, training skills, and/or experience. This is defined by the job description for each employee.

### **6.2.2 Competence, Awareness and Training**

All employees of Merit Electronics have appropriate training for their assigned tasks. Qualifications, including training requirements, are documented in job descriptions. Current job descriptions are maintained for all job positions. Training needs for all employees are identified or determined at the time of hiring. Records of all education, training, skills and

experience for pre-employment training verification are maintained in the personnel files. New employees receive quality training at time of hire. Records are maintained per section 4.2.4 of this Quality Manual.

### **6.3 Infrastructure**

Top management determines and provides, as appropriate, the requirements for the infrastructure of Merit Electronics to meet conformity to product requirements. This includes (but is not limited to) workspace, equipment and any supporting services, as needed.

### **6.4 Work Environment**

It is the responsibility of top management to identify and manage the necessary work environment to achieve product requirements.

## **7 Product Realization**

### **7.1 Planning of Product Realization**

The processes for Merit Electronics have been set up to support the quality objectives listed in section 5.4.1 of this quality manual. Processes and documentation have been developed to support the needs of a electronic component distribution facility. Inventory is confirmed prior to accepting a purchase order. Engineering or design of products is not done at Merit Electronics. This is a distribution company only and processes have been set up to monitor, analyze, and document results. Inspections are incorporated into the receiving of all inventory. Records for all of these processes are controlled by section 4.2.4 of this quality manual.

### **7.2 Customer-Related Processes**

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

Customer requirements are provided in the form of a RFQ. Requirements are evaluated prior to acceptance of a order. If necessary, additional resources are procured to complete a sale.

#### **7.2.2 Review of Requirements Related to the Product**

Product specifications and quantities are defined and provided by the customer. All orders are reviewed prior to acceptance. Orders are reviewed for resources and a determination made as to whether Merit Electronics can meet the customer's requirements. Delivery dates are reviewed and agreed upon prior to acceptance of order. If changes to the order occur, after an order has been accepted, pertinent documentation will be updated and reissued to reflect the new revision number, any changes in delivery dates, specifications or quantities.

### **7.2.3 Customer Communication**

Customer communication, in regards to product information and orders, including amendments, is processed by the work instruction 7.2.0-0001W. Merit Electronics will continually contact the customer for feedback. Customer complaints are handled through the Corrective Action process, section 8.5.2 of this quality manual.

## **7.3 Purchasing**

### **7.3.1 Purchasing Process**

Anyone may propose supplier candidates to purchasing.

Suppliers shall be authorized by Purchasing representatives.

Suppliers are authorized, when possible, on the basis of the following criteria:

#### **Financial review.**

- Consideration shall be given for the length of time in business
- Supplier shall have sufficient financial resources to effect quality product
- Consideration shall be given on the risk of size and capacity compared to company revenue

#### **Technical process review.**

- Supplier shall demonstrate satisfactory quality system
- Supplier shall demonstrate compliance to regulatory requirements as applicable (i.e. UL, CSA, CE, ANSI, FCC, FAA, OSHA, etc.)
- Supplier shall have controlled working methods
- Consideration shall be given to equipment capabilities
- Supplier shall demonstrate the ability to provide and control materials
- Supplier shall show evidence of employing qualified workforce

#### **Sample materials.**

- Supplier shall demonstrate conforming material prior to authorization upon request
- Evaluation of production parts is desirable. In certain cases, commensurate with the risks involved, conformance may be based upon historical data, customer referrals, third-party inspection reports, process quality data and other information

#### **Completed application form.**

Particular supplier may be authorized without completing Supplier Application form if: Purchasing determined that the annual business transaction with said supplier would not exceed \$20K/year.

Purchasing determines a delivery requirements may be needed prior to a pre-application

approval process, but will follow up with supplier documentation.

Purchasing will maintain all qualification records.

### **Procedure**

Suggestions for new suppliers are forwarded to Purchasing.

Purchasing will review business requirements to determine the need for a new source.

If a new source is deemed necessary, and the forecasted amount of business transaction would exceed \$20K/year, Purchasing will initiate sending a supplier application form to a prospective supplier.

Purchasing will maintain a history of returned applications.

Purchasing will validate information received on the returned form and make authorization decisions.

If required or feasible, in accordance with prudent business decisions and the application's review results, Purchasing will schedule and coordinate an on-site survey to validate supplier's capability.

If supplier is *authorized*:

Purchasing is responsible to:

- Assign authorized supplier code number
- Notify supplier
- Enter into Master Database
- Determine Terms

If supplier is *disapproved*:

Purchasing is responsible to:

- Notify supplier of the disapproval
- Clarify the areas of deficiencies which must be corrected prior to re-submitting the application

Suppliers listed in the ASL will be classified as:

- Certified supplier (ISO 9000 certified)
- Authorized supplier (non ISO 9000 certified)

All qualification records shall be retained for 5 years minimum.

## **8 Measurement, analysis and Improvement**

### **8.1 General**

The QMS has been set up to monitor, measure and improve processes and demonstrate conformity to order requirements. At appropriate places in the QMS processes, data collection has been set up and will be reviewed and analyzed to measure performance to the process or product requirements and to the quality objectives.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

Customer satisfaction is measured by on time performance and through the CAPA process. Customers will be contacted by Merit Electronics for feedback. This information is reviewed per section 5.6.1 of this manual.

#### **8.2.2 Internal Audit**

Internal Auditing is not an option for Merit Electronics at this time. For auditing of the QMS, Merit Electronics will retain help from a third party. Records of auditing will be maintained per section 4.2.4 of this Quality Manual.

#### **8.2.3 Monitoring and Measurement of Processes**

The QMS processes are continually measured and monitored. Monthly management reports are created that show the results of the QMS. These reports are reviewed by the Quality Council for suitability and effectiveness. In the event the planned results are not achieved, the CAPA process will be used to perform the corrective action necessary to ensure the conformity of the product.

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

The requirements for controlling nonconforming product or material is stated by the procedure 8.3.0-0001P.

### **8.4 Analysis of Data**

Data is collected to analyze and demonstrate the effectiveness of the QMS. This information is collected per the procedure or work instruction for that process. This data may be in the form of graphs or other types of reports. This information is reviewed at a minimum at Quality Council meetings per section 5.6.1. When applicable, the CAPA process (section 8.5.2 and 8.5.3) will be used to correct problems or for preventive action opportunities.

## **8.5 Improvement**

### **8.5.1 Continual Improvement**

The processes within Merit Electronics are set up to continually improve the processes used to support electronic component orders. The Quality Council reviews the effectiveness of the QMS to the quality policy, objectives, audit results, analysis of data, and corrective and preventive action at regular intervals (see section 5.6). As needed, Corrective or Preventive action is used to improve or correct a problem or a potential problem or to improve a process.

### **8.5.2 Corrective Action**

A process has been developed that incorporates both Corrective and Preventive Action. This process is intended to eliminate or prevent nonconformities or their reoccurrence and to continually improve processes. The CAPA Procedure # 8.5.3-0001P defines this process.

### **8.5.3 Preventive Action**

A process has been developed that incorporates both Corrective and Preventive Action. This process is intended to eliminate or prevent nonconformities or their reoccurrence and to continually improve processes. The CAPA Procedure # 8.5.3-0001P defines this process.