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Maxtronic Technologies LLC

QUALITY ASSURANCE MANUAL

Revision 3

January 26, 2002

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1. Introduction

This Quality Assurance Manual and the Operating Procedures referenced herein describe the Quality Assurance System of Maxtronic Technologies LLC.

2. Scope

The Maxtronic Quality Assurance System applies to each department and employee of Maxtronic Technologies LLC., as described in this manual and the referenced procedures.

3. Distribution and Revision

The Quality Assurance Department provides distribution of the Quality Assurance Manual. Distribution shall include customers upon request.

The Quality Assurance Department shall review and revise the Manual as necessary.

4. Quality System Description

4.1 Management Responsibility

4.1.1 Quality Policy

Maxtronic has become a leading supplier of electrical components through continual development of techniques and state of the art equipment to manufacture higher quality competitive products. We are committed to providing products to meet our customer's needs as we continue to pursue our company objectives.

4.1.2 Responsibility and Authority

The Director of Quality Assurance is responsible for the Quality Policy of the company. The QA department works in conjunction with each manufacturing department, supplier, and customer to achieve mutual goals resulting in products and services that meet customer satisfaction.

The Director of Quality Assurance reports to the President of the Company.

4.2 Quality System

4.2.1 Quality System Description and flow down

Maxtronic's Quality Assurance System was developed to comply with the following standards:

ISO-9000, Quality System Requirements, Design, Manufacturing, and Distribution requirements. (General).

In addition, Maxtronic recognizes the needs of some Customers for special procedures and services that are unique to a Customers requirement. In addition to adhering to the specifications listed above, MAXTRONIC welcomes the opportunity to provide special services for our Customers.

The Documentation for the Quality System is described in:

QA Manual……...Tier I
Operating Procedures……Tier II
Method Sheets……Tier III (applicable to special requirements)

The Quality Assurance Manual is designed to be informative and provide a description of the policy and activities that are used at Maxtronic . The Operating Procedures provide detailed instructions for each department to achieve the goals described in the Quality Assurance Manual. An additional Method Sheet can be developed to further control the quality of some products, where specific requirements are unique to a particular customer.

4.2.2 Quality System Procedure Availability

Copies of the Operating Procedures are available in each department thru a master electronic file. Master copies are maintained by the Quality Assurance department. Operating Procedures are available for customer viewing, on the premises. Requests for copies can be made to the Director of Quality Assurance.

4.3 Contract Review

Requests for Quotation and new Purchase Orders are subjected to a review by Engineering and Technical Services, Quality Assurance, Production Control, and Sales. Each department reviews the order information with applicable referenced drawings, revisions, clauses, and specifications for content that describes the finished product required by the customer, and as applicable to the reviewing department. Adequate definition of requirements is addressed by each reviewing department. Capacity and capability are also addressed by each department. Any extraordinary requirements are highlighted for special attention. Engineering, Technical Services, Quality Assurance, and Sales may call the customers agent to clarify requirements or discuss improvements to product, cost, and quality. Notes are attached to the order and returned to the Sales department for filing. Notes to the Sales Record are made for special instructions, certifications and other customer requirements.

All exceptions and clarifications are documented by the Sales department and provided to the customer. Customers may also be required to provide signature acceptance of notes and clarifications to drawings or terms and conditions as they are added. Records of contract review are maintained by the Sales department.

4.4 Design Control

Maxtronic has a design control process that ensures specified requirements are met. The design control process contains the following major elements; Planning, Interfaces, Input, Output, Review, Verification, Validation, and Changes. Responsibilities and authorities for approval are described in the applicable Operating Procedure. Maxtronic does not subcontract any design activity. When development activities are subcontracted, the control of the subcontracted activity will adhere to the Design Control Operating Procedure.

4.5 Document and Data Control

4.5.1 Procedures for Document Control

Engineering drawings are documents controlled with a revision level and file number. The drawing is electronically filed and recalled for use as an instruction throughout the production cycle. This ensures that only the latest revision is used for critical operations.

Any document that is called out by the customer to be a specific revision level must be referenced with the corresponding revision level. If the document is not available, the customer may be contacted for more information.

Documents that are called out by a customer but are not identified to be a specific or latest revision can be referenced with the document available in the library. No effort to validate the revision level is required when the customers reference is not specific.

4.5.2 Change Management

Maxtronic incorporates all product changes through an Engineering Change Notice (ECN) process. Any change to a product form fit or function must be presented and implemented by an ECN. Changes are described in full by the initiator with consideration to the impact on production methods, tooling, inventory on hand, and other effected areas. The ECN is then routed for department review and approval. Each department reviews the change feasibility and impact. A department manager signature is required before routing the change proposal to the next department. Problems and clarifications are brought to the attention of the ECN initiator before signature. Changes that effect customer parts are presented to the customer for review and authorization to proceed by Sales, Quality Assurance, or Engineering. A copy of all ECNs and the original drawing are kept on file along with the latest revision. It is the responsibility of Engineering and Technical Services to maintain this file.

In the interest of improved product designs and industry requirements, Maxtronic reserves the right to change catalog products (standards) without notification to the customer, provided the change does not effect the product form fit or function.

4.6 Purchasing

4.6.1 Purchasing Procedures

Maxtronic has developed Purchasing operating procedures to ensure that product purchased for manufacturing meets specified requirements.

4.6.1 Purchasing Documents

The Purchasing documentation system consists of Requisitions approved by department manager and the President with applicable specifications and drawings attached, Purchase Orders describing delivery requirements, Receiving paperwork including applicable Material Safety Data Sheets (MSDS).

Purchasing Documentation is filed for a period of 2 years, MSDS files are maintained indefinitely.

4.6.2 Purchase Product Verification

Maxtronic Quality Assurance performs receiving inspection on purchased material. Inspection procedures are developed to insure that product specifications and manufacturing requirements are met. Each part number received at Maxtronic has a descriptive inspection procedure for that particular product. A combination of mechanical inspections, performance testing and supplier certifications are used to validate purchased material. These inspection instructions are constantly modified to focus on problem features when they are discovered. Lot Control for received product begins at Receiving Inspection. Material Lot Numbers are recorded along with the results of the inspection. Acceptable material is released to stock and is identified with an acceptance label or stamp. Rejected material is quarantined and described on a Reject Material Report (RMR). The RMR is then processed by the Quality Assurance department to obtain a Return Authorization and Corrective Action from the Supplier. The Quality Assurance department retains the inspection results, lot number, certifications, and any other supplied documents for two years to seven years, dependant on contract requirements.

4.6.3 Right of Entry

The Maxtronic Quality Assurance Department shall receive and respond to any customer's request to visit Maxtronic, its subcontractors, and suppliers for the purpose of performing a survey, investigation, or audit. Maxtronic reserves the right to discontinue any visit, survey, or audit that is not in our opinion of a mutual benefit to the parties concerned.
Requests for plant survey's, tours, audits, at Maxtronic and its subcontractor, or supplier must be provided in writing to the Director of Quality Assurance. A written agenda must accompany the request. The agenda must provide insight into what is to be discussed, expectations for a plant tour, and introduction to other personnel. Maxtronic reserves the right to schedule and limit surveys, tours, and audits to maintain the environment required to meet our manufacturing commitments to all other customers. Maxtronic reserves the right to limit access to the facility where processes are in our opinion proprietary.

4.6.4 Supplier and Subcontractor surveillance

Maxtronic performs periodic supplier and subcontractor surveillance through a three-step method. All supplier and subcontractor material is subject to receiving inspection to determine quality of workmanship and adherence to specification. In addition, suppliers are required to complete a periodic survey describing their quality operating system. Finally, some specific suppliers are periodically surveyed and audited at their facility, including a tour of their process.

4.6.5 Special Process Sources Subcontractors

Maxtronic does not use subcontractors for any special process (i.e. testing, inspection). Special processes for Maxtronic products are performed in-house. Customers may request the use of their own approved subcontractor for a specific special process. This must be identified at the time of the quote. Maxtronic Quality Assurance will work with the Customer to determine necessary surveillance levels for such a request. Subcontracted special process sources must by approved by the Customer.

4.6.6 Evaluation and approval of Subcontractors

Material for production use is purchased from approved suppliers only. An approved Supplier list is maintained for reference when placing orders. Suppliers are evaluated based on price competitiveness, quality of workmanship, conformance to specification, and on time delivery. The performance metrics are determined by the Purchasing and Quality Assurance departments on a continuous basis. This information is used to determine the approved supplier list.

4.7 Control of Customer Supplied Product

When customer supplied material is required for Maxtronic production, the handling, control, inspection, verification, and storage instructions shall be incorporated into the Receiving Inspection procedure for that material. This information is to be discussed by Maxtronic Quality Assurance and the Customer at the time of the initial order. Any Customer Supplied Product that is damaged, lost, or defective will be reported to the customer.

On occasion, material is purchased from suppliers that Maxtronic has been directed to do business with. Directed suppliers are defined as those suppliers that were selected by the customer to supply product to Maxtronic for incorporation into a product for the customer. Maxtronic will create a Receiving Inspection procedure for this type of material to reasonably safeguard the defective supplier product from entry into the manufacturing process. It is the responsibility of the customer to initially survey and validate a directed supplier prior to Maxtronic's purchasing of said material. These suppliers may not be added to the Maxtronic approved supplier List if product purchased will only be used as directed by the customer.

4.8 Product Identification and Traceability

Product is identified at each stage of production through travelers, identification labels, inventory identification numbers, and lot numbers. Lot Traceability is maintained from raw material receiving thru delivery. The method of identification is described in operating procedures in each department in the company.

4.9 Process Control

4.9.1 Method for Control in Manufacturing

Maxtronic manufacturing is made up of 2 major departments: PCB assembly, Cable and Wiring Harnesses and Membrane Switche. The method for control is defined in Operating Procedures developed for each department.

4.9.2 Manufacturing Traveler and Job Reports

Manufacturing work instructions are described on travelers, work orders and job reports that identify requirements for the product. In addition, Control Plans are developed for customers with extraordinary and unique requirements.

4.9.3 Accountability and Configuration Control

Manufacturing Travelers, Work Orders, and Job Reports describe the part number, revision level, completed stage of production, additional steps for processing, lot number, inspection status, additional notes during processing or inspection, Operator, and Inspector. These documents are retained for a period of 6 months to seven years, depending on the application.

4.9.4 Split Order Quantities

Maxtronic products can be released in split order quantities. Minimum processing requirements must be met for some specific manufacturing processes. However, in some cases, order expediting can be accommodated by contacting the Sales Department.

4.9.5 Customer Approved Sources

If a customer approved source for a product to be processed by Maxtronic is required, the product will be treated as material requiring receiving inspection and no other source will be used without the explicit permission of the customer.

If a customer approved process is required, the process will be documented in a control plan and no changes to the process will occur without notification to the customer.

4.9.6 Tooling management

Maxtronic has a dedicated Tool Crib to safeguard and control tooling in manufacturing. Tooling is managed thru Operating Procedures that describe inventory reorder point levels, maintenance procedures and records, proper set up and use of tooling. In addition, tooling that is critical to function is inspected and approved prior to being put into service. Records are maintained for traceability.

4.10 Inspection and Testing

4.10.1 Product Quality Control

Quality Control is the responsibility of every department manufacturing product. It is the goal of our Quality Control program to eliminate defects at the earliest stage of detection. Defects are to be detected by the department empowered to take corrective action. Toward this goal, each production department maintains a staff of Quality Control Inspectors. These Inspectors report directly to the Manager for the area they are employed within. Quality Control methods are described in operating procedures for each department.

4.10.2 Product Inspection

Quality Control Inspection ensures that product released from the production department conforms to all specifications. This is achieved by inspecting dimensional conformance, performance testing, and packaging as required to Maxtronic and Customer specifications.

4.10.3 Material Certification and Test

Material certifications can be used to perform receiving inspection on some raw materials. Suppliers must certify material to ASTM or other industry acceptable standards. Maxtronic reserves the right to perform material content testing, either in house or by an independent certified source to resolve any dispute or further an investigation. In addition, material performance is verified by trial production run as part of the receiving inspection process.

4.10.4 Final Inspection

The Quality Assurance Department has the responsibility of certifying product and performing tests for specific Customer requirements prior to delivery. Quality Control Inspection records can be used for some Certifications that are requested to verify that in process tests were performed. Testing required by the Customer may also be performed on the product prior to shipping, regardless of the existence of a redundant in-process test.

Outside service test labs may also be used provided they are Certified or the equivalent. Certification proof is required to be on file with Maxtronic Quality Assurance prior to using outside labs. Testing and Certification is specific to the needs of the Customer and must be specified in the Purchase Order. All Certifications and Test Reports will be reviewed and signed by a Maxtronic Quality Assurance Representative.

4.10.5 First Article Inspection

First Article Inspection is available for customers. At a minimum, First Article Inspections will include dimensional inspection, production functions, and material content. Additional requirements should be provided by the customer at the time of the order. Because Maxtronic product must meet minimum batch sizes for some processes, First Article Inspections cannot be performed prior to committing to a full production run. However, arrangements can be made to provide the customer with a First Article package when the order is delivered. Records will be retained for a period of 6 months to 7 years, dependant on the customer requirements.

4.11 Control of Inspection Measuring and Test Equipment

4.11.1 Calibration Procedure

This procedure is used to control the accuracy of measuring, test, and calibration standards. Calibrations are performed on a daily, weekly, and annual basis as required by the type of tool and the environment they are used in. Calibration intervals are established to the extent necessary to ensure continued measurements of the required accuracy. Measurement and Test Equipment shall be stored and handled in a manner that will not adversely effect the calibration or the condition of the equipment. Each manufacturing department or the quality assurance lab shall maintain a calibration record. A Calibration Log is kept of their conformance to the standard and the date it was verified.

Employee owned measuring tools are considered part of this calibration program and shall be calibrated under the same conditions and controls.

Measurement tools that are not used to verify manufacturing product are not subject to calibration (i.e. machine shop and reference gages).

4.11.2 Standards Traceability

Measurement standards used for the calibration of measurement tools shall be traceable to N.I.S.T. and be at least four times the accuracy of the tool they are used to calibrate.

4.11.3 Equipment Identification

All tools shall be identified by a calibration cycle tag or a serial number. Serial Numbers shall correspond to a calibration record that describes the last date calibrated. Serial numbers and logs are used to identify equipment calibration status, due to the environmental conditions of some manufacturing areas.

4.11.4 Recall Procedure

The Calibration procedure describes the process by which product should be recalled, in the event that an out of calibration condition adversely effected the classification of product.

4.12 Inspection Status

4.12.1 Identification and Traceability

Product inspection and test status is identified on manufacturing department travelers and product labels. Inspection and test status indicates pass or fail status as well as the individual responsible.

4.13 Control of Non-conforming Product

4.13.1 Procedures for control of Non-conforming product

Product that does not meet specification, found by any department, must be marked as "defective" with a tag or rejected stamp. The tag must state the part number, date, lot number, problem description, quantity, and the originator. All defective material shall be segregated from material that is good or to be inspected. For large bulk material, reasonable precautions must be taken to assure that defective product is not inadvertently used in production. The area used to store defective material must be clearly marked as a “Quarantine” area. Each Production department is responsible to maintain a Quarantine area.

4.13.2 Policy on rework, regrade, repair, use as is, and scrap

All defective material is subject to the Material Review Board (MRB) process. The MRB consists of the Director of Manufacturing, Director of Quality Assurance and the Department Manager. On occasion, the Customer may also be involved in the process. The purpose of the Board is to review non-conforming material to determine the best possible disposition for all concerned. This process is also provides a safeguard against defective material being released from Manufacturing. Any Material that is defective must be held for MRB disposition. MRB decisions are documented on the appropriate inspection paperwork describing the problem to be reviewed.

During MRB, defects are categorized as Critical, Major, or Minor. A Critical defect is one that could go undetected until failure in the field, and if such a failure occurred would likely cause a hazardous or unsafe condition or prevent function of the end item assembly. A Major defect is one that is likely to result in a failure or reduce the usability of the product for its intended purpose. A Minor defect is one that if left undetected or not corrected will not have any effect on the form fit or function of the major end item and would not cause hazardous or unsafe conditions. MRB results shall fall into one of the following categories; use as is, rework, repair, and scrap.

Maxtronic does not “regrade” product in any way. Product must always meet the applicable Customer specification prior to release.

4.13.3 Reinspection of reworked product

Any material that is reworked must be submitted to at least the same in-process inspection as first run material. Additional inspection may be required to verify the effectiveness of the rework. An inspection record of reworked material must be maintained by the Department performing the rework or re-inspection.

4.13.4 Scrap identification and segregation

Scrap Material must be marked as scrap and removed from the production area by placing it in Quarantine. All scrapped material are segregated into specific scrap recovery containers in accordance with department scrap procedures.

4.13.5 Customer notification of recall

Maxtronic Quality Assurance has the responsibility of notifying Customers of out of tolerance conditions, problems, and investigations as necessary, whenever these issues can affect the Customer. This responsibility is described in the MRB procedure.

4.14 Corrective Action Program

4.14.1 Procedure for Corrective Actions

The Quality Assurance department documents and takes action to correct internal and external complaints of product quality. Quality concerns are reported through out the organization as they are described by the Customer in a Quality Alert. Acknowledgment of a Customers quality concern is typically provided within 24 hours of reporting the problem. Maxtronic Quality Assurance maintains a Corrective Action program to document problems and the solutions implemented to resolve them. The Quality Assurance Director assigns Corrective Actions to individual departments. Both internal and externally driven Corrective Actions are covered by this procedure.

4.14.2 Corrective Action requirements

Corrective Action responses to Customers will address root cause, immediate corrective action or containment, root cause corrective action, verification plan, team members, and restatement or conclusion (dependant on Customer requirement).

Corrective Actions are reviewed by the President, Director of Manufacturing, and Director of Quality Assurance during a monthly quality concern review.

4.15 Handling, Storage, Packaging, Preservation and Delivery

Each department is responsible for safeguarding production material from being damaged or mixed during handling. Material handling procedures shall be written into the operating procedures for each manufacturing department as applicable. Material should be protected with reasonable means during all sequences of production and inspection. Material storage, both long and short term shall provide adequate protection from damage and mixing.
Customer specific packaging and delivery requirements are described to the Shipping department for all orders.

4.16 Control of Quality Records

4.16.1 Purpose, Retention, and Availability

Quality records are maintained to demonstrate conformance to specified requirements and quality procedures. Quality records are retained for a period of 6 months to seven years, dependant on Customer requirements. Quality records are available for Customer review upon request.

4.17 Internal Quality Audits

4.17.1 Procedure for internal audits

Maxtronic has a Self-Audit program for all operating procedures used in both administration and manufacturing. This program provides for a periodic audit of every procedure used in these departments. Audit records are available for review.

Audit results are discussed with department managers, and other appropriate personnel. Audit failures are documented with a Corrective Action process.
Corrections and revisions to the department procedures are drafted by the department manager and discussed with the auditor to close out the open item. Audit failures due to operating deficiencies must have supporting evidence to show that a correction has been implemented prior to closing the open item.

4.18 Training

Training programs are continuously developed and implemented for all employees performing functions that require special instructions. Company wide training is provided by the Human Resources and Safety departments for all new employees. This type of training is usually general in its application and required of all employees in the Company. For example, Safety and Hazardous Material Handling training is made part of every employees orientation program. Departments that require a special skill shall implement department specific training. An instructor shall provide the training with reasonable qualifications through either formal training or experience.

In addition, all departments have an established Training Plan for each procedure. Training records for each person on the Training Plan are maintained by the department Manager. Human Resources initiates a Training Program for management and office staff as required. The program is customized for the individual and the position they will occupy in the organization. Typically new employees will be subject to an orientation program where by they will become familiar with each operation of the plant.

Records of training shall be made available.

4.19 Servicing

4.20 Statistical Techniques

Maxtronic does not perform any type of servicing of their products.

4.20.1 Procedure for SPC

Maxtronic's Statistical Process Control Program provides a service to the Manufacturing departments to determine process capability. SPC is typically performed by a collective effort of the Quality Assurance and Manufacturing department. Statistical Process Control training is provided by the Quality Assurance department for each department involved in using this technique to monitor a feature and process.

Statistical Process Control is a continuous program used by Maxtronic Quality Assurance and Manufacturing. This program is performed on a sample basis or as required by a Customer. Product is selected for SPC at the earliest manufacturing stage. Data is collected and a Capability Study is then performed to determine the ability to hold tolerances and minimize defects.

Significant characteristics are monitored based on our knowledge of the features most critical to our Customers. The data is then analyzed to determine if the process will produce material with a normal distribution within the control limits. Quality Assurance and the Manufacturing Department discuss sources of process variation. The Capability index is correlated to the sources of variation. Cp and Cpk values are then provided to the Operator for further process monitoring. As a Company standard, a Cpk of 1.33 is used to indicate the minimal acceptable indication of process control and amount of defects per million. Additional requirements are also discussed with Customers, specific to their application.

4.20.2 Sampling Plan

When required by contract or specification, only Customer approved sampling plans are used. For all other requirements, quality control operating procedures in each manufacturing department describe the sampling plan for the inspection or test.

4.21 Continuous Improvement

Our commitment to continuous improvement in Customer Satisfaction is measured with internal Performance Metrics. Performance indicators have been developed to track our ability to meet target goals for on time delivery and customer complaints. Each Department is rated for the number of shipping late occurrences and customer rejections. Periodically, target goals are set by Senior Management to drive the performance to a level consistent with our company goals and objectives. Industry bench marking regarding the services expected by our Customers and internal corporate strategies are used to determine performance goals.

5. Revision

Revision	Date	Description of Change
1.0	03/15/1998	General revisions and updates, all sections.
2.0	03/10/1999	Added Revision section, general revisions and updates on all sections
3.0	01/26/2002	General revisions and updates