



# **Axon Circuit, Incorporated**

## **Quality System Manual (QSM)**

Revision K

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*Quality System Manual rev K.doc*

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## 1.0 Introduction

Axon Circuit, Inc. is committed to producing quality products through the implementation of its Quality System. This manual outlines the policies of the company relating to this Quality System.

### 1.1 Scope

This Quality System Manual and its policies apply to all activities, all locations and all personnel of Axon Circuit. This manual replaces all previous revisions of the *Axon Circuit Quality Control Manual*.

### 1.2 Purpose

The primary purpose of this *Quality System Manual (QSM)*, is to describe and document the Quality System currently in place at Axon Circuit. It is effective across all disciplines and at all levels within the company.

This manual is the central source of general policies, procedures, and responsibilities that in turn authorize and govern creation of subsidiary quality related documentation and activities.

This Manual provides comprehensive evidence to all customers, suppliers, and employees that Axon Circuit is committed to establishing and maintaining acceptable levels of measurable quality in its products and services.

The requirements and procedures addressed in the *Quality System Manual* are intended to meet or exceed the requirements of ISO 9001:2000 Standard [ANSI/ASQC/ISO Q9001:2000] and customer and regulatory requirements.

### 1.3 Authority

This manual is issued under the authority of the President of Axon Circuit.

### 1.4 Issue of the Manual

Copies of the manual will be controlled by a means described in the procedure ***Document & Data Control***. The master copy of the manual will be held by Document Control.

Document Control is responsible for the issue of amendments to the manual, withdrawal of obsolete information and the maintenance of the master copy of the manual.



Uncontrolled copies may be distributed to organizations or persons at the discretion of the Quality Assurance Manager and/or the President. These will be current at the date of issue only and will not be subject to amendment action. These copies will be annotated "UNCONTROLLED."

**1.5 Amendments**

Controlled manuals will be updated and revised as required.

**1.6 Review**

The Quality System shall be audited on a continuous basis to affirm that the current practices conform to the policies set out in the manual. As needed, this manual shall be revised to reflect changes in the Quality System and the results of Management Review.

**1.7 Products & Company Information**

Axon Circuit, with its primary facility in Tampa FL, is a leading manufacturer of quality printed circuit boards and provides a complete line of single-sided, double-sided and multilayer boards for use in commercial and industrial applications. A detailed description of each product can be found in our sales literature. Axon Circuit maintains the necessary facilities and personnel to manufacture complex printed circuits and can provide all the necessary quality assurance and documentation to support manufacture of those products.

Axon Circuits' Tampa location was certified to ISO 9002:1994 by International Management Systems, an RAB-accredited registrar, in 1997. This system was upgraded to ISO 9001:2000 compliance in 2002.

In 2000, Axon opened its second facility in Longwood FL to better facilitate customer needs and output. This facility is fully incorporated into the Quality Management System.

Axon Circuit is a member in good standing of The Institute for Interconnecting & Packaging Electronic Circuits (IPC) since 1990.



## 2.0 Company Quality Policy

At Axon Circuit, our commitment is to:

- Consistently supply our customers with **high quality products**
- Provide **on time delivery**, every time
- Allow for **continuous improvement**
- Encourage **employee participation**

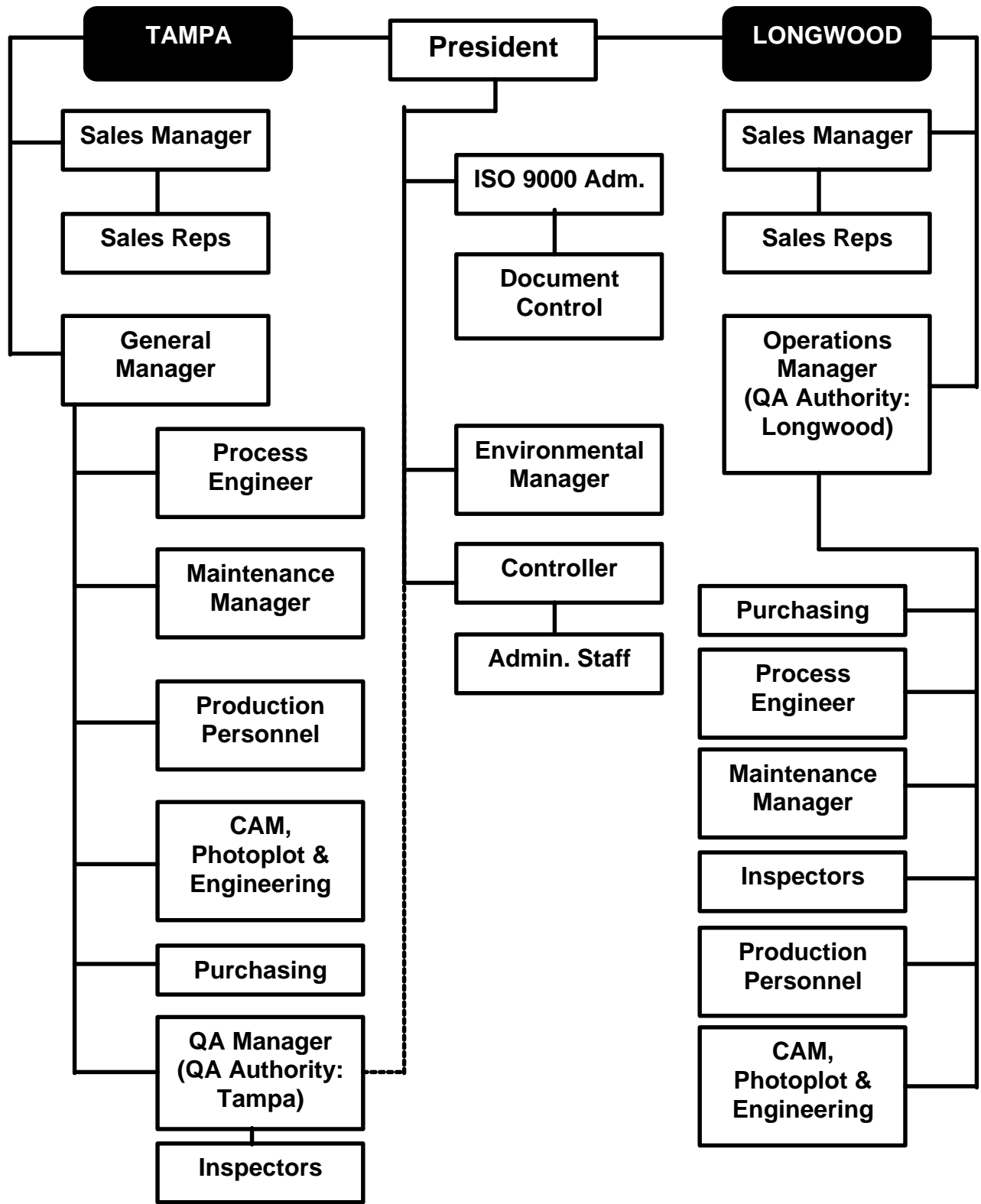
The successful administration of our Quality Policy is the responsibility of all Axon employees, with the full commitment and involvement of management.

Quality is a way of life at Axon Circuit.

*Chandra Patel*  
*President*



### 3.0 Organizational Chart





## 4.0 Quality Policies and Responsibilities

### 4.1 Management Responsibility

#### 4.1.1 Quality Policy

The corporate quality policy of Axon Circuit is stated in section 2.0 of this manual, and has been developed and agreed to by the senior management of the company. The company is committed to achieve this policy through the implementation and maintenance of a Quality System.

#### 4.1.2 Quality Objectives

From the Quality Policy, the management of Axon Circuit has developed specific quality objectives that are measured to ensure the effectiveness of the quality management system, and to provide evidence of that effectiveness.

The following objectives are measured:

- **Product Quality:** measured with:
  - Internal Scrap Rate
  - Customer Returns (scrap and rework)
- **On-Time Delivery:** measured through analysis of delivery performance data.
- **Continual Improvement:** measured through analysis of redundant issues processed through the Corrective & Preventive Action system. Also monitored by way of analyzing trends of other Quality Objectives during management review.
- **Employee Participation:** measured with:
  - Minimum goals for employee submittals of CAR's
  - Minimum number of audits conducted with department managers or supervisors (alongside trained auditors)
- **Customer Satisfaction:** measured through analysis of customer satisfaction data. See section 4.1.3 below.

For each objective, a numerical goal is established by management during the management review meeting. At each management review the current period's data is reviewed and those goals adjusted accordingly.

To communicate these to employees, management will post the current Quality Objective results and future goals throughout the facility.



### 4.1.3 **Customer Satisfaction**

Axon measures and monitors the levels of satisfaction of its customers through the use of satisfaction interviews, surveys, analysis of customer feedback and review of customer complaints and returns. This is further defined in the **Quality Index** procedure.

### 4.1.4 **Communication**

#### 4.1.4.1 Internal Communication

In order to ensure communication throughout the company, between all levels of personnel, all employees are empowered to submit requests for corrective or preventive action in order to report existing or potential nonconformances. In addition, the training program makes clear the right of each employee to raise quality issues, including suggestions for improvement, with their managers.

Management shall conduct at least one meeting annually with all employees to briefly review the status of the company and the Quality Management System, and to open the discussion for any issues or suggestions by employees. In addition, minutes of Management Review shall be posted prominently throughout for all employees to review, in order to ensure proper communication of the status and effectiveness of the quality system throughout the company.

Daily production meetings shall be conducted to ensure supervisors and managers are up to date on scheduling issues, production resource needs, and ongoing employee issues. Minutes are not kept of these meetings, but CAR's are filed as needed to address issues.

Internal auditing shall judge the effectiveness of communication relative to the quality system.

#### 4.1.4.2 External Communication

Communication received from customers, regulatory authorities or other third parties shall be routed as follows:



<b>Communication regarding:</b>	<b>Routed To</b>	<b>Record required?</b>
Product information	Sales Rep. or Engineering	No.
Open orders: status queries	Sales Representative	No.
Open orders: other queries	Sales Representative	CAR if complaint
Amendments to active orders	Sales Representative	Sales Change Order
Reports of product nonconformance	Quality Assurance Mgr.	CAR
Customer feedback (not product related)	Sales Representative	CAR if complaint
Quality management system	ISO 9000 Admin.	CAR if complaint

## 4.1.5 Organization

### 4.1.5.1 Responsibility & authority

It is the responsibility of the President of Axon Circuit to define the organizational and reporting structure of the company.

Axon currently has two facilities, at each of which is designated a "QA Authority." This is further defined on the Organizational Chart in section 3.0. This term shall not be confused with "QA Manager."

It is the responsibility of the QA Manager to hold and/or not ship product that does not meet customer requirements and to determine disposition of nonconforming materials.

The ISO 9000 Administrator shall oversee the mechanisms in place which provide solutions for nonconformities (such as Corrective & Preventive Action) and verify the implementation of these solutions (such as Internal Quality Auditing.) The ISO 9000 Administrator shall also coordinate management review activity.

It is the responsibility of all Axon employees to identify non-conformances and request corrective action in order to prevent the occurrence of any nonconformities.

All managers are responsible for ensuring that their staff are conversant with the company's Quality Policy and its Quality System.

### 4.1.5.2 Resources

It is the responsibility of the President to provide the resources necessary to implement and maintain the Quality System and policies of this Manual.



#### 4.1.5.3 Management Representative

Axon's ISO 9000 Administrator shall have the responsibility of implementing, maintaining and reporting on the performance of this Quality System, and shall interface with all appropriate registrars as required.

The duties of the ISO 9000 Administrator may be shared among individuals appointed by the President.

#### 4.1.6 Management Review

The Quality System shall be reviewed on a defined interval by the President and department heads in conjunction with the ISO 9000 Administrator to ensure its continued effectiveness. Records of management review shall be kept. The execution of this policy, and definition of the defined interval, is detailed in the system procedure ***Management Review***.

The minimum agenda of the meeting shall be as follows:

- Review of the Quality Policy for adequacy and currency
- Review and updating of Quality Objectives and related goals
- Quality audit results and trends thereof
- Review of resources for equipment, infrastructure, work environment, human resources, quality system, etc.
- Status of open CAR's (corrective and preventive)
- Review of Corrective & Preventive Action results and trends thereof
- Review of vendors and subcontractor performance
- Review of changes to the company that may impact the quality system
- Recommendations for improvements to the quality system
- Follow-up activities from previous Management Reviews

Top management will generate requests for corrective and/or preventive action, and take other recorded action, as a result of review topics in an effort to improve the Quality Management System, products, processes and services, as well as to address resource needs.

The result of this review shall be documented and agreed non-compliances shall be processed in accordance with the company's corrective action system.



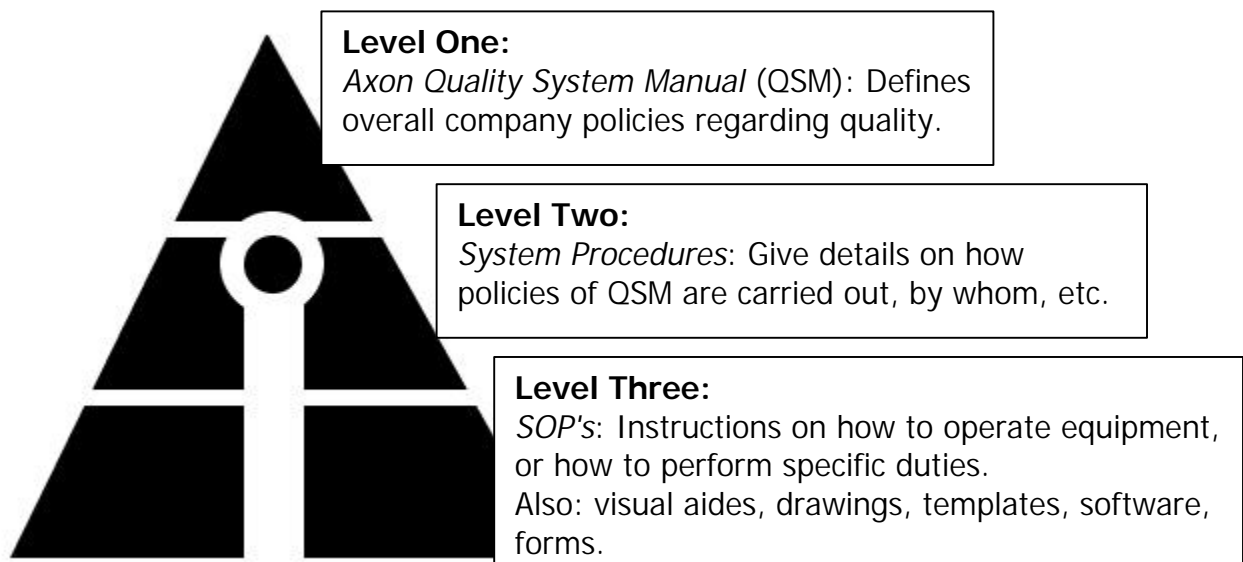
Analysis of quality data shall be performed by the QA Manager in accordance with the procedure **Quality Index** in order to continually gauge the results of the Quality System and to give a means to monitor Axon's continuous improvement.

## 4.2 Quality System

4.2.1 Quality System Manual (see illustration)

4.2.2 System Procedures (see illustration)

The following represents Axon's quality system documentation structure:



Department heads and authorized employees shall have the responsibility for creation and revision of necessary quality documents; such authority shall be indicated by way of approvals as referenced in the **Document & Data Control** procedure.

All Department Heads are responsible for the implementation of the System Procedures in their area required by the Quality System.

It is the responsibility of all members of management to familiarize themselves with the Quality System requirements and to ensure that these are observed accordingly.

## 4.2.3 Quality Planning



Quality planning will be an integral part of the Quality System through the implementation of procedures which address the following requirements for quality:

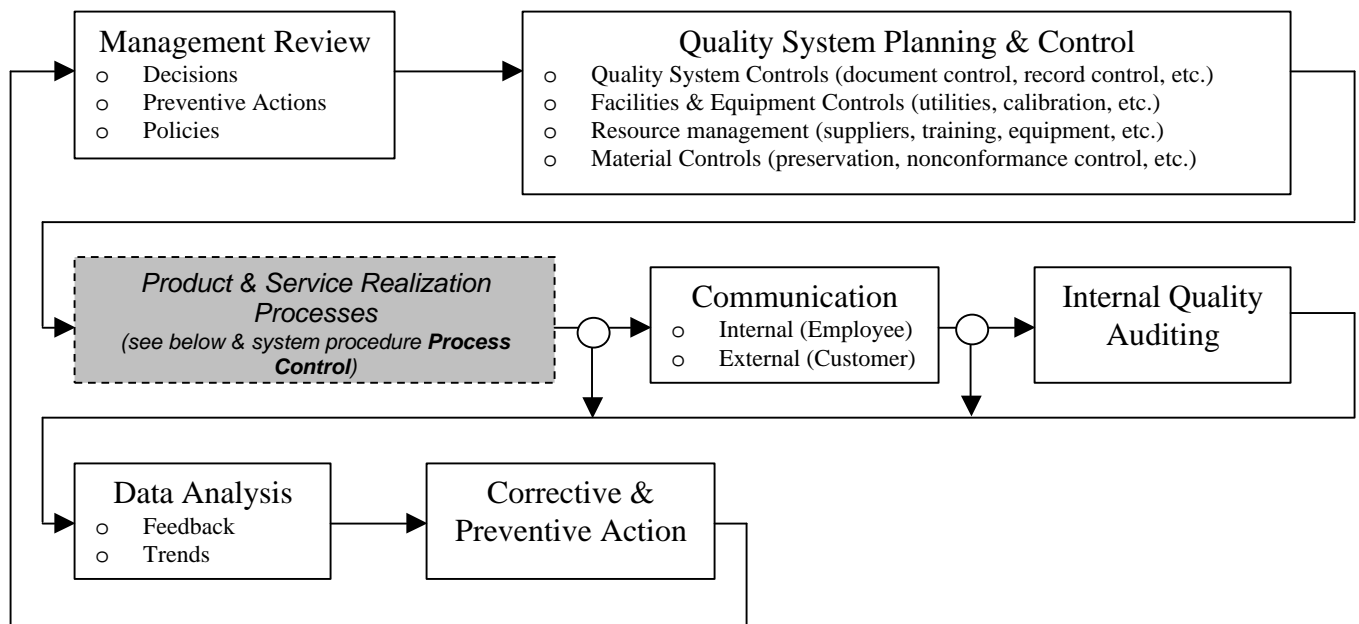
- identification and acquisition of any required controls, processes, equipment, fixtures, resources, and skills.
- verification of the compatibility of the production process, inspection and test procedures and supporting documentation.
- updating, as required, of quality control, inspection and testing techniques, including development of new instrumentation.
- timely identification of any measurement requirement involving capability that exceeds the known state of the art.
- identification of suitable verification stages during production of the product.
- identification of standards of acceptability for all critical product requirements.
- identification and preparation of quality records

As required, specific quality plans may be developed for individual products or technologies; these plans shall include the information given above. In such cases, the QA Authority shall have overall responsibility for the development of quality plans, with input from department heads.

#### 4.2.4 Process Management

Axon has identified and controls its processes for the implementation and maintenance of the quality management system, and for its product realization processes.

The following chart represents the interaction and sequence of QMS processes:





## MANAGEMENT PROCESSES

Process	Process Owner	Criteria Monitored	Verification Frequency	Verification Quantity	Verification Method	Reaction Plan	Reference
<b>Management Review</b>	ISO Admin.	MRM Effectiveness	Annually	Meeting minutes since last audit	Internal Audit	CAR	Sys Proc: Management Review
<b>Internal Communication</b>	President	Min. # of employee CAR submittals	Semi-Annually	CARs filed since last meeting	MRM Objective	CAR	QSM sec. 4.1.4
<b>External (customer) Communication</b>	Sales Manager	Capture of customer communications	Annually	Sampled by auditor	Internal Audit	CAR	QSM sec. 4.1.4
<b>Internal Auditing</b>	ISO Admin.	Audit program effectiveness	Semi-Annually	Previous period's audits	Management Review	CAR or MRM output	Sys Proc: Internal Quality Audits
			Annually	Sampled by auditor	Internal Audit program	CAR	
<b>Data Analysis</b>	ISO Admin.	Is data analysis conducted & thorough?	Annually	MRM minutes	Internal Audit Program	CAR	Sys Proc: Quality Index
<b>Corrective &amp; Preventive Action</b>	ISO Admin.	CAR redundancy	Semi-Annually	All CAR's	Management Review	MRM Output	Sys Proc: Corrective Action
		CAR system effectiveness	Each CAR	Each CAR action plan	Effectiveness review	New CAR filed	

## PRODUCT REALIZATION PROCESSES

Process	Process Owner	Criteria Monitored	Verification Frequency	Verification Quantity	Verification Method	Reaction Plan	Reference
<b>Quoting &amp; Order Review</b>	Sales Rep.	Requirements captured?	Ev. RFQ or customer PO event	All quotes / orders	Review by Sales Rep	Revise Quote	Sys Proc: Contract Review
		Process effectiveness	Annually	Sampled by auditor	Internal Audit	CAR	
<b>Purchasing</b>	Buyers & Controller	Review of PO info and terms	Every purchase	All PO details	By Purchasing	Revise PO	Sys Proc: Purchasing
		Process effectiveness	Annually	Sampled by auditor	Internal Audit	CAR	
<b>Receiving</b>	Production Manager	Acceptability of received goods	Each delivery	Each line item	Receiving Inspection	NMR	Sys Proc: Receiving
		Process effectiveness	Annually	Sampled by auditor	Internal Audit	CAR	

(continued on next page)



Process	Process Owner	Criteria Monitored	Verification Frequency	Verification Quantity	Verification Method	Reaction Plan	Reference
<b>CAD Engineering</b>	Eng. Mgr.	Final Plot	Every new job	Each plot	See SOP.	Correct plot	Related SOP's
<b>Photoplot</b>	Eng. Mgr.	Final Plot	Every new job	Each plot	See SOP.	Correct plot.	Related SOP's
<b>Shear / Pin</b>	Drill Supervisor	Acceptance Criteria	Each order	100%	Visual by Operator	MRB	Related SOP's
<b>Multilayer Lamination</b>	Prod. Mgr.	Acceptance Criteria	Each order	First article	First article Inspection	X-ray lot	Related SOP's
<b>Drill</b>	Drill Supervisor	Acceptance Criteria	Each order	Sample	Compares against drill plot; pin gages	MRB	Related SOP's
<b>Image</b>	Image Supervisor	Artwork acceptability	Each order	All artwork	Visual by operator	Rework	Related SOP's
<b>DPS / Pattern Plate</b>	Wet Proc. Supervisor	Acceptance Criteria	Each order	Sampled	Pin gages; 1 cross section per shift	MRB, adjust process	Related SOP's
<b>Resist Strip</b>	Wet Proc. Supervisor	Acceptance Criteria	Each order	100%	Visual by operator	MRB	Related SOP's
<b>Etching</b>	Wet Proc. Supervisor	Acceptance Criteria	Each order	100%	Visual by operator	MRB	Related SOP's
<b>Solder Strip</b>	Wet Proc. Supervisor	Acceptance Criteria	Each order	100%	Visual by operator	MRB	Related SOP's
<b>Soldermask Screen</b>	Prod. Mgr.	Acceptance Criteria	Each order	100%	Visual by operator	Rework	Related SOP's
<b>HASL</b>	Wet Proc. Supervisor	Acceptance Criteria	Each order	100%	Visual by operator	Rework	Related SOP's
<b>Legend</b>	Prod. Mgr.	Acceptance Criteria	Each order	First Article	First article Inspection	Realign	Related SOP's
<b>Routing</b>	Drill Supervisor	Acceptance Criteria	Each order	100%	First article Inspection	See Supervisor	Related SOP's
<b>Electrical Test</b>	QA Mgr.	Electrical Acceptance Criteria	Each order req'g ET	100%	See SOP.	MRB	Related SOP's
<b>QC Inspection</b>	QA Mgr.	Acceptance Criteria	Each order	IP: Sampled Final: 100%	IPC-A-600	Inspection Report	Related SOP's
<b>Pack &amp; Ship</b>	Prod. Mgr.	Packaging requirements	Each order	100% (packages)	Visual by packager	Correct packaging	Related SOP's



## 4.3 Contract Review

### 4.3.1 General

Orders received from customers ("contracts") shall be reviewed in accordance with the procedure **Contract Review**. No orders shall be released to production which have not undergone this review process.

### 4.3.2 Review

Axon Circuit will review all orders to ensure that customer requirements are adequately defined, reconciled with Axon capabilities, and that discrepancies are resolved with agreement by the customer prior to acceptance of the order.

It is the responsibility of the Sales Manager and Engineering Manager to oversee Contract Review procedures and to meet the requirements of this policy. Other department managers may be utilized to determine Axon's ability to meet customer requirements.

The Sales or Engineering Manager must provide information concerning any special quality requirements to the Quality Assurance Authority. The Quality Assurance Manager is responsible for implementing the customer's quality requirements.

### 4.3.3 Amendments to Contracts

Axon will make every effort to see that customer-stipulated changes (amendments) to contracts are addressed as quickly as possible so that manufacturing may reflect these changes. In cases where such changes cannot be met, this condition will be communicated to the customer.

Changes to contracts stipulated by Axon shall be immediately communicated to the customer, in order to renegotiate terms or requirements.

### 4.3.4 Records

Records of contract review shall be maintained by Sales in a manner according to the **Control of Quality Records** procedure.

## 4.4 Design Control



Axon Circuit receives design information from its customers in the form of data files and/or printed design specifications. Axon makes no changes to the customer-specific portion of the design, and does not offer design services to its customers.

Therefore, Axon excludes clause 7.3 of the ISO 9001:2000 standard from its quality management system.

## **4.5 Document & Data Control**

### **4.5.1 General**

Axon shall control all documentation used to assure or control the quality of the company's products, including procedures forming the Quality System, as detailed in the system procedure **Document & Data Control**. Documentation may be in the form of printed or electronic media. Customer-supplied electronic data (such as Gerber files) shall be controlled according to the procedure **Control of Engineering Data**.

It is the responsibility of the ISO 9000 Administrator, through Document Control, to ensure that the document control procedures are implemented and effective in meeting the requirements of this policy.

It is the responsibility of all company personnel originating, acquiring or amending any process or material which falls within the scope of controlled documentation to ensure that such activities are recorded in the appropriate documentation in accordance to procedures.

It is the responsibility of the General Manager (Tampa) and Operations Manager (Longwood) to assure clarification of written documents is available, through qualified and authorized personnel, for those individuals who may require it.

### **4.5.2 Document & Data Approval & Issue**

The issue and amendment of all such documentation will be reviewed, approved, controlled and recorded.

The issue and amendment control procedures will ensure that current information is available as required throughout the company and that obsolete information is withdrawn from use.

### **4.5.3 Document & Data Changes**

In recognition that procedures and instructions are "living documents," all such quality documentation is subject to revision. Revisions shall



be reviewed and approved by the same functions responsible for original issue, unless otherwise designated; such revisions shall be controlled in the same manner as original issues.

## **4.6 Purchasing**

### **4.6.1 General**

The purchasing of materials and services used in the manufacture of the company's products shall be in accordance with the procedure ***Purchasing***.

It is the responsibility of the Purchasing Manager to ensure that the procedures established for the control of the purchasing activity are implemented.

### **4.6.2 Evaluation of Subcontractors**

Vendors ("subcontractors") shall be evaluated and approved according to the ***Purchasing*** procedure. A list or database of acceptable vendors shall be maintained. Records of the evaluations of vendors are also maintained.

The Purchasing Manager is responsible for establishing and maintaining the approved supplier list with input from the Quality Assurance Department.

### **4.6.3 Purchasing Data**

All purchased materials and services required for the manufacture of products will be the subject of written purchase orders which will clearly describe all requirements, including quality system requirements if necessary.

### **4.6.4 Verification of Purchased Product**

In line with the company's policy of using only materials which meet the required quality, all materials used in manufacture will be purchased to the company's specification. Incoming materials will be verified when received according to the procedure ***Receiving*** and subject to inspection according to the procedure ***Inspection & Testing***. The level and amount of incoming product inspection shall be determined by the vendor's quality history, results of quality audits, Certificates of Compliance (or some other indication of conformance to industry standards), and other factors determined by the management.



Axon reserves the right to verify product at its vendor's premises, and will include such requirements in the PO.

When specified by the customer, Axon will allow customers to verify materials at Axon. Axon will make every effort to allow its customers to inspect materials at its vendors' site(s) if required by the customer, and include this requirement in the contract and/or PO.

It is the responsibility of the QA Authority to coordinate QA inspection activities at his/her facility.

It is the responsibility of the General Manager (Tampa) or Operations Manager (Longwood) to oversee receiving activities; the QA Authority shall oversee receiving inspections.

#### **4.7 Control of Customer-Supplied Product**

All customer supplied product will be examined upon receipt for condition, quantity and conformance with delivery details.

Such items will be positively identified and stored in a designated area.

Damaged or deteriorated customer-supplied product shall be recorded and reported to the customer as soon as such condition is noticed.

Material will only be issued according to the terms under which it was supplied.

All employees are responsible for following the procedure ***Control of Customer-Supplied Product*** as it pertains to their function. The QA Authority is responsible for the overall implementation of this policy.

#### **4.8 Product Identification and Traceability**

All production materials will be identified on receipt and during storage, pending issue and use. Laminates will be identified by marked skids or shelving; all other raw materials shall be identified by their manufacturer's labels.

All in-process products will be identified by one or more methods throughout the manufacturing and test cycle; these methods include etching of identification numbers on parts, physical segregation, barcoding, and/or association with process traveler, product status tag, etc. Additional identification and traceability measures will be employed as required by the customer.



Where traceability is required by the customer, Sales shall include this requirement on the contract.

The execution of this policy is detailed in the system procedure ***Product Identification.***

All personnel are responsible for observing the requirements of the procedures which implement this policy.

#### **4.9 Process Control**

Axon shall plan the methods of production which directly affect quality, and apply these plans through its policies, procedures and instructions.

Standard Operating Procedures (SOP's) will be documented and approved which include a definition of the methods and equipment to be used, the test procedures to be employed, and references to workmanship standards, visual aids, samples and quality standards, where applicable. Details of applicable in-process and post-process quality control checks will be referenced. In some cases, training by qualified personnel will replace SOP's.

Appropriate inspection and test steps will be identified and documented in the procedure ***Process Control.***

The company will provide a suitable work environment and the resources necessary to maintain that environment.

Equipment will be maintained and calibrated where required to provide continuous process capability, according to the procedures ***Equipment Maintenance*** and ***Control of Inspection, Measuring & Test Equipment.***

A record of the production will be maintained to meet the requirements of the product traceability section of this manual.

Any special processes requiring pre-qualification shall be identified, and individuals performing such special processes shall be qualified, with such qualification recorded within relative training records.

Department Managers are responsible for establishing and approving processes used to manufacture Axon products, and for establishing and approving relative documents.

It is the responsibility of the QA Manager to define and



document appropriate inspection and test steps within the manufacturing process.

The Maintenance Manager is responsible for equipment and facilities maintenance, including preventive maintenance of critical equipment.

All personnel are responsible for maintaining the production record(s) as it applies to their department.

## 4.10 Inspection and Testing

### 4.10.1 General

Axon Circuit shall conduct inspection and testing activities in order to verify product meets specifications. These activities shall be performed according to the procedure ***Inspection & Testing***.

### 4.10.2 Receiving Inspection & Testing

Axon will ensure that incoming product is inspected and/or tested to ensure it conforms to specified requirements. The level of receiving inspection shall be determined relative to evidence of the quality of the vendor. No material shall be released to production without the required inspection, test or certification.

### 4.10.3 In-process Inspection & Testing

All products shall receive inspection for visual and mechanical properties either at a 100% rate or a sampled rate determined by customer requirements or Axon procedures. Products shall receive electrical testing at a rate determined by the customer. In addition, management may require some product undergo electrical testing even if not required by the customer. Other tests, such as testing of electroplated copper thicknesses, shall be conducted according to documented procedures and/or customer requirements.

Sampled inspections/tests shall be conducted according to a sampling plan outlined in ***Inspection & Testing*** and/or a plan specified by the customer. Inspection levels and AQL's, if applicable, shall be defined in appropriate procedures or work instructions.

All departments are responsible for conducting inspections on their work before sending product through to the next phase. Additional in-process inspection steps are identified in various SOP's and procedures.



#### 4.10.4 Final Inspection & Test

All products will be subject to final inspections to confirm conformance to specified requirements.

In addition to the inspection of finished product characteristics, checks will be made to establish that all previous inspections have been carried out with satisfactory results.

The QA Manager is responsible for this function.

#### 4.10.5 Inspection & Test Records

Records of inspection and test activities will be maintained according to documented procedures.

It is the responsibility of the Quality Assurance Authority to:

- Determine and document test methods within SOP's or other process instructions
- Establish inspection methods and acceptance criteria based on input from customers, engineering, and industry standards.
- Maintain related quality records.

It is the responsibility of all personnel carrying out inspection and test activities to observe the established procedures.

### 4.11 Control of Inspection, Measuring & Test Equipment

4.11.1 Equipment used to verify conformance to specified requirements will be subject to regular calibration; the procedure ***Control of Inspection Measuring & Test Equipment*** shall reference specific calibration schedules and procedures. Any such equipment incapable of calibration will be tested for functionality and/or condition. "Equipment" in this sense shall include test software and comparative references.

#### 4.11.2 Control Procedure

The QA Authority shall ensure that equipment shall be selected and used which is capable of the accuracy required.

Equipment used for calibration of test and measurement equipment either internally or by an outside calibration agency will be traceable to nationally-recognized standards, preferably those of the National Institute of Standards and Technology (NIST).



Equipment requiring calibration shall be identified to show its calibration status. Such equipment shall be safeguarded against adjustments that would invalidate calibration settings, through storage, training of operators and other means.

Records of calibration will be maintained. When equipment is found to be out of calibration, the effect of that error on product will be reviewed and appropriate corrective action taken.

Suitable conditions shall be maintained for the inspection and test activities, calibration activities, as well as the storage and preservation of the equipment itself.

The Quality Assurance Manager is responsible for coordinating the calibration activity with the proper Manufacturing department heads, and for ensuring that the ongoing needs for inspection, measurement and test equipment are identified and assigned accordingly, and of overseeing training of personnel on the proper handling and storage of such equipment.

The Quality Assurance Manager is responsible for the review of the effect of out-of-calibration equipment on product, any recalls required, and for implementation of required corrective actions.

The President is responsible for determining on-going equipment needs, with input from the General Manager (Tampa), Operation Manager (Longwood) and Process Engineering Manager.

The Maintenance Manager is responsible for preventive maintenance of equipment.

It is the responsibility of all personnel to ensure that the equipment used is suitable and within its calibration period.

#### **4.12 Inspection and Test Status**

All materials and products will be suitably identified as to their inspection and/or test status throughout each stage of manufacture.

Nonconforming materials or products will be segregated pending investigation and disposition, and will be clearly identified.

It is the responsibility of the QA Authority to ensure that the procedures required to implement this policy are established and maintained.



It is the responsibility of all personnel to observe the requirements of the procedures which implement this policy.

The procedure **Product Identification** documents how this policy is executed.

## 4.13 Control of Nonconforming Product

### 4.13.1 General

When an article or material departs from specifications, it shall be identified and segregated from normal production flow, pending investigation and disposition. This shall apply as well to material received from customers (customer-supplied product), or suppliers (production materials) which deviate from specifications. The execution of this policy is detailed in the system procedure **Control of Nonconforming Product**.

Records of all nonconformance will be maintained and will be periodically reviewed to establish trends and thereby determine the need for further preventative action.

It is the responsibility of all personnel detecting nonconforming product to ensure that this is properly identified, segregated and reported.

### 4.13.2 Review & Disposition of Nonconforming Product

All nonconforming products will be reviewed to determine the need for corrective/preventative action and the subsequent material disposition. Concerned functions, including customers, shall be notified as required.

Nonconforming materials will be dispositioned subject to one of the following:

- Rework - If the article is such that it can be returned to a condition that meets prints and specifications, it may be reworked. After rework, the article shall be resubmitted to the normal flow and inspections.
- Scrap - If the material does not meet contractual requirements and is not repairable or deemed to be uneconomical to rework, it may be scrapped.
- Return - Return to the supplier.
- Accepted w/ Approval - Accepted with consent of customer.



The QA Authority shall oversee the disposition of nonconforming product in accordance with procedures.

#### **4.14 Corrective and Preventive Action**

##### **4.14.1 General**

Product, process or Quality System nonconformances detected will be analyzed to determine their magnitude and cause, and to prevent recurrence, according to the system procedure **Corrective Action**.

Such nonconformances may relate to the product, processes in use, or the quality system itself.

##### **4.14.2 Corrective Action**

Corrective Action is directed at eliminating the cause for nonconformities related to product, process and quality system, and shall be engaged to address nonconformances reported by customers (through complaints and/or returns), or Axon employees and management.

The ISO 9000 Administrator, in overseeing the corrective action system, has the responsibility to assure that prompt, effective action is taken by the responsible department to prevent recurrence of the nonconformance.

The QA Manager shall oversee that trends of internal defects and customer returns are analyzed as the basis for implementing preventive actions. Trends and ongoing assessments of the corrective action system shall be reviewed by management in accordance with the **Management Review** procedure.

All Axon employees are empowered to initiate corrective action according to procedures.

##### **4.14.3 Preventive Action**

Preventive Action, aimed at preventing nonconformances before their occurrence, shall be performed as a part of the **Corrective Action** procedure. The same controls, responsibilities and verification activities shall apply.

All Axon employees are encouraged to initiate preventive action according to procedures.



## 4.15 Handling, Storage, Packaging, Preservation and Delivery

### 4.15.1 General

Handling, storage, packaging, preservation and delivery shall be in accordance with documented procedures (referenced below.)

The General Manager (Tampa) and Operations Manager (Longwood) shall oversee the implementation of this policy, however it is the responsibility of all employees to follow the procedures which implement this policy.

### 4.15.2 Handling

General material handling requirements are detailed in the system procedure **Handling**. Additional handling requirements required by the customer will be transmitted to Production and other functional areas as required, and adhered to as part of the customer's specifications. Handling requirements shall be carried out with the intent to prevent any risk to material quality during all stages of manufacture, inspection and test.

### 4.15.3 Storage

Storage of product and materials shall be in accordance with the system procedure **Storage & Preservation**. Checks of material shall be made to confirm its acceptable condition during monthly inventory. Materials shall be stored in a manner which does not compromise its condition. Where material shelf-life is a concern, proper procedures will be implemented and documented to assure material is not used beyond its shelf life.

Material awaiting use or shipment will be identified and segregated in secure storage areas. Suitable measures will be taken to prevent damage or deterioration.

### 4.15.4 Packaging

The company's products will be packed in accordance with the system procedure **Packaging**, and/or customer packaging specifications, and using materials designed to ensure that the product quality is maintained during transit. Order and product identification will be clearly marked and will provide for any order or carrier requirements.

### 4.15.5 Preservation



Procedures for handling, storage, packaging, preservation and delivery shall account for proper preservation of product as long as product is under the control of Axon Circuit. Additional preservation procedures are detailed in **Storage & Preservation**.

#### 4.15.6 Delivery

Delivery of finished product to the customer shall be in accordance with the system procedure **Shipping**. All customer-specified shipping requirements shall be followed, and records of delivery maintained.

#### 4.16 Control of Quality Records

Each department is responsible for maintaining required quality records that demonstrate required quality and the effective operation of the company's Quality System, in accordance with the system procedure **Control of Quality Records**. These records may be in the form of completed logs, worksheets, forms, data files, or other instruments.

Records will be suitably stored and maintained to ensure their safe keeping and subsequent retrieval.

The retention periods and the authority for the disposal of records will be defined in written procedures. Access to quality related records will be made available to the customer or his representative upon approval of the President and/or QA Manager, or when contractually required.

The QA Manager is responsible for determining retention times of quality records. The responsible manager(s) (as defined in **Control of Quality Records**) is/are responsible for collecting and indexing such records.

The President is responsible for assigning personnel to maintain the integrity, security, and accessibility of all data-format quality records and documentation.

It is the responsibility of all personnel to ensure that quality related records are compiled in a complete, legible and accurate manner and are correctly filed and stored in the location provided where applicable. The use of correction fluid or tape is not allowed on quality records.

#### 4.17 Internal Quality Audits

Axon Circuit will ensure that all aspects of its Quality System are objectively audited, and to ensure that quality activities and related



results comply with internal and external requirements, as detailed in the procedure **Internal Quality Audits**. Audits will be scheduled according to importance of the function audited, as determined by the ISO 9000 Administrator.

Audit findings or other results shall be addressed through corrective action. In addition, management will review audit results during Management Review Meetings to ascertain that the Quality System is effective in achieving its objectives, in accordance with the **Management Review** system procedure.

Audits will be conducted by trained personnel who are independent of the area being audited.

The head of each department being audited is responsible for investigating, planning and implementing any corrective action agreed upon as a result of the audit. Resulting corrective actions will be followed-up with additional audits to confirm effectiveness.

#### **4.18 Training**

All staff, including management, will receive appropriate training in manufacturing operations, testing operations, and in the quality system itself, as defined in the system procedure **Training**. Training programs shall be devised to ensure complete familiarity with all requirements of the process. Records will be maintained of training given. Periodic reviews of training requirements will be made to ensure that training remains effective. Department Heads shall be responsible for identify training and retraining needs within their departments.

Training data shall be gathered and analyzed in order to display and predict training needs; these needs shall be reported to management during Management Review Meetings.

Department Heads are responsible for ensuring that only personnel who are suitably qualified perform tasks requiring acquired skill.

It is the responsibility of the General Manager (Tampa) or Operations Manager (Longwood) to analyze instances of non-conformance for evidence of insufficient skill, job knowledge or training.

#### **4.19 Servicing**

Axon Circuit shall offer servicing to its customers in the form of rework or repair of returned product; such returned product shall be treated as customer-supplied product during rework.



The records kept of servicing shall be in the form of same records used during normal manufacturing, inspection, etc.

The Quality Assurance Manager shall oversee customer returns and subsequent on-site reworking of product; data on such returns shall be maintained by the QA Manager and reported to management during Management Review.

## **4.20 Statistical Techniques**

### **4.20.1 Identification of Need**

The QA Manager shall be responsible for identifying the need to use statistical techniques for establishing, controlling, and verifying process capability and product characteristics.

### **4.20.2 Procedures**

The use of statistical techniques for quality index reporting is detailed in the system procedure ***Quality Index***. Statistical techniques employed in other operations are defined in specific procedures or instructions.



## 5.0 Approval & Revision History

### 5.1 Revision History

Rev. #	Date	Nature of Change(s)
D	2/6/95	Final draft of original issue.
E	1/19/98	Various changes: see master copy file for details.
F	3/25/99	"Quality Assurance/Control Manual" reformatted for full ISO compliance. Renamed "Quality System Manual."
G	5/12/99	Various changes as a result of ISO registrar's desk audit of QSM. See CAR # 029 for details.
H	6/15/99	Various changes as a result of ISO registration audit observations and comments. See second addendum to CAR # 029 for details.
I	3/8/2001	--- Manual re-written to include Longwood facility. --- Org Chart revised --- "Document Control" dept. now referenced.
J	11/07/2002	Updated for ISO 9001:2000 compliance.
K	10/1/2003	Update 4.2.4 Organized Process Sequence

### 5.2 Approvals:

President: \_\_\_\_\_  
*signature* *date*

QA Manager: \_\_\_\_\_  
*signature* *date*