



Axon Circuit, Incorporated

Quality System Manual (QSM)

Revision N

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Quality System Manual rev N.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 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 referenced in this *Quality System Manual* are intended to meet or exceed the requirements of ISO 9001:2015 Standard, "Quality Management System – Requirements" (Fifth edition; 2015-09-15.)

1.2 Authority

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

1.3 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."



NOTE: The section numbering of this Quality System Manual has been revised to align with the high level structure of ISO 9001:2015.

1.4 Amendments

Controlled manuals will be updated and revised as required.

1.5 Review

The Quality System is audited routinely to affirm that the current practices conform to the policies set out in the manual. As needed, this manual will be revised to reflect changes in the Quality System and the results of Management Review.

1.6 Products & Company Information

Axon Circuit 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 Circuit was certified to ISO 9002:1994 by International Management Systems, an ANAB-accredited registrar, in 1997. This system was upgraded to ISO 9001:2000 compliance in 2002, and ISO 9001:2008 compliance in 2009. International Management Systems was acquired by ANAB-accredited registrar NQA in 2008, and NQA continues to provide Axon with third-party compliance certification services. The QMS was revised again in 2016 to comply with ISO 9001:2015.

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**

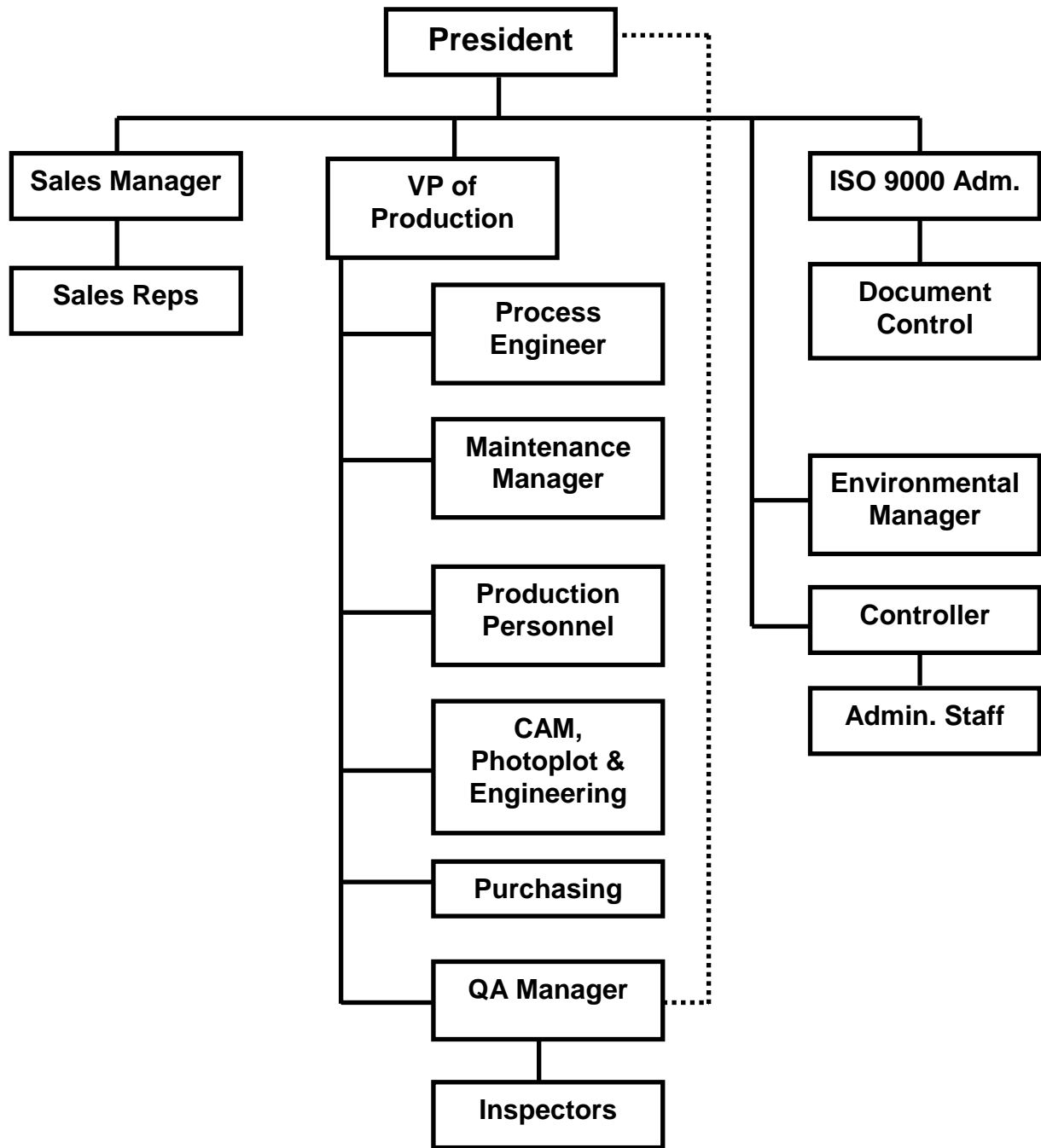
The successful administration of our Quality Policy is the responsibility of all Axon employees, with the full commitment and involvement of management.

Quality is a way of life at Axon Circuit.

Chandra Patel
President



3.0 Organizational Chart





4.0 Context of the organization

4.1 Understanding the organization and its context

The management of Axon Circuit maintains a Risk Register that outlines the external and internal issues that are relevant to our purpose and strategic direction and that affect our ability to achieve the intended results of our quality management system (QMS). At minimum, management monitors and reviews information about these external and internal issues during Management Review (see **Management Review** System Procedure).

4.2 Understanding the needs and expectations of interested parties

Axon Circuit's management understands that the needs and expectation of interested parties can have a significant effect or potential effect on our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements. Therefore, we maintain a list of interested parties and their requirements that are relevant to our QMS as part of our Risk Register. At minimum, management monitors and reviews information about these interested parties and their relevant requirements during Management Review (see **Management Review** System Procedure).

4.3 Determining the scope of the quality management system

Axon Circuit has determined the boundaries and applicability of the QMS for establishing the system's scope. Considerations in determining the QMS scope included a) the external and internal issues referred to in 4.1 above; b) the requirements of relevant interested parties referred to in 4.2 above; and c) our products and services.

The scope of QMS for our facility in Tampa FL, is:

The 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. We offer servicing to our customers in the form of rework or repair of returned product; such returned product is treated as customer-supplied product during rework.

The following flowchart reflects Axon's normal manufacturing process. Specific quality plans, process plans, and/or customer requirements may override this process



QMS support processes are outlined in this manual and include: Sales, Purchasing, Quality, ISO Administration, including Document Control,

The scope of our QMS is documented above in this manual, which is made available to our interested parties as requested.

The manual addresses the requirements of ISO 9001:2015 with exception of the requirements that do not apply to our operation. Please see these non-applicable requirements, with justification, in the table below.

Clause or Sub-clause	Non-Applicable Requirements	Justification
8.3	Design and development of products and services	Axon Circuit receives design information from our 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 8.3 of the ISO 9001:2015 standard from its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of

4.4 Quality management system and its processes

4.4.1 Axon Circuit management is committed to maintaining and continually improving our QMS, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015. We have adopted a process approach for our management system, which includes identifying the top-level processes within the company, and then managing each of these discretely. This approach reduces the potential for nonconforming products discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes. The controls indicated here are applicable to the top-level processes identified in section 4.3 above. Each of these processes may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has an associated Process Table (Attachment 1). Each of the Process Matrices defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- resources needed



5.0 Leadership

5.1 Leadership and commitment

5.1.1 General

The President and management team demonstrates leadership and commitment with respect to the QMS by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization;
- c) ensuring the integration of the QMS requirements into our business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the QMS are available;
- f) communicating the importance of effective quality management and of conforming to the QMS requirements;
- g) ensuring that QMS achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the QMS;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

Top management provides leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the 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 that is appropriate to the purpose and context of the organization and supports our strategic direction.

5.2.2 Communicating the Quality Policy

The Axon Circuit Quality Policy is posted throughout our operation and management periodically holds meetings to ensure it remains understood and is applied throughout our organization. We also make the Quality Policy available to relevant interested parties, as appropriate, such as posting it at the visitor entrance and on our company website.



5.3 Organizational roles, responsibilities and authorities

The President of Axon Circuit ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood, including the organizational and reporting structure of the company (see Section 3.0 above). The President and management also ensure that the responsibility and authority for:

- Ensuring that the quality management system conforms to the requirements of ISO 9001:2015; for example:
 - 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 ISO 9000 Administrator oversees facilitates finding solutions for nonconformities (such as Corrective & Preventive Action) and verifying the implementation of these solutions (such as Internal Quality Auditing.).
 - The duties of the ISO 9000 Administrator may be shared among individuals appointed by the President.
 - All managers are responsible for ensuring that their staff is conversant with the company's Quality Policy and its Quality System.
- Ensuring that the processes are delivering their intended outputs; for example:
 - All Axon employees are empowered to identify non-conformances and request corrective action in order to prevent the occurrence of any nonconformity.
 - The QA Manager is authorized to hold and/or not ship product that does not meet customer requirements and to determine disposition of nonconforming materials.
- Reporting on the performance of the QMS and on opportunities for improvement (see 10.1), in particular to top management; for example:
 - The ISO 9000 Administrator coordinates the management review activity.
- Ensuring the promotion of customer focus throughout the organization; for example:
 - Management holds periodic company wide quality meetings to review performance of the QMS in meeting internal and customer requirements.
- Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented; for example:
 - Management Review meetings cover changes to the QMS
 - Also, see section 6.3 below.

6.0 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the QMS, the President, in consultation with management, considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determines the risks and opportunities. To address significant risks, the President maintains a Risk Register to address the risks and opportunities and help give assurance that the quality management system can achieve its



intended result(s); enhance desirable effects; prevent, or reduce, undesired effects; and achieve improvement.

6.1.2 Actions to address these risks and opportunities are addressed in the Risk Register and such actions include integration into the QMS processes and evaluation of the effectiveness of these actions. Actions taken are proportionate to the potential impact on the conformity of our product.

6.2 Quality objectives and planning to achieve them

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.

Records for the Quality Objectives are maintained in the Management Review meeting minutes.

6.2.2 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.

6.3 Planning of changes

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

When managing changes, consideration is given to:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the quality management system;



- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.

7.0 Support

7.1 Resources

7.1.1 General

It is the responsibility of the President to provide the resources necessary to implement and maintain the QMS and supporting policies referenced in this Manual. When reviewing resource needs, the President considers the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers.

7.1.2 People

The President and management team determines and provides the persons necessary for the effective implementation of our QMS and for the operation and control of its processes.

7.1.3 Infrastructure

The President and management team determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Axon Circuits Infrastructure includes:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.4 Environment for the operation of processes

The President and management team determines, provides and maintains the work environment necessary for the operation of its processes and to achieve conformity of products and services.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

Equipment used to verify conformance to specified requirements will be subject to regular calibration; the procedure ***Control of Inspection Measuring & Test Equipment*** references 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.

The QA Manager ensures that equipment is selected and used which is capable of the accuracy required.



7.1.5.2 Measurement traceability

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.

Software used in calibration shall be validated prior to use; this is typically done by way of comparing calibration results from the non-validated software against a known good or other validated, traceable source. When using such software, it shall be controlled to ensure only the proper version is used.

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 VP of Production 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.

7.1.6 Organizational knowledge

The President and management team determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. Organizational knowledge is knowledge specific to Axon Circuit and it is generally gained by experience. It is information that is used and shared to achieve our objectives. Typically such knowledge and information is obtained from:

- a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
- b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.



This knowledge is maintained, and made available to the extent necessary. When addressing changing needs and trends, Axon Circuit's management considers our current knowledge and determines how to acquire or access the necessary additional knowledge and required updates and determines how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

The President and department heads determine the necessary competence of person(s) doing work under our control that affects the performance and effectiveness of the quality management system in accordance with the system procedure ***Competence, Awareness, and Training***. This procedure outlines are process for:

- a) ensuring that employees and any contractors under our control are competent on the basis of appropriate education, training, or experience;
- b) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- c) retain appropriate records as evidence of competence.

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 ***Competence, Awareness, and Training***. programs are 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 is gathered and analyzed in order to display and predict training needs; these needs are 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 VP of Production to analyze instances of non-conformance for evidence of insufficient skill, job knowledge or training.

7.3 Awareness

Axon Circuit's department heads ensure that persons doing work under the organization's control are aware of:

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



7.4 Communication

Axon Circuit's President and management team determines the internal and external communications relevant to the QMS, including:

7.4.1 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 conducts 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 are 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 are 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 provides insight on the effectiveness of communication relative to the quality system.

7.4.2 External Communication

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

Communication regarding:	Routed To	Record required?
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
Quality Policy	Interested Parties	Posted on company website

7.5 Documented information

7.5.1 General

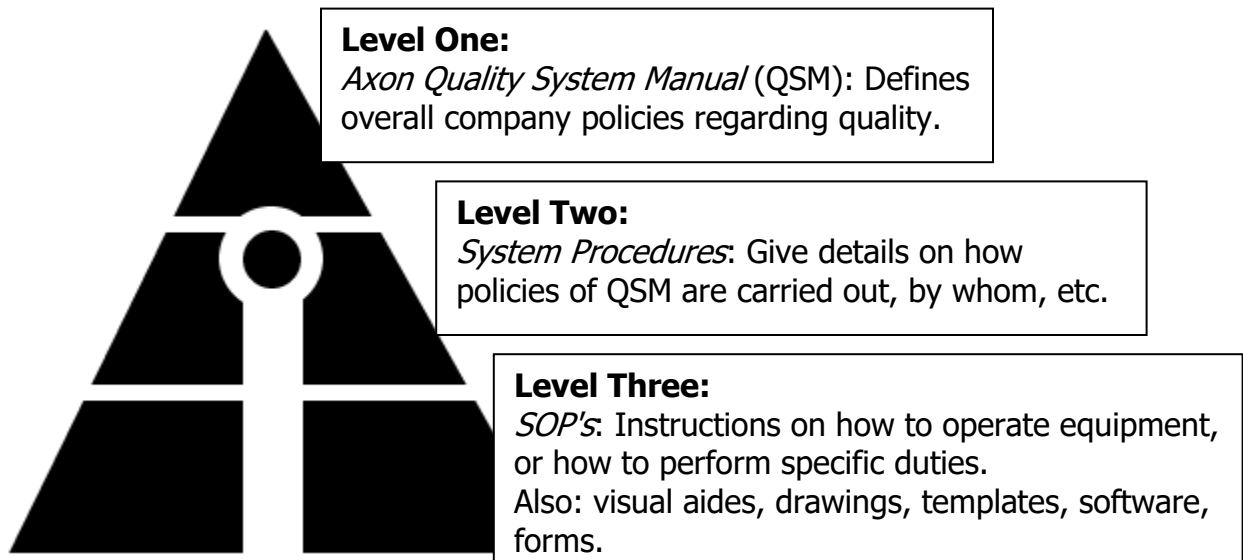
Axon Circuit's QMS documentation includes:

- a) documented information required by ISO 9001:2015;



- b) documented information determined by us as being necessary for the effectiveness of the QMS.

The following represents Axon's quality system documentation structure:



7.5.2 Creating and updating

Department heads and authorized employees have the responsibility for creation and revision of necessary quality documents; such authority is indicated by way of approvals as referenced in the ***Document & Data Control*** system procedure, which includes:

- identification and description (e.g. a title, date, author);
- format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- review and approval for suitability and adequacy.

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***.

7.5.3 Control of documented information

7.5.3.1 Documented information, which includes procedures and records, required by the Axon Circuit QMS and by the ISO 9001:2015 standard are controlled to ensure:

- they are available and suitable for use, where and when it is needed;
- they are adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).



Documents are controlled in accordance with the system procedures **Document & Data Control** system procedure. Records are managed in accordance with the system procedure, **Control of Records**.

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. 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 QMS requirements and to ensure that these are observed accordingly.

7.5.3.2 Collectively, the system procedures, **Document & Data Control**, **Control of Engineering Data**, and **Control of Records** address the following:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

It is the responsibility of the VP of Production to assure clarification of written documents is available, through qualified and authorized personnel, for those individuals who may require it.

Axon controls external (third party) documents deemed necessary for the planning and operation of its quality management system. For example, external documents include the ISO 9001 standard and other documents that are utilized when referenced in contractual or order documents. Personnel ensure the proper revision is used matching that called out by the requirements. In some cases, requirements may demand the usage of obsolete standards, and this is permitted in such cases.

During contract review activities, sales personnel ensure that any referenced or required external documents (such as specifications, standards, etc.) are referenced with a required revision level.

Electronic versions of external documents will be stored on a server subject to backups.

Records that are retained as evidence of conformity are protected from unintended alterations managed in accordance with the system procedure, **Control of 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 are 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.

8.0 Operation

8.1 Operational planning and control

Axon Circuit's ***Process Control*** system procedure provides the means for controlling the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

Operational planning is an integral part of the QMS through the implementation of procedures and processes which address the following requirements:

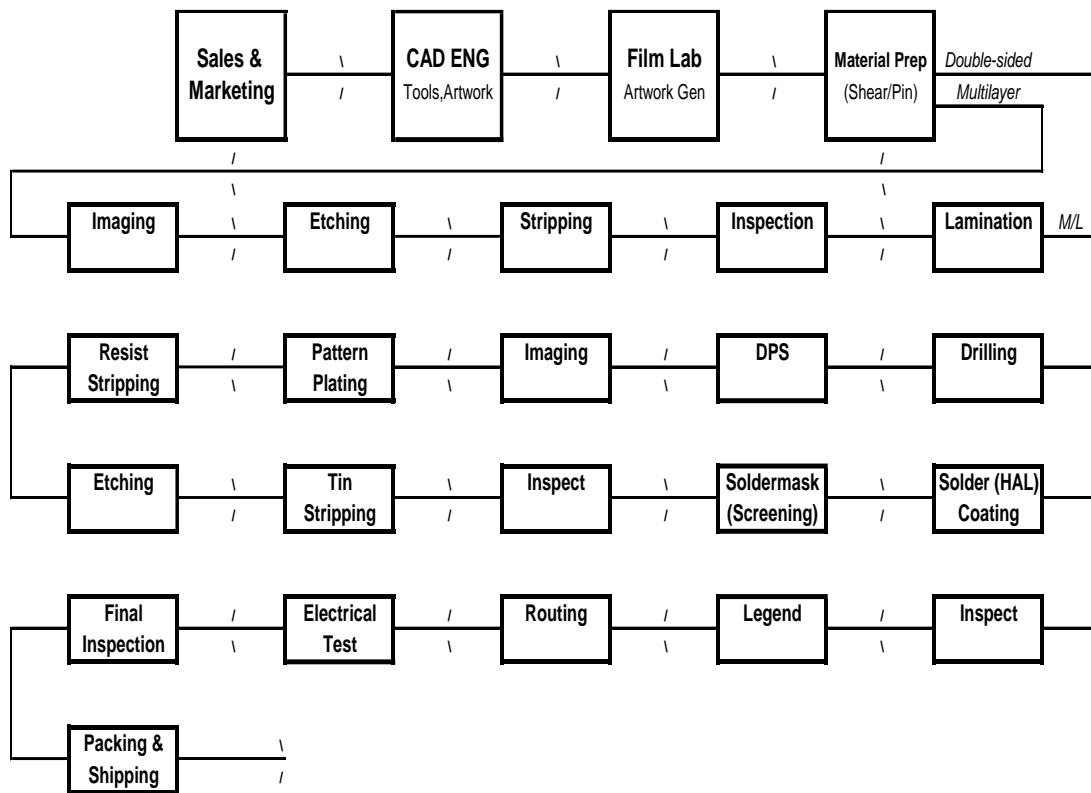
- identification and acquisition of any required controls, processes, equipment, fixtures, resources, and skills.
- verification of the compatibility of the production process, inspection and test procedures and supporting documentation.
- updating, as required, of quality control, inspection and testing 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 Manager has overall responsibility for the development of quality plans, with input from department heads.

Management ensures control over planned changes, identifying the consequences of unintended changes and taking action to mitigate any adverse effects, as necessary.

Axon Circuit ensures that outsourced processes are controlled in accordance with the ***Purchasing*** system procedure (see 8.4).

The flow diagram below outlines our Product & Service Realization Processes





8.2 Requirements for products and services

8.2.1 Customer communication

Axon Sales representative are responsible for facilitating the communications with our customers, which include:

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

8.2.2 Determining the requirements for products and services

Orders received from customers ("contracts") are reviewed in accordance with the procedure **Contract Review**. No orders are released to production which has not undergone this review process. During the initiation of new business, Axon Circuit's Sales captures:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
 1. statutory and regulatory requirements related to the product;
 - a. any additional requirements determined as necessary by Axon.
- b) the organization can meet the claims for the products and services it offers.

8.2.3 Review of the requirements for products and services

8.2.3.1

Axon Circuit reviews all orders to ensure that customer requirements are adequately defined, including the requirements for delivery 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, including defining requirements not stated by the customer, but necessary for the specified or intended use, when known. Also, statutory and ensuring any regulatory requirements applicable to the products and services are reviewed prior to order acceptance. 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.

Quality requirements to be considered shall also include post-delivery requirements such as rework or repair of customer returned products; see section 4.19.



8.2.3.2 The **Contract Review** System Procedure defines the applicable records to be maintained relative to the results of the review and on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

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 and that relevant persons are made aware of the changed requirements, 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.

8.3 Design and development of products and services – not applicable

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, clause 8.3 of the ISO 9001:2016 standard does not apply to the Axon QMS.

8.4 Control of externally provided processes, products and services

8.4.1 General

The purchasing of externally provided processes, products and services used in the manufacture of the company's products is managed in accordance with the **Purchasing** System Procedure. It is the responsibility of the Purchasing Manager to ensure that the controls of the purchasing activities are implemented and maintained.

The **Purchasing** System Procedure ensures that controls are applied to externally provided processes, products and services when:

- a) products and services from external providers are intended for incorporation into the our products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of the Axon Circuit;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by Axon Circuit.

The **Purchasing** procedure is used to define the criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Records of these activities and any necessary actions arising from the evaluations are maintained in accordance with the **Purchasing** procedure.

8.4.2 Type and extent of control

Axon's purchasing process ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The **Purchasing** System Procedure defines how:



- a) externally provided processes remain within the control of its quality management system;
- b) the controls that we apply to an external provider and that we apply to the resulting output;
- c) considerations are made relative to:
 - the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - the effectiveness of the controls applied by the external provider;
- d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.
 - Incoming material is 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 is 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.

Vendors ("subcontractors") are evaluated and approved according to the **Purchasing** procedure. A list or database of acceptable vendors is 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.

8.4.3 Information for external providers

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. Axon's Purchasing Manager ensures the adequacy of requirements prior to their communication to the external provider. 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.

Communication to external providers its requirements include, as applicable:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) 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 Manager to coordinate QA inspection activities at his/her facility.

It is the responsibility of the VP of Production to oversee receiving activities; the QA Manager oversees receiving inspections.

8.5 Production and service provision

8.5.1 Control of production and service provision

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

Standard Operating Procedures (SOP's) are 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 provides a suitable infrastructure and work environment and the resources necessary to maintain that environment.

The appointment of competent persons, including any required qualification;

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.

The implementation of actions to prevent human error.

The implementation of release, delivery and post-delivery activities.

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 proper completion of the production record(s) as it applies to their department.

8.5.2 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.

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.

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**. It is the responsibility of the QA Manager 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.

8.5.3 Property belonging to customers or external providers

All property supplied by customers or external providers 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. We will continue to protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. Material will only be issued according to the terms under which it was supplied.

Damaged or deteriorated customer or externally supplied property is recorded on what has occurred and reported to the customer or external provider as soon as such condition is noticed. All employees are responsible for following the system procedure **Control of Property Belonging to Customers or External Providers** as it pertains to their function. The QA Manager is responsible for the overall implementation of this policy.

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

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



The VP of Production shall oversee the implementation of this policy; however it is the responsibility of all employees to follow the procedures which implement this policy.

8.5.4.1 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.

8.5.4.2 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.

8.5.4.3 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.

8.5.4.4 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*.

8.5.4.5 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.

8.5.5 Post-delivery activities

Axon Circuit provides 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. In determining the extent of servicing activities that are required, we consider:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with the servicing of the product
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

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



The QA 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.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

Axon Circuit's management team reviews and control changes for production or service activities, to the extent necessary to ensure continuing conformity with requirements.

8.6 Release of products and services

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

8.6.1 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.

8.6.2 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, are 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.

8.6.3 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, which includes ensuring the release of products and services to the customer does not proceed until inspection and testing have been



satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

8.6.4 Inspection & Test Records

Records of inspection and test activities will be maintained according to documented procedures. These records provide traceability to the person(s) authorizing the release and evidence of conformity with the acceptance criteria.

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.

8.7 Control of nonconforming outputs

8.7.1 When an article or material departs from specifications, it is identified and segregated from normal production flow, pending investigation and disposition. This applies as well to material received from customers (customer-supplied product), or suppliers (production materials) which deviate from specifications. Our control also applies to nonconforming products detected after delivery of products. It is the responsibility of all personnel detecting nonconforming product to ensure that this is properly identified, segregated and reported. The execution of this policy is detailed in the system procedure ***Control of Nonconforming Product***.

All nonconforming products will be reviewed to determine the need for corrective action and the subsequent material disposition. We will take appropriate action based on the nature of the nonconformity and its effect on the conformity of products. Concerned functions, including customers, shall be notified as required.

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

- a) Rework (correction) - 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 subject to QA inspections.
- b) Scrap - If the material does not meet contractual requirements and is not reparable or deemed to be uneconomical to rework, it may be scrapped.
- c) Return - Return to the supplier.
- d) Accepted w/ Approval - Accepted with consent of customer.

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



8.7.2 Axon maintains records in accordance with ***Control of Nonconforming Product*** that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.

Records of nonconformances will be reviewed during Management Review, at minimum, to establish trends and thereby determine the need for further corrective action.

9.0 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

Axon Circuit's management team determines:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring shall be performed;
- d) when the results from monitoring and measurement shall be analyzed and evaluated.

We evaluate the performance and the effectiveness of the QMS through internal audits and through Management Review and retain appropriate records as evidence of the results.

9.1.2 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.

9.1.3 Analysis and evaluation

Axon Circuit's management team evaluates appropriate data and information arising from monitoring and measurement during Management Review (see section 9.3 below).

Additionally, analysis of quality data is 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. The combined results of analysis are used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the QMS;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- a) the performance of external providers;
- f) the need for improvements to the quality management system.



9.2 Internal audit

9.2.1 Axon Circuit will ensure that all aspects of its Quality System are objectively audited to determine if the QMS is effectively implemented and maintained. Audits will also help confirm if quality activities and related results comply with internal and external requirements, including ISO 9001:2015, as detailed in the procedure *Internal Quality Audits*.

9.2.2 Audits will be scheduled according to importance of the function audited, changes affecting the organization, and the results of previous audits, as determined by the ISO 9000 Administrator in consultation with the President. The ISO 9000 Administrator will also:

- define the audit criteria and scope for each audit;
- select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- ensure that the results of the audits are reported to relevant management;
- select trained auditors who are independent of the area being audited.

Audit findings or other results shall be addressed through corrective action. 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 without undue delay. Resulting corrective actions will be followed-up with additional audits to confirm effectiveness.

The ISO 9000 Administrator retains records as evidence of the implementation of the audit program and the audit results. 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.

9.3 Management Review

9.3.1 General

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 continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review minimum agenda of the meeting includes:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;
- c) information on the performance and effectiveness of the quality management system, including trends in:
 - 1) customer satisfaction and feedback from relevant interested parties;
 - 2) the extent to which quality objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;



- 6) audit results;
- 7) the performance of external providers;

- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.

9.3.3 Management review outputs

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.

Records of management review shall be kept. The execution of this policy, and definition of the defined interval, is detailed in the system procedure

10.0 Improvement

10.1 General

Axon Circuit's management team determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These include:

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

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, management follows the **Corrective Action** System Procedure and takes the following steps:

- a) reacts to the nonconformity and, as applicable:
 - 1) takes action to control and correct it;
 - 2) deals with the consequences;

- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) reviewing and analyzing the nonconformity;
 - 2) determining the causes of the nonconformity;
 - 3) determining if similar nonconformities exist, or could potentially occur;

- c) implements any action(s) needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;



- f) make changes to the quality management system, if necessary.

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.

All Axon employees are empowered to initiate corrective action according to procedures. We will take corrective action(s) appropriate to the effects of the nonconformities encountered.

Trends and ongoing assessments of the corrective action system shall be reviewed by management in accordance with the **Management Review** procedure.

10.2.2 Axon maintains records of corrective actions in accordance with the **Corrective Action System Procedure**. Corrective action records include, at minimum:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

10.3 Continual improvement

Axon Circuit strives to continually improve the suitability, adequacy and effectiveness of our QMS. We consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.



11.0 Approval & Revision History

11.1 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
L	5/23/2007	Update Pattern Plate Verification Method
M	5/11/2009	Updated for ISO 9001:2008 compliance: Section 1.2: added language to refer to ISO 9001:2008. Section 1.4: added clarifying language about structure of QSM still aligning with 1994 version of ISO 9001, yet content updated to 2008 version. Section 1.7: Updated references to IMS as acquired by NQA; updated references to RAB to ANAB (new name); updated facility location as Tampa only. Section 3.0: updated organizational chart. Added section 4.5.4 on external documents and control thereof. Sec. 4.3.2: added language regarding post-delivery requirements. Sec. 4.11.2: added language regarding control of software used in calibration of equipment. Sec. 4.13.2: added language clarifying that reworked product is subject to reinspection.
N	8/4/2016	Completely updated for ISO 9001:2015 compliance.

11.2 Approvals

President: _____ *Chandra Patel* _____ 8/22/16 _____
signature date

QA Manager _____ *Manish Patel* _____ 8/22/16 _____
signature date

