PICONICS

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PICONICS, INC.
QUALITY MANUAL

PQM-1

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Reviewed by:	Brian Goodhue	**Date:**	12/23/09
Approved by:	Daniel Merrill	**Date:**	12/29/09

REV	DESCRIPTION OF CHANGE	APPROVAL	DATE
AA	Entire Re-write of Quality System Manual	Daniel Merrill	06/05/09
AB	Revise Section 7.3.7 (DCR# 290066)	Daniel Merrill	12/29/09
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AE	Changes per DCR # 320008	Daniel Merrill	1/31/12
AF	Changes per DCR# 330029	Daniel Merrill	11/07/13

CONTROLLED

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Company Introduction

Piconics Incorporated was founded in 1963 by Mr. Stephen Slenker and has established itself as a leading manufacturer of miniaturized electronic components (micro electronics). Since its inception, Piconics has concentrated on exotic and difficult to manufacture devices for the space, military, microwave and medical markets. Piconics is considered a "made to order" shop and will manufacture very small quantities. However, we have successfully delivered orders of 10 million parts. Piconics currently has about 25 employees.

Piconics has worked with Harvard, MIT, Cornell, University of Michigan and many other colleges and universities on research in a diversity of areas. Much of the research was conducted to benefit studies relating to medicine and humanity. We consider it our civic duty to provide our unique talents in this critical area.

Piconics is proud of the role it has played pioneering the micro miniature inductor field and promises to be just as innovative in the future. Piconics is "the source" when primary considerations are engineering, quality and service.

Quality Policy/Mission Statement

QUALITY POLICY

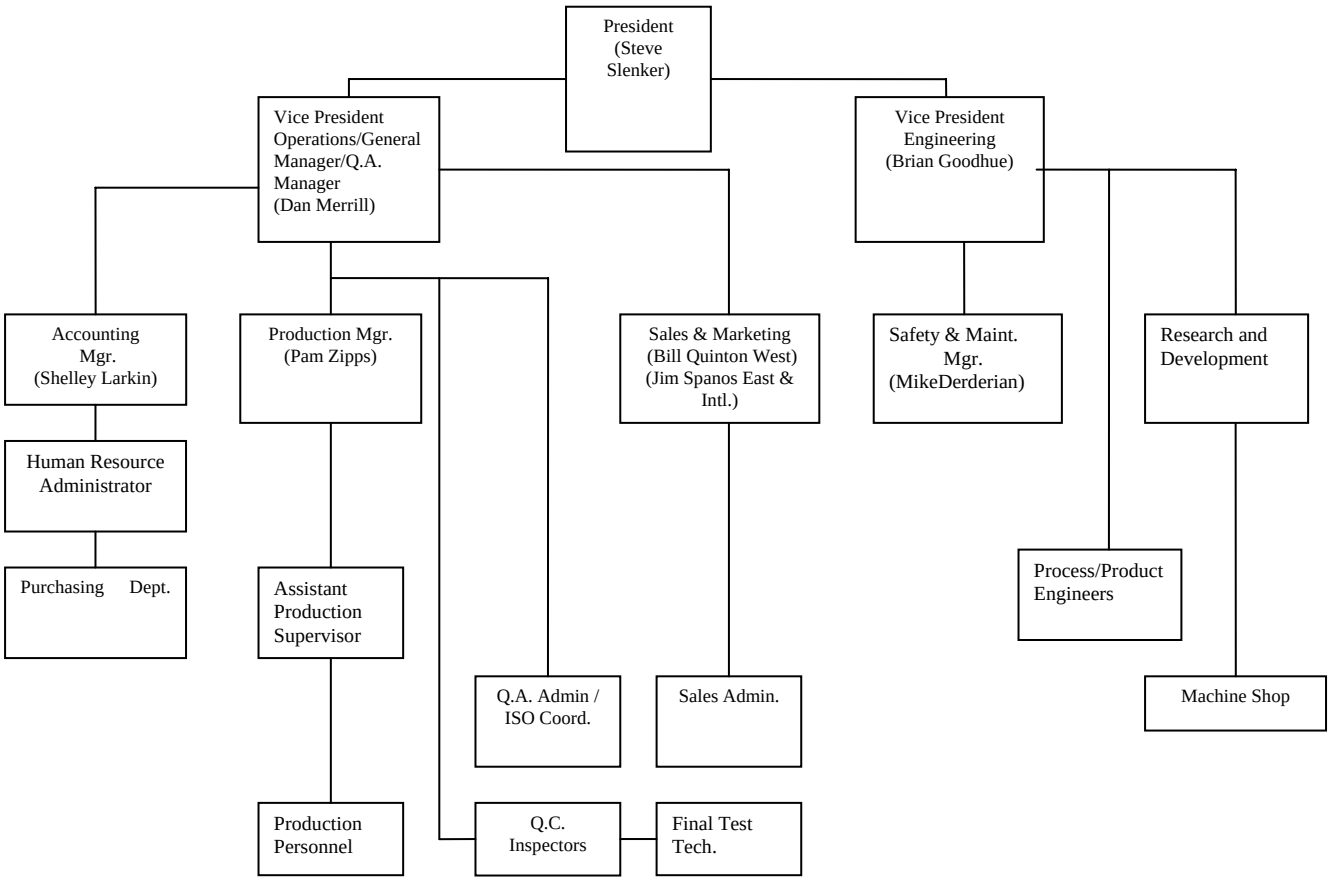
Through a commitment to quality, excellence and innovation, Piconics pledges to provide products that satisfy customer requirements for performance, delivery and value.

We recognize continuous improvement as a primary business objective and involve Piconics employees in establishing, measuring and achieving our quality goals.

MISSION STATEMENT

Piconics is committed to providing the highest level of performance in an inductor through excellence in engineering, manufacturing, quality control and customer service at a reasonable price with on time delivery. We focus on partnering with our employees and the customer to provide the best solution for the most demanding applications.

Organizational Chart



Piconics, Incorporated Organizational Chart

0.0 Introduction

This quality manual describes the Quality System in place at:

Piconics, Inc.
26 Cummings Road
Tyngsboro, MA 01879-1406
(978) 649-7501
www.Piconics.com

In business for more than 40 years, Piconics, Inc. offers a wide selection of microelectronic inductors. Piconics, Inc. is proud of the role it has played in the microelectronics industry and continually strives to provide the highest quality and service.

0.1 General

This manual establishes guidelines and practices for Piconics, Inc. employees to ensure the highest level of customer satisfaction with our products. Piconics, Inc. has a documented quality management system that satisfies or exceeds the requirements of:

ISO 9001:2008	*Quality Systems – Model*
MIL-PRF-15305 MIL-PRF-55342 MIL-PRF-83446	*Military Specifications for Quality in Production*

0.2 Process Approach

This manual promotes a process approach for developing, implementing and improving the quality management system to enhance customer satisfaction by meeting customer requirements. Piconics, Inc. utilizes a process approach as an effective way to identify and manage numerous linked activities. See **Figure 1**, "ISO Process Approach Diagram," and **Figure 2**, "Internal Process Approach Diagram."

Figure 1 - ISO Process Approach Diagram

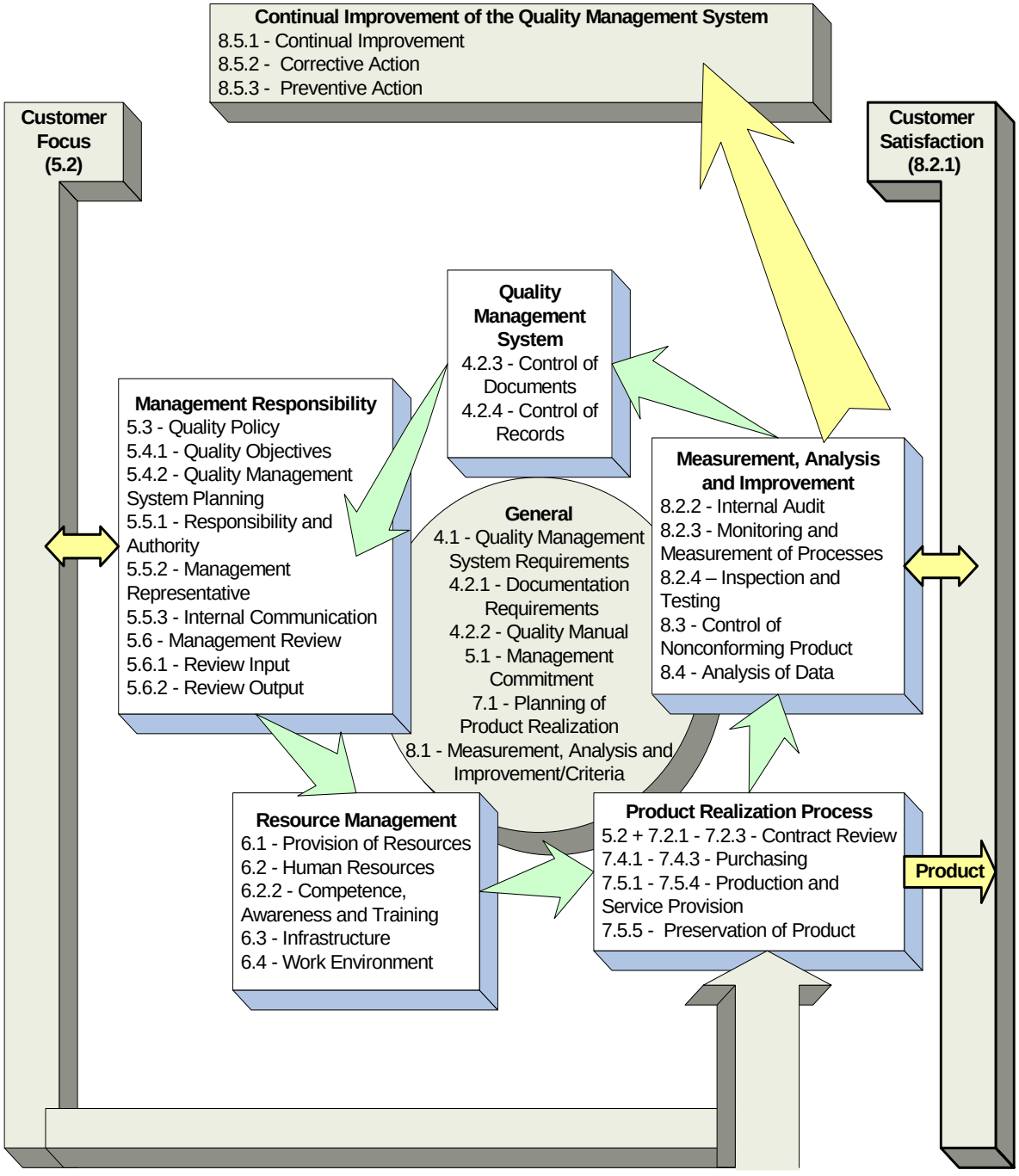


Figure 2 - Internal Process Approach Diagram

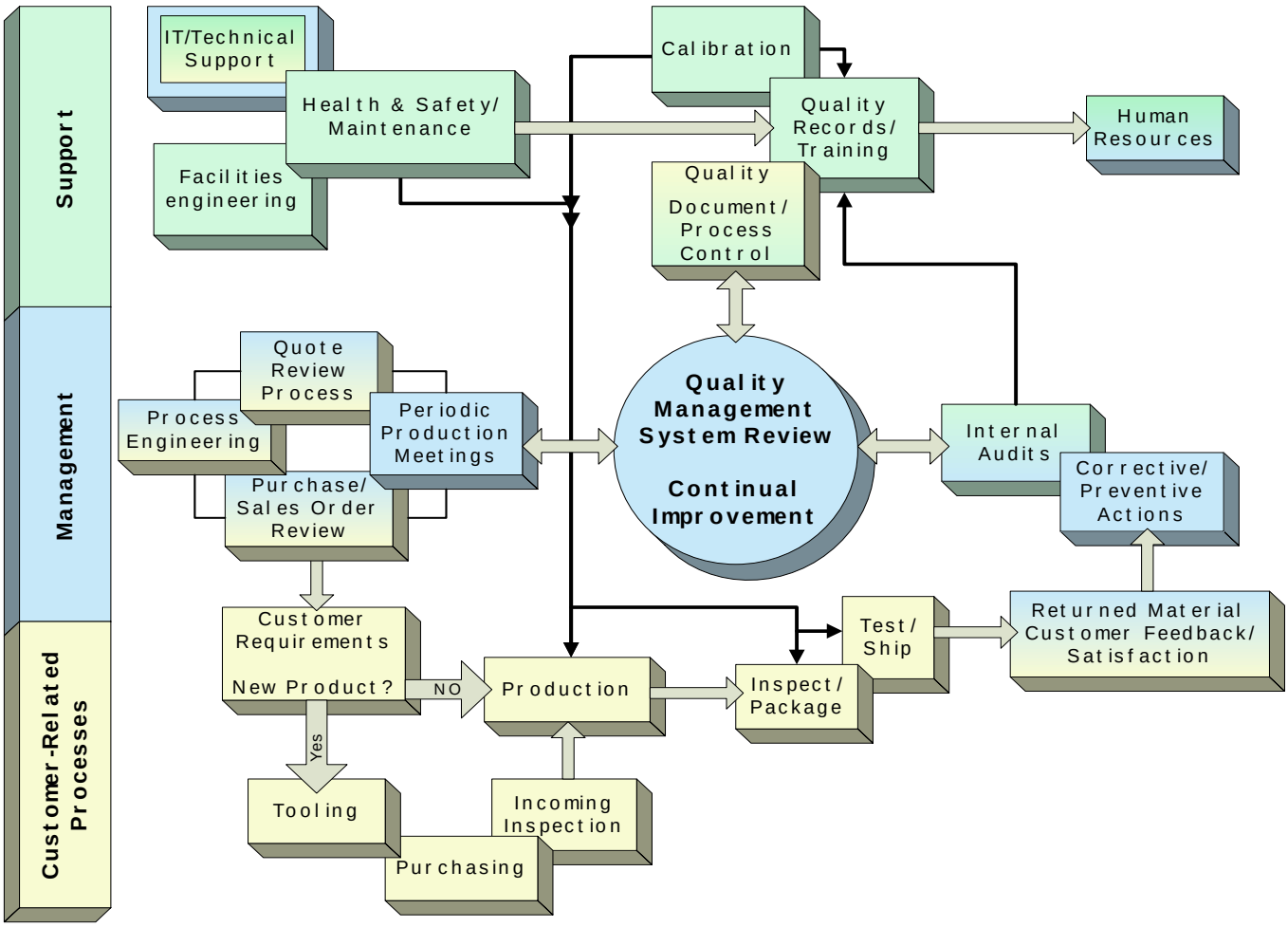


Figure 3 - Documentation Structure

The documented components of the quality management system are structured around the following categories:

Level 1 Documents	PQM-1, *Piconics, Inc. Quality Manual*, and its incorporated quality policy.
Level 2 Documents (POPs)	Operating procedures that describe the coordination of quality management system activities based on, but not limited to, the elements of ISO 9001:2008.
Level 3 Documents (PICs)	Work instructions, reports and forms that detail and/or augment specific job tasks.
Level 4 Documents	Product and/or customer-specific Level 3 documentation, including drawings.
Documents of External Origin	Documentation generated and used in production processes for visual reference. These include, but are not limited to, assembly parts, fabrication drawings, mechanical drawings, specification sheets and military standards.

1.0 Scope

1.1 General

This document specifies requirements for a Quality Management System (QMS) where Piconics Incorporated:

a). Demonstrates its ability to provide consistent product that meets customer and applicable statutory and regulatory requirements.

b). Addresses customer satisfaction enhancement through the effective application of the system, including processes for continual improvement and the assurance of conformity to customer and applicable statutory and regulatory requirements.

1.2 Application

Piconics, Inc. performs manufacturing and testing of custom and standard passive microelectronic components for the RF, telecommunications, medical, military and commercial markets.

Piconics, Inc. does not undertake any design work in its normal course of business. Products are manufactured from customer-provided designs and production drawings.

Any drawings produced by Piconics, Inc., in addition to those supplied by the customer, are for verification and clarity only. They do not constitute design.
Piconics, Inc. is a manufacturing facility and not a post delivery service provider.

Piconics, Inc. does not have any Special Processes within the system.
Therefore, Section 7.3, "**Design and Development**",7.5.1 " **Control of Production and Service Provision** and 7.5.2 "**Validation of Processes for Production and Service Provision**" of the ISO 9001:2008 Standard is not applicable to Piconics, Inc. and is excluded from the quality management system.

2.0 Normative Reference

Reference Standards (Current revision)

ISO 9000 Quality Management Systems - Vocabulary
ISO 9001 Quality management Systems - Requirements

3.0 Terms and Definitions

For the purpose of this quality manual the terms and definitions given in ISO 9001:2008 Quality Management Systems apply.

Note: The terms in this manual describing the supply-chain are as follows:

Supplier >>> Organization (Piconics, Inc.) >>> Customer

4.0 Quality Management System

4.1 General Requirements

Piconics, Inc. maintains an effective Quality management System (QMS) in accordance to ISO 9001:2008. The Quality Management System is designed to continually improve the organization's performance and satisfy customer requirements. To implement the Quality Management System, Piconics, Inc.:

a). Identifies the processes needed for establishment of the Quality Management System and their application throughout the organization.
b). Determines the sequence and interaction of these processes.
c). Selects the criteria and methods to ensure that both the operation and control of these processes are effective.
d). Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
e). Monitors, measures (where applicable) and analyzes these processes.
f). Takes the necessary actions to achieve the planned results and continual improvement.

Where Piconics, Inc. chooses to outsource any process that may affect product quality, conformity to requirements is controlled through a pre-determined and communicated quality plan **POP-05** (*Purchasing Procedure*).

4.2 Documentation Requirements

4.2.1 General

The Quality Management System documentation includes:

a). Documented quality policy and objectives.
b). Quality Manual
c). Documented procedures and records as required by ISO 9001:2008.
d). Documents, including records, determined to be necessary to ensure the effective planning, operation and control of the processes.

Procedures, instructions and forms are reviewed and approved by the ISO management representative and the quality manager as a minimum. Changes to the quality system documents can be requested by submitting the request to the ISO management representative.

The master documents and procedures are in electronic and hard copy format.

Piconics, Inc., uses four levels of documentation as detailed in **Figure 3.**
Document hierarchy as depicted in **Figure 3**

Note: *The extent of quality management system documentation is dependent on the size of departments, the complexity and interaction of particular processes, and competence of personnel. Other documentation may be added to the quality management system to ensure effective planning, operations and process control.*

4.2.2 Quality Manual

This quality manual defines the requirements of the ISO 9001:2008 standard as it pertains to Piconics, Inc., the scope of the Quality Management System and details exceptions Piconics, Inc. takes to this standard.

Relevant documented procedures are referred to in section 4.2.1 and **Figure 3. Figure 2** depicts the QMS processes and their interaction.

This manual is maintained as a controlled document. Distribution other than identified on the controlled circulation list shall not be controlled.

4.2.3 Control of Documents

Documents required for the QMS are controlled according to **POP-04** (*Documentation and Data and Records Control Procedure*), which provide for the review and approval of new or revised documents for adequacy prior to distribution. The current revision status is identified on each page of the document.

Current documents (hard copies) are available at all designated locations and on the intranet.
Obsolete documents are promptly removed. When retained, obsolete documents are suitably identified to prevent their use. As a minimum, one electronic copy of obsolete controlled documents is retained.

Changes are reviewed and approved either by the original approving function or another designated function, which has access to pertinent background information upon which to base its decision.

The quality management system includes, where necessary, externally generated documentation such as external standards. Such documentation is identified, maintained and distributed accordingly.

Other documents of external origin including technical references, desk references, books and freely available documents on the internet (i.e. technical data sheets, guidance documents, catalogs, etc.) are not controlled in order to provide a free flow of information and promote continuous learning and improvement. It is the user's responsibility to verify that the most current revision of any document of external origin is utilized.

4.2.4 Control of Records

Records that are established to provide evidence of conformity to the requirements and of the effective operation of the QMS are controlled according to **POP-16** *(Control of Quality Records procedure*). This procedure defines the controls required for the identification, storage, protection, retrieval, retention and disposition of records. Records are to be legible, readily identifiable and retrievable.

Reference Documents

POP-05	Purchasing Procedure
POP-04	Document and Data Control Procedure
POP-16	Control of Records Procedure

5.0 Management Responsibility

5.1 Management Commitment

Piconics, Inc. management is committed to the development and implementation of the Quality Management System (QMS) by adopting and certifying the QMS to the requirements ISO 9001:2008. Management is committed to improving and maintaining the effectiveness of the QMS in order to meet customer and regulatory requirements.

This is accomplished by:

a). Communicating the importance of meeting customer, statutory and regulatory requirements through planning, directives, performance metrics, and training. Communication will be realized through training, employee meetings, postings on bulletin boards, staff meetings etc.

b). Defining the quality policy and assuring its appropriateness to the organization by executive management approval.

c). Establishing quality objectives and ensuring they remain suitable at all levels throughout the organization.

d). Ensuring the availability of adequate resources by periodic manpower and workload reviews.

e). Ensuring customer requirements are identified and fulfilled with focus on enhancing customer satisfaction through contract reviews, customer visits and technical reviews.

f). Ensuring the integrity of the QMS through the Internal Audit Program and Management Review.

5.2 Customer Focus

Piconics, Inc. management ensures that customer requirements are identified **POP-03** *(Contract Review Procedure*) and fulfilled with the aim of enhancing customer satisfaction and that customer satisfaction is continuously assessed for improvement.

5.3 Quality Policy

Piconics, Inc. management developed the organizations quality policy, as shown in previous page, to guide the actions of all employees regarding quality. To ensure the policy is communicated and understood at all levels of the organization, the quality policy is presented and explained during employee orientation and during annual training. The quality policy is reviewed during management review meetings to assure continuous suitability for company goals and objectives.

5.4 Planning

Quality planning is an integral part of the quality management system and essential to ensure continual improvement of products provided to customers. Upper management ensures quality objectives, requirements, and processes are planned, established, implemented, and reviewed throughout the organization, as further detailed in **POP-02** (*Quality System Procedure*).

5.4.1 Quality Objectives

Upper management plans and establishes measureable quality objectives, including those needed to meet product requirements. The objectives are consistent with the quality policy and are deployed at relevant functions and levels of the organization.

Quality objectives are reviewed at Management Review meetings.

5.4.2 Quality Management System Planning

Planning of the QMS is conducted to meet quality objectives and general requirements of the quality management system. The management representative ensures that changes to the QMS are controlled and the integrity of the QMS is maintained during these changes.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The responsibilities, authorities and interrelationships of personnel within Piconics, Inc. who manage, perform and verify work affecting quality are shown in the organizational chart. Such responsibilities and authorities include the organizational freedom necessary to perform tasks affecting quality. Management responsibility is further defined in **POP-01** (*Management Responsibility Procedure)*.

The organizational chart is posted within the organization to communicate and facilitate effective quality management.

All personnel who manage, perform and verify work-affecting quality have the authority and independence necessary to perform these tasks.

Each member of management is ultimately responsible for setting goals in alignment with the QMS and providing the means to achieve them.

5.5.2 Management Representative

The General /Quality Assurance Manager has appointed the Quality Assurance Administrator as the ISO Management Representative. The ISO Management representative has the responsibility and authority to:

a). Ensure the quality management system is established, implemented and maintained.
b). Interface with other members of management, including the President of the organization, on the performance of the quality system including any required improvements.
c). Ensure the promotion of customer requirements are throughout Piconics, Inc.
d). Act as liaison with external parties on matters relating to the quality management system.
e). Chair the Quality System Management Review.

In the event the ISO Management Representative is not available, alternate ISO Management Representatives are appointed by the General Manager with the same responsibilities as the ISO Management Representative.

5.5.3 Internal Communication

Top management ensures appropriate communication processes are established, effectively implemented and maintained, within the organization, as part of the Quality Management System. This communication ensures that the QMS is effective and accomplishes stated objectives.

Internal communication vehicles are, but not limited to, the posting of summary and trend data of non-proprietary metrics, conducting periodic operation reviews with employees, issuing memos and e-mail. All departments are provided with the latest information, controlled documents and quality objectives.

All processes, which are implemented into the quality management system are communicated and understood by affected personnel through training. The effectiveness of the training is evaluated by management through internal system audits and reviewed during management review meetings.

5.6 Management Review

5.6.1 General

Upper management reviews the quality management system at least once per calendar year to ensure its continual suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement and the need for changes to the organizations QMS including quality policy and quality objectives.

5.6.2 Review Input

The quality management system review follows the quality management system review agenda described in **POP-01** (*Management Responsibility Procedure)*. This review may include, but is not limited to, current performance and improvement options and analysis of data related to:

a). Sales efforts and production activity from previous quarter.
b). Follow-up of action items from previous quality management system review meetings.
c). Customer feedback, satisfaction, complaints, returns.
d). Status of preventive/corrective actions.
e). Process performance and product conformance, including lead times, production yields and actions taken to achieve goals.
f). Results of audits performed, internal and external, since the last quality management system review.
g). Quality system overview, including changes that could affect the quality management system (e.g., provision of resources, resource limitations).
h). Recommendations for improvement.

5.6.3 Review Output

The output of the management review is the meeting minutes which will consist of a summary report that includes decisions and actions necessary for QMS improvement. Outputs from quality management system reviews include, but are not limited to, any decisions and actions related to:

a). Improvements of the effectiveness to the quality management system and its processes
b). Maintenance of review records.
c). Resource needs and allocation.
d). Additional work training for employees.
e). Improvements to Piconics, Inc. products and associated processes.
f). Review of internal audits regarding processes and departments.
g). Timely implementation of review-generated corrective/preventive actions forwarded to appropriate department managers or designees.

Reference Documents:

POP-03	Contract Review Procedure
POP-02	Quality System Procedure
POP-01	Management Responsibility Procedure

6.0 Resource Management

6.1 Provision of Resources

Piconics, Inc. management team assesses and identifies resource needs depending on the operations manufacturing workload. The organizational resources needed are provided to implement, improve and maintain the quality management systems effectiveness and enhance customer satisfaction by meeting customer requirements. Resources provided include, but are not limited to; the assignment of trained personnel, for management, performance of work and assessment activities.

6.2 Human Resources

6.2.1 General

The Human Resource Department is responsible for recruiting and selecting new employees on the basis of appropriate training, skills and experience per each departments needs; and to ensure the personnel performing work affecting product quality are qualified.

6.2.2 Competence, Awareness and Training

Personnel employed by Piconics, Inc. are hired on the basis of their existing knowledge relevant to the applied for position.

No training requirements need to be implemented within the company, except in those procedures specific to Piconics, Inc. However, this does not preclude the need for personnel to continue training and education and to remain current in procedures, processes and techniques as they develop. Need determines such training allocation to ensure that only qualified personnel are undertaking tasks affecting quality.

Piconics, Inc. has:

a). Determined the necessary competency needs for personnel performing work-affecting quality.
b). Provided necessary training or taken other action (e.g. coaching, communication, reading) to satisfy these needs.
c). Evaluated training effectiveness and documented such via employee training records.

d). Ensured that employees are aware of the significance of their activities and how they contribute to the achievement of the organizations quality objectives.
e) Maintained appropriate records of education, experience, training and skills.

This section shall meet all requirements of **POP-18** (*Training Procedure)*.

6.3 Infrastructure

Piconics, Inc. Management Team determines, provides and maintains the infrastructure to achieve conformity to product requirements.

Facilities may include, but are not limited to:

a). Buildings, workspace and associated utilities.
b). Process, laboratory and machine shop equipment as well as computer hardware and software.
c). Supporting systems (such as transport, communications and information systems).

The Safety and Maintenance Manager ensures proper maintenance of production equipment and facilities.

6.4 Work Environment

Piconics, Inc. identifies and manages the human and physical factors of the work environment needed to achieve conformity to product requirements and **POP-09** (*Process Control Procedure) including the following*;

a). Adequate health, cleanliness, clothing and safety conditions.
b). Suitable equipment and work instructions.
c). Secure and well-maintained working environment.

The requirements detailed in specific safety procedures (**PIC-O-XXXX**), apply to this section.

Reference Documents:

POP-18	Training Procedure
PIC-0802	Preventive Maintenance Procedure
POP-09	Process Control Procedure
PIC-O-XXXX	Various Safety Procedures

7.0 Product Realization

7.1 Planning of Product Realization

Piconics, Inc. plans and develops the processes required for product realization. Where appropriate, the following are determined for the product:

a). Quality objectives and requirements for the product.
b). Processes, documents, and resources.
c). Verification, validation, monitoring, inspection, test activities, and criteria for acceptance.
d). The records necessary to validate that the processes and resulting product meet the specific requirements.

Planning of product realization begins in the engineering department. Objectives and requirements for the product are established and documented through work instructions. Production and test processes are developed with consideration to the appropriate verification, validation, monitoring, and inspection and test activities. Records are created and maintained.

The process charts illustrated in **Figures 1** and **2** of this manual detail the sequence and interaction of realization processes at Piconics, Inc.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Verbal or written customer requirements are determined, documented, verified, reviewed and approved per **POP-03** (*Contract Review Procedure).*

Piconics, Inc. determines customer specified requirements, including delivery and post-delivery activity, any requirements which are not stated but required for specific or intended use, if known, any statutory or regulatory requirements related to the product and any additional requirements determined by the organization.

7.2.2 Review of Requirements Related to the Product

Piconics, Inc. reviews customer requirements prior to commitment to supply products to customers and ensures that:

a). Product requirements are defined.
b). Contract or order requirements differing from those previously expressed (exceptions on a quotation) are resolved.
c). The organization has the capabilities to meet the defined requirements.

Piconics, Inc. maintains records of the reviews and where there is no documented statement of requirements, the requirements are confirmed verbally before acceptance then followed up in hard copy format. In the event of requirement changes the organization assures that any applicable documents are revised and communicated to the pertinent personnel.

7.2.3 Customer Communication

Piconics, Inc. recognizes customer communication as an important aspect to achieving product and customer satisfaction and ensures that:

a). Product information is gathered during early consultation with customers. Personnel assigned to oversee product provision(s) are responsible for additional required information.

b). Sales inquiries from customers are promptly addressed, and contract amendments are communicated in a timely manner to all functional areas involved in contract execution.

c). Customer feedback and complaints are administered accordingly based on origin. Inquiry-based customer communication is directed to Sales, Quality and/or personnel responsible for product provision(s). Personnel responsible for product provision(s) approve department communications and inquiries within Piconics, Inc.

d). Customer complaints are handled per Section 8.3 of **POP-13** (*Control of Nonconforming Product Procedure*). Customer satisfaction/dissatisfaction is monitored per Section 8.2.1, “Customer Satisfaction.”

7.3 Design and Development

Piconics, Inc. does not perform design and development and therefore exempt from ISO 9001:2008 section 7.3 **Design and Development** and subsections 7.3.1 through 7.3.7.

7.3.1 Product Design and Development Planning

Exempt (See section 7.3 above).

7.3.2 Design and Development Inputs

Exempt (See section 7.3 above).

7.3.3 Design and Development Outputs

Exempt (See section 7.3 above).

7.3.4 Design and Development Review

Exempt (See section 7.3 above).

7.3.5 Design and Development Verification

Exempt (See section 7.3 above).

7.3.6 Design and Development Validation

Exempt (See section 7.3 above).

7.3.7 Control of Design and Development Changes

Exempt (See section 7.3 above).

7.4 Purchasing

Piconics, Inc. ensures that methods and responsibilities are defined for procuring product, including functions relative to the purchasing process, purchasing information, and verification of purchased product.

7.4.1 Purchasing Process

Piconics, Inc. maintains controlled procedures to ensure that purchased materials conform to specified requirements. The type and extent of control applied to the supplier and purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.

Piconics, Inc. evaluates and selects suppliers based on their ability to provide conforming product, service, and delivery expectations. In the event of declining performance Piconics, Inc. may re-evaluate and recommend the supplier's removal from the approved vendor list.

Records are maintained regarding the evaluations as well as and necessary actions resulting from the evaluation.

7.4.2 Purchasing Information

Piconics, Inc. ensures that all purchasing information adequately describes the product to be purchased, including, where appropriate:

a). Requirements for approval of product, process, procedures and equipment.
b). Requirements for qualification of personnel.
c). Quality management system requirements applicable to purchased product.

The purchaser ensures the adequacy of specified requirements contained in the purchasing documents prior to their release.

7.4.3 Verification of Purchased Product

Inspection and other activities necessary for ensuring purchased product meets the required purchase requirements are established and have been implemented. Where Piconics, Inc., or its customer, proposes to perform verification activities at the supplier's premises, this organization specifies the intended verification arrangements and method of product release in the purchasing information.

Verification by the customer does not absolve Piconics, Inc. of the responsibility to provide an acceptable product.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Piconics, Inc. is not a post delivery service provider and takes exclusion from this part of 7.5.1.
Piconics, Inc. carries out production under controlled conditions. Controlled conditions include as appropriate:

a). Availability of information that describes the key characteristics of the product.
b). Availability of work instructions, as necessary.
c). Use of suitable equipment.
d). Availability and use of monitoring and measuring equipment.
e). Implementation of monitoring and measurement.
f). Implementation of product release processes and delivery and applicable post activity activities.

7.5.2 Validation of Processes for Production and Service Provision

Piconics, Inc. does not have special processes within our system and therefore exempt from ISO Standard 9001:2008 section 7.5.2.Validation of Processes for Production and Service Provision.

7.5.3 Identification and Traceability

Piconics, Inc. identifies products by suitable means throughout product realization. Product status is identified with respect to monitoring and measurement requirements throughout product realization.
Piconics, Inc. controls and records the unique identification of the product where traceability is a requirement.

Product identification and traceability is maintained per **POP-07** (*Product Identification and Traceability Procedure)*.

7.5.4 Customer Property

Piconics, Inc. exercises care with customer property while it is under our control or being used by our organization. We identify, verify, secure, protect and safeguard customer property provided for use or incorporation into their products. This is to include any intellectual property and personal data. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, this is reported to the customer and records are maintained.

7.5.5 Preservation of Product

Preservation of products produced by Piconics, Inc. is the responsibility of the manufacturing operations and includes identification, handling, packaging, storage, and protection. Preservation of product also applies to the constituent parts of a product. Piconics, Inc. maintains a documented procedure for control of limited shelf life materials.

7.6 Control of Inspection, Measuring and Test Equipment

It is the function of the Quality Assurance Department to identify the measurements to be taken as well as the monitoring and measurement devices required for assuring product conformity to specified requirements. Monitoring and measuring devices used are controlled to ensure that measurement capability is consistent with the monitoring and measurement requirements. Control of monitoring and measurement devices is performed in accordance with **POP-11** (*Control of Inspection, Measuring and Test Equipment procedure*).

Where applicable, monitoring and measuring devices are:

a). Calibrated and/or verified at prescribed intervals, or prior to use, against measurement standards traceable to the National Institute of Standards and Technology (N.I.S.T.); where no such standards exist, the basis used for calibration or verification is recorded.
b). Adjusted or re-adjusted as necessary.
c). Identified in order to determine its calibration status.
d). Safeguarded from adjustments that would invalidate the measurement result.
e). Protected from damage and deterioration during handling, maintenance and storage.

Calibration records of monitoring and measuring devices are maintained. Calibration status information is recorded in an electronic database.

Reference Documents:

POP-10	Inspection and Testing Procedure
POP-12	Inspection and Test Status Procedure
POP-04	Document and Data Control Procedure
POP-09	Process Control Procedure
POP-03	Contract Review Procedure
POP-02	Quality System Procedure
POP-13	Control of Nonconforming Product Procedure
POP-05	Purchasing Procedure
PIC-Q3-XXX	Various Incoming Inspection Procedures
POP-07	Product Identification and Traceability Procedure
POP-11	Control of Inspection, Measuring and Test Equipment Procedure
POP-06	Control of Customer-Supplied Product Procedure
POP-15	Handling, Storage, Packaging, Preservation and Delivery Procedure
PIC-Q-569	Shelf Life Monitoring Procedure

8.0 Measurement, Analysis and Improvement

8.1 General

General planning and implementation of Monitoring and Measurement Analysis and improvement processes are the responsibility of all employees at Piconics, Inc. The primary responsibilities lie with Manufacturing Operations and Quality Assurance. These processes are performed to demonstrate product conformity, ensure conformity of the Quality Management System and to continually improve the QMS through the application of planned methods, and where appropriate, statistical techniques. Planned methods include, but are not limited to, Customer Satisfaction Evaluation, Internal Audits, Incoming Inspection, Final Inspection, Records, Control of Nonconforming Product, Data Collection and Analysis, Continual Improvement, Corrective and Preventive Action.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

The Piconics, Inc. Management Team is responsible for determining customer satisfaction through analysis of information relating to customer perception. Piconics, Inc. determines customer satisfaction by obtaining written and/or verbal customer and end-use information from internal and external sources.

Examples of customer-related information may include, but is not limited to:

a). Feedback on all aspects of product
b). Customer needs and contract information
c). Market needs
d). Product delivery data

Resulting information addresses product conformance to specified requirements, including meeting customer expectations as well as product delivery and price.

Sources of customer satisfaction information may include, but are not limited to:

a). Customer complaints
b). Direct communication with customers
c). Customer Feedback Log
d). Piconics, Inc. Quality Performance Survey
e). Consumer and/or media reports and sector studies

Customer satisfaction, returns and complaints are discussed and evaluated at quality management system review meetings

8.2.2 Internal Audit

Internal audits are performed by trained auditors at pre-determined intervals to determine if the documented QMS is effectively implemented, maintained, and conforms to the specific standards of the most current ISO 9001 document, other procedures defined in this manual as well as any requirements determined by Piconics, Inc.

Quality Assurance develops the audit plan annually, taking into consideration the status and importance of the activities and areas to be audited as well as the results from previous audits.
The audit criteria, scope, frequency, and methods are defined. Audits are conducted by personnel other than those who perform the activity being audited. **POP-17** (*Internal Quality Audit Procedure*) describes the responsibilities and requirements for conducting audits, recording results, and reporting to management.

Management ensures that corrective/preventive action is taken without undue delay to eliminate detected nonconformances. Follow-up activities include the verification of any actions taken and reporting the verification results. Records of audits and their results are maintained.

8.2.3 Monitoring and Measurement of Processes

Piconics, Inc. has suitable methods for monitoring and, where applicable, the measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure product conformity.

Measurement methodologies may include, but are not limited to:

a). Accuracy, timeliness and dependability

b). Reaction time of processes/people to special internal and external requests
c). Cycle time or quantity per hour
d). Effectiveness and efficiency of people
e). Utilization of technologies
f). Cost reduction
g). Data Analysis

Quality management system review meetings are utilized to determine if on-time product delivery and customer satisfaction goals are continually being met. The same quality management system review meetings determine the failure of these goals and the appropriate improvement actions necessary to reach desired targets.

8.2.4 Monitoring and Measurement of Product

Piconics, Inc. monitors and measures product characteristics to verify that all product requirements have been met. This is conducted at appropriate stages of the product realization process in accordance with planned arrangements and documented procedures.

Evidence of conformity to acceptance criteria is maintained and product release cannot proceed until all planned phases of manufacturing and test or customer approval, when applicable, have been completed.

8.3 Control of Nonconforming Product

Piconics, Inc. has documented procedures for the identification and segregation of product, which does not conform to product requirements. The controls, related responsibilities and authorities are further defined in **POP-13** (*Control of Nonconforming Product Procedure*).

Nonconforming products are managed by taking one or more of the following actions:

a). Taking action to eliminate the detected nonconformity.
b). Authorizing its use, release or acceptance under concession by a relevant authority.
c). Taking action to preclude its original intended use or application.
d). Taking action appropriate to the effects, or potential effects of the nonconformity.

When nonconforming product is corrected, it is subjected to re-evaluation to verify conformity to the requirements.

Records of the nature of nonconformities and subsequent actions taken, including concessions obtained, are maintained as part of Piconics, Inc. QMS.

8.4 Analysis of Data

Piconics, Inc. determines, collects, and analyzes appropriate data to determine the suitability and effectiveness of the QMS and to evaluate where continual improvements can be made. This includes data generated by monitoring and measurement of data from other relevant sources.

Piconics, Inc. analyzes this data to provide information on:

a). Customer satisfaction.
b). Conformity to requirements.
c). Characteristics and trends of processes and products, including opportunities for preventive action.
d). Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

The effectiveness of the QMS is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

Piconics, Inc. implements corrective action to avoid and eliminate the cause of nonconformance's in order to prevent recurrence. Corrective action is to be appropriate to the effects of the nonconformities encountered.

The system for corrective action is defined in **POP-14** (*Corrective and Preventive Action Procedure*) and defines the requirements for:

a). Reviewing nonconformities (including customer complaints).
b). Determining the causes of nonconformities.
c). Evaluating the need for action to ensure that nonconformities do not recur.
d). Determining and implementing the action required.
e). Recording the results of action taken.
f). Reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive Action

Piconics, Inc. defines preventive action as the actions taken to eliminate a potential nonconformance in order to prevent recurrence. Preventive actions are appropriate to the

effects of the potential problems. The system for preventive action is defined in **POP-14** (*Corrective and Preventive Action Procedure*) and defines the requirements for:

a). Determining potential nonconformities and their causes.
b). Evaluating the need for action to prevent occurrence of nonconformities.
c). Determining and implementing action needed.
d). Recording the results of action needed.
e). Reviewing the effectiveness of the preventive action taken.

Reference Documents:

POP-17	Internal Quality Audit Procedure
POP-13	Control of Nonconforming Product Procedure
POP-14	Corrective and Preventive Action Procedure