

Document Title	<i>Piconics, Inc. Quality Manual</i>		
Document Number	<i>PQM-1</i>	Rev	<i>AL</i>



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PICONICS, INC.

QUALITY MANUAL

PQM-1

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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 (microelectronics). 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 55 employees.

In business for more than 50 years, Piconics offers a wide selection of microelectronic inductors. Piconics is proud of the role it has played in the microelectronics industry and continually strives to provide the highest quality and service.

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 (ref PIC-Q-575 rev A)

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

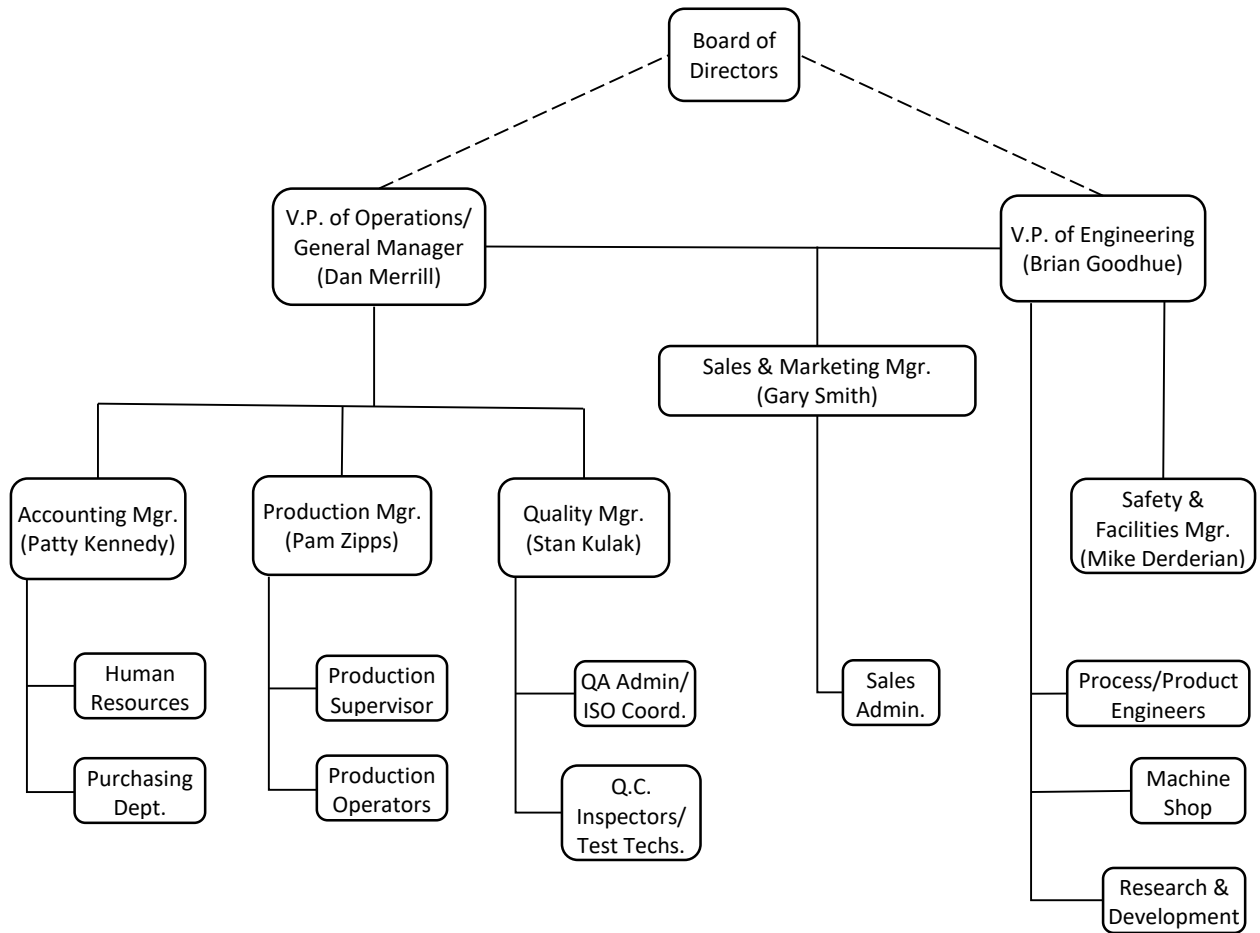
We recognize continuous improvement as a primary business objective and involve Piconics employees in establishing, measuring and achieving our quality goals.

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.

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Piconics, Inc. Organizational Chart



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0.1 General

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

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

ISO 9001:2015	Quality Management Systems – Requirements
MIL-PRF-83446	General Specification for Coils, Radio Frequency, Chip, Fixed or Variable
MIL-PRF-15305	General Specification for Coils, Electrical, Fixed and Variable, Radio Frequency
MIL-PRF-55342	General Specification for Resistor, Chip, Fixed, Film, Non-established Reliability, Established Reliability, Space Level

0.2 Process Approach

This manual promotes a process approach for developing, implementing and improving the quality management system and to enhance customer satisfaction by meeting or exceeding customer requirements. The Plan-Do-Check-Act cycle is incorporated into this process approach, as well risk-based thinking, where risk and opportunity is addressed throughout the processes. This is the basis for increasing the effectiveness of the Quality Management System. Piconics utilizes a process approach as an effective way to identify and manage numerous linked activities. See **Figure 1**, “Piconics Process Interrelationships Approach Diagram”

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Internal Process Interrelationships Approach Diagram

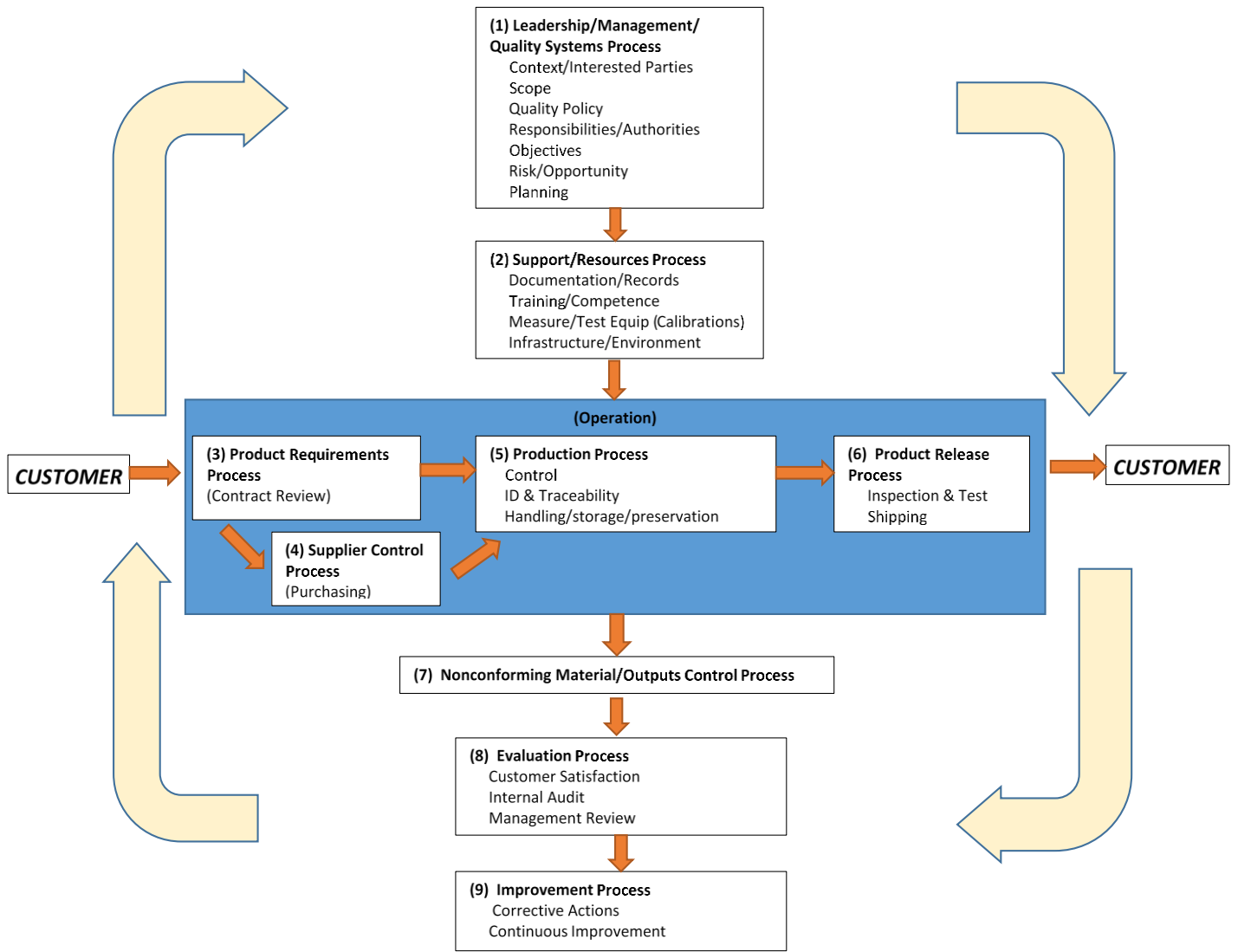


Figure 1

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1.0 DOCUMENT SCOPE

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

- 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 improvements to the system and assurance of conformity to customer and applicable statutory and regulatory requirements.

2.0 NORMATIVE REFERENCES

Reference Standards (Current revision)

ISO 9000 Quality Management Systems – Fundamentals and Vocabulary

ISO 9001 Quality management Systems - Requirements

3.0 TERMS AND DEFINITIONS

- 3.1 **External Providers** – Also known as suppliers or vendors. May provide a product, process, part of a process, or service.
- 3.2 **Documented information** – Also known as Documents and/or Records
- 3.3 **Outputs of production** – Also known as products
- 3.4 **QMS** – Quality Management System
- 3.5 **Top Management** – All department managers who play a significant role in day-to-day management of the company and QMS including, but not limited to: General Manager, Safety and Maintenance Manager, Engineering Managers, Quality Manager, Human Resources Administrator, Accounting Manager and Production Manager.

4.0 CONTEXT OF THE ORGANIZATION

- 4.1 **The Organization and Its Context** – Piconics determines the applicable external and internal issues that are relevant to the organizational purpose and strategic direction, and that affect the ability to achieve the results of the QMS. Information regarding these issues is monitored and reviewed by top management.

External context may include issues such as, but not limited to, legal, technological, competitive, market, cultural, social and economic environments.

Internal context may include issues such as, but not limited to, the values, culture, knowledge and performance of the organization

- 4.2 **Needs and Expectations of Interested Parties** – Because of the possible effects on the ability of Piconics to provide product that meets customer and applicable statutory and regulatory requirements, interested parties that are relevant to the QMS and their requirements are determined. Information regarding the relevant requirements of these interested parties is monitored and reviewed by top management.
- 4.3 **Scope of the Quality Management System** – Piconics has determined the boundaries and applicability of the QMS and established its scope, by considering the external and internal issues that define the organizational context, the requirements of relevant interested parties, and the products produced. All applicable requirements of the ISO 9001:2015 standard are applied if they are within the scope of the QMS. The scope of the QMS is maintained and available as documented information within this document and provides justification for any requirements of the ISO 9001 standard that are determined to be not applicable within the

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QMS. Requirements are only determined to be not applicable if they do not affect the ability of Piconics to ensure product conformity and enhance customer satisfaction.

SCOPE OF THE QMS FOR PICONICS, INC.

Piconics, Inc., located in Tyngsboro MA, performs manufacturing and testing of custom and standard passive high quality microelectronic inductor components such as broadband conical, RF and microwave air coils, or fixed and tunable QPL & COTS inductors for the RF, Telecommunications, medical, military and commercial markets.

Piconics does not undertake any design work in the normal course of business. Products are manufactured from customer-provided designs and production drawings. Any drawings produced by Piconics, in addition to those supplied by the customer, are for verification and clarity only and do not constitute design. Piconics has determined that all of section 8.3 *Design and Development of Products* of the ISO 9001:2015 is not within the scope of the QMS and is therefore, not applicable.

Piconics is a manufacturing facility and does not provide post-delivery activities beyond warranty replacement of any non-conforming parts that have been delivered to a customer, in accordance with established terms and conditions, and customer communications or feedback regarding delivered product. Procedures are established, addressing these activities.

Piconics does not have processes that cannot be verified by subsequent monitoring or measurement, therefore it has determined that 8.5.1.f of the *Control of Production* section of the ISO 9001:2015 is not applicable within the scope of the QMS.

- 4.4 Quality Management System and Its Process** – Piconics has established, implemented, maintains and continually improves its QMS, including the required processes and interactions, in accordance to ISO 9001:2015. The QMS provides for improvements to the organizational performance and satisfying customer requirements.

Piconics determines the processes needed for the QMS and their applications throughout the organization, including:

- a) Determining the required inputs and expected outputs from these processes.
- b) Determining the sequences and interactions of these processes
- c) Selecting the criteria and methods, including appropriate monitoring, measurement and related process indicators, to ensure that both the operation and control of the processes are effective.
- d) Determining and ensuring the availability of resources needed for these processes.
- e) Assigning the responsibilities and authorities for these processes
- f) Addressing risks and opportunities in these processes, as applicable
- g) Evaluating these processes and implementing needed changes to ensure the process meet its intended results
- h) Improving the processes and QMS

Documented information, such as procedures, is maintained in support of the operation and the required processes, and documented information, such as records, are retained to provide confidence and evidence that the process are being carried out as planned.

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5.0 LEADERSHIP

5.1 Leadership and Commitment

5.1.1 General – Top management at Piconics demonstrates its leadership and commitment to the development and implementation of the Quality Management System (QMS) by adopting and certifying the QMS to the requirements of the ISO 9001 International Standard for Quality Management System Requirements. Top management is committed to maintaining and improving the effectiveness of the QMS in accordance with *POP-01 (Management Responsibility Procedure)*, in order to meet customer and regulatory requirements by:

- a) Being accountable for the effectiveness of the QMS.
- b) Establishing a quality policy and quality objectives for the QMS that are compatible with the context and strategic direction of Piconics.
- c) Ensuring that the QMS is integrated into the business processes.
- d) Promoting the use of the process approach and risk based thinking.
- e) Ensuring the availability of adequate resources required for an effective QMS are available by periodic manpower and workload reviews.
- f) Communicating the importance of an effective QMS and conformance to requirements to all employees.
- g) Ensuring that the QMS achieves its intended results.
- h) Engaging, directing and supporting all employees to contribute to the effectiveness and continual improvement of the QMS.
- i) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility and the QMS.

5.1.2 Customer Focus – Top management at Piconics demonstrates leadership and commitment to customer focus by ensuring that customer and applicable statutory or regulatory requirements are determined, understood and consistently met, in accordance with *POP-03 (Contract Review Procedure)*. Risks and opportunities that can affect product conformity and customer satisfaction are determined and addressed, with a focus on maintaining and enhancing customer satisfaction.

5.2 Quality Policy – The top management of Piconics have established, implemented and maintains a quality policy to guide the actions of all employees regarding quality. The quality policy is included at the beginning of this document, and controlled as documented information. The policy is appropriate for the purpose and context of the organization and supports the strategic direction of the company. The policy provides a framework for setting quality objectives, a commitment to satisfy applicable requirements and a commitment for continual improvement of the QMS.

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, and is available for other appropriate interested parties, upon request. The quality policy is reviewed during management review meetings to assure that it continues to be suitable for the organizations goals and objectives.

5.3 Roles, Responsibilities and Authorities – Top management at Piconics has determined and assigned the responsibilities and authorities for the relevant roles identified in the organizational chart. This chart is controlled within this document and posted in order to communicate and provide understanding of the organizational structure to all employees. Responsibilities and authorities include the organizational freedom necessary to perform tasks affecting the QMS and are further defined in *POP-01 (Management Responsibility*

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Procedure). 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.

Top management at Piconics has assigned responsibility and authority for:

- a) Ensuring that the QMS conforms to the requirements of the ISO 9001 standard, as a minimum.
- b) Ensuring that processes are delivering their intended outputs
- c) Reporting to top management on the performance of the QMS and any opportunities for improvement
- d) Ensuring and promoting customer focus and satisfaction throughout the operation
- e) Ensuring that the QMS integrity is maintained when changes to the QMS are planned and implemented.

Reference Documentation (Section 5)

POP-01 (Management Responsibility Procedure)

POP-03 (Contract Review Procedure)

6.0 PLANNING

6.1 Actions to Address Risks and Opportunities – When planning for the Quality Management System, Piconics considers the internal and external issues that are relevant to the context of the organization, as well as the needs, expectations, and requirements of relevant interested parties, in order to determine the risks and opportunities that need to be addressed. This is done in order to assure the Quality Management System can achieve the intended results, promote and enhance positive effects, prevent or reduce negative effects and to achieve improvement within the QMS.

Piconics plans and takes action to address identified risks and opportunities that are proportionate to the potential impacts on product conformity. This is integrated and implemented within the QMS and the actions are evaluated for effectiveness.

Risk may be addressed by avoiding risk, eliminating the source of risk, sharing risk, taking risk to pursue an opportunity, changing the likelihood or consequences of risk, or accepting risk based on an informed decision. Opportunities may lead to new practices, new products, opening new markets or new customers, establishing or building partnerships, new technologies, or other possibilities to address the needs of Piconics or its customers.

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

6.2.1 Top management plans and establishes measurable quality objectives, including those needed to meet product or other applicable requirements and enhance customer satisfaction, which are consistent with the quality policy. These objectives are deployed at relevant functions and levels within Piconics and are monitored, communicated throughout the organization and updated as appropriate. Documented information on the quality objectives is maintained and reviewed and evaluated during Management Review meetings.

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6.2.2 When planning to achieve quality objectives, Piconics determines what activities are required, what resources are needed to provide these activities, who is responsible for performing the activities, the timeframe for completion, and how the results are evaluated.

6.3 Planning of Changes – When changes to the QMS are needed, they are done in a controlled manner. Piconics considers the reason for, and potential consequences of the change while maintaining the integrity of the QMS. The resource requirements and availability are also considered, as well as any allocation or reallocation of responsibilities and authorities that may be required.

Reference Documentation (Section 6)

POP-02 (Quality System Procedure)

7.0 SUPPORT

7.1 Resources

7.1.1 General – Piconics assesses, identifies and provides the resources needed to establish, implement, maintain and continually improve the Quality Management System. This is done with consideration for the capabilities and constraints on the existing resources as well as what needs to be obtained from external sources.

7.1.2 People – Piconics determines and provides the personnel necessary for the effective implementation of the QMS and the operation and control of the processes.

7.1.3 Infrastructure – Piconics determines, provides and maintains the necessary infrastructure for operation and control of the processes and to achieve conformity to product requirements. The Safety and Maintenance Manager ensures the proper maintenance of production equipment and facilities. The infrastructure may include, but is not limited to:

- a) Buildings, workspace, and associated utilities.
- b) Process, laboratory, and machine shop equipment as well as required hardware and software.
- c) Any required transportation resources.
- d) Information and communication technology.

7.1.4 Environment for the Operation of Processes – Piconics determines, provides and maintains an environment necessary for the operation and control of the processes, and to achieve conformity to product requirements. This is done by managing the human and physical factors and in accordance with *POP-09 (Process Control Procedure)* and requirements detailed in specific *Safety Procedures (PIC-O-XXXX)*, including the following:

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

7.1.5 Monitoring and Measuring Resources – It is the function of the Quality Assurance department to identify the measurements to be taken, and the monitoring and measurement devices require for ensuring valid and reliable results when used to verify product conformity to specified requirements. Piconics ensures that the monitoring and measurement resources are suitable for the specific type of activity being undertaken and are maintained to ensure they remain fit for use. Control of

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monitoring and measurement devices is performed in accordance with **POP-11 (Monitoring and Measuring Resources/Control of Inspection, Measuring and Test Equipment Procedure)**. Calibration and/or service records are maintained as evidence that the monitoring and measurement resources retain their fitness of purpose.

When measurement traceability is required or considered essential for providing confidence in the validity of measurement results, Piconics uses measuring equipment that is:

- a) Calibrated and/or verified at specified intervals, or prior to use, against measurement standards traceable to national or international standards (NIST). If no such standard exists, the basis used for calibration and/or verification is recorded and retained.
- b) Identified in order to determine its calibration status
- c) Safeguarded from adjustments, damage or deterioration that would invalidate the measurement results.

In the event that any measuring equipment has been found to be out of calibration or otherwise unfit for its intended purpose Piconics will determine if previous measurement results are valid or have been adversely affected, and will take appropriate action as necessary.

7.1.6 Organizational Knowledge – Piconics determines the necessary knowledge specific to the organization, for the operation of its processes and to achieve product conformity. This is maintained and made available as necessary, primarily through, but not limited to, taking knowledge gained from experience, lessons learned from projects, failures or testing, and the results of process or product improvements, and incorporating them into procedures and guides as well as providing for cross-training of employees. When changing needs or trends are being addressed, the current level of knowledge is evaluated and the acquisition of any additional knowledge or updates is determined.

7.2 Competence – Personnel employed by Piconics are hired on the basis of their existing knowledge relevant to the applied for position.

Training requirements are implemented within the company, to procedures specific to Piconics however, this does not preclude the need for personnel to continue training and education to remain current in procedures, processes, and techniques as they develop. Piconics determines and provides such training to ensure that only trained and competent personnel are undertaking tasks affecting quality in accordance with **POP-18 (Training Procedure)**. Piconics:

- a) Determines the necessary competency needs for personnel performing work that affects the performance and effectiveness of the QMS
- b) Ensures that personnel are competent on the basis of appropriate education, training or experience.
- c) Takes action, as applicable, to acquire the necessary competence by providing training or taking other action (e.g. coaching, communication, reading, re-assigning currently employed personnel, hiring or contracting competent personnel), and evaluates the effectiveness of the actions taken.
- d) Establishes and retains records of employee training as evidence of employee competence.

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7.3 Awareness – Piconics ensures that employees are aware of the Quality Policy and quality objectives, as well as how they contribute to the effectiveness of the QMS, including how improvement in performance can help the company and the implications of nonconformance to the QMS.

7.4 Communication – Top management at Piconics has determined and ensures appropriate communication processes are established and maintained, as part of the QMS. This communication ensures that the QMS is effective and accomplishes stated objectives.

Internal communication vehicles include, but are 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 QMS are communicated and understood by affected personnel through training. Procedures addressing these processes identify additional internal and external communication requirements, including what is communicated, when and with whom it is communicated, who is responsible for the communication and the applicable methods of communication.

7.5 Documented information

7.5.1 General – The Quality Management System of Piconics includes documented information, such as procedures and records, required by the ISO 9001:2015 standard, as well as other documented information that has been determined to be necessary for effectively implementing the QMS. This includes:

- a) A documented quality policy and objectives
- b) This quality manual
- c) Documented information required by the ISO 9001:2015 standard.
- d) Other documented procedures and records required to ensure effective planning, operation and control of the QMS as well as ensuring production output that conforms to requirements.

The creation, updating and control of documented information is maintained per *POP-04 (Document and Data Control Procedure)* and *POP-16 (Control of Quality Records Procedure)*

Piconics uses four levels of documentation as detailed below.

Level 1 Documents	PQM-1, <i>Piconics Quality Manual</i> , 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 requirements of the ISO standard.
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.

7.5.2 Creating and Updating – When documented information is created, revised or updated, Piconics ensures that it is described and identified and the format or media is appropriate. The master documents and procedures are in hard copy and electronic format. Prior to distribution, new or revised procedures, instructions and forms are

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reviewed and approved by the ISO management representative and the Quality Manager as a minimum, to ensure they are suitable and adequate. Changes to the quality system documents can be requested by submitting the request to the ISO management representative.

7.5.3 Control of Documented Information – Documented information required for the QMS is controlled according to *POP-04 (Document and Data Control Procedure)*. Current documents (hard copies) are available for all personnel at designated locations, as well as on the intranet in electronic format. The current revision status of these documents is identified on each page of the document. Hard copy documents are identified with a red stamp and electronic documents are read-only for personnel without designated document control authority.

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.

Obsolete documents are promptly removed from use. When retained, obsolete documents are suitably identified to prevent their use. As a minimum, one electronic copy of an obsolete controlled document is retained.

The Quality Management System includes, where necessary, externally generated documentation such as external standards. Such documentation is identified, maintained and distributed as appropriate. 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, catalogues, 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.

Documented information in the form of quality records are established and controlled to provide evidence of product conformity and effective operation of the QMS according to *POP-16 (Control of Quality Records Procedure)*. This procedure defines the controls required for the identification, storage, protection from unintended alteration, retrieval, retention and disposition of records. Records are to be legible, readily identifiable, and retrievable.

Reference Documentation (Section 7)

POP-04 (Document and Data Control Procedure)

POP-09 (Process Control Procedure)

POP-11 (Monitoring and Measuring Resources/Control of Inspection, Measuring and Test Equipment Procedure)

POP-16 (Control of Quality Records Procedure)

POP-18 (Training Procedure)

PIC-O-XXXX (Safety Procedures)

8.0 OPERATION

8.1 Operational Planning and Control - Piconics plans, implements and controls the processes required for the provision of products, and implements actions as a result of planning activities. This is done by:

- a) Determining product requirements
- b) Establishing process and product acceptability criteria

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- c) Determining the necessary resources to achieve product conformity
- d) Implementing process controls in accordance with the criteria
- e) Determining, maintaining and retaining documented information necessary to show that processes have been carried out as planned and that products conform to their requirements.

Planning for the provision of products begins in the Engineering department. Objectives and requirements for the product are established and documented through work instructions, drawings or other technical data. Production and test processes are developed with consideration to the appropriate verification, validation, monitoring, inspection and test activities. Planned changes are controlled and action is taken to mitigate the consequences of unintended changes. Any outsourced processes are planned and controlled per **POP-05 (Purchasing Procedure)**

The process chart illustrated in **Figure 1** of this document detail the sequence and interaction of processes required for the provision of products at Piconics.

8.2 Requirements for Products

8.2.1 Customer Communication – Piconics recognizes that customer communication is 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, contracts or orders 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. Customer complaints are handled as defined in **POP-13 (Control of Nonconforming Product Procedure)**. Customer satisfaction or dissatisfaction is monitored per section 9.1.2 of this document, “Customer Satisfaction”
- d) When customer supplied property is required or specified, Piconics will communicate with the customer to establish any specific handling or control requirements. If customer property is found to be lost, damaged or otherwise unsuitable for use, the customer will be notified.
- e) In the event that contingency actions are required that affect a customer, Piconics will communicate with the customer to establish any relevant specific requirements to address the contingency.

8.2.2 Determining Product Requirements – Piconics determines the requirements for the products that it offers and ensures that applicable statutory and regulatory requirements, or other requirements considered necessary by Piconics have been defined and that any claims for the products that Piconics supplies can be met.

8.2.3 Review of Product Requirements – Piconics performs a review of requirements prior to commitment to supply products to a customer per **POP-03 (Contract Review Procedure)**. This is to ensure the ability to meet customer specified requirements including delivery and post-delivery activities, any requirements which are not stated but are required for specific or intended use, if known, any statutory or regulatory

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requirements applicable to the product, or any contract or order requirements that are different from what has previously been expressed. In the event that requirements are different from what was previously defined, these differences will be resolved with the customer prior to product shipment.

Piconics reviews and confirms customer requirements and where there is no documented statement of requirements, the requirements are confirmed verbally before acceptance, then followed-up in hard copy format. The results of the reviews and any new or revised product requirements are documented and retained.

8.2.4 Changes to Product Requirements – Relevant documented information is revised as a result of any changes (external or internal) to product requirements and these changes are communicated to the pertinent personnel.

8.3 Design (N/A)

8.3.1 Piconics has determined that design and development is not within its scope of operations, therefore all requirements of section 8.3 of the ISO 9001:2015 standard are not applicable to Piconics. Products are manufactured from customer provided designs and production drawings. Any drawings produced by Piconics, in addition to those supplied by the customer, are for verification and clarity only. They do not constitute design activity. (See sec 4.3 Scope of the QMS)

8.4 Control of Externally Provided Processes, Products and Services

8.4.1 General – Piconics ensures that the methods and responsibilities are defined for procuring externally provided products, processes or services to ensure they conform to requirements. This includes functions relative to the type and extent of control in the purchasing process, purchasing information and verification of purchased product per *POP-05 (Purchasing Procedure)*

Piconics has determined controls to be applied to suppliers when products or services from suppliers are incorporated into its products, when a process or part of a processes is supplied, or in the event that a product is provided directly to a customer by a supplier on the behalf of Piconics.

Piconics determines and applies criteria for evaluating, selecting, monitoring of performance, and re-evaluation of suppliers based on their ability to provide conforming product, process or service, and delivery requirements. In the event of declining performance, Piconics may re-evaluate and request corrective action or recommend the removal of the supplier from the approved vendor list.

Where Piconics chooses to outsource any process that may affect product quality, conformity to requirements is controlled through a pre-determined and communicated quality plan.

Records are retained regarding the evaluations of suppliers as well as any necessary actions resulting from the evaluation.

8.4.2 Type and Extent of Control - Piconics ensures that supplied processes, products or services do not negatively affect the ability to consistently provide product to its customers that conform to requirements. This is done by:

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- a) Ensuring that externally provided processes are within the control of the established quality management system.
- b) Defining the controls that are applied to the supplier and to the resulting output.
- c) Considering the potential impact of supplied product, process or services on the ability of Piconics to consistently meet customer, statutory and regulatory requirements as well as the effectiveness of the controls that are applied to suppliers.
- d) Determining any verification or other activities that are necessary to ensure that supplied products, processes or services meet requirements.

Inspection or other activities necessary for ensuring that purchased product conforms to requirements are established and implemented. In the event that Piconics, or its customer, proposes to perform verification activities at a suppliers premises, the intended verification arrangements and method of product release will be specified in the purchasing information. Verification by the customer does not absolve Piconics of the responsibility to provide conforming product.

8.4.3 Information for External Providers – Piconics ensures that purchasing information adequately describes the requirements of the product, process or service to be provided, prior to it being communicated to the supplier. This includes requirements, where appropriate, for:

- a) Processes, products or services to be provided.
- b) Any approval requirements for the product or service, methods, processes or equipment, or release approval of the product or service.
- c) Any qualification, training or competence requirements of supplier personnel.
- d) Any requirements for supplier interactions with Piconics.
- e) Any requirements for control and monitoring of the supplier performance to be applied by Piconics.
- f) Any requirements for verification or validation activities that Piconics or its customer intends to perform at a suppliers premises.

8.5 Production Provision

8.5.1 Control of Production – Piconics carries out production under controlled conditions according to *POP-09 (Process Control Procedure)*. These include, as applicable:

- a) The availability of documented information defining the characteristics of the products being produced or the activities being performed and the expected results.
- b) The availability and use of suitable monitoring and measurement resources.
- c) Implementing monitoring and measuring activities at various appropriate stages to verify the control of processes and their outputs, as well as product acceptance criteria have been met.
- d) The use of suitable infrastructure and environment for the operation of the processes.
- e) Appointing competent personnel for the operation of the processes, including any required qualification, as applicable.
- f) Piconics does not have any process that cannot be verified by subsequent monitoring or measurement, therefore it has determined that 8.5.1.f in the Control of Production section of the ISO 9001:2015 is not applicable within the scope of the QMS. (See sec. 4.3 Scope of the QMS)
- g) Implementing actions to prevent human error

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h) Implementing release, delivery and post-delivery activities.

8.5.2 Identification and Traceability – Piconics identifies product by suitable means throughout the production processes to ensure conformity of the product. Product status is identified with respect to monitoring and measurement requirements throughout the production processes. Piconics controls the unique identification of the product and retains records necessary to ensure traceability, where traceability is a requirement. Product identification and traceability is maintained per *POP-07 (Product Identification and Traceability Procedure)*.

8.5.3 Property Belonging to Customers or External Providers – Piconics exercises care with property that belongs to the customer or an external provider while it is under our control or being used by our organization. Piconics identifies, verifies, secures, protects and safeguards customer or external provider’s property that has been provided for use or incorporation into their products. This also includes 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 of what has occurred are maintained.

8.5.4 Preservation – Piconics preserves the production outputs to ensure that product conforms to requirements per *POP-15 (Handling, Storage, Packaging, Preservation and Delivery)*. This is the responsibility of the manufacturing operations and includes identification, handling, contamination control, packaging, storage, and protection. Preservation of product also applies to the constituent parts of a product. Piconics maintains documented procedures for the control of limited shelf-life materials.

8.5.5 Post-Delivery Activities – Piconics is a manufacturing facility and does not provide post-delivery services beyond the following:

- a) Warranty replacement of any non-conforming parts that have been delivered to a customer, in accordance with the established terms and conditions.
- b) Customer communications and feedback regarding delivered product.

8.5.6 Control of Changes – Piconics reviews and controls changes to the Quality Management System and changes for the production provision, in order to ensure conformance to requirements. Documentation describing the results of the review of changes, personnel authorizing the change, and any necessary actions resulting from the review are retained.

8.6 Release of Product – Piconics monitors and measures product characteristics to verify that all product requirements have been met in accordance with *POP-10 Inspection and Testing/Product Release Procedure*. This is conducted at appropriate stages of the production process in accordance with planned arrangements and documented procedures.

Evidence of conformance to acceptance criteria is maintained and product cannot be released to the customer until all planned phases of manufacturing, tests and inspections have been satisfactorily completed, unless otherwise approved by the customer or other relevant authority.

Records are retained to show evidence that the product conforms to acceptance criteria and is traceable to the person(s) authorizing the release.

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8.7 Control of Nonconforming Outputs – Piconics ensures that product that does not conform to requirements is identified and controlled to prevent unintended use. The controls, related responsibilities and authorities are further defined in *POP-13 (Control of Nonconforming Products Procedure)*. Action is taken, as appropriate, based on the nature of the nonconformance, and its effect on the conformity of product. This includes where a nonconformance is detected after delivery of products to a customer.

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

- a) Correction to eliminate the nonconformity
- b) Segregation, containment, return, or suspension of production
- c) Providing notification of the nonconformity to the customer
- d) Obtaining authorization for acceptance by waiver or concession by customer or other relevant authority.

When nonconforming product is corrected, it is subject to re-evaluation to verify conformance to the requirements.

Records of the nature of the nonconformity, the subsequent actions taken, including concessions obtained and the identification of the person deciding the action taken in respect to the nonconformance are retained.

Reference Documentation (Section 8)

- POP-03 (Contract Review Procedure)*
- POP-05 (Purchasing Procedure)*
- POP-07 (Product Identification and Traceability Procedure)*
- POP-09 (Process Control Procedure)*
- POP-10 (Inspection and Testing/Product Release Procedure)*
- POP-13 (Control of Nonconforming Product Procedure)*
- POP-15 (Handling, Storage, Packaging, Preservation and Delivery)*

9.0 PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General – In order to evaluate operational performance, Piconics determines:

- a) What needs to be monitored and measured
- b) Appropriate methods for monitoring, measurement, analysis and evaluation needed to ensure valid results
- c) When monitoring and measurement is to be performed
- d) When the results of monitoring and measurement is analyzed and evaluated.

General planning and implementation of monitoring, measurement, analysis and evaluation processes are the responsibility of all employees at Piconics. The primary responsibilities lie with Manufacturing Operations and Quality Assurance. These processes are performed to demonstrate product conformity, ensure conformity of the QMS and to continually improve the QMS through the application of planned methods. 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 and Corrective Action.

Piconics has suitable methods for monitoring and, where applicable, the measurement of the QMS processes. These methods demonstrate the ability of the

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process to achieve planned results and allow for evaluation of the performance and effectiveness of the QMS. When planned results are not achieved, corrective actions are taken, as appropriate.

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
- h) Yield 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 goals. Records of the evaluations are maintained as part of the management review records.

9.1.2 Customer Satisfaction – The Piconics management team is responsible for determining customer satisfaction through analysis of information relating to customer perception of the degree to which their needs and expectations have been fulfilled. Piconics determines customer satisfaction by obtaining written and/or verbal customer and end-use information from internal and external sources.

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

- a) Feedback on all aspects of the 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 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 Quality Performance Survey
- e) Customer and/or media reports and sector studies.

Customer satisfaction, returns and complaints are discussed and evaluated during management system review meetings.

9.1.3 Analysis and Evaluation – Piconics analyzes and evaluates appropriate data and information arising from monitoring and measurement, and other relevant sources. The results of the analysis are used to provide information and evaluate:

- a) Product Conformity
- b) The degree of customer satisfaction
- c) The performance and effectiveness of the QMS
- d) If planning has been implemented effectively

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- e) The effectiveness of actions taken to address risk and opportunities
- f) The performance of external providers (suppliers)
- g) The need for improvements to the QMS

9.2 Internal Audit – Internal audits are performed by trained auditors at pre-determined intervals to determine if the documented QMS system is effectively implemented, maintained and conforms to the specific requirements of the ISO 9001:2015 standard, other procedures defined in this manual as well as any requirements determined by Piconics for its quality management system.

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

Management ensures that timely corrective actions are taken to eliminate any detected audit nonconformities. Follow-up activities include the verification of any actions taken and reporting the verification results. Records of audits and their results are maintained.

9.3 Management Review

9.3.1 General – Top management reviews the Quality Management System at least once per calendar year to ensure its continual suitability, adequacy, and effectiveness as well as the alignment with the strategic direction of Piconics. The review includes assessing opportunities for improvement and the need for changes to the QMS, including quality policy and quality objectives. The Quality System Management Review is performed in accordance with *POP-01 (Management Responsibility Procedure)*

9.3.2 Management Review Inputs – Management review is performed, taking into consideration current performance and improvement options and analysis of data related to:

- a) The status of actions from previous management reviews
- b) Any changes in internal and external issues that are relevant to the QMS
- c) Information on the performance and effectiveness of the QMS including customer satisfaction and feedback from relevant interested parties, the extent to which quality objectives have been met, process performance and product conformity, nonconformities and corrective actions, monitoring and measurement results, audit results, and the performance of external providers (suppliers).
- d) Adequacy of resources
- e) Effectiveness of actions taken to address risk and opportunities
- f) Opportunities for improvement.

9.3.3 Management Review Outputs – The output of the management review is the meeting minutes, which consist of a summary report that includes decisions and actions necessary for QMS improvement. This record is maintained as evidence of the results of the reviews. Outputs from the QMS review include, but are not limited to decisions and actions related to:

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- a) Opportunities for improvement to the QMS, product or processes of Piconics.
- b) Any need for changes to the QMS
- c) Resource needs and allocations, including additional work training for employees.

Reference Documentation (Section 9)

POP-01 (Management Responsibility Procedure)

POP-17 (Internal Quality Audit Procedure)

10.0 IMPROVEMENT

10.1 General – Piconics identifies opportunities for improvement and implements actions necessary meet or exceed customer requirements and enhance customer satisfaction. This includes opportunities for:

- a) Making product improvements 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 QMS.

10.2 Nonconformity and Corrective Action – When a nonconformity occurs, including any that are due to complaints, Piconics reacts to the nonconformity in accordance with ***POP-13 (Control of Nonconforming Material Procedure)***. Nonconforming products are managed by taking action to control the material and correct it, as applicable, as well as taking appropriate action to deal with the effects or consequences of the nonconformity.

Nonconformities are reviewed and analyzed in order to determine the causes and to determine if similar nonconformities exist or could potentially occur. Action is taken, as appropriate, to eliminate the cause of the nonconformity and to prevent it from recurring or occurring elsewhere.

When applicable, Piconics implements action in accordance with ***POP-14 (Corrective and Preventive Action Procedure)***. The action is appropriate to the effects of the nonconformity encountered. The effectiveness of any corrective action taken is reviewed and, if necessary any risks or opportunities that have been determined during the planning stages are updated. When necessary, changes to the QMS are made as a result of corrective actions.

Piconics retains documented information and records describing the nature of nonconformities and subsequent actions that have been taken as well as the results of any corrective actions.

10.3 Continual Improvement – Piconics continually strives to improve the suitability, adequacy and effectiveness of the QMS. This is done by considering the results of analysis and evaluation, as well as management review outputs, to determine if there are needs or opportunities for improvement that can be addressed.

Reference Documentation (Section 10)

POP-13 (Control of Nonconforming Material Procedure)

POP-14 (Corrective and Preventive Action Procedure)