

**PCB Piezotronics, Inc.**

3425 Walden Avenue  
Depew, NY 14043-2495

# **Quality Management System Policy Manual**

**Documentation  
Level: I**

***“Total Customer Satisfaction”***

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- Quality Assurance Manager
- Quality Management System Representative
- Calibration Laboratory Services Manager
- Lead Assessor

**Organization:**

PCB Piezotronics, Inc.  
3425 Walden Avenue  
Depew, New York 14043-2495  
USA

PCB Piezotronics of North Carolina, Inc.  
10869 Highway 903  
Halifax, North Carolina 27839  
USA

**Industry Codes:** S.I.C: 3679      N.A.I.C.S: 334419**President:** David T. Hore

**Quality Management System  
Policy Manual  
Corporate Profile**

PCB Piezotronics Inc. was founded in 1967 as a manufacturer of piezoelectric quartz sensors, accelerometers, and associated electronics for the measurement of dynamic pressure, force, and vibration. The unique expertise of the company was the incorporation of microelectronic signal conditioning circuitry within these sensors to make them easier to use and more environmentally compatible. These ICP® sensors gained wide popularity and became the foundation for the company's success.

Subsequent growth and steady investment in facilities, machinery, and equipment permitted a constant broadening of the product offering. Measurement capabilities expanded with the addition of piezoceramic, tourmaline, capacitive, piezoresistive, and strain gage sensing technologies. Ensuing products include industrial accelerometers, DC accelerometers, load cells, torque sensors, microphones, pressure transmitters, and calibration equipment.

PCB's World Headquarters and Technology Center is located on a six-acre campus outside of Buffalo, NY. The campus includes PCB's 100,000 sq. ft. (9290 sq. m.) main building and a separate 50,000 sq. ft. (4645 sq. m.) building housing the Precision Machining Center. Other facilities include Halifax, NC producing Piezoelectric, ICP®, piezoresistive, acoustic, force, shock & vibration sensors; PCB Load & Torque located in Farmington Hills, MI producing precision load cells, wheel force transducers, torque transducers, telemetry systems, and fastener torque-tension test systems; Larson Davis located in Provo, UT, producing precision microphones, sound level meters, noise dosimeters, audiometric calibration systems; Accumetrics located in Latham, NY producing digital rotor telemetry (the wireless acquisition of measurement signals from the rotors of rotating machines); and The Modal Shop located in Cincinnati, OH, offering a complete line of automated calibration systems and recalibration services to support dynamic vibration, shock, pressure, and force sensors.

PCB Piezotronics, Inc. is a wholly-owned subsidiary of MTS System Corporation.

**Business Classification And Statements Of Compliance**

PCB Piezotronics, Inc. complies and/or can be identified according to the following characteristics:

- 1) is a large business, which currently employs approximately 770 people, and when combined with other PCB Group affiliated companies, employs approximately 900 people.
- 2) is an equal opportunity employer that posts EEO notices in our non-segregated facilities and annually files EEO-1 reports
- 3) has developed an affirmative action program.
- 4) complies with all requirements associated with Clean Air and Water Certification.
- 5) has never been on the EPA List of Violating Facilities.
- 6) meets all local, State and Federal environmental laws and regulations per facility locations.
- 7) is entirely US owned and operated.
- 8) operates a drug-free workplace.
- 9) is not located in a Labor Surplus Area.
- 10) has not used federally appropriated funds for the purpose of influencing any government employee.
- 11) has not provided, attempted to provide, offered, solicited or accepted any kickback.
- 12) is not currently and has never been debarred, suspended, proposed for debarment or declared ineligible for award of public contracts or grants by any federal agency.
- 13) has not been convicted of or had a judgment rendered against it or been indicted for commission of fraud or criminal offense connected with a public contract or violation of federal or state antitrust statutes or similar criminal offenses.
- 14) has never defaulted on any public contract, grant or loan.
- 15) prices its products independently without agreement with any other offeror or competitor of a public solicitation.
- 16) does not use in any process or manufacture any products, which contain ozone-depleting substances as identified by state requirements per facility locations.
- 17) is an open shop with no union affiliations.
- 18) complies with all applicable OSHA regulations per facility locations.

**Internal Structure:**

PCB has implemented integrated facilities, which includes most steps from initial sale to product shipment. This continuous reinvestment into facilities and equipment provides a high degree of self-sufficiency and offers flexible manufacturing, fast prototyping and customization services to meet developmental needs. Following is a detailed description of PCB's equipment and facilities.

**Sales and Marketing:** The sales and marketing staff has over 90 full time employees dedicated to sales and customer service: approximately 60 in Domestic Sales, 25 in International Sales, 10 for Marketing and additional support personnel. Their efforts are supported by an extensive network of direct sales offices, which can be found in the USA as well as in Germany, France, Italy, United Kingdom, Japan, China and Sweden. This combined sales force serves as an efficient vehicle for supporting existing products as well as for bringing new technology to the market. Currently, PCB Piezotronics realizes approximately 55% of its annual sales volume in the USA.

**Engineering:** The engineering staff consists of over 90 full-time engineers and 15 support personnel. Approximately 20 of the engineers and 5 support personnel are dedicated full-time to R&D of new technologies, while the remaining personnel work on designing custom application solutions or manufacturing continuous improvement. All personnel rely heavily on tools such as Design for Six Sigma (DFSS), Design or Process Failure Mode and Effects Analysis (D/P-FMEA), Design of Experiments (DOE), Finite Element Analysis (FEA) and Circuit Simulations, to rapidly evaluate and diagnose complex electrical, mechanical and electromechanical designs. In addition, CAD/CAM tools allow accurate documentation and quick prototyping. Automated test equipment, environmental chambers, analyzers, digital oscilloscopes, shakers, shock tubes and other similar test equipment allow engineers to fully evaluate and test devices under a range of operating conditions.

**Manufacturing:** Utilizing approximately 2/3 of individual facilities and typically operating at 50% capacity, exceptional capability exists in transducer and signal conditioner manufacturing. Three production shifts, totaling approximately 400 personnel, utilize highly sophisticated, computer controlled, automated machining equipment, including CNC mills, dual-spindle lathes, swiss-style screw machines, punch presses, wire EDM's, and lapping wheels. In addition to the primary production operations, ten tool room lathes are dedicated to small quantity runs for prototypes and customer specials. Approximately 150,000 precision-machined parts are produced each month by our Machining Department. Automatic wirebonders, pick-and-place machines and laminar flow clean benches are used for fabricating the miniaturized electronic circuits, which are incorporated into most of the sensors. Other manufacturing capabilities include: laser welding, laser marking, grinding, sandblasting, wave soldering, hermetic connector and crystal manufacturing. Final products are tested under a variety of conditions using automated calibration workstations accredited to ISO17025, which utilize NIST and/or European PTB traceable standards.

**Administration / Support:** Approximately 50 personnel are utilized for various administrative and support functions, which include human resources, purchasing, accounting, information technology, legal, maintenance and shipping/receiving.

Each employee's job responsibilities and work instructions define the methods by which they support the customer's needs, their direct supervisor and/or Senior Leadership Team member supports each employee.

Senior Leadership Team, Directors and Managers report directly to the president David T. Hore.

### **Quality Management System Certification Information:**

PCB Piezotronics Inc. Headquarters facility located at 3425 Walden Avenue, Depew, New York:

The quality management system is certified to the International Quality Standards AS9100 and ISO9001 (See Appendix section of this Quality Policy Manual for all current facility certifications), with scope of certification defined as: *The design, manufacture, repair and recertification of sensors and signal conditioning electronics used for measurement of pressure, force, shock, or vibratory motion for commercial, military and aerospace applications. The manufacture of precision machined parts.*

These two standards provide a model for aerospace quality assurance in design, development, production, installation and servicing. Compliance with all applicable processes and procedures is mandatory for all personnel. PCB is accredited to ISO17025 by The American Association for Laboratory Accreditation (A2LA). Our Laser Welding process is certified by the National Aerospace and Defense Contractors Accreditation Program (NADCAP). Production Quality Assurance Notification for ATEX and IECEx certification schemes issued by DEKRA (identification number 0344) under ATEX114 and specification IEC80079-34. IECEx Quality Assessment Reporting process is conducted by CSA International.

In addition, the facility complies with ISO10012; ANSI-Z540.3, former MIL-STD-45662A; MIL-Q-9858 and MIL-I-45208. Is a commercial-grade supplier to the Nuclear Power industry in accordance with applicable requirements of 10CFR50 Appendix B and reporting requirements of 10CFR21, and has implemented system requirements providing customers with products compliant to Directive 2011/65/EU regarding restriction of hazardous substances (RoHS) and their disposal. Product Manufacturing Approval (PMA) realized will be in accordance with 14CFR21 and Authorized Repair Station requirements 14CFR145. All calibration standards used within the facility are traceable, at a minimum, to NIST and/or the European PTB Standards Organization.

The ISO-17025 portion of our quality management system provides calibrations performed using processes having a test uncertainty ratio (TUR) of four or more times greater than the unit calibrated, unless otherwise noted on the calibration certificate. Calibration at 4:1 TUR provides reasonable confidence that the instrument is within product specifications.

PCB Piezotronics Of North Carolina Inc. Facility located at 10869 Highway 903, Halifax, North Carolina:

The quality assurance system is certified to the International Quality Standards AS9100 and ISO9001 (See Appendix section of this Quality Policy Manual for all current facility certifications), with scope of certification defined as: *The manufacture of sensors and signal conditioning electronics used for measurement of force and vibratory motion.*

These two standards provide a model for quality assurance in design, development, production, installation and servicing. AS9100 Clauses 8.1, 8.2 and 8.3 are not applicable as the Depew, N.Y. location conducts these processes. Compliance with all applicable processes and procedures is mandatory for all personnel. The facility is accredited to ISO17025 by The American Association for Laboratory Accreditation (A2LA). Production Quality Assurance Notification for ATEX and IECEx certification schemes issued by DEKRA (identification number 0344) under Directive ATEX114 and specification IEC80079-34. IECEx Quality Assessment Reporting process is conducted by CSA International.

In addition, the facility complies with ISO-10012; ANSI-Z540.3, former MIL-STD-45662A; MIL-I-45208. Is a commercial-grade supplier to the Nuclear Power industry in accordance with applicable requirements of 10CFR50 Appendix B and reporting requirements of 10CFR21, and has implemented system requirements providing customers with products compliant to Directive 2011/65/EU regarding restriction of hazardous substances (RoHS) and their disposal. All calibration standards used within the facility are traceable, at a minimum, to NIST or the European PTB Standards Organization. Calibration at 4:1 TUR provides reasonable confidence that the instrument is within product specifications.

Larson Davis located in Provo, Utah, is certified to ISO9001, ISO17025 and ANSI-Z-540.3.

PCB Load & Torque located in Farmington Hills, Michigan, is certified to ISO9001, ISO17025 and ANSI-Z-540.3.

### **Financial Information:**

Fiscal year is beginning of October to end of September.

Federal Taxpayer Identification Number - Depew: 16-1503703

Federal Taxpayer Identification Number - Halifax: 20-2128287

Duns Number: 04-256-8774

### **General Information:**

Cage Code: 52681

Congressional District: 26

Internet Address: [www.pcb.com](http://www.pcb.com)

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**Quality System Manual    Level: I    Revision: K    Revision Date: 07/16/2017**

**Introduction:**

PCB Piezotronics, Inc. has adopted the AS9100 standard for our quality management system in the effort to improve our overall performance and provide a basis for the sustainable development of initiatives. This process approach incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking, that enables our organization to plan our processes; and their interactions, to ensure our processes are adequately resourced and managed, and that opportunities for improvement are determined and acted upon.

Risk-based thinking enables our organization to determine factors that could cause our processes and quality management system to deviate from planned results, and to implement preventive controls to minimize negative effects and make maximum use of opportunities as they arise. Understanding and managing the interrelated processes of our quality management system contributes to our organizations effectiveness and efficiency in achieving the intended results for our products and services.

**Documentation Structure of the Quality Management System:**

The quality management system of PCB Piezotronics, Inc. is documented in the following manner. Access to this documentation is made available to all employees, at all facilities involved in operations essential to the effective functioning of the system, through the TCS electronic documentation viewing system.

1. **Level I:** The quality system manual (QSM), sometimes referred to as the quality policy manual; is considered the top-level document of the PCB Piezotronics, Inc. quality management system. The manual defines our quality policy and objectives; the senior leadership team's commitment to quality and the identification of our processes. The manual is revised accordingly to keep current with our processes as they are continually improved upon. Policy manual revision is maintained by an electronic document control system. Printed copies are considered uncontrolled. A cross-referencing system identifies the level II supporting procedures that are linked to the relevant processes identified in this manual. The Headquarters Quality Assurance Manager controls and maintains this document.
2. **Level II:** The quality assurance manual (QAM) level II procedures define the primary responsibilities within each of the documented processes. This company wide documentation supports and links the policies established in this policy manual to the level III documentation. The Headquarters Quality Assurance Manager controls and maintains this document.
3. **Level III:** The departmental level III procedure manuals support the level II quality assurance procedures. This is required for consistently performing the execution of specific tasks on a routine bases. A Level III document contains forms with instructions, quality system documented information requirements and may be in the form of text document, drawing, shop router (traveler) or other means of ensuring consistent communication of information necessary for performing procedural tasks. Process owners and delegated document administrators are responsible for creating, coordinating, maintaining and improving these documents. Level of detail is commensurate with the complexity of the task.



### **Quality Policy:**

The president of PCB has selected the following statement to convey the PCB Quality Policy: “It is the policy of PCB Piezotronics, Inc. to do whatever is necessary to realize our vision of TOTAL CUSTOMER SATISFACTION. We have selected this term in the effort to communicate the policy to our customers. Our quality management system policy deployment metrics ensure the goal and vision of TOTAL CUSTOMER SATISFACTION is consistently achieved.”

The senior leadership team is dedicated and committed to the continual improvement of business and quality objectives monitored through policy deployment. The minimum policy deployment quality objectives are:

- Quality at the Customer (ppm)
- On-Time Delivery (%)
- Scrap As Percent Of Sales (%)
- Shipments As % Of Goal

The senior leadership team conducts management review of the quality system on a periodic basis. These reviews include, at a minimum, policy deployment quality objectives (listed above), the results of internal and external audits, customer complaints and their feedback, process and product conformity, recommendations for improvements, corrective and preventive actions, matters arising from previous reviews, review of explosive atmospheres product, aerospace processes and product programs, review of calibration service programs, and status of employee training. Supporting records for these criteria are incorporated into the policy deployment status spreadsheets. We trust that these items satisfy both our internal needs and the expectations of our customers.

In an effort to reach our goal of TOTAL CUSTOMER SATISFACTION, if at any time there is a conflict between the PCB quality management system and customer, statutory or regulatory requirements, the customer, statutory or regulatory requirements will take precedence.

All PCB personnel are required to understand our goal of TOTAL CUSTOMER SATISFACTION, to familiarize themselves with the required quality management system documentation, and to follow the policies and procedures applicable to their job description responsibilities.

In addition to this general PCB quality policy for both manufacturing and service activities, the senior leadership team is committed to good professional practice and quality of calibration service for our clients. To this end, PCB’s calibration activities shall maintain accreditation with ISO17025, ISO10012 and ANSI-Z540.3.

### **Mission Statement:**

The Management Team has published the following mission statement. The quality policy, policy deployment objectives and this statement combine to form the basis for our company.

***“Helping You Make Better Measurements With Quality, Innovative Instruments.”***

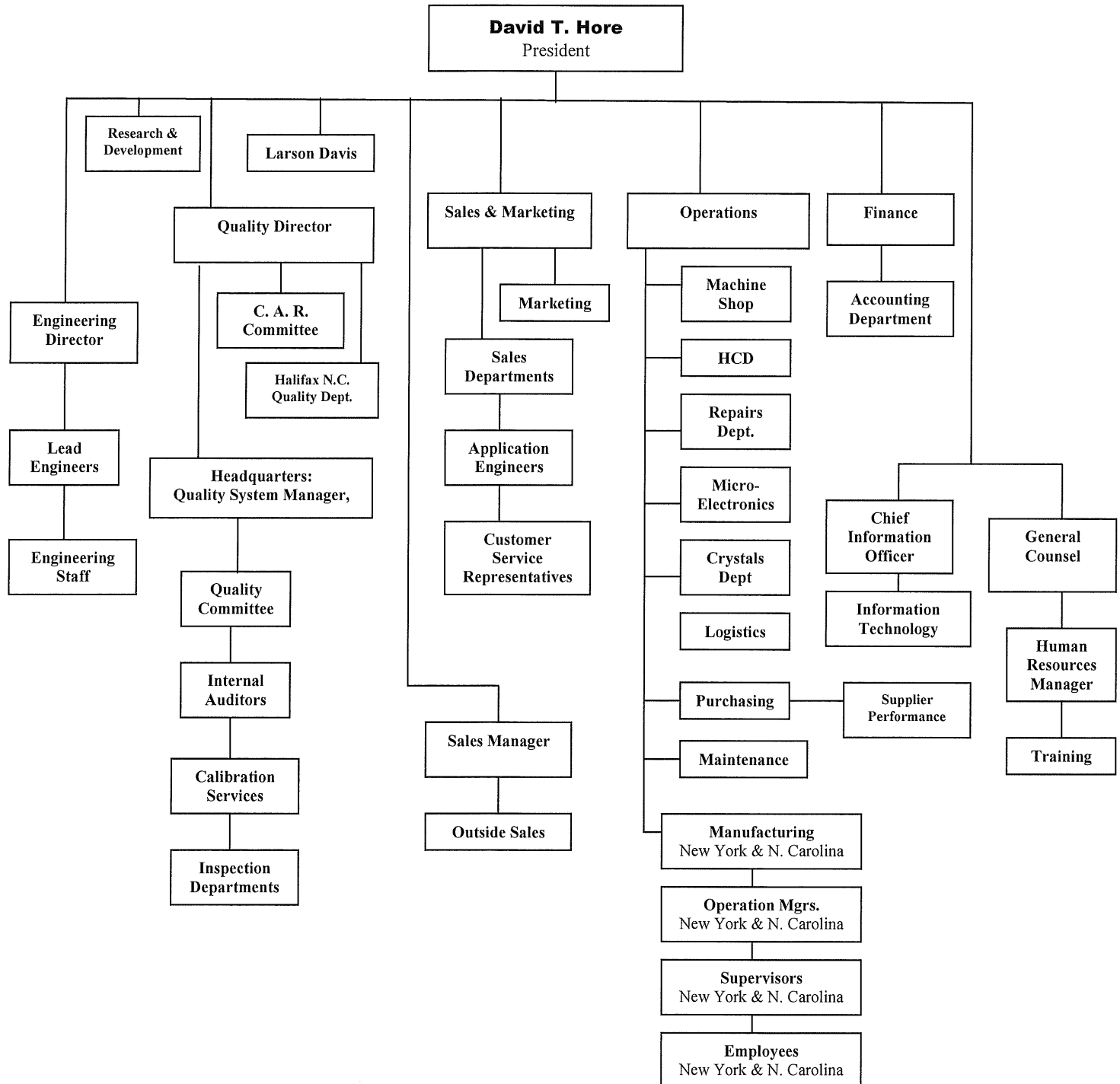
### **Organization Structure:**

Key components of the PCB organization are defined as follows:

- **President.**
- **Senior Leadership Team:** Directors, Vice-Presidents, Managers and General Counsel directly reporting to President.
- **Manufacturing Centers:** Pressure, Force, Vibration, MEMS Products, Microphones, Electronic products and custom products.
- **Market Sectors:** Test and Measurement, Industrial and Systems.
- **Internal Suppliers:** Microelectronics, Machine Shop, Hermetic Connectors, Crystal Manufacturing, Repairs Department, Microfabrication, Welding, and Etching.
- **Functional Support Groups:** Drafting, Logistics, Marketing, Maintenance, Quality Assurance, Purchasing, Planning, Inventory Control, Information Technology, Human Resources, R & D, Finance, and Legal.
- **Corrective Action Committee, Quality Committee, Training Committee, Internal Auditors, Material Review Board, Document Administrators, Special Process Approval Authorities.**

**PCB Piezotronics, Inc.**

**Organization Structure:**



**Identification Of Level II Process Procedures**

**ISO9001**

**AS9100**

**Clause**

**Procedure Title**

4 - 4.4.2	Context Of The Organization
5 – 5.3	Leadership
6 – 6.3	Planning
7 – 7.1.4	Support
7.1.5	Monitoring And Measuring Resources
7.1.6	Organizational Knowledge
7.2 – 7.4	Competence, Awareness and Communication
7.5	Documented Information
8 – 8.1	Operations
8.2	Requirements For Products And Services
8.3	Design And Development Of Products And Services
8.4	Control Of Externally Provided Processes, Products And Services
8.5 – 8.6	Production And Service Provision
8.7	Control Of Nonconforming Outputs
9 – 9.1	Performance Evaluation
9.2	Internal Audit
9.3	Management Review
10	Improvement

## **4. Context Of The Organization**

### **4.1 Understanding the Organization and Its Context**

PCB Piezotronics, Inc. has determined external and internal issues relevant to our purpose and strategic direction, and that affect our ability to achieve intended results of our quality management system. PCB monitors and reviews external issues such as: legal, technological, cultural, and economic as well as the internal performance of our organization.

### **4.2 Understanding the Needs and Expectations of Interested Parties**

PCB Piezotronics, Inc. consistently provides products and services that meet or exceed customer and applicable statutory and regulatory requirements. Potential effects upon this process by relevant interested parties and their corresponding requirements have been determined. Information about these interested parties and their relevant requirements are monitored and reviewed.

### **4.3 Determining the Scope of the Quality Management System**

PCB Piezotronics, Inc. has determined the boundaries and applicability of the quality management system to establish our scope. This scope is based upon external and internal issues, requirements from relevant interested parties, and products and services we provide. All applicable requirements of AS9100 are applied in accordance with the scope of the quality management system. The scope is documented, maintained and made available to interested parties. The scope identifies the types of products and services covered, and provides justification for any requirement determined as not applicable to our quality management system. Any requirement that does not affect our ability to ensure conformity of our products and services, or enhance customer satisfaction, may be deemed as not applicable.

### **4.4 Quality Management System and Its Processes**

**4.4.1** PCB Piezotronics, Inc. has established, implemented, maintains and continually improves our quality management system including processes needed and their interactions required by AS9100 and, where applicable, ensures compliance of product with the type described in the EC type-examination certificates. Our quality management system also addresses customer and applicable statutory and regulatory requirements.

PCB Piezotronics, Inc. has determined the processes needed for the quality management system and their application throughout the organization. Required process inputs, expected outputs, sequence and interaction have been determined. Process performance indicators are monitored to ensure effective operation, control and availability of resources. Assigned responsibilities, authorities and associated risks and opportunities have been determined for our processes. Processes are evaluated to ensure intended results are achieved with any needed changes implemented to improve the quality management system.

**4.4.2** PCB Piezotronics, Inc. maintains the necessary documented information to support the operation of our processes. This retained information provides confidence that our processes are achieving planned results. Documented information includes: general description of interested parties, scope including boundaries and applicability of the quality management system, description of processes and their application, process sequence and interaction, and assignment of responsibilities and authorities for these processes.

## **5. Leadership**

### **5.1 Leadership and Commitment**

**5.1.1** The Senior Leadership Team (SLT) continually demonstrates their leadership and commitment regarding our quality management system. The SLT is accountable for the effectiveness of the quality management system, and ensures that the established quality policy and objectives are appropriate for our corporate context and strategic direction. Our quality management system is integrated with our business processes through use of the process approach and risk-based thinking. The SLT demonstrates the importance of the quality system management by ensuring required resources are made available, and communicating that conformance to requirements is expected to achieve intended process results. All employees are supported and directed to contribute to the effectiveness of the quality management system thus promoting company-wide improvement. The SLT demonstrates support for all relevant management positions in accordance to their area of responsibility.

### 5.1.2 Customer Focus

The Senior Leadership Team (SLT) demonstrates leadership and commitment regarding customer focus by ensuring that customer and applicable statutory and regulatory requirements are determined, understood and consistently met. The risks and opportunities that can effect conformity of our products and services have been determined and action taken to enhance and maintain customer satisfaction. Product and service conformity and on-time delivery performance are monitored with appropriate action taken in the event planned results are not achieved.

## 5.2 Policy

### 5.2.1 Establishing the Quality Policy

The Senior Leadership Team (SLT) has defined a Quality Policy that is appropriate to the purpose and context of our organization, and that also supports our strategic direction. The Quality Policy is the framework for creating our organizational Quality Objectives with each area satisfying goals relevant to the support of these objectives, including the commitment to continuous improvement.

### 5.2.2 Communicating The Quality Policy

The Quality Policy is documented, available and maintained within our quality management system. The Quality Policy is reviewed for continuing suitability during management review and all department managers are responsible for communicating how the Quality Policy applies to each employee's specific function. The Quality Policy may be made available to appropriate interested parties upon request or at our website: [www.pcb.com](http://www.pcb.com).

## 5.3 Organizational Roles, Responsibilities, And Authorities

The Senior Leadership Team (SLT) has ensured that the defined and assigned responsibilities and authorities for our relevant organizational roles is effectively communicated and understood by our employees. Organization charts indicate interrelations of the corporate functions and this quality policy manual shows management responsibilities and related procedures identify corresponding authorities within the quality management system.

The SLT has assigned responsibility and authority for ensuring our quality management system conforms to the requirements of the AS9100 Standard (as well as other interested party required standards), ensuring that quality system processes deliver their intended outputs, reporting on process performance and identifying opportunities for improvement, promoting total customer satisfaction throughout our organization and ensuring the integrity of our quality management system is maintained when changes are planned and implemented.

The SLT has appointed a specific management employee of our organization as the management representative having the responsibility and authority for oversight of the quality management system. The management representative has the organizational freedom and unrestricted access to the President and SLT for resolving quality system issues.

## 6. Planning

### 6.1 Actions To Address Risks And Opportunities

**6.1.1** Planning of our quality management system has considered issues regarding the context of our organization and also the requirements of interested parties to determine and address identified risks or opportunities. The planning of our quality management system provides assurance that our quality management system can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects and achieve improvement.

**6.1.2** The Senior Leadership Team (SLT) has planned the required actions to address the identified risks and opportunities of our quality management system. These actions have been integrated and implemented into our quality system processes, are proportionate to the potential impact on product conformity, and are evaluated for effectiveness.

### 6.2 Quality Objectives And Planning To Achieve Them

**6.2.1** The Senior Leadership Team (SLT) has established quality objectives at relevant functions, levels, and processes required by the quality management system. Our quality objectives are consistent with our quality policy, are measurable, account for applicable requirements, are relevant to the conformity of our products and services, enhance Total Customer Satisfaction, and are appropriately monitored, communicated and updated as required. Quality objectives and supporting information are documented and maintained.

**6.2.2** When planning how to achieve our quality objectives, the Senior Leadership Team (SLT) has determined what will be done, what resources will be required, identified the responsible employees, determined expected completion time and how results will be evaluated.

### **6.3 Planning Of Changes**

When changes to our quality management system are determined to be required, these changes are conducted in a planned manner. When planning such changes the Senior Leadership Team (SLT) considers the purpose and potential consequences of the change, the integrity of the quality management system, availability of resources, and the allocation or reallocation of associated responsibilities and authorities.

## **7. Support**

### **7.1 Resources**

**7.1.1** The Senior Leadership Team (SLT) has determined and provided the necessary resources needed for establishing, implementing, maintaining and continually improving our quality management system. This planning has considered the capabilities of, and constraints on, existing internal resources and what may need to be obtained externally.

**7.1.2 People** - The Senior Leadership Team (SLT) has determined and provided the employees necessary to effectively implement and maintain our quality management system, and for the operation and control of our processes.

**7.1.3 Infrastructure** - The Senior Leadership Team (SLT) has determined, provided, and maintains the infrastructure necessary for the operation of our processes and to achieve conformity of our products and services. This infrastructure includes buildings, utilities, equipment, hardware, software, transportation resources and information and communication technologies.

**7.1.4 Environment For The Operation Of Processes** - The Senior Leadership Team (SLT) has determined, provided, and maintains the environment necessary for the operation of our processes and conformity of our products and services. A suitable work environment for our product and service considers human and physical factors, ergonomics, workplace location, hygiene, cleanliness, temperature, humidity, lighting, protection from electrostatic discharge, stress-reducing work methods and workplace safety.

### **7.1.5 Monitoring And Measuring Resources**

**7.1.5.1** The Senior Leadership Team (SLT) has determined and provided the resources required to ensure that the monitoring or measuring of our products and services to requirements are reliably validated. These resources are suitable for the type of activity being undertaken, are maintained to ensure continuing fitness for use and have appropriate documented information retained as evidence.

**7.1.5.2 Measurement Traceability** is considered essential for providing confidence in measurement result validity. Measurement equipment is calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. In the event no such standards exist, the calibration method and subsequent verification documented information is retained. All measurement resources are identified providing status, safeguarded from adjustment, damage, or deterioration that may invalidate calibration status and associated measurement results.

PCB has established, implemented and maintains a recall process for monitoring and measuring equipment requiring calibration or verification. A register of monitoring and measuring equipment is maintained and includes equipment type, unique identification, location, calibration or verification method, frequency and acceptance criteria. This equipment may include test hardware, test software, automated test equipment, plotters used for verification data, and personally or customer supplied equipment used to provide evidence of product and service conformity. Suitable environmental conditions are defined for calibration or verification of our monitoring and measuring equipment. In the event equipment is found to be unfit for its intended purpose, previous measurement results are reviewed and appropriate actions taken as necessary.

### **7.1.6 Organizational Knowledge**

PCB has determined the internal and external knowledge necessary for the operation of our processes and to achieve product and service conformity. This knowledge is maintained and available to the extent necessary to

support our processes. When addressing the changing needs and trends of our industry, PCB considers current knowledge and determines how to acquire or access any necessary additional knowledge or required updates in the effort to achieve our organizational goals.

## **7.2 Competence**

The Senior Leadership Team (SLT) has determined the necessary competence of person(s) doing work under our control that may affect performance and effectiveness of our quality management system. The SLT ensures person(s) are competent on the basis of appropriate education, training or experience, and takes action, as applicable, to acquire the necessary competence and evaluate the effectiveness of the actions taken. Appropriate documented information is retained as evidence of periodic review of necessary competence.

## **7.3 Awareness**

The Senior Leadership Team (SLT) ensures that persons doing work under our control that may directly affect our products and services are aware of: the quality policy, relevant quality objectives, their contribution to the effectiveness and improved performance of our quality management system, the implications for not conforming to our quality system requirements, the current relevant quality system documented information and any proposed changes, their contribution to our product and service conformity, their contribution to product safety and the importance of ethical behavior.

## **7.4 Communication**

The Senior Leadership Team (SLT) has determined the internal and external communications and corresponding feedback relevant to our quality management system including what is communicated, when and with whom, how, and who is responsible for the communication.

## **7.5 Documented Information**

PCB's quality management system includes documented information required by the AS9100 standard and also determined as being necessary for the effectiveness of our quality management system.

### **7.5.2 Creating And Updating**

When creating and updating our documented information, PCB has ensured appropriate identification, description, format and review and approval for suitability and adequacy. Authorized persons and approval methods are identified for the various types of our documented information.

### **7.5.3 Control Of Documented Information**

**7.5.3.1** Documented information required by our quality management system and by the AS9100 standard is controlled and adequately protected to ensure availability and suitability at point of use.

**7.5.3.2** Control of our documented information addresses distribution, access, retrieval, use, storage, preservation, legibility preservation, change control, retention, disposition, and the prevention of unintended use of retained obsolete documented information. Documented information of external origin deemed necessary for the planning and operation of our quality management system is identified and controlled. Documented information retained as evidence of conformity is protected from unintended alteration. Protection processes are defined for our electronically managed documented information.

## **8 Operation**

### **8.1 Operational Planning And Control**

PCB plans, implements and controls quality system processes needed to meet the requirements for the provision of products and services, and implements the actions determined during the planning of these processes by: determining the requirements for the product or service, establishing criteria for processes and product or service acceptance, providing resources to achieve product or service conformity and to meet their on-time delivery, implementing process controls in accordance with the established criteria, determining, maintaining and retaining documented information to the extent necessary for ensuring processes have been carried out as planned and to demonstrate product or service conformity to requirements, determining the process, production process and controls needed to manage identified critical or key characteristics, engaging representatives of affected planning and control functions, providing the process and resources supporting use and maintenance of our product or

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service, determining products and services to be obtained from external providers, and establish controls required to prevent the delivery of a nonconforming product or service to our customer.

PCB has planned and manages product or service provision (project management) in a structured and controlled manner appropriate to our organizational, product, service and the customer's requirements. This includes scheduled events conducted in a planned sequence to meet requirements at acceptable risk and within resource and schedule constraints. The output of this planning process is suitable for our operation with the control of planned changes, and the review of consequences of unintended changes, allow mitigating actions to be taken as deemed necessary. PCB ensures that outsourced processes are controlled.

PCB has established, implemented and maintains processes to plan and control the temporary or permanent transfer of work and to ensure the continuing conformity of the work to requirements. These processes ensure that work transfer impacts and risks are managed.

### 8.1.1 Operational Risk Management

PCB has planned, implemented, and controls processes for managing operational risks to the achievement of applicable requirements including those appropriate to our organization, products and services. Operational risk management identifies the assignment of responsibility, risk assessment criteria, identification, assessment, and communication of risks throughout operations, identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and the acceptance of risks remaining after implementation of mitigating actions.

### 8.1.2 Configuration Management

PCB has planned, implemented, and controls a process for configuration management appropriate to our organization, products and services ensuring identification and control of physical and functional attributes throughout the product lifecycle. This process controls product identity and traceability to requirements including implementation of identified changes, and ensures that the documented information is consistent with the actual attributes of the product or service.

### 8.1.3 Product Safety

PCB has planned, implemented, and controls an appropriate process required to ensure product safety during the entire product life cycle. Product safety information such as installation instructions and hazardous location markings enhance this process.

### 8.1.4 Prevention Of Counterfeit Parts

PCB has planned, implemented, and controls processes appropriate for our organization and product; for the prevention of counterfeit or suspect counterfeit part use or inclusion into products delivered to our customers. Our process considers verification or testing of supplied electronic component items relevant to our products and services.

## 8.2 Requirements For Products And Services

### 8.2.1 Customer Communication

PCB ensures effective communication with our customers by providing information related to our products and services, handling enquiries, contracts or orders, including changes, obtaining customer feedback and complaints relating to product or service, handling and controlling customer property, and when relevant the establishing of specific requirements for contingency actions.

### 8.2.2 Determining The Requirements For Products And Services

When determining the requirements for our products and services offered to our customers, PCB ensures that; the requirements for the product or service is defined including any applicable statutory and regulatory requirements or those considered necessary by our organization, claims offered for the product or service are met, special requirements for the product or service are determined and operational risks have been identified.

### 8.2.3 Review Of The Requirements For Product And Services

**8.2.3.1** PCB ensures that proper planning has provided the ability to meet the requirements for products and services to be offered to customers. Before committing to supply products and services to the customer, PCB conducts review including: requirements specified by the customer including delivery and post-delivery activities,



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requirements not stated by the customer but necessary for the proper use of specified or intended product when known, organizational requirements, statutory and regulatory requirements applicable to our products and services, and contract or order requirements differing from those previously expressed. Contract or order requirement review is coordinated with applicable functions of our organization, if review determines that some customer requirements cannot be met or only partially addressed, PCB will negotiate a mutually acceptable resolution with the customer. For contract or order requirements differing from those previously defined, as well as when the customer does not provide documented order requirements, product or service requirements are resolved and confirmed before order acceptance.

**8.2.3.2** Required documented information is retained for the results of order or contract review, and on any new requirements for the product or service.

### **8.2.4 Changes To requirements For Products And Services**

PCB ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements when the requirements for products and services are changed.

## **8.3 Design And Development Of Products And Services**

**8.3.1** PCB has established, implemented and controls a process for design and development suitable for ensuring the provision of our products and services.

### **8.3.2 Design And Development Planning**

The design and development process defines stages and controls that consider the nature, duration, and complexity of our design and development activities, the required process stages including applicable design and development reviews, verification and validation activities, developmental responsibilities and authorities, internal and external resource needs, the control of interfaces between persons involved in the design and development process, involvement of the customer or end user, requirements for provision of the product or service, required controls expected for the design and development process by customers and other interested parties and the documented information needed for demonstrating that design and development requirements have been met. Dependent upon complexity, the design plan may be structured into distinct activities whereby each activity defines the required tasks, resources, responsibilities, design content, inputs and outputs, and the ability to provide, verify, test and maintain our products and services.

### **8.3.3 Design And Development Inputs**

Requirements essential for our types of products and services to be designed and developed considers functional and performance requirements, lessons learned from previous similar design and development activities, statutory and regulatory requirements, standards and practices that our organization has committed to implement, the potential consequences of failure due to the nature of the product or service and the applicable potential consequences of obsolescence. Design and development inputs are adequate, complete and unambiguous. Conflicting design and development inputs are resolved as well as corresponding documented information retained.

### **8.3.4 Design And Development Controls**

Controls applied to our design and development process ensure that the results to be achieved are defined, periodic reviews are conducted to evaluate our ability to meet design and development requirements, verification activities are conducted to ensure design and development outputs meet the input requirements, validation activities are conducted to ensure our resulting product or service meets the requirements for the specified application or intended use, necessary actions are taken on problems detected during review, verification or validation, retaining documented information of these activities, authorization for progression to the next design plan stage and include representatives of functions concerned with the design and development stage being reviewed.

**8.3.4.1** Tests necessary for verification and validation activities are planned, controlled, reviewed, and documented to ensure and provide evidence that test plans or specifications identify the test item and the required resources, test objectives and conditions are defined, parameters to be recorded and the relevant acceptance criteria, test procedures identify test method to be used and how to perform and record test results, confirming that correct configuration of the test item is used for testing, the test plan and test procedure requirements are observed and acceptance criteria are met. Monitoring and measuring devices used for testing are controlled per requirements of the AS9100 and ISO17025 standards. At completion of our design and development process, test reports, calculations and test results are retained as documented information demonstrating that the design for the product or service meets the specification requirements for all operational conditions.

### 8.3.5 Design And Development Outputs

Our design and development process ensures that design outputs meet input requirements, are adequate for the provision of our products and services, include appropriate monitoring, measuring and acceptance criteria, specify product or service characteristics that are essential for their intended purpose and their safe and proper provision, indicate any applicable critical or key characteristic and specific actions required for these items and are approved by authorized personnel prior to release. Data required to allow the product to be identified, manufactured, verified, used and maintained is defined as well as supporting documented information retained.

### 8.3.6 Design And Development Changes

Design changes to our products or services are identified, reviewed and controlled either during or subsequent to the design and development process ensuring there is no adverse impact on conformity to requirements. Our design and development process defines criteria for customer notification, prior to implementation, of changes that may affect their requirements. Documented information is retained for design and development changes, results of design reviews, authorization of design changes and the actions taken to prevent adverse impacts. Design and development changes are controlled in accordance with the configuration management requirements defined in the AS9100 standard.

## 8.4 Control Of Externally Provided Processes, Products, And Services

**8.4.1** PCB Piezotronics, Inc. maintains documented procedures to ensure that externally provided processes, products, and services conform to specified requirements. PCB maintains responsibility for the conformity of all externally provided processes, products, and services including those sources defined by our customers. When designated by our customers, approved external providers and sources, including special processes, are used. Risks associated with the use of such external processes, products, or services, as well as the selection and use of these external providers, are identified and managed. Appropriate controls are applied to external providers and require that these providers flow-down appropriate controls to their direct and sub-tier external providers to ensure that requirements are met. Controls to be applied to externally provided processes, products, and services are determined when the externally provided product or service is intended for incorporation into our own products and services, are provided directly to the customer by the external provider on behalf of our organization, or when a process, or part of a process, is provided by an external provider as a business decision of our organization. Criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers has been determined and applied based upon their ability to provide processes or products and services to requirements. Documented information of these activities is retained including any necessary actions arising from these evaluations.

**8.4.1.1** PCB Piezotronics, Inc. has defined our process, responsibilities and authorities for the approval status decision, changes of this approval status, and the conditions for controlled use of external providers in accordance with their approval status. A register is maintained of these external providers that includes approval status and the scope of the approval. External provider performance is periodically reviewed including process, product and service conformity, as well as on-time delivery, with necessary actions taken when external providers do not meet requirements. Requirements are provided for controlling documented information created and/or retained by external providers.

### 8.4.2 Type And Extent Of Control

Documented quality system processes ensure that externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers. Externally provided processes are subject to the controls required by our quality management system that define both the controls applicable to the external provider and their resulting output. Consideration is given to the potential impact of the externally provided process, product, or service upon our ability to consistently meet customer and applicable statutory and regulatory requirements. Effectiveness of controls applied to the external provider and the results of periodic external provider performance review, as well as necessary verification activities, ensure that the externally provided process, product or service meets requirements.

Verification activities for externally provided processes, products, and services are performed in accordance to the risks identified by our organization. These activities include applicable inspection or periodic testing when there is high risk of nonconformities including counterfeit parts. Our organization is responsible for

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provisioning acceptable processes, products, and services that comply with requirements regardless of any other interested party verification activities. Verification activities for our external providers include, but are not limited to, review of requested certifications for material, process, product, or service, test reports, manufacturing records, on-site quality system assessment, inspection of products or verification of service upon receipt and review of any delegations to the external provider.

PCB Piezotronics, Inc. does not release any externally provided product for production use until all required verification activities have been completed. In the event our organization delegates verification activities to an external provider, the scope and delegation requirements are defined and a register of delegations maintained. Delegated verification activities are periodically monitored to ensure continued effectiveness. When external provider test reports are utilized to verify externally provided products and raw materials, a system is in place to select and validate the accuracy of raw material test reports through a third party. This process ensures that effective process and controls are in place for the validation and qualification of externally provided documented information.

### 8.4.3 Information For External Providers

Purchase order requirements are reviewed for adequacy prior to communication to the external provider. This communication ensures that our external providers possess the requirements for the process, product, or service being provided including identification of relevant technical data. PCB Piezotronics, Inc. also communicates to external parties our requirements for the approval of products, services, methods, processes, equipment and the release of products and services. Requirements are also communicated for competence and qualification of relevant persons, interaction between our organization and the external provider, control and monitoring of the external providers' performance as applied by our organization, verification or validation activities to be conducted at the external providers premises by our organization or our customer, design and development control, special items, critical items, key characteristics, tests, inspections, process verifications, use of statistical techniques for product or service acceptance and related instructions for acceptance as defined by our organization.

Communication to external providers also defines their need to implement a quality management system, use customer-designated or approved external providers including those performing special processes, notifying our organization of any nonconforming process, product, or service and obtaining an authorized approval for disposition, preventing the use of counterfeit parts, notifying our organization and obtaining prior approval for any changes to processes, product, or service, external provider or location of manufacture, flow-down of requirements including customer requirements, provide test specimens for design approval, inspection, investigations or audits and ensure retention time and disposition requirements for documented information is defined. PCB Piezotronics, Inc., our customers, and regulatory authorities require right of access to all applicable areas of facilities and documented information, at any level of the supply chain. This activity ensures that affected persons are aware of their contribution to the conformity of products and services, product safety and the importance of ethical behavior.

## 8.5 Production And Service Provision

### 8.5.1 Control Of Production And Service Provision

PCB Piezotronics, Inc. has implemented production and service provision under controlled conditions that include, as applicable, the availability of documented information defining the characteristics of the products being produced, services to be provided, activities to be performed, the results to be achieved, availability and use of suitable monitoring and measuring resources, implementation of monitoring and measuring activities at appropriate stages to verify criteria for control of processes or outputs, and acceptance criteria for products and services have been met. Monitoring and measuring activities for product acceptance provides documented information that includes the criteria for product acceptance or rejection, where in the manufacturing sequence verification operations are performed, measurement results retained as evidence of acceptance or rejection, and required monitoring and measuring equipment with associated instructions for use. When sampling is used as a means of product acceptance, the sampling plans are based upon recognized statistical principles, standards, or based upon criticality of the product and/or the process capability. Documented information also defines the use of suitable infrastructure and environment for operating our processes and the appointment of qualified or competent persons. For special processes whereby the resulting output cannot be verified by subsequent monitoring and measurement, validation and periodic revalidation is conducted to confirm planned results are achieved. Additional controlled conditions include the implementation of actions to prevent human error, implementing release, delivery, and post-

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delivery activities, established workmanship criteria, accountability of all products during production, identified critical item and key characteristic control and monitoring in accordance with documented processes, methods for measuring variable data are defined, the identification of in-process inspection points when adequate verification of conformity cannot be performed at later manufacturing stages, documented evidence demonstrating that all manufacturing, inspection and verification operations have been completed as planned, provisions for the prevention, detection, and removal of foreign objects and the control and monitoring of utilities and supplies that may affect conformity to product requirements. Products for use in production are not released until after completion of all required measuring and monitoring activities.

### **8.5.1.1 Control Of Equipment, Tools, And Software Programs**

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to their final release and are maintained. Requirements are defined for the storage of production equipment and tooling including periodic preservation checks.

### **8.5.1.2 Validation And Control Of Special Processes**

For our processes where the resulting output cannot be verified by subsequent monitoring or measurement, PCB Piezotronics, Inc. has established relevant validation arrangements such as defining criteria for the review and approval of the process, maintaining conditions for the process approval, approval of facilities and equipment, qualification of persons, use of specific methods and procedures for implementation and monitoring the process and retaining appropriate required documented information.

### **8.5.1.3 Production Process Verification**

PCB Piezotronics, Inc. has implemented production process verification activities to ensure our production processes are able to produce products that meet requirements. A representative item from the first production run of a new part or assembly is used to verify that the production processes, production documentation, and tooling are able to provide parts and assemblies that meet requirements. If a change occurs that invalidates the original results this process is repeated. First Article Inspection (FAI) standard AS9102 is used to document and retain the results of production process verification.

## **8.5.2 Identification And Traceability**

PCB Piezotronics, Inc. uses suitable means for identifying outputs when it is necessary to ensure conformity of our products and services. Identification of the configuration of the product or service is maintained to identify any differences between the actual configuration and the required configuration. Status of outputs are identified regarding monitoring and measurement requirements throughout production and service provision. Acceptance authority media are used and controls established. Outputs are controlled with unique identification and traceability is enabled by corresponding retained documented information.

## **8.5.3 Property Belonging To Customers Or External Providers**

PCB Piezotronics, Inc. exercises care when handling or using customer or external provider property while under our control. The property provided for use or incorporation into our products and services is identified, verified, protected, and safeguarded. In the event such property is lost, damaged, or otherwise found to be unsuitable for use, documented information on what has occurred is retained and reported to the customer or external provider.

## **8.5.4 Preservation**

During product or service provision, outputs are preserved to the extent necessary ensuring continued conformity to requirements. Preservation includes identification, handling, contamination control, packaging, storage, transportation and protection. When required by specification or in accordance with statutory or regulatory requirements, preservation of outputs include provisions for cleaning, prevention, detection, and removal of foreign objects, special handling and storage for sensitive products, marking and labeling including safety warnings and cautions, shelf life control and stock rotation, and special handling and storage for hazardous materials.

## **8.5.5 Post-Delivery Activities**

PCB Piezotronics, Inc. ensures post-delivery activities associated with our products and services meet their requirements. The extent of post-delivery activities required considers statutory and regulatory requirements, potential undesired consequences associated with the product or service, the nature, use, and intended lifetime of

the product or service, customer requirements and feedback, collection and analysis of in-service data, the control, updating, and provision of technical documentation related to product use, maintenance, repair, and overhaul, controls for any work undertaken outside our facility, and customer support. In the event problems are detected after delivery, appropriate investigative and reporting action is taken. Post-delivery activities can also include warranty provision, recycling, and final disposal instructions.

#### **8.5.6 Control Of Changes**

PCB Piezotronics, Inc. reviews and controls changes for production and service provision to the extent necessary for ensuring conformity with requirements. Persons authorized to approve production or service provision are identified. These changes can include those affecting processes, production equipment, tools or software programs. Documented information describing the results of the review of changes, persons authorizing the change, and any necessary actions arising from the review are retained.

#### **8.6 Release Of Products And Services**

PCB Piezotronics, Inc. has implemented planned arrangements at appropriate stages to verify our product or service meets requirements. Products and services are not released to the customer until the planned arrangements have been completed or unless authorized by a relevant authority and, as applicable, by the customer. Documented information is retained on the release of products and services including evidence of conformity with the acceptance criteria, and traceability to the person(s) authorizing the release. To demonstrate product qualification, documented information is retained providing evidence that the product or service meets requirements. Documented information required to accompany the product or service is provided at delivery.

#### **8.7 Control Of Nonconforming Outputs**

**8.7.1** Outputs that do not conform to their requirements are identified and controlled to prevent unintended use or delivery. Nonconforming outputs include nonconforming product or service generated internally, received from an external provider, or identified by a customer. Appropriate action is taken based upon the nature of the nonconformity and its effect on conformity of our products and services. This activity also applies to nonconforming products and services detected after the delivery of products or during or after the provision of services. Our nonconformity control process is maintained as documented information including provisions for defining responsibility and authority for review and disposition of nonconforming outputs and the process for approving persons making these decisions, taking necessary action to contain the effect of the nonconformity on other processes, products, or services, reporting in a timely manner nonconformities affecting delivered products and services to our customers and relevant interested parties (e.g., external providers, customers), and defining corrective actions for nonconforming products and services detected after delivery as appropriate to their impact.

Nonconforming outputs are addressed by correction activities, segregation, containment, return or suspension of the product or service, customer notification, and obtaining authorization for acceptance under concession by a relevant authority and when required by the customer. Nonconforming product dispositions of use-as-is, or repair, are only implemented after obtaining approval from an authorized representative responsible for the design (or person having delegated authority from our design department), or after documented authorization is provided by our customer; in the event the nonconformity results in a departure from the contract agreement. Product dispositioned for scrap is conspicuously and permanently marked and/or positively controlled until physically rendered unusable. Counterfeit, or suspect counterfeit parts are controlled to prevent reentry into the supply chain. When nonconforming outputs are corrected, verification to requirements is conducted demonstrating conformity.

**8.7.2** Nonconforming output documented information is retained that describes the nonconformity, actions taken, any concessions obtained, and the identification of relevant authorities making the decisions.

### **9. Performance Evaluation**

#### **9.1 Monitoring, Measurement, Analysis, And Evaluation**

**9.1.1** PCB Piezotronics, Inc. evaluates the performance and effectiveness of our quality management system and has determined what needs to be monitored and measured, the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results, when monitoring and measuring shall be performed, and when the results

from monitoring and measurement shall be analyzed and evaluated. Appropriate documented information is retained as evidence of the results.

### 9.1.2 Customer Satisfaction

PCB Piezotronics, Inc. has implemented a process for obtaining, monitoring, and reviewing customer perception information (e.g., customer feedback on delivered products and services, warranty claims) to an extent ensuring their needs and expectations have been fulfilled. Information monitored and used for evaluating customer satisfaction include, but are not limited to, product and service conformity, on-time delivery performance, customer complaints and corrective action requests. Customer satisfaction improvement plans have been implemented that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

### 9.1.3 Analysis And Evaluation

Appropriate data and information arising from monitoring and measurement, or from relevant external sources, are analyzed and evaluated including use of statistical techniques. The results of this analysis are used to evaluate conformity of products and services, the degree of customer satisfaction, quality management system performance and effectiveness, planning and implementation effectivity, effectiveness of actions taken to address risks and opportunities, external provider performance, and the need for improvement of our quality management system.

## 9.2 Internal Audit

**9.2.1** Internal audits are conducted at planned intervals providing information on whether our quality management system conforms to our own quality management system requirements, the requirements of the AS9100 and other relevant standards, and is effectively implemented and maintained. Internal audit results provide performance indicators, when applicable, to verify the quality management system is effectively conducted and maintained.

**9.2.2** An audit program has been planned, established, implemented and is maintained that includes the frequency, methods, responsibilities, planning arrangements, and reporting required, and that considers the importance of the process concerned, changes effecting our organization, and the results of previous audits. Our audit program defines the criteria and scope for each audit, select auditors and conduct audits ensuring objectivity and impartiality of the audit process, ensure that audit results are reported to relevant management, taking appropriate correction and corrective actions without undue delay, and retain documented information as evidence of the audit program and subsequent audit results.

## 9.3 Management Review

**9.3.1** The Senior Leadership Team (SLT) reviews the quality management system at planned intervals ensuring its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of our organization.

### 9.3.2 Management Review Inputs

Management review is planned and carried out taking into consideration the status of actions from previous management reviews and changes to external and internal issues that are relevant to our quality management system. Information on the performance and effectiveness of our quality management system includes trends for customer satisfaction, relevant interested party feedback, the extent to which our quality objectives have been met, process performance and the conformity of products and services, nonconformities and corrective actions, monitoring and measuring results, audit results, external provider and on-time delivery performance. Management review also considers adequacy of resources, the effectiveness of actions taken to address risks and opportunities, and opportunities for improvement.

### 9.3.3 Management Review Outputs

Outputs of our management review process include decisions and actions related to opportunities for improvement, the need for any changes to our quality management system, resource needs, and identifying risks. Documented information is retained as evidence of the results of management reviews.

## 10. Improvement

**10.1** PCB Piezotronics, Inc. has determined and selected opportunities for improvement and has implemented any necessary actions to meet our customer's requirements and enhance customer satisfaction. These improvement opportunities include improving products and services to meet requirements as well as to address future needs and

expectations, correcting, preventing, or reducing undesired effects, and improving the performance and effectiveness of our quality management system.

## **10.2 Nonconformity And Corrective Action**

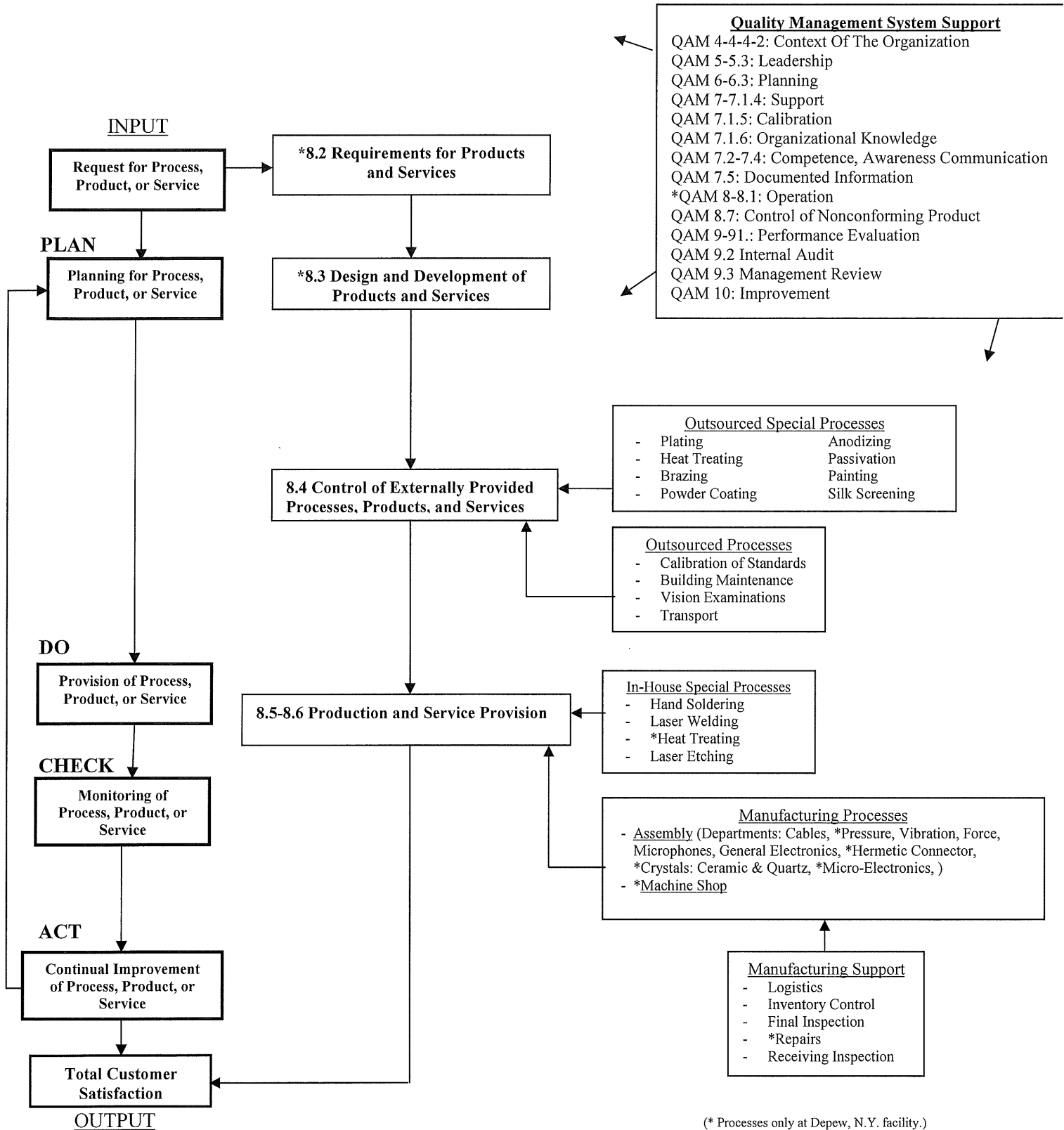
**10.2.1** When a nonconformity occurs, including any arising from complaints, our organization reacts to the nonconformity and takes applicable action to control and correct the problem and deal with the consequences. PCB Piezotronics, Inc. evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere; by reviewing and analyzing the nonconformity, determining the causes of the nonconformity including applicable related human factors, and determining if similar nonconformities exist or could potentially occur. Other corrective action activities include implementing action needed, reviewing effectiveness of any corrective action taken, updating risks and opportunities determined during planning as necessary, making changes to the quality management system as necessary, flowing-down corrective action to an external provider when it is determined that the external provider is responsible for the nonconformity, and taking specific actions when timely and effective corrective actions are not achieved. Corrective actions taken shall be appropriate to the effects of the nonconformities encountered. Documented information is maintained that defines our nonconformity and corrective action management processes.

**10.2.2** PCB Piezotronics, Inc. retains documented information as evidence of the nature of the nonconformity and any subsequent actions taken, and the results of any corrective action.

## **10.3 Continual Improvement**

PCB Piezotronics, Inc. continually improves the suitability, adequacy, and effectiveness of our quality management system. This process considers the results of analysis and evaluation, and the outputs from management review to determine if there are needs or opportunities for continual improvement that shall be addressed. Implementation of improvement activities are monitored to evaluate the effectiveness of the results.

Sequence and Interaction of Processes





## **Glossary of Terms**

(Reference applicable ISO, AS, ANSI, IEC, EN, CFR and FAA standards for definitions used in this manual.)

## **Bibliography**

ISO-9001

Quality Management System - Requirements

ISO-17025

General Requirements For The Competence Of Calibration And Testing Laboratories

ATEX114 (and IEC80079-34)

Explosive atmospheres – Application Of Quality Systems

ISO-10007

Quality Management System – Guidelines For Configuration Management

ISO-10002

Customer Satisfaction – Guidelines For Complaints Handling In Organizations

ISO-10012

Measurement Management Systems - Requirements For Measurement Processes And Measuring Equipment

ANSI Z540.3

Calibration Laboratories and Measuring and Test Equipment - General Requirements

10CFR21

Code of Federal Regulations – Reporting of Defects and Noncompliance

10CFR50 Appendix B

Code of Federal Regulations – Quality Assurance For Nuclear Power Plants And Fuel Reprocessing

ASQ Z1.4

Sampling Procedure And Tables For Inspection By Attributes

AS-9100

Quality Management Systems – Requirements For Aviation, Space, And Defense Organizations

AS-9101

Quality Management Systems – Audit Requirements For Aviation, Space, And Defense Organizations

AS-9102

Aerospace – First Article Inspection Requirement

AS-9103

Variation Management Of Key Characteristics

14CFR145

Code of Federal Regulations – Repair Stations

14CFR21

Code of Federal Regulations – Parts Manufacturing Approval (PMA)

(See current certifications supplemental to this manual.)