

SAE AS9100 DOCUMENT

PRECISION SENSORS

QUALITY ASSURANCE MANUAL

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IS STAMPED 'CONTROLLED' IN RED INK*

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CONTROL PAGE

QUALITY SYSTEM MANUAL

Manual Number: 1

Issued To: AS / ISO Management Representative

This manual is controlled.

PRECISION SENSORS HISTORY

Precision Sensors Division of United Electric Controls Corporation

Precision Sensors (PSI) was founded in 1962 to service the needs of aerospace and defense customers. PSI became part of the United Electric Controls Company (UEC) in 1989. PSI operates from a 10,000SF facility in Milford, CT. The facility houses primary machining, assembly, and clean room operations as well as engineering, quality assurance, marketing, customer service, materials, purchasing, manufacturing and production engineering.

Precision Sensors (PSI) is a vertically integrated supplier of pressure, vacuum, liquid level, flow, altitude/airspeed switches and sensors to aerospace, military and semiconductor process markets. PSI delivers fundamental value in the form of cost effective, reliable threshold detection **and continuous sensing** products that are **used** to protect people, equipment and processes. PSI has the in-house capability to produce primary and secondary parts and assemblies for **the majority of products that it manufactures**. Specialty machining to achieve 5Ra finishes for products **sold to the semiconductor industry**, EB and laser welding, and other chemical finishing processes are mostly performed by outside suppliers. PSI increases sales by developing new products for existing markets. PSI considers itself a time to market leader. Customers acknowledge that PSI products are the “best in their class”.

PSI has received source delegation (ship to stock) and supplier certification awards from leading aerospace/defense companies. Leading semiconductor equipment manufacturers have designated PSI as their “first choice” for pressure and vacuum switches.

PRECISION SENSORS QUALITY POLICY & OBJECTIVES
LOCATED IN ADDENDUM 2 TO
QUALITY ASSURANCE MANUAL

ORGANIZATIONAL CHART

**Organizational Chart is located in Addendum 3 to
Quality Assurance Manual**

EIGHT QUALITY MANAGEMENT PRINCIPLES AS A BASIS OF ISO9001

CUSTOMER FOCUS: An organization depends on their customers and should therefore understand current and future needs. An organization should also meet customer requirements and strive to exceed customer expectations.

LEADERSHIP: Leadership establishes unity of purpose and direction. Strong leadership creates and maintains an operating environment in which people can become fully involved in achieving organizational objectives.

INVOLVEMENT: People at all levels are the essence of an organization. Full involvement enables their abilities to be used for the organization's benefit.

PROCESS APPROACH: A desired result is achieved more efficiently when activities and related resources are a managed process.

SYSTEM APPROACH TO MANAGEMENT: Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

CONTINUAL IMPROVEMENT: Continual improvement of the organization's overall performance should be a permanent objective of the organization.

FACTUAL APPROACH TO DECISION-MAKING: Effective decisions are based on the analysis of the data and information.

MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS: An organization and its suppliers are independent and a mutually beneficial relationship enhances the ability of both to create value.

These eight quality management principals form the basis for the quality management system standards within the ISO 9000 family.

Source ANSI/ISO/ASQ Q9000-2000

PROCESS APPROACH

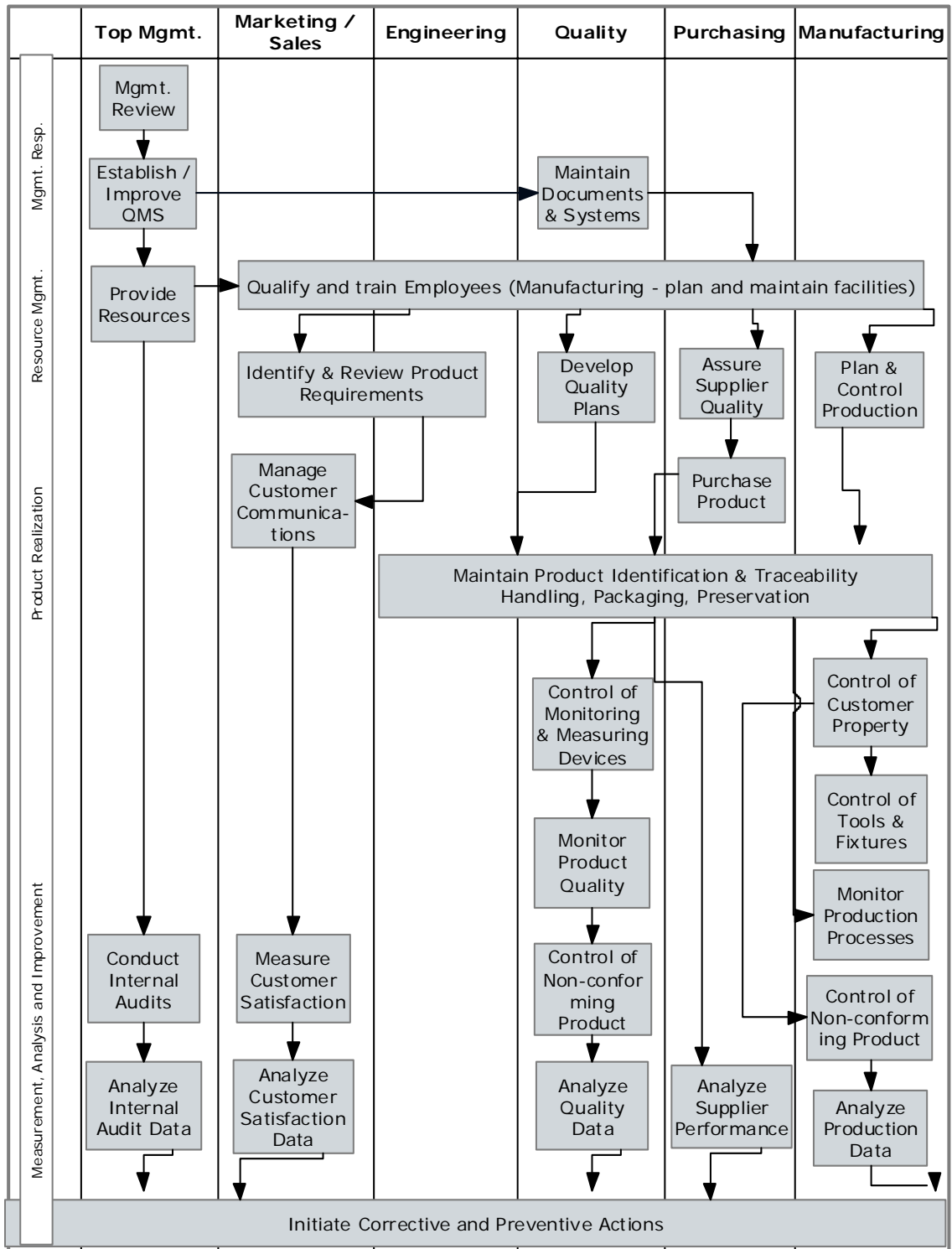
The basic requirement of a quality management system is that the organization must identify and manage the family of processes needed to ensure conformity. The quality management system ensures compliance of the quality policy and quality objectives are met. Organizations should not lose sight of these basic concepts. It is too easy to get so absorbed in documenting a system that the basic concept is lost. While documentation is important, the organization's primary emphasis should be on developing and implementing effective quality management system processes.

Clause 4.1 requires that processes be developed and implemented to make up the overall system. It also requires that the processes be managed and continually improved. These improvement activities must include the monitoring, measurement and analysis of these processes.

Precision Sensors needs to consider the following activities:

1. The identification of processes and their interrelationships, sequences and interactions.
2. The establishment of criteria and means to effectively operate, monitor, measure, analyze and control the process.
3. The improvement of the Quality Management System's effectiveness including improvements to the process.
4. The achievement of the Quality Management System processes outsourced to another organization that affect product conformity.

PRECISION SENSORS INTERACTION OF PROCESSES



SUMMARY OF CHANGES

Revision / DCN #	Change(s)	Effective Date	Approved by
QAM 001 03-022	Original	October 20, 2003	Warren Root
QAM 002 03-028	Added to 4.1 <i>“Where an organization chooses to outsource...”</i> ; Added to 4.3 ref. to document ES12; qualified servicing exclusion in 4.2.2 to read 7.5.1.5 (from 7.5); Added to 7.3.1 <i>“Precision Sensors defines the different design and development tasks to be carried out...”</i> ; Identified in 7.4.3 how controls over outsourcing will be applied; and added to 8.2.4 <i>“When key characteristics have been identified, they are monitored and controlled.”</i> as per documentation audit. Removed reference to SAE AS9100 Rev. level in 4.1	Nov. 17, 2003	Warren Root
QAM 003 03-033	Revised 8.2.1 See Record Copy	December 10, 2003	Warren Root
QAM 004 08-014	REMOVED FLOW CHART FOR SALES PROCESS AND REPLACED IT WITH FLOW CHART FOR INTERACTION OF PROCESSES	10/29/08	Warren Root
QAM 005 10-012	Revised manual in accordance with changes to ISO 9001:2008 with editorial and spelling corrections throughout. Moved Quality Policy and Objectives to Addendum 2 of QAM	10/27/10	Warren Root

4.0 Quality Management System

4.1 General requirements: Precision Sensors has established, documented, implemented and maintains a Quality Management System and continually improves its effectiveness in accordance with the requirements of SAE AS9100 and ISO9000:2008.

Precision Sensors **shall**:

- a) **determine** the processes as needed for the Quality Management System,
- b) determine the sequence and interaction of these processes,
- c) determine the criteria and methods required for ensuring the effective operation and control of these processes,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable, and analyze these processes, and
- f) implement action necessary to achieve planned results and continual improvement of these processes.

Precision Sensors shall manage these processes in accordance with the requirements of the SAE AS9100 and **ISO9000:2008** international standard.

Where Precision Sensors chooses to outsource any process that affects product conformity to requirements, Precision Sensors will ensure control over such processes. The type and extent of control to be applied to these outsourced shall be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3: Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) **the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements,**
- b) **the degree to which the control for the process is shared,**
- c) **the capability of achieving the necessary control through the application of 7.4.**

4.1.1 Precision Sensors' Quality System consists of four levels:

Level One: The Quality Manual

The Quality Manual describes the corporate Quality Policy and the structure and methods for maintaining the system. The Quality Manual will include the quality system Standard Operating Procedures.

Level Two: The Standard Operating Procedures (SOP) Manual.

The SOP manual is a set of procedures that describes the overall activities that relate to those sections that require SOPs.

Level Three: Work Instructions

Work Instructions describe in detail how particular tasks are performed. These instructions are required where the absence of such instructions would adversely affect the quality of the product or service.

Level Four: Records, tags and forms

Records and forms are used to provide evidence that the System has been implemented. Tags and labels are used as methods of identification.

4.2 Document requirements

4.2.1 **General:** Precision Sensors Quality Management System documentation shall include

- a) documented statements of a Quality Policy and Quality Objectives,
- b) a Quality Manual,
- c) documented procedures **and records** required by this International Standard, **and**
- d) documents, **including records, determined** by the organization **to be necessary** to ensure the effective planning, operation, and control of its processes, and
- e) quality system requirements imposed by the applicable regulatory authorities.

Precision Sensors shall ensure that personnel have access to Quality Management System documentation and are aware of relevant procedures. Customer and/or regulatory authority representatives shall have access to Quality Management System documentation.

NOTE 1: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established,

documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

4.2.2 Quality Manual: This manual is issued to describe the Quality Management System and related processes employed in all operations by Precision Sensors. This manual and the systems and processes it describes serve to:

- ensure conformance to customer requirements
- implement Precision Sensors' Quality Policy and Quality Objectives
- address the intent and requirements of AS9100 and ISO9000:2008

The scope of this manual includes requirements for controlling the following:

- Controlled documents
- Records
- Management responsibility (including an organizational chart, quality policy and quality objectives)
- Quality planning
- Responsibility of authorities
- Customer focus and customer satisfaction
- Resource management and provisions
- Training and skills requirements
- Infrastructure and work environment
- Product realization
- Production control
- Quality Assurance testing
- Internal Auditing
- Control of Measuring Devices (calibration)
- Control of Nonconforming Product
- Data Analysis
- Continuing Improvement
- Corrective and Preventive Action
- A process approach to quality
- References to supporting second-level documentation, as applicable.

Excluded from the scope of this manual:

- ❖ ***Clause 7.5.1.5, Service Provisions, as Precision Sensors does not currently provide after-market servicing of any kind.***

When referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.

4.2.3 Control of documents: Precision Sensors has established a procedure to control all data and documents (including all external standards and drawings) as needed, in accordance with SAE AS9100 (see SOP 4.2.3).

- a) Procedures are established to approve all documents prior to issue.
- b) Procedures are established to review, update and re-approve all documents as necessary.
- c) The company maintains a master list that identifies the latest changes and revision status of all documents to preclude the use of obsolete documents. The changes are identified on the document by printing the change in bold letters.
- d) Steps are taken to ensure that the up-to-date issue is available at all locations where required.
- e) Care is taken to ensure that documents remain legible and are readily available.
- f) To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and**
- g) All obsolete documents retained for information or for legal reasons are stamped "OBSOLETE" and filed in an area to preclude the accidental use of the document.
- h) All documents used for reference are clearly identified as such.
- i) All SOPs will be controlled by a "Controlled" stamp in red ink on the front of the document.

Precision Sensors has a system to ensure the review, disposition, implementation, and maintenance of all authorized and released controlled documentation quarterly. Precision Sensors will coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

4.2.4 Control of records: Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. Precision Sensors shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. **Records shall remain legible, readily identifiable and retrievable.** (see SOP 4.2.4). Quality records

- a) are maintained to demonstrate conformance to the standard and the effective operation of the system;
- b) are legible and stored in a manner such as will prevent damage or deterioration;
- c) are easily retrievable;
- d) retention time is established in SOP 4.2.4.
- e) that are created by and/or retained by suppliers are controlled by a documented procedure;

- f) are made available for review by customers and regulatory authorities in accordance with contract or regulatory requirements, as needed.

4.3 Configuration management:

Precision Sensors established, documented and maintains a configuration management process appropriate to the product (in accordance with guidelines in ISO 10007, or specified contractual requirements). **Details of Engineering's configuration management procedures are outlined in internal documents ES17, ES12, ES2, SOP 7.5.3, W.I. 3.1, W.I. 3.2 and W.I. 3.3.**

5.0 Management responsibility

5.1 Management commitment: The management at Precision Sensors has a commitment to the development and implementation of the Quality Management System, as well as a commitment to continually improve its effectiveness. This will be accomplished

- a) by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) by having a has clearly defined quality policy,
- c) by establishing and periodically reviewing quality objectives for relevancy to organizational goals as well as customer expectations/needs,
- d) through management reviews where the executive management reviews the quality system, including the Quality Policy, to ensure its continuing suitability and effectiveness in satisfying the requirements of this standard (at least annually. The review will include but not be limited to the following: Internal Audits; Customer complaints; Corrective and Preventive Action Reports; Complaints against the Quality System; Additional Training Requirements; The need for statistical techniques; and additional resource requirements), and
- e) by management taking full responsibility for identification of resource requirements and the provision of adequate resources such as trained personnel for management and for performance the various duties and verification activities (such as internal auditing), required to maintain the Quality Management System.

5.2 Customer focus: Precision Sensors ensures that the customer requirements are determined and met with the aim of enhancing customer satisfaction.

5.3 Quality policy: Executive management at Precision Sensors shall ensure that its quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the Quality Management System,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives: Executive management must ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality planning: Executive management shall ensure that

- a) the planning of the Quality Management System is carried out in order to meet the requirements given in 4.1 as well as quality objectives, and
- b) the integrity of the Quality Management System is maintained when changes to it are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority: Management shall ensure that responsibilities and authority are defined and communicated to all employees with an organizational chart and clearly defined job descriptions.

5.5.2 Management representative: Top management has appointed the organization's Quality Assurance Manager as the AS/ISO Management Representative who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that the process as needed for the Quality Management System are established, implemented, and maintained,
- b) reporting to top management on the performance of the Quality Management System and any needed improvement and
- c) ensuring the promotion of awareness of customer requirements throughout the organization, and
- d) the organizational freedom to resolve matters pertaining to quality.

5.5.3 Internal communication: Management shall ensure that appropriate communication processes are established within the organization and communication takes place regarding the effectiveness of the Quality Management System. This will be accomplished using departmental and full employee meetings

5.6 Management Review:

5.6.1 General: The executive management reviews the quality system, including the Quality Policy, to ensure its continuing suitability and effectiveness in satisfying the requirements of this standard at least annually. This review includes assessing opportunities for improvements and the need for change to the Quality Management System (including the quality policy and quality objectives). Precision Sensors maintains minutes of the reviews

5.6.2 Review Input: The input to management review shall include but not be limited to the following:

- a) results of audits;
- b) customer feedback and complaints;
- c) process performance and product conformity;
- d) preventive and corrective action reports;
- e) follow-up actions from previous management reviews;
- f) complaints that are made against or changes made that could effect the Quality Management System;
- g) recommendations for improvements, new statistical techniques, additional resource requirements (including infrastructure and work environment) or additional training; and
- h) infrastructure.

5.6.3 Review output: The output from the management review may include decisions/actions relating to

- a) improvements of the Quality Management System and its processes;
- b) improvements of products toward addressing customer needs; and
- c) resource needs and special requirements.

6.0 Resource management

6.1 Provision of resources: Precision Sensors determines and provides resources needed

- a) to implement and maintain the Quality Management System and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General: All Precision Sensors employees performing work affecting **conformity to product requirements shall be** competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, training and awareness: Precision Sensors

- a) **determines the necessary competence for personnel performing work affecting conformity to product requirements.** (see SOP 6.2.2);
- b) **where applicable, provides training or take other actions to achieve the necessary competence, and** ensures that personnel are qualified to perform specific tasks on the basis of previous experience, education and/or on the job training;
- c) evaluates the needs for additional training during the annual management review.

The department managers are responsible for the training of all employees and ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Department managers are responsible for the maintaining their respective employee training records.

As a part of an orientation process all new employees shall receive the following instructions:

- Quality Policy
- Safety
- Plant procedures (hours, lunch and other breaks, absenteeism)
- Hazard Communication Standard

6.3 Infrastructure: Precision Sensors determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport, communication **or information systems**).

6.4 Work environment: Precision Sensors determines and manages the work environment needed to achieve conformity to product requirements, with special emphasis on factors that may affect the conformity of the product.

NOTE: The term “work environment” relates to those conditions under which work is performed including physical, environmental

and other factors (such as noise, temperature, humidity, lighting or weather).

7.0 Product realization

7.1 Planning of product realization: Precision Sensors plans and develops the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System. While planning product realization, Precision Sensors determines the following as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes **and** documents, and **to** provide resources specific to the product;
- c) required verification, validation, monitoring, **measurement**, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements;
- e) the identification of resources to support operation and maintenance of the product.

The output of this planning shall be in a form suitable for our method of operations.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product: Precision Sensors determines

- a) requirements specified by the customer, including the requirement for delivery and post delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known,
- c) statutory **and** regulatory requirements **applicable** to the product, and
- d) any additional requirements **considered necessary** by the organization.

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

7.2.2 Review of requirements related to the product: Precision Sensors reviews the requirements related to the product prior to accepting the customer's order (SOP 7.2.2 provides detailed information of this process). This review ensures that

- a) product requirements are defined,

- b) contract or order requirements differing from those previously expressed are resolved prior to accepting the contract, and
- c) Precision Sensors has the ability to meet the defined requirements,
- d) risks (e.g., new technology, short delivery time scale) have been evaluated.

Records of the review will be maintained as per 4.2.4.

7.2.3 Customer communication: The Sales Department reviews all inquiries (including RFQs, POs, amendments, and new orders). Selected inquiries are identified and registered for follow-up.

All customer feedback and complaints are directed for review to the Vice President/General Manager.

Amendments to orders are directed to the Sales Manager for approval.

The primary vehicle for communicating with customers at Precision Sensors is either via telephone or email.

7.3 Design and development

7.3.1 Design and development planning: Precision Sensors plans and controls the design and development of a product. Precision Sensors has an SOP for Design Control (see SOP 7.3.1)

During the design and development planning Precision Sensors determines

- a) the design and development stages (in respect of organization, task sequence, mandatory steps, significant stages and methods of configuration control),
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

Where appropriate, due to complexity, Precision Sensors gives consideration to the following activities:

- structuring the design effort into significant elements;
- for each element, analyzing the tasks and the necessary resources for its design and development.

This analysis will consider an identified responsible person, design content and data planning constraints, and performance conditions. This input data specific to each element shall be reviewed to ensure consistency with requirements.

Precision Sensors shall manage the interfaces between different groups involved in the design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

Precision Sensors defines the different design and development tasks to be carried out according to the specified safety and functional objectives of the product in accordance with customer and/or regulatory requirements.

NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

7.3.2 Design and development inputs: Inputs relating to product requirements shall be determined and records maintained. These shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs: The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs

- a) meet the requirements for design and development,
- b) provide appropriate information for purchasing, production and service provision,
- c) contain or make reference to the acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.
- e) identify key characteristics, when applicable, in accordance with design or contract requirements.

The design output is reviewed prior to being released.

Precision Sensors shall define all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained. Examples of such data can include:

- drawings, parts lists, specifications;
- a listing of those drawings, parts lists, and specifications necessary to define the configuration and design features of the product;
- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

NOTE: Information for production and service provision can include details for the preservation of product.

7.3.4 Design and development review: At appropriate stages of the design, formal documented reviews (including representatives of all functions concerned with the design stage) are conducted.

- a) to evaluate the ability of the results of design and development to meet requirements;
- b) to identify any problems and propose necessary actions, and
- c) to authorize progression to the next stage.

7.3.5 Design and development verification: The design is verified at various stages to ensure that the design stage output meets the requirements of the design input. Records of the results of the verification and any necessary actions will be maintained.

Design and/or development verification may include activities such as:

- a) performing alternative calculation,
- b) comparing the new design with a similar proven design, if applicable,
- c) undertaking tests and demonstrations, and
- d) reviewing the design stage documents before release.

7.3.6 Design and development validation: Design and development validation will be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specific application or intended use. Where possible, validation shall be completed prior to delivery or implementation of the product. Records of the results of validation and any actions will be maintained.

- Design and/or development validation follows successful design and/or development verification.
- Validation is normally performed under defined operating conditions.
- Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.
- Multiple validations may be performed if there are different intended uses.

7.3.6.1 Documentation of design and/or development verification and validation. At the completion of design and/or development, Precision Sensors shall ensure that reports, calculations, test results, etc.,

demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.6.2 Design and/or development verification and validation testing. Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

- a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;
- b) test procedures describe the method of operation, the performance of the test, and the recording of the results;
- c) the correct configuration standard of the product is submitted for the test;
- d) the requirements of the test plan and the test procedures are observed;
- e) acceptance criteria are met.

7.3.7 Control of design and development changes: Design and development changes will be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of the design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Precision Sensors' change control process will provide for customer and/or regulatory authority approval of changes where required by contract or regulatory requirement. Records of the results of the review of changes and any necessary actions shall be maintained.

7.4 Purchasing

7.4.1. Purchasing process: The type and extent of control applied to the supplier and the purchased product is dependent upon the effect the purchased product has on subsequent product realization or the final product.

Precision Sensors will be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

Precision Sensors evaluates and selects suppliers on their ability to supply product in accordance with their requirements (see SOP 7.4). Criteria for selection, evaluation and reevaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

Precision Sensors shall:

- a) maintain a register of approved suppliers that include the scope of the approval;

- b) periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;
- c) define the necessary actions to take when dealing with suppliers that do not meet the requirements;
- d) ensure where required that both the organization and all suppliers use customer-approved special process sources;
- e) ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.

7.4.2 Supplier control process: Purchasing information shall describe the product to be purchased, including where appropriate

- a) requirements for approval , procedures, and equipment,
- b) requirements for the qualification of personnel,
- c) Quality Management System requirements,
- d) The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- e) requirements for design, test, examination, inspection and related instruction for acceptance by Precision Sensors,
- f) requirements for test specimens (e.g. production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- g) requirements relative to supplier notifications to Precision Sensors of nonconforming product and arrangements for Precision Sensors' approval of supplier of nonconforming material,
- h) requirements for the supplier to notify Precision Sensors of changes in product and/or process definition and, where required, obtain Precision Sensors' approval
- i) right of access by Precision Sensors, their customer and regulatory authorities to all facilities involved in the order and to all applicable records,
- j) requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

The Materials Manager or his/her designee will approve all purchase orders for adequacy.

Precision Sensors has receiving work instructions for the receipt of purchased materials and services.

7.4.3 Verification of a purchased product: Precision Sensors has established and implemented the inspection or other activities necessary to ensure that purchased product meet specified purchase requirements

Verification activities may include

- a) obtaining objective evidence of product quality from suppliers (e.g. accompanying documentation, certificate of conformity, test reports, statistical records, process control),
- b) inspection and audit at supplier's premises,
- c) review of the required documentation,
- d) inspection of products upon receipt, and
- e) delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Precision Sensors will exercise control over processes that are outsourced that may affect product conformity by flow-down of inspection and/or testing requirements (deemed applicable) to the supplier on the Purchase Order, performing receiving inspections (that may include full dimensional analysis), or both.

Where Precision Sensors utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. Precision Sensors shall periodically validate test reports for raw material.

Where Precision Sensors delegates' verification activities to the supplier, the requirements for delegation shall be defined and a register of delegation maintained.

When a customer or Precision Sensors intends to perform verification at the suppliers premise the verification arrangements and the method of product release will be stated in the purchase order.

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises a Precision Sensor's premises that subcontracted product conforms to specified requirements.

Verification by the customer shall not be used by Precision Sensors as evidence of effective control of quality by the supplier and shall not absolve Precision Sensors of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

7.5 Production (Process Control)

7.5.1 Control of production: Planning shall consider, as applicable,

- a) the establishment of process controls and development of control plans where key characteristics have been identified
- b) the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,

- c) the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics and,
- d) special processes.

Precision Sensors carries out production under controlled conditions, which include, as applicable

- a) the availability of information that describes the characteristics of the product,
- b) the availability of instructions as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring **equipment**,
- e) the implementation of monitoring and measurement, and
- f) the implementation of **product** release, delivery **and post delivery** activities,
- g) accountability for all product during manufacture (e.g. parts quantities, split orders nonconforming product),
- h) evidence that all manufacturing. And inspection operations have been completed as planned, or as otherwise documented and authorized,
- i) provision for the prevention, detection, and removal of foreign objects,
- j) monitoring and control of utilities and supplies such as water, compressed air, electricity, and chemical products to the extent they affect product quality, and
- k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g. written standards, representative samples or illustrations).

7.5.1.1 Production documentation. Production operations shall be carried out in accordance with approved data. This data shall contain as necessary

- a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g. manufacturing plans, traveler, router, work order, process cards); and inspection documents, and
- b) a list of specific and non-specific tools and numerical control (N.C.) machine programs and any specific instructions associated with their use

7.5.1.2 Control of production process changes. Persons authorized to approve changes to production processes should be identified.

Precision Sensors shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tool and programs shall be documented. Procedures shall be available to control their implementation.

The result of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

7.5.1.3 Control of production equipment, tools and numerical control

N.C. Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design/data specification.

Storage requirements including periodic preservation/condition checks, shall be established for production equipment or tooling in storage (see W.I. 9.2 and W.I. 11.1).

7.5.1.4 Control of work transferred, on a temporary basis, outside Precision Sensors' facilities: When planning to temporarily transfer work outside the Precision Sensor's own facilities, Precision Sensors will define the process to control and validate the quality of the work.

7.5.2 Validation of processes for production: Precision Sensors shall **validate** any processes for production **and service provision** where the resulting output cannot be verified by subsequent monitoring or measurement **and, as a consequence deficiencies become apparent only after the product is in use or the service has been delivered.**

Note: These processes are frequently referred to as special processes.

Validation processes shall be monitored to ensure planned results are achieved.

Precision Sensors shall establish arrangements for these processes including, as applicable

- a) defined criteria for review and approval of the processes, qualification and approval of special processes prior to use,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
- e) requirements for records, and
- f) revalidation.

7.5.3 Identification and traceability: Where appropriate, Precision Sensors also identifies the product as to the monitoring and measuring requirements of the product throughout the production process. Precision Sensors has an SOP describing the procedures for identification and traceability (see SOP 7.5.3).

Precision Sensors shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Precision Sensors shall identify the product status with respect to monitoring and measurement requirements **throughout product realization.**

Precision Sensors has established a procedure (and related work instructions) for the control of acceptance authority media such as stamps, electronic signatures and passwords. (See SOP 7.5.3.1).

Where traceability is a **requirement**, Precision Sensors **shall** control the unique identification of the product **and maintain records.** (see SOP 7.5.3).

According to the level of traceability required by contract, regulatory, or other established requirement, Precision Sensors' system shall provide for:

- a) identification to be maintained throughout the product life;
- b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
- c) for an assembly, the identity of its components and those of the next higher assembly to be traced; and
- d) for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

7.5.4 Customer Property: Precision Sensors identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. **If any customer property is lost, damaged or otherwise found to be unsuitable for use, Precision Sensors shall report this to the customer and maintain records.**

NOTE: Customer property can include intellectual property and personal data.

7.5.5 Preservation of product: Precision Sensors **shall** preserve the product during internal processing and delivery to the intended destination **in order to maintain conformity to requirements. As applicable, preservation shall include** identification, handling, packaging, storage, and protection. **Preservation shall also** apply to the constituent parts of a product **including** where applicable (in accordance with product specification and/or applicable regulations), provisions for:

- a) cleaning;
- b) prevention, detection and removal of foreign objects;
- c) special handling for sensitive products;
- d) marking and labeling including safety warnings;
- e) shelf life control and stock rotation;
- f) special handling for hazardous materials.

Precision Sensors shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration. Precision Sensors has a procedure for preservation and handling (see SOP 7.5.5).

7.6 Control of monitoring and measuring equipment

Precision Sensors **shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.** Required accuracy is determined and appropriate measuring devices are selected to check the required parameters.

7.6.1 A master list of all inspection, measuring, and test equipment that can affect product quality is maintained by the Quality Assurance Manager with the gauge identification, location of the gauge and with the calibration frequency, acceptance criteria and method of calibration. The calibration record will also be a part of this list.

7.6.2 If a gauge is found inappropriate for determining a specification, the gauge will be recalled and a more appropriate gauge will be assigned.

7.6.3 Precision Sensors shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

7.6.4 All calibration will be performed under suitable environmental conditions

7.6.5 When necessary to ensure valid results:

- a) All inspection, measuring, and test equipment shall be calibrated **or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.**
- b) be adjusted or adjusted as necessary;
- c) All calibrated equipment is identified with a sticker or tag that denotes the date of calibration and the month of the next calibration;
- d) All inspection, measuring, and test equipment are protected from unauthorized adjustment;

- e) All gauges shall be protected from damage and stored in suitable environmental conditions;
- f) All gauges shall be recalled to a defined method when requiring calibration.

7.6.6 Records of the results of calibration and verification shall be maintained. Precision Sensors assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements.

7.6.7 All measuring and test equipment is used in a manner so that the measuring uncertainty is known and is consistent with the required accuracy.

7.6.8 Precision Sensors does not use computer hardware or software in accepting product to our customer's specification.

8.0 Measure, analysis and improvement

8.1 General: Precision Sensors shall plan and implement the monitoring, measurement, analysis and improvement process needed

- a) to demonstrate conformity **to product requirements**.
- b) to ensure conformity of the Quality Management System, and
- c) to continually improve the effectiveness of the Quality Management System.

This determines applicable methods and the extent of their use. Precision Sensors has a documented procedure for statistical techniques (see SOP 8.1).

According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- design verification (e.g. reliability, maintainability, safety);
- process control;
- selection and inspection of key characteristics;
- process capability measurements;
- statistical process control;
- design of experiment;
- inspection - matching sampling rate to the criticality of the product and the process capability;
- failure mode and effect analysis.

Precision Sensors uses Statistical Process Control (SPC) and has a documented procedure for the controlling this process (see W.I 8.1).

8.2 Monitoring and measurement

8.2.1 Customer satisfaction: Precision Sensors evaluates customer correspondences, complaints and comments accompanying returned/rejected material in measuring customer satisfaction.

Customer's complaints are evaluated and may be placed on a corrective action request. If requested, customers are subsequently informed of the results of such actions.

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliment, warranty claims and dealer (distributor) reports.

8.2.2 Internal audits: Precision Sensors conducts internal audits at least once per year to determine if the Quality Management System

- a) conforms to the planned arrangements, to the requirements of this standard, and to the Quality Management System requirements established by Precision Sensors; and
- b) is effectively implemented and maintained.

The selection of auditors and conduct of audits shall ensure objectivity and partiality of the audit process. The audits shall be performed by trained internal assessors that are independent of the areas audited. This obviates any chance that auditors audit their own work. The audit is scheduled on the basis of the status and the importance of the area being audited. The AS/ISO Management Representative schedules the audits at the beginning of the year and may alter the audit frequency for individual requirements, as deemed necessary.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results (see SOP 8.2.2).

Records of the audits and their results shall be maintained (see 4.2.4). This program takes into consideration the importance of the processes and areas to be audited, as well as the results of the previous audits. The scope, frequency and the method are defined in the required documented procedure.

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their clauses.

Detailed tools and techniques shall be developed such as check sheets, process flowcharts, or any similar method to support audit of the Quality Management System requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits shall also meet contract and/or regulatory requirements.

The internal audit reports are maintained by the AS/ISO Management Representative and are part of the annual management review.

8.2.3 Measurement and monitoring: Precision Sensors applies suitable methods for monitoring and, where applicable, measuring the Quality Management System processes. These measurements shall demonstrate the ability of the process to achieve planned results. **When planned results are not achieved, correction and corrective action shall be taken as appropriate.**

In the event of process nonconformity, Precision Sensors shall

- a) take appropriate action to correct the nonconforming process,
- b) evaluate whether the process nonconformity has resulted in product nonconformity, and
- c) identify and control the nonconforming product in accordance with clause 8.3.

NOTE: When determining suitable methods, Precision Sensors may consider the type an extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4 Measurement and monitoring of a product: Precision Sensors monitors and measures the characteristics of the product to verify that product requirements have been met. These will be carried out at **appropriate stages** of the **product realization process** in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

When key characteristics have been identified, they are monitored and controlled.

When Precision Sensors uses sampling inspections as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.

Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of the required measurement and monitoring activities.

Evidence of conformity with the acceptance criteria is maintained.

Precision Sensors has a procedure to control the inspection and testing process (see SOP 8.2.4).

Precision Sensors has a procedure for controlling the identification of inspection and testing status (see SOP 7.5.1 Section 5.0).

8.2.4.1 Inspection documentation: Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include

- a) criteria for acceptance and/or rejection,
- b) where in the sequence measurement and testing operations are performed,
- c) a record of the measurement results, and
- d) type of measurement instruments required and any specific instructions associated with their use.

Test records shall show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product qualifications, Precision Sensors will ensure that records provide evidence that the product meets the defined requirements.

8.2.4.2 First Article Inspection: Precision Sensors' systems shall provide a process for the inspection, verification and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result (or per customer request).

8.3 Control of nonconforming product: Precision Sensors has an established procedure to ensure that product that does not conform to standards is prevented from unintended use or installation. This procedure includes controls for defective material returned from a customer (see SOP 8.3).

A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product and the process to approving personnel making these decisions.

Where applicable, Precision Sensors **shall** deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority, and where applicable by the customer;
- c) by taking action to preclude its original intended use or application.
- d) **By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.** This may include telephoning, faxing or emailing the customer (and relevant government authority if so required by contract) where the nature of the nonconformity is deemed severe enough to warrant such action.

This control provides for:

- Identification
- Segregation (where appropriate)
- Documentation
- Evaluation
- Disposition
- Notification of functions concerned

The Quality Assurance Manager has the responsibility to review and dispose of all Discrepant Material Reports. The material shall be:

- Reworked or repaired to meet the requirement
- Accepted "As is"
- Accepted with a deviation
- Returned to vendor
- Scrap

If contractually required, a disposition of "Accept as is" or "rework or repair" must be reported to the customer for their acceptance.

Precision Sensors does not use dispositions such as use-as-is or repair unless specifically authorized by the customer, if the product is produced to customer design or the nonconformity results in a departure from contract requirements.

Product dispositioned as scrap shall be conspicuously and permanently marked, or positively controlled by mutilation to prevent unintended use or installation.

When nonconforming product is corrected it shall be **subject to re-verification to demonstrate conformity to the requirements.** Records of the nature of the nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

Appropriate quality records are evaluated and analyzed at least annually to detect potential causes of nonconformities. The records shall include (but not be limited to):

- Customer complaints
- Inspection and Test reports
- Process Reports
- Concessions
- Internal and External audits

In addition to any contract or regulatory authority reporting requirements, Precision Sensors' system shall provide timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes, as necessary, parts affected, customer and/or Precision Sensor's part numbers, quantity and date(s) delivered.

8.4 Analysis of data: Precision Sensors determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the Quality Management System, and to evaluate where continual improvement of the effectiveness of the Quality Management System can be made. This uses data generated as a result of monitoring and measurement and from any other relevant resources.

The analysis of data shall provide information relating to

- a) customer satisfaction,
- b) conformity to product requirements, (**see 8.2.4**).
- c) characteristics and trends of processes and products including opportunities for preventive action (**see 8.2.3 and 8.2.4**), and
- d) suppliers (**see 7.4**).

8.5 Improvement

8.5.1 Continual improvement: Precision Sensors continually improves the effectiveness of the Quality Management System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action: Precision Sensors has a documented procedure for implementing corrective action appropriate to the effects of the nonconformities encountered (see SOP 8.5.2).

Precision Sensors shall take action to eliminate the causes of nonconformities in order to prevent recurrence.

All changes to the documented procedures caused by corrective action are made and implemented.

A documented procedure has been generated to define the requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the cause of the nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of actions taken (see 4.2.4), and
- f) reviewing **the effectiveness of the** corrective action taken,
- g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and
- h) specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive action: Precision Sensors determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action shall be appropriate to the effect of the potential problem.

A documented procedure has been generated (see SOP 8.5.3) for preventive action to define the requirements for

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken (see 4.2.4), and
- e) reviewing **the effectiveness of the** preventive action taken.

ADDENDUM 1

Section 9.0 This addendum addresses the requirements set forth by the Federal Aviation Administration for PMA parts manufactured by Precision Sensors.

Section 9.1 *REPORTING OF FAILURES, MALFUNCTIONS AND DEFECTS*

9.1.1 Precision Sensors has a documented procedure for reporting failures, malfunctions and defects of FAA-PMA parts to the FAA. (Reference W.I. 21.1)

Section 9.2 *REQUIRED DESIGN CHANGES FOR PMA PARTS*

9.2.1 Precision Sensors has a documented procedure for the submittal of required design changes of PMA parts to the FAA. (Reference W.I. 21.2)

Section 9.3 *AIRWORTHINESS DIRECTIVES*

9.3.1 Precision Sensors has documented procedures for implementing Airworthiness Directives. (Reference W.I. 21.3)

Section 9.4 *FAA-PMA MARKING INSTRUCTIONS*

9.4.1 Precision Sensors has a documented procedure for marking FAA-PMA parts. (Reference W.I. 21.4)

Section 9.5 *APPROVAL OF MINOR / MAJOR DESIGN CHANGES OF PMA PARTS*

9.5.1 Precision Sensors has a documented procedure for the approval of major and minor changes of PMA parts.

Section 9.6 *CUSTOMER NOTIFICATION (CUSTOMERS, FAA, GOVERNMENT)*

9.6.1 Precision Sensors has a documented procedure for customer notification of relocation or expansion. (Reference W.I. 21.6)

ADDENDUM 2

PRECISION SENSORS QUALITY POLICY

Precision Sensors promises our customers that we will distinguish ourselves as a supplier of first-rate solutions, high quality products and prompt services.

This goal will be achieved through continuous improvement of the Quality Management System and

“A United Commitment to Quality”

PRECISION SENSORS QUALITY OBJECTIVES

- 1) Reduce customer returns, deemed Precision Sensors responsibility, to less than 1%.
- 2) Improve employee productivity 10%.
(Target = \$16 in sales per \$1 of DL)
- 3) Improve on time delivery by 25%.

Tim Straub, Vice President & General Manager

Warren Root, Quality Assurance Manager

Paul Zaczkowski, Production Manager

Q347 10/03

ADDENDUM 3
PRECISION SENSORS
ORGANIZATIONAL CHART