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102	Section 1 through 10. Rewrite complete and addition of Section 9	02/22/88	N/R	Ø
103	Section 3, page 12 of 13, Section II, Paragraph B & Page 13 of 13.	04/08/88	N/R	©\$
104	Section 4, Page 3 of 6, Paragraph 1, Sent. 2, Paragraph 2, Sent. 2	09/07/88	N/R	<u>o</u> r
105	Section 4, Page 4 of 6, Paragraph 2, Sent. 1, Paragraph 3, Sent. 4	09/07/88	N/R	S
106	Section 3, Page 7 of 13, Paragraph 2.	09/07/88	N/R	Ø
107	Section 6, Page 2 of 9	09/07/88	N/R	Ø
108	Section 7, Page 4 of 14	09/07/88	N/R	G
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114	Section 4.8.5 revised to delete sampling as the inspection process and to reflect current Executive Management responsibility	03/15/99	N/R	Ø

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118	Revised to include more detail to process interaction (4.2.2)	10/21/03	P. Kirsch	Ø3
119	Revised Org. Chart to include Human Resources, eliminate reference to Senior Technical Advisor position.	11/1/05	M. Golden	R. Ayala
120	Revised to add reference to pest control policy, update Warranty flow chart & make minor corrections.	01/08/07	M. Golden	R. Ayala
121	Revised to correct references to outdated industry standards, ISO9002 and Z-540-1-1994.	11/26/08	D. Miller	R. Ayala
122	Revised all "A2LA" references to state ISO 17025. Updated multiple sections to align the manual with ISO 17025:2005.	2/12/13	D. Miller	R. Ayala
123	Revised the Quality Policy to be more succinct, and added the Management Representative to the QA Manager in the Org Chart	9/17/13	D. Miller	R. Ayala
124	Added a statement required by ISO17025 to sections 5.6.1 and 6.2.2.1. Updated section 6 through 8 to current practices.	8/24/15	D. Miller	R. Ayala
125	Updated Org Chart and corrected grammatical errors. Removed reference to retired QAP-0411.	8/14/17	M. Golden	R. Ayala
126	Revised to include all applicable documentation for ISO 9001:2015 compliance.	3/1/18	M. Golden	R. Ayala
127	Revised to comply with Impartiality (4.1.4) of ISO/IEC 17025:2017. See Section 6.2.2.1.	7/30/21	F. Loza	R. Ayala

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129	Revised to include re 2.0 References.	eference to ANSI/NCSL Z540	0.3 in section	7/14/22	P. Kirsch	R. Ayala
	l <u>.</u>					

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QUALITY POLICY

QUALITY POLICY

It is the policy for Precision Measurements, Inc to establish a vendor/customer partnership for a positive business relationship to ensure that our customer's requirements are understood and being met. All customers shall be served with impartiality, respect and integrity.

Precision Measurements, Inc. team has the goal of total customer satisfaction through SERVICE, QUALITY, and ADDED VALUE. The quality policy shall be communicated, understood and implemented throughout all functions and levels within our organization. The responsibility of quality starts with each and every employee of Precision Measurements, Inc.

We will continuously monitor the progress through customer feedback and internal quality audits. Appropriate measures will be employed to ensure that the customer confidentiality and proprietary rights are maintained at all times.

Management, in support of the above policies and will empower the appropriate personnel with the authority to ensure compliance.

QUALITY STATEMENT

"...to establish a vendor/customer partnership for a <u>POSITIVE BUSINESS RELATIONSHIP</u> to ensure that all of our customers' requirements are met..."

Richard D. Ayala President Carlos Valdez Vice President

1.0 INTRODUCTION AND SCOPE

Precision Measurements, Inc. is an independent metrology laboratory providing calibration of measuring and control equipment. These services are utilized by a broad spectrum of industries and play a vital role in assisting customers in those industries to not only meet or exceed their product quality goals, but also, helping customers satisfy their regulatory compliance requirements. See the Precision Measurements, Inc. Scope of Accreditation for a full list of Disciplines, Capabilities and parameters covered.

Precision Measurements, Inc.'s Quality System (described in the Quality Assurance Manual and Calibration System Description) is integral to this objective and is intended to cover the services offered in their entirety. Consistent with its quality objectives, Precision Measurements, Inc. acquired registration under ISO 9002 (currently ISO 9001) in 1997, and received Laboratory Accreditation under ISO/IEC 17025 (formally ISO/IEC GUIDE 25) in 2001.

2.0 **REFERENCES**

This Quality Assurance manual is maintained in compliance with the applicable requirements set forth in the following Codes and Standards:

- ISO 9001 current revision, Quality Management Systems.
- ISO/IEC 17025 current revision, General Requirements for the Competence of Testing and Calibration Laboratories.
- ANSI/NCSL Z540-1 current revision, American National Standard for Calibration—Calibration Laboratories and Measuring & Test Equipment—General Requirements.
- ANSI/NCSL Z540.3 current revision, American National Standard for Calibration—Requirements for the Calibration of Measuring and Test Equipment
- ISO 10012-1, Quality Assurance Requirements for Measuring Equipment—Part 1: Metrological Confirmation System for Measuring Equipment.
- MIL STD-45662A, August 1, 1988, Military Standard, Calibration Systems Requirements.
- 21CFR820, Food and Drugs (as applicable).
- NCSL Recommended Practices (as applicable).

3.0 PURPOSE

The purpose of this Quality Assurance Manual is to outline the Quality System Program in place at Precision Measurements, Inc.; which is formulated according to the following guidelines:

- a) Overall quality policy and objectives.
- b) Quality planning, implementation and product realization
- c) Quality responsibility and employee empowerment.
- d) Quality control and quality improvement.

The Quality Assurance Manual is the responsibility of the Precision Measurements, Inc. Quality Assurance Manager and under whose authority it is maintained current, distributed and controlled.

4.0 QUALITY MANAGEMENT SYSTEM

4.1 GENERAL REQUIREMENTS

Precision Measurements has identified, documented and implemented the service and service processes necessary to ensure that customer needs and Quality System Requirements are met.

The documented Quality Management System incorporates sequential, interactive and controlled service processes; and provides for the monitoring, measuring and analysis of data and resource needs leading to process improvement.

Additionally, the Quality Management System identifies and provides for controls that are applied to outsourced service processes.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

Precision Measurements, Inc. documentation is categorized according to the following structure:

- a) Quality Assurance Manual and Quality Policy.
- b) Operational Procedures consisting of
 - Quality Procedures (QAs).
 - Work Instructions (QAPs)
- c) Calibration System Description including:
 - Measurement Uncertainties Program reference.
 - Interlaboratory Proficiency Testing Program reference.
- d) Technical Library Documentation including:
 - Calibration Procedures (Precision Measurements, Inc. and Commercial Origin).
 - Customer-Furnished Calibration Specifications and Procedures.
- e) Forms (Quality and Service Process)
- f) Labels and Tags.
- g) Quality Records.

4.2.2 QUALITY MANUAL

The Quality Assurance Manual, including referenced lower-tier procedures (QAs and QAPs) documents Precision Measurements, Inc.'s quality system. These documents define the organizational structure, service ranging from general to specific work instructions, which address and satisfy the Codes and Standards identified in 2.0 References, and therefore ensure that all service requirements are met.

All service processes are carried out in accordance with documented procedures to ensure the quality of calibration services.

All processes interact through customized databases with personnel having access to individual queues related to a particular process(s). Process records are forwarded to different areas of the databases for processing. (See Sequence and Interaction of Processes Chart on page 20)

4.2.3 CONTROL OF DOCUMENTS

Precision Measurements, Inc. established and maintains a documented procedure (QA-0045) to control documents and data related to the requirements of Codes and Standards identified in 2.0 References, customer service quality requirements, and the quality objectives set forth in this Quality Assurance Manual. The index to various PMI Calibration Procedures and Work Instructions (QAPs) is the "Controlled Documents Master List (Latest Revision)". Customer supplied procedures and manufacturer manuals are identified and maintained in the PMI Technical Library.

Documents of external origin, including applicable quality and regulatory standards listed in 2.0, References, calibration procedures and manufacturer's manuals, etc., are maintained and controlled by Document Control. Documentation may be maintained in the form of printed matter or electronic media such as software, CD-ROM, microfilm, or other suitable media.

The Document Control function is the responsibility of the Quality Assurance Department.

4.2.3.1 DOCUMENT, DATA APPROVAL, AND ISSUE

Controlled documents and related data are reviewed and approved for adequacy by authorized personnel prior to issue.

The Controlled Documents Master is maintained on the PMI Intranet by the Information Technology Manager under the responsibility of the Quality Assurance Manager.

The Quality Manager with the cooperation of Information Technology Manager is responsible for ensuring that:

- a) Pertinent issues of applicable documents are available at all required functional locations via PMI Intranet.
- b) Calibration procedures of PMI origin are developed and revised, as needed, by Metrology staff personal technically knowledgeable of the operating characteristics and application of the applicable equipment. Details of the Calibration Procedure development are provided in QA-0145.

The Quality Assurance Manager has the authority and responsibility for the approval, distribution and revision of all controlled Operational Procedure documents. The Electronics and Mechanical/Dimensional Metrology Laboratory Managers/ Supervisors are responsible for the maintenance, issuance and appropriate use of equipment calibration and repair procedural documentation.

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4.2.3.2 DOCUMENT AND DATA CHANGES

Changes to documents and related data, including the Quality Assurance Manual, are reviewed and approved by the same functions that performed the original review and approval, unless otherwise specified.

Reviewing function-related personnel have access to pertinent background information upon which to base their review and approval.

Document change (revision) proposals include the nature of the change, reason, justification and any applicable attachments, if appropriate.

Any employee may submit proposed changes to any controlled operational procedure document. Proposed changes are reviewed by the Quality Assurance Manager and affected department manager/supervisor. The authority and responsibility for final approval and distribution rests with the Quality Assurance Manager.

4.2.4 CONTROL OF RECORDS

Precision Measurements, Inc. established and maintains a documented procedure (QA-0416) for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of Quality Records.

The Quality Records maintained demonstrate conformance to customer and operating standards requirements, compliance in following established procedures to maintain the adequacy of all measuring and testing equipment, and the effectiveness of the Precision Measurements, Inc. Quality System.

4.2.4.1 CALIBRATION CERTIFICATES

Calibration results shall be documented in a form that includes all of the information necessary for the interpretation of the calibration of results and all information required by the method used. Details of minimum information required for calibration certificates performed under accredited and non-accredited services are addressed in QA-1000.

4.2.4.2 ADEQUACY OF RECORDS

Records shall be sufficient to permit repetition of calibrations or verifications. Original observations, calculations and derived data where possible, calibration certificates, including identity of personnel performing sampling, preparation, calibrations or verifications are maintained as quality records.

4.2.4.3 SECURITY OF RECORDS

All records, including records pertaining to equipment history and reference materials, calibration certificates and reports, are safely stored, held secure, and in confidence.

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Precision Measurements, Inc.'s Quality Records include, but are not necessarily limited to:

- a) Certificates of Calibration, Service Reports and service-related Data Reports
- b) Shipping and Receiving records
- c) Subcontractor (supplier) audit, survey and/or other supplier qualification records
- d) Subcontractor service records
- e) Internal Audit reports and Corrective Actions
- f) Supplier Corrective Action Reports
- g) Customer feedback (complaint) records
- h) Inspection records
- i) Status Reports
- j) Management Reviews of the Quality System
- k) Training Records
- 1) Pertinent service quality records and certificates supplied by subcontractors
- m) Contract Files
- n) Database archives
- o) Equipment history and all reference materials significant to the calibrations or tests performed
- p) Proficiency testing and measurement assurance results
- q) Environmental records
- r) Field service records
- s) ISO 17025 Scope of Accreditation records and customer or third-party (i.e., Registrar) surveillances
- t) Authorized Signatories List
- u) Computer and automated test equipment system records

Precision Measurements, Inc.'s hard copy Quality Records must be legible, and are stored and retained so as to be readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration or loss.

Where practical, certain Quality Records are stored and retained electronically in the Precision Measurements, Inc. computer database. The Precision Measurements, Inc. database is maintained in accordance with requirements identified in the Quality Assurance Manual. Retention times of quality records have been established, and are identified and recorded in the Master List (matrix) of Quality Records maintained by the Quality Assurance Manager.

NOTE: Records of each major item of equipment and all reference materials significant to the calibration performed, including temperature and humidity records, are maintained for a minimum of five (5) years. Customer equipment service records are maintained a minimum of five (5) years, unless longer periods are specified in individual contracts.

Applicable Quality Records may be made available, upon request by contract customers, for inspection and evaluation. Such inspections shall be at the Precision Measurements, Inc. facility.

The authority and responsibility for the control and maintenance of Precision Measurements, Inc.'s Quality Records is defined in the documented procedure (QAP-0416) for the control of Quality Records.

4.2.4.4 CONFIDENTIALITY OF RECORDS AND DATA

Documented procedures address criteria for protecting customer confidentiality and proprietary rights through all phases of providing PMI service; including during the transmission of records and data by telephone, facsimile or other means (e.g. Internet access, etc.). Internet access is held secure by PIN assignment unique to each customer and buffering from PMI's internally networked database.

4.2.5 NEEDS AND EXPECTATIONS OF INTERESTED PARTIES.

Precision Measurements, Inc. has established that the following parties have a relevant impact on the quality management system.

- **Customers**: Need calibration and repair services. They expect high quality of work performed and a turnaround time that is within their agreement with PMI. This is monitored with our Customer Satisfaction procedure (QAP-0821).
- **Employees**: Need work security and satisfactory wages but in return, PMI expects employees to be well trained and to perform their duties as outlined in the company's procedures. This is in part monitored in accordance to PMI procedures for Training (QA-0418) and Technician Proficiency Testing (QAP-1418).
- **Vendors**: PMI needs the products and services provided by vendors to be of high quality and expects to receive the products and services within an agreed upon time frame. This is monitored with PMI's Vendor Qualification and Registration procedure (QA-0146).

5.0 MANAGEMENT RESPONSIBILTY

5.1 MANAGEMENT COMMITMENT

The Precision Measurements, Inc.'s executive management has defined and documented a quality policy and system that enables the company to realize its established quality goals, including progressive quality improvement. The management is committed to providing quality services and recognizes its proactive role in establishing policy, resource allocation, quality training and awareness, as well as planning and implementing continuous quality improvement. Precision Measurements, Inc.'s quality processes are distributed throughout the company's infrastructure. Individual operating departments are responsible for the quality of their respective processes, and ensuring that the established quality policies are understood and implemented at every level within the department.

5.2 CUSTOMER FOCUS

The Precision Measurements, Inc. Sales/Marketing Manager reviews all tenders and Requests for Quotation (RFQ), and contracts or orders prior to submission or acceptance to ensure that:

- a) The customer's requirements are adequately defined and documented; or in the case of verbal orders received, that agreement is obtained in writing as to order requirements prior to acceptance.
- b) Any differences between the contractor accepted order requirements and tender or RFQ are resolved.
- c) Precision Measurements, Inc. has the appropriate facilities and resources (personnel and equipment) to meet the contract or order requirements prior to commencing such work, based on review of the equipment to be calibrated by the President, or his delegate (normally the Quality Manager).
- d) Notice of calibration requirements under the ISO 17025 Scope of Accreditation is communicated and agreed to by the customer in writing.

5.3 QUALITY POLICY

The Precision Measurements, Inc.'s Quality Policy is defined at the front of this Quality Assurance Manual. The Quality Policy is communicated to all employees through the following means:

- a) New Employee Orientation
- b) Process specific training
- c) Company Meetings
- d) Quality Information Memoranda

5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

Precision Measurements, Inc.'s Quality objectives are defined as follows:

- Consistently meet all contractually specified service requirements. Performance is measured through contract renewal rate and the customer feedback process.
- Establish, implement and maintain the Quality System Program requirements set forth in this Quality Assurance Manual throughout the company. Quality audits and management reviews are used to measure and evaluate the performance and effectiveness of the Quality System Program in meeting the Quality Policy objectives and commitments.
- Detect, correct and continuously reduce service process discrepancies through sequential in-process inspection. Discrepancy reduction is measured through inspection data analysis.

5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

Precision Measurements, Inc. defines and documents its quality plans according to new opportunities, such as customer-driven requirements and changes in Metrological Standards as well as ability to limit risk of losing customer base.

Documentation may be in the form of purchase orders for new measurement standards, service process procedure revisions, or staff/skill enhancement records.

Quality Planning includes consideration of the following:

- a) Identification and acquisition of any controls, processes, equipment, skills and personnel required to achieve quality requirements and objectives.
- b) Ensuring the compatibility of servicing processes; including test and inspection procedures, and applicable documentation.
- c) Updating quality control, inspection and test procedures, and instrumentation as necessary.
- d) Identification of extraordinary measurement requirements in sufficient time to acquire needed capability.
- e) Identification of suitable verification activities in the service process, including in-service checks where possible.
- f) Clarification of service specifications and control requirements.
- g) Identification and preparation of quality records.

NOTE: Quality planning is an integrated activity in the service contract negotiation and consummation process.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 **RESPONSIBILITY AND AUTHORITY**

The President has the overall responsibility for defining and establishing the Precision Measurements, Inc.'s Quality Policy and ensuring that all functions and activities are in compliance. Organizational knowledge specific to PMI is disseminated at the sole discretion of the President through the channels defined by the Organizational Chart.

Precision Measurements, Inc. executive management is comprised of the President and Vice President, each having parity authority. Functional responsibilities within the organization are outlined and depicted in Management Organizational Charts.

a) The Quality Assurance Manager, as Management Representative, has the authority and overall responsibility for the surveillance of the Precision Measurements, Inc. quality system and Document Control. The President assumes all responsibilities delegated to the Quality Assurance Manager in the event of his absence or inability to fulfill his responsibilities.

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- b) The President has the responsibility and authority for the implementation of the quality system throughout the functional areas of Electronic Metrology, Mechanical/Dimensional Metrology, Field Service, Administrative Support, Data Management, Shipping/Receiving, Customer Service, and Human Resources. The President is the designated alternate for assuming the responsibilities of the Technical Operations Manager in the event of his absence or inability his respective duties and responsibilities.
- c) The Vice President has the authority and responsibility for the implementation of the quality system throughout the functional areas of Sales and Marketing. Department managers/supervisors are authorized by and responsible to their respective executive managers for ensuring that all Precision Measurements, Inc.'s functionally related quality activity is in accordance with the quality policies set forth in this manual and the requirements of Codes and Standards identified in 2.0, References.
- d) The Electronic and Mechanical/Dimensional Metrology Supervisors are responsible for the work performed under their authority and for identifying, implementing and evaluating effectiveness of needed training for their respective staff.
- e) The Technical Operations Manager oversees the Metrology Laboratory, Field Service, Shipping/Receiving, and Administration and activities.
- f) The Quality Assurance Manager has the responsibility for overall surveillance of the PMI quality System including:
 - Internal audit scheduling and implementation.
 - Processing Internal Corrective Action Requests including following up to verify effectiveness of corrective actions.
 - Initiating and processing Supplier Corrective Action Requests, and verifying effectiveness of corrective actions.
 - Processing customer complaints (Customer Feedback) including verification that necessary corrective and preventive actions have been implemented.
 - Document control
 - Establishing, adjusting (as appropriate) calibration intervals for PMI Standards.
 - Qualifying PMI calibration subcontractors.
 - Monitoring the care, handling and storage of PMI Standards.
 - Filing PMI staff qualification and training records.
 - Quality awareness training
- g) The Field Service Supervisor is responsible for assigning site calibration service support and identifying implementing and evaluating the effectiveness of technical training for technicians.
- h) Technicians are responsible for performing calibration and related equipment services In-House (at the PMI facility) or at the customer's site (Field Service) as assigned.
- i) Data Management (IH) verifies customer equipment information and creates initial service records for service provided at the PMI facility.
- j) Data Management (FS) creates final reports of calibration and related customer equipment service performed on-site (Field Service).

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- k) Customer Service is the primary functional liaison between the customer and PMI to provide service status to the customer and to communicate customer concerns and complaints (Customer Feedback) to the Quality Assurance Manager for processing and closure.
- 1) Shipping/Receiving is responsible for documenting and transporting customer equipment to and from the PMI facility.

Note: Additional functional responsibility details are addressed and defined in applicable QA-xxxx and QAP-xxxx procedures.

The authority and responsibility to identify and record quality nonconformities and initiate corrective and preventive action transcends all levels of management.





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5.5.2 MANAGEMENT REPRESENTATIVE

The Quality Assurance Manager, as Management Representative, has the authority and overall responsibility for the implementation, surveillance and improvement of the Precision Measurements, Inc. quality system and Document Control.

5.5.3 INTERNAL COMMUNICATION

Management's policies and commitment to quality are communicated throughout all functions and levels within Precision Measurements, Inc. through the following means:

- a) New Employee Orientation
- b) Company Meetings
- c) Quality Information Memoranda

Audit reports, both internal and external, and related Internal Corrective Action Requests (ICARs) are made available for review with the applicable personnel audited; and forwarded to QA for review and follow-up action, if indicated, during the Management Review process.

Special Customer Information forms and emails are used to communicate customer requests for Special Requirements.

QAP changes are communicated when they are revised via internal memos and e-mail.

5.6 MANAGEMENT REVIEW

5.6.1 GENERAL

The Management Review Process is carried out at least annually by a team consisting of the President and the Quality Assurance Manager, to determine overall effectiveness of the system in meeting management's objectives and commitments, customer requirements, corrective action(s) to be taken; and to identify areas for improvement. The agenda for the Management Review Meeting includes all external and internal issues that are relevant to the purpose and strategic direction of PMI Quality. The Vice President, Technical Operations Manager and functional area managers/ supervisors support and participate in the management review process as appropriate for their areas of responsibility. Once completed a copy of the current Management Review shall be made available to PMI employees via the PMI Intranet for the employees to see the effectiveness of the management system.

5.6.2 **REVIEW INPUT**

The Management Review Process includes review of the following elements as appropriate to the period reviewed. These elements are intended to include status and changes in external and internal issues relevant to Quality

- a) Matters arising from the previous review to include effectiveness of actions taken to address risks and opportunities.
- b) Reports from audits by clients and 3rd party (e.g., ISO 17025 Accrediting Body, ISO, etc.).
- c) Review of Internal Audit Reports, including laboratory calibration and verification audits, and related Internal Corrective Action Reports (ICAR(s)).
- d) Review of customer feedback and customer audit reports for trends and closure, and determination of corrective action for closure of open reports.
- e) Review of Internal Corrective Actions and analysis for trends.
- f) Review of Total Customer satisfaction statistics.
- g) QC Error Log review
- h) Review of In process Quality checks
- i) Results of participation in proficiency testing.
- j) Upcoming audits scheduled and/or pending.
- k) Review of the Precision Measurements, Inc.'s Quality Assurance Manual (QAM) and operational procedures for suitability and effectiveness, including the Quality Policy.
- 1) Quality improvement and Preventative Action and their effectiveness in addressing opportunities identified during the year.
- m) Review of changes and volume of work.

5.6.3 REVIEW OUTPUT

Conclusions, findings, actions and recommendations of the review team in the review process to address risks and opportunities are documented for record and necessary action initiated to implement Quality Improvement actions. Planning will include estimates of what resources will be required for each action, who will be responsible, when it will be accomplished and how it will be evaluated.

- a) Review of proposed amendments or revisions to Precision Measurements Inc.'s Operational Procedures.
- b) Proposed quality improvement actions.
- c) Preventive Actions
- d) Process quality planning and improvement implementation.
- e) Future plans and estimates for new work, new staff, new equipment, etc.

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6.0 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

Precision Measurements, Inc.'s management has identified in its quality system documentation, the resources, including personnel, required to meet the quality system goals and satisfy customer requirements.

6.2 HUMAN RESOURCES

6.2.1 GENERAL

Adequately trained or experienced personnel, and necessary equipment and materials have been provided to the various functional areas to ensure that all activity meets the Quality Policy and customer quality requirements.

The Approved Signatories are maintained current under the authority of the President and identifies those individuals with authority and qualifications to sign calibration reports under the ISO 17025 Scope of Accreditation.

6.2.2 COMPETENCE, AWARENESS AND TRAINING

A training and employee qualification system is established and implemented by Precision Measurements, Inc. for all personnel involved in activities affecting service quality. In addition, a training program is in place applying to all employees throughout the organization to ensure quality awareness and sensitivity to customer service requirements.

Documented procedures (QA-0418 and QAP-1418) are established for identifying training needs, providing training on a current basis consistent with identified needs, employee assignments and development, and recording training activities.

6.2.2.1 PERSONNEL

The laboratory maintains sufficient personnel with the necessary qualifications (i.e. education, training, technical knowledge) and experience for their duties. Training is obtained through formal classroom and/or on-the-job training. Proficiency is demonstrated through qualifications testing, and performance testing. Personnel are free from undue pressures which might adversely affect the quality of their work. All employees are to remain impartial in all of the work they produce. Risk to impartiality is maintained through an "Impartiality Questionnaire" (PM-IQ001), that is filled out upon hiring the employee, and once a year thereafter during their annual performance review.

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6.3 INFRASTRUCTURE

6.3.1 GENERAL

Precision Measurements, Inc. maintains a physical plant that includes individual distinct environmentally controlled and monitored laboratory areas. Adequate workspace is designated and provided according to required functionality and service objectives to achieve effective and efficient product realization. Adequate facility security measures including restricted and controlled access and video surveillance devices are in place to protect and preserve equipment and material.

Equipment in the form of calibration standards are in place and maintained to ensure the adequacy and integrity of calibrations.

A uniquely designed computer network system is utilized and maintained to capture, document and retain service process information, as well as generate service and support documentation.

Precision Measurements, Inc. maintains specially equipped vehicles for the safe and secure transport of customer and PMI owned equipment.

Workmanship standards, in the form of specific equipment manufacturer-supplied manuals are available and utilized for equipment repair, as applicable.

Preventive maintenance, when required, is performed as an integral part of the equipment service process; and noted, if applicable on the related service documentation.

Precision Measurements, Inc. utilizes controlled processes consisting of process flow charts, work instructions, and equipment identification tags and labels to maintain service quality.

Records of personnel qualifications, and where possible, history of equipment utilized in the processes are maintained.

6.3.2 SPECIAL PROCESSES

Incidences of service requiring special processing are continuously monitored to ensure all special service requirements are met. Special processes include customer equipment returns for warranty evaluation, and emergency service.

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6.3.3 CALIBRATION AND TEST METHOD

Documented procedures (QA-1000 and Calibration Procedures) are maintained current and address the use and operation of all relevant equipment, handling and preparation of items for calibration and internal process control schemes.

Calibration methods and procedures include those obtained from commercial or other external sources such as manufacturers manuals, GIDEP-supplied and other equipment specific procedures and internally generated procedures. Procedures of external origin are controlled and maintained in the PMI Technical Library database. Internally generated calibration procedures are either instrument-specific or generic to cover a family of an instrument type and are controlled and maintained by Quality Assurance (QA-0045). All instructions, standards manuals and reference data relevant to the laboratory activities are maintained up-to-date and readily available to the staff.

6.3.4 COMPUTERS AND AUTOMATED TEST EQUIPMENT (ATE) SYSTEMS

Precision Measurements, Inc. utilizes a database to document, process, record, report, store/retrieve and track calibration services and customers. Proprietary information is also made available to customers through password access over the Internet. Automated test equipment is utilized, where available, to perform calibrations. These activities are performed in accordance with QAP-2145 to ensure the following:

Computer software is documented and adequate for use (whether developed commercially or internally). The following are addressed, as applicable:

- a) Inventory
- b) Software performance tests
- c) Hardware operating systems
- d) Operating instructions
- e) Software verification procedures using known data sets, program listing, flowcharts, configuration control system, system management
- f) Backup procedures
- g) Data archival
- h) Password protection
- i) Read/write protection
- j) Hierarchical user access scheme
- k) The integrity of data is protected, including integrity of data entry or capture, data storage, processing and data transmission, in accordance with established procedures that are implemented and maintained current to ensure data is not corrupted or tampered with
- 1) Required environmental control and operating conditions are provided to ensure proper functioning of computers or automated test equipment systems to maintain data integrity
- m) The security of data, preventing unauthorized access to computer records and unauthorized amendments of computer records is password controlled

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6.4 WORK ENVIRONMENT

Calibration services are performed in an environment appropriate to the services performed. Documented procedures address lighting, temperature, humidity and ventilation considerations. Environmental issues such as location where calibrations are performed, monitoring, controlling and recording environmental conditions, effective separation between areas where activities are incompatible, controlled access, good housekeeping practices, etc. are considered to ensure that calibration results and accuracy are not adversely affected or invalidated. Pest control measures are taken on a monthly basis to prevent infestation/contamination of the premises as well as customer owned instruments.

6.4.1 ENVIRONMENTAL CONTROLS

Calibrations are performed, and standards are maintained in an environment controlled to the extent necessary to ensure valid results. Environmental considerations include:

- Temperature and Relative Humidity
- ESD
- Ventilation and Dust control
- Lighting
- Vibration (Gravimetric/Mass calibration)
- Access Control
- Housekeeping

7.0 PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

Precision Measurements, Inc., has planned and developed documented process procedures (QA-0049) and for the fulfillment of product realization including control of each process through which all customer equipment and Precision Measurements, Inc., test and measuring equipment are identified, verified, serviced, tracked, inspected and handled according to product quality objectives and customer requirements, and product acceptance criteria.

The respective managers/supervisors involved in the service process are responsible for ensuring that suitably qualified personnel are available and appropriately assigned to ensure all service requirements are met. Records of personnel qualifications are maintained.

Workmanship standards in the form of equipment manufacturer-supplied manuals, in-house generated calibration procedures and technical service documents from other outside sources are available and utilized in the equipment service process.

Documented support processes including Customer Service, In-House and Field Service scheduling and coordination, and database management (In-House and Field Service) are in place and utilized to provide necessary support to fulfill product realization requirements and goals.

Inspection and testing are performed in accordance with documented procedure (QA-0410) to ensure that all service quality and contractual requirements are met.

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

Precision Measurements, Inc., has documented procedures (QA-0143, QA-2143) for determining and reviewing customer-specified service requirements, requirements known but not specified by the customer such as required for compliance according to applicable Meteorological Standards (e.g. ANSI/NCSL Z540, etc.) and regulatory codes.

7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

The Precision Measurements, Inc. Sales/Marketing Manager reviews all tenders and Requests for Quotation (RFQ), and contracts or orders prior to submission or acceptance to ensure that:

- a) The customer's requirements are adequately defined and documented; or in the case of verbal orders received, that agreement is obtained in writing as to order requirements prior to acceptance.
- b) Any differences between the contractor accepted order requirements and tender or RFQ are resolved.
- c) Precision Measurements, Inc. has the appropriate facilities and resources (personnel and equipment) to meet the contract or order requirements prior to commencing such work, based on review of the equipment to be calibrated by the President, Technical Operations Manager, and Mechanical/Dimensional Supervisor.
- d) Notice of calibration requirements under the ISO 17025 Scope of Accreditation is communicated and agreed to by the customer in writing.

Records of contract reviews; including tenders, RFQs, and the acceptance of service contracts, are maintained as quality records.

Records of all contract amendments and revisions, including any customer correspondence, are maintained on file.

7.2.3 CUSTOMER COMMUNICATION

A documented procedure (QA-0043) is in place, which defines the Contract Amendment and Review Process.

Verbal orders for any level of equipment service are documented on the Precision Measurements, Inc.'s Verbal/FAX Quote Form (VQ-222), for record.

Verbal requests for changes to a contract are documented on the Precision Measurements, Inc.'s Customer Request Form (PM-CR014).

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Any deviations from requirements of this Quality Assurance Manual, the Calibration System Description, Standards, Operational Procedures or Calibration Procedures, shall be implemented in accordance with QA-0242. PMI Quality Assurance Manager approval, and customer approval, where applicable, is required prior to departing from documented and established policies or procedures.

Customer complaints or kudos (Feedback) expressed verbally, in writing (or both) shall be handled in accordance with QAP-0314. A record is kept of all complaints and resolutions. Corrective action reports are generated for valid complaints and are implemented as described in 8.5 of the Quality Assurance Manual.

The Quality Assurance Manager investigates concerns pertaining to laboratory compliance with policies and procedures or requirements concerning calibrations or verifications promptly during the complaint resolution process; and audits, where applicable, will be conducted promptly in accordance with provisions of 8.2 of the Quality Assurance Manual.

A documented procedure (QA-0142) is maintained to protect confidentiality and proprietary rights of Precision Measurements, Inc. and its customers. Implementation requirements and the nature of information considered confidential or proprietary are addressed.

Customers wishing to visit Precision Measurements for the purposes of discussing or witnessing a calibration may do so by contacting PMI in writing to schedule an appointment. The appointment is to allow PMI to maintain the confidentiality of other customers while the visit is taking place. Continuous contact with customers is encouraged during Field Service calls and during large equipment influx periods to keep the customer informed on the progress of their equipment.

7.3 DESIGN AND DEVELOPMENT

Precision Measurements, Inc. provides services only and does not design, manufacture, or supply a tangible product. Therefore, this element does not apply; nor is it included as a quality system requirement as described in the applicable ISO 9000 standards.

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7.4 PURCHASING

7.4.1 PURCHASING PROCESS

It is Precision Measurements, Inc.'s policy to purchase repair material and parts, repair services, and calibration services and consumable materials, which conform to specified requirements. A documented procedure (QA-0046) is in place to ensure purchased calibration services and consumable materials that affect calibration services, comply with PMI Quality System and customer service quality requirements. An Approved Vendor list is maintained by Purchasing under the responsibility of Quality Assurance Manager.

The responsibility for the timely, accurate and quality-ensured purchase of repair parts and services and consumable materials that affect calibration, is the responsibility of the requester, cognizant buyer; and in the case of PMI standard calibration services, the Quality Assurance Department.

All Purchase Requisitions require executive management approval prior to actual purchase.

7.4.1.1 EVALUATION OF SUB CONTRACTORS (SUPPLIERS)

Precision Measurements, Inc. evaluates and selects suppliers based on their ability to meet Quality (including the Quality Program System and ISO 17025 Scope of Accreditation criteria), cost, and delivery requirements according to documented procedures and specifications. Specific criteria and evaluation methods are defined in Precision Measurements, Inc.'s Calibration System Description, QA-1000.

For non-accredited laboratory services, long standing subcontractors who have demonstrated continued satisfactory performance may continue as approved suppliers without periodic, formal re-evaluation. This determination is contingent on the characteristics identified below.

The degree and extent of quality assurance inspection, test, audit and surveillance of any subcontractor depends upon:

- a) The nature of service to be rendered
- b) On calibration traceability
- c) The impact on Precision Measurements, Inc. services, and
- d) Previously demonstrated capability and performance of the subcontractor.

An Approved Vendor list and supporting records of subcontractor evaluations and performance history are maintained, as described in the Calibration System Description, and QA-0146.

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7.4.1.2 SUBCONTRACTED SERVICES (ISO 17025 SCOPE OF ACCREDITATION)

Any portion of the calibration or testing work subcontracted under the ISO 17025 Scope of Accreditation, will be performed by ISO 17025 accredited laboratories or laboratories approved by the Current Accrediting Body (e.g., NVLAP, etc.) (Unless a waiver is obtained from the Accrediting Body) to ensure the adequacy of calibration performed. No non-accredited laboratories are to be used for the purpose of an accredited calibration. In addition, Precision Measurements, Inc. customers are notified in writing of any intent to subcontract any portion of ISO 17025 Scope of Accreditation services and records of subcontracted work will be maintained.

7.4.2 PURCHASING INFORMATION

Purchase Orders for products which impact Precision Measurements, Inc.'s service quality contain data clearly describing the product ordered, including where relevant:

- a) Nomenclature, class, size, grade or other precise identification.
- b) Title or other identification of specifications, process requirements,
- c) Inspection instructions and other relevant technical data including
- d) Requirements for approval or qualification of the product.
- e) Title and/or identity of applicable quality, military or national standards.

All final purchasing documents shall include sufficient information and unambiguous data to ensure fulfillment of ordered product requirements.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

PMI Metrology personnel verifies the quality of incoming repair material and parts, consumable materials that affect calibration, and subcontracted services using inspection, test, supplier certification and/or other techniques, as applicable prior to acceptance and use.

Wherever possible, purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations concerned. Records of all suppliers that provide support services or supplies for calibration services are maintained.

If source inspections at the supplier's premises are required, the arrangements and requirements for product release are specified in the purchase order.

When established by agreement between Precision Measurements, Inc. and its customer, the customer has the option of verifying a purchased product at the supplier's premises. However, Precision Measurements, Inc. assumes and maintains the responsibility for the acceptance and release of incoming material and subcontracted services.

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All incoming purchased parts and material required for the repair and servicing, including consumable materials that affect calibration of customer equipment, are inspected or otherwise verified as conforming to specifications prior to release for use according to documented procedures.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION AND SERVICE

Precision Measurements, Inc. established documented, controlled processes to carry out the calibration, repair and servicing of customer and Precision Measurements, Inc. equipment (QAP-1049, QAP-2049).

Equipment specifications and performance characteristics criteria in the form of manufacturer's manuals, individual specification documents and standards are on file or otherwise available and utilized in the calibration and service process.

7.5.1.1 CALIBRATION AND TEST METHODS

Documented procedures are maintained current and address the use and operation of all relevant equipment, handling and preparation of items for calibration and internal process control schemes.

Calibration methods and procedures include those obtained from commercial or other external sources such as manufacturer's manuals, GIDEP-supplied, other equipment specific procedures and internally generated procedures. Procedures of external origin are controlled and maintained in the PMI Technical Library database. Internally generated calibration procedures are either instrument-specific or generic to cover a family of an instrument type and are controlled and maintained by Quality Assurance. All instructions, standards manuals and reference data relevant to the laboratory activities are maintained up-to-date and readily available to the staff.

Calibration uncertainties are sufficiently small, so as to not affect the adequacy of the measurement. Where well-defined and documented measurement uncertainties are not used to verify adequacy of measurements, the collective measurement uncertainty of standards shall not exceed 25% of the manufacturer's specification for each characteristic being calibrated or tested.

7.5.1.2 STANDARDS AND REFERENCE MATERIALS

All items of equipment (including reference materials, natural physical standards, etc.) required for the correct performance of calibrations and tests are maintained and available to the laboratory for its use. Documented procedures (QAP-2149, QA-1000) address equipment maintenance, records, handling and labeling requirements.

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7.5.1.3 MEASUREMENT TRACEABILITY AND CALIBRATION

All instruments, Measurement and Test Equipment owned, rented, borrowed or leased, having an effect on the accuracy and validity of calibrations or verifications are calibrated and/or verified before being placed into service in accordance with the Calibration System Description. Measures addressed to ensure traceability and include:

- a) Equipment recall or removal from service;
- b) Unbroken chain of traceability;
- c) Uncertainty of measurements;
- d) Measurement assurance techniques and practices;
- e) Identity, calibration and use of reference standards;
- f) In-service checks between calibrations and verifications;
- g) Traceability of Standard Reference Materials (SRMs).

7.5.1.4 RELEASE AND DELIVERY

The verification that all services have been performed according to customer/PMI process and system requirements takes place through an inspection process and is the responsibility of the Quality Control Inspector under the authority of the Quality Assurance Manager.

Nonconforming services are identified, corrected, and verified in accordance with the Quality Assurance Manual.

All customer equipment requiring local delivery is individually marked as to identity and customer. Equipment is transported in specially equipped vehicles and is protected with high-density foam. Where appropriate, small and fragile equipment is placed in foam-lined containers.

All related service documentation is delivered with the equipment.

NOTE: The term "customer equipment" includes equipment owned, rented, borrowed or leased by Precision Measurements, Inc. and used to perform calibrations, as well as that equipment submitted by its outside or contracted customers for calibration by Precision Measurements, Inc.

7.5.1.5 POST-DELIVERY ACTIVITIES

Customer returns are processed to determine warranty status and subsequent actions to be taken according to policy and customer-specific contractual terms.

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7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

Incidences of service requiring special processing are continuously monitored to ensure all special service requirements are met. Special processes include customer equipment returns for warranty evaluation, and emergency service.

Any deviations from requirements of this Quality Assurance Manual, the Calibration System Description, Standards, Operational Procedures or Calibration Procedures, shall be implemented in accordance with QA-0242. The Quality Assurance Manager's approval, and customer approval, where applicable, is required prior to departing from documented and established policies or procedures.

Precision Measurements, Inc. utilizes a database to document, process, record, report, store/retrieve and track calibration services and customers. Proprietary information is also made available to customers through password access over the Internet.

Automated test equipment is utilized, where available, to perform calibrations. These activities are performed in accordance with QAP-2145 to ensure the following:

- a) Computer software is documented and adequate for use (whether developed commercially or internally). The following are addressed, as applicable:
 - Inventory;
 - Software performance tests;
 - Hardware operating systems;
 - Operating instructions;
 - Software verification procedures using known data sets, program listing, flowcharts, configuration control system, system management;
 - Backup procedures
 - Data archival;
 - Password protection;
 - Read/write protection, and
 - Hierarchical user access scheme.
- b) The integrity of data is protected, including integrity of data entry or capture, data storage, processing and data transmission, in accordance with established procedures that are implemented and maintained current to ensure data is not corrupted or tampered with.
- c) Required environmental control and operating conditions are provided to ensure proper functioning of computers or automated test equipment systems to maintain data integrity.
- d) The security of data, preventing unauthorized access to computer records and unauthorized amendments of computer records is password controlled.

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7.5.3 IDENTIFICATION AND TRACEABILITY

7.5.3.1 GENERAL

Procedure (QA-0048) addressing unique identification, verification and traceability are maintained for all equipment submitted for calibration and/or repair according to customer service requirements. Materials and repair parts acquired to meet service requirements are identified and controlled. All related information is maintained in the Precision Measurements, Inc.'s database. Identification and traceability of Precision Measurements, Inc. equipment is addressed in the Calibration System Description.

7.5.3.2 EQUIPMENT AND REFERENCE MATERIALS

All items of equipment (including reference materials, natural physical standards, etc.) required for the correct performance of calibrations and tests are maintained and available to the laboratory for its use. Documented procedures (QAP-2149) address equipment maintenance, records, handling and labeling requirements.

7.5.3.3 INCOMING CUSTOMER EQUIPMENT

The identification of customer equipment submitted for service and the level of services required is performed according to documented procedures; and is the responsibility of the Shipping/Receiving Department. Verification is the responsibility of the data entry personnel.

Incoming equipment is reviewed upon receipt for condition, including abnormalities or departures from standard condition as prescribed in the relevant calibration or test method. The customer is contacted where there is any doubt as to the item's suitability for calibration or test services, when the calibration or test required is not specified, when the item does not conform to its description provided, or if additional preparation is to be performed or arranged by the laboratory.

7.5.3.4 INCOMING MATERIALS THAT AFFECT CALIBRATION

The Shipping/Receiving Department is responsible for the proper receipt, processing and stocking of all incoming repair material, parts and consumable materials. Consumable materials that have an impact on calibration services or traceability are processed in accordance with the Calibration System Description and their proper application and use is the responsibility of the respective metrology department.

7.5.3.5 IN-PROCESS VERIFICATION

Identification of equipment requiring calibration and repair services, verification that all required service actions are taking place and that all equipment being serviced is properly identified is the responsibility of the Electronic and Mechanical/Dimensional Metrology Managers/Supervisors.

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The inspection and test status of all customer and Precision Measurements, Inc. measuring and test equipment is identified at each step of the servicing and Quality Control Process. The identification is through the use of tags, Status Reports, and appropriately annotated Certificate of Calibration, Service Reports, and/or Data Reports or travelers (incoming) tags. Only equipment and related service documentation passing inspection is released for return to the customer.

The Quality Assurance Department is responsible for the maintenance of the Quality Control Inspection system.

7.5.3.6 APPLICATION

Equipment and related service documentation which meets all customer service and operational criteria is identified as to status and released by authority of the Quality Control Inspector's signature appearing on the Certificate of Calibration, Service Report, and/or Data Report.

Equipment requiring repair is documented in Equipment Status (in PMI database) and segregated in the equipment holding area for further action. The respective Metrology Managers/Supervisors are responsible for identifying the status of equipment requiring repair.

Completed but nonconforming equipment and related documentation is identified, segregated and referred back to the responsible personnel for rework. Equipment requiring repair; but at the customer's option, may be returned "as is", is identified by red-tagging and recording status on the related paperwork, which is inspected and electronically signed by the Quality Control Inspector.

7.5.3.7 STATUS INDICATORS

All equipment is labeled to identify calibration status. Status indicators (e.g., labels) identify the date calibrated, the due date or usage equivalent. Status indicators indicating limited use are affixed to equipment that is not calibrated to their full capability. Status labels may be affixed to the equipment case where it is impracticable to affix the status indicator directly to the equipment.

Tamper-resistant seals are affixed to operator accessible controls or adjustments by the technician, which if moved will invalidate the calibration. Use and application are addressed in the Calibration System Description.

7.5.3.8 INSPECTION AND TEST RECORDS

Records indicating incoming and in-process inspection status are maintained. The initialed and dated Receiver Form is the evidence indicating that review (inspection) has taken place and that the inspection criteria have been met.

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Calibration Certificates, Service Reports and Data Reports provide records that customer equipment has passed calibration and/or has been serviced according to all service requirements. The person performing the test or inspection is indicated on the document(s).

Certificates prepared under the ISO 17025 Scope of Accreditation are signed by the responsible authorized signatories.

Final inspection of Precision Measurements, Inc. product (service and service documentation) is performed according to specific customer service quality and Calibration System Standards requirements. Service nonconformities identified in the Final Inspection process are documented on the QC/Nonconformance Report. Charts and graphs generated from the report are used for nonconformance trend analysis leading to corrective and preventive action. Closure of the service documentation(s) and input of a "Release Date" together with the QC Inspector's name (in Precision Measurements, Inc. database) is evidence the product has passed inspection and been released for return to the customer.

Nonconforming product (rejects) are processed for correction and re-inspected following rework. Any re-inspection is documented on the nonconformance report (8.3 of the Quality Assurance Manual).

Copies of manually generated and subcontractor supplied service documents are filed for future reference and retrieval.

7.5.4 CUSTOMER PROPERTY

Precision Measurements, Inc, established and maintains documented procedures (QAP-1415 and QAP-6415) for the control of verification, storage, maintenance and preservation of customer-supplied products for incorporation in service activities. Any loss or damage to a customer-supplied product is recorded and reported to the customer.

7.5.5 PRESERVATION OF PRODUCT

Documented procedures address the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

All customer equipment is protected from electrical and physical damage throughout the servicing process, from pick-up and receipt, cleaning, calibration and repair, inspection, and delivery or shipment. The respective department managers are responsible for monitoring and ensuring the proper handling of all equipment throughout the process, including any storage, to ensure that the calibration or condition of the equipment is not adversely affected.

Appropriate facilities and environmental controls ensure that items are protected throughout storage, handling, preparation, and calibration or verification to avoid damage or deterioration to the item. Relevant instructions received with the item are followed.

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7.5.5.1 HANDLING

Adequate care is exercised in the handling of equipment from receipt through delivery or shipment utilizing experienced personnel and suitable protective materials, according to documented procedures (QA-0415).

Repair parts and materials, including consumable materials that impact calibration, are handled to prevent damage or deterioration. Where appropriate, accepted Electrostatic Discharge Control protection and detection devices are used to prevent damage to repair parts and materials in accordance with QAP-7415.

7.5.5.2 STORAGE

Outgoing serviced customer equipment is segregated and placed in a designated area pending delivery or shipment.

Repair parts and materials are marked for identification and placed in a controlled stocking area. Parts and materials having limited shelf life are dated upon receipt and utilized on a First In-First Out (FIFO) basis. Electrostatic Discharge sensitive parts are stored in their original protective packaging. Precision Measurements, Inc. procedure (QAP-3415) stipulates the method and authority for the receipt to, and dispatch from the storage areas for serviced equipment and repair materials or consumable materials that impact calibration.

Time-sensitive or limited shelf life materials are checked at appropriate intervals and/or prior to use to detect deterioration. Where items have to be stored or conditioned under specific environmental conditions, those conditions are maintained, monitored and recorded, where necessary.

Where a calibration or test item is held secure (e.g. reasons of record or to perform check calibrations later), storage and security arrangements protect the condition and integrity of the secured item or portion secured.

7.5.5.3 PACKAGING

Precision Measurements, Inc. controls the packing, packaging, labeling and shipment of serviced equipment according to documented procedures (QAP-2415) to ensure conformance to specified requirements. Labeling must stay intact and remain legible throughout the handling, storage and shipment or delivery process.

Customer equipment to be shipped by common carrier is packaged in containers that are adequate according to size and weight and is protected from possible damage utilizing static-free bubble wrap, and electronic grade expanded foam peanuts, and/or foam-fill material. Related service documentation is packed with the equipment.

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7.5.5.4 PRESERVATION

Customer equipment held for repair is segregated in an environmentally controlled area pending disposition.

7.6 CONTROL OF MONITORING AND MEASURING DEVICES

Documented procedures have been established for the calibration, maintenance and control of all Inspection, Measuring and Test Equipment utilized by Precision Measurements, Inc. for the calibration, repair and servicing of customer equipment.

Test software is maintained and verified for application validity prior to use by utilizing calibration standards of known accuracy.

The Quality Assurance Manager is responsible for and has the authority for establishing and implementing the control procedures for all Precision Measurements, Inc.'s Inspection, Measuring and Test Equipment, whether owned, rented, borrowed or leased.

Establishing suitability and applicability of any item of Inspection, Measuring and Test Equipment to satisfy any given service requirement is the responsibility of the respective Metrology Manager/Supervisor.

7.6.1 CONTROL PROCEDURE

All Inspection, Measuring and Test Equipment used in the calibration, repair and servicing of customer equipment is identified and controlled through the Precision Measurements, Inc. database, and equipment is controlled and calibrated per documented and approved procedures according to the following criteria:

- a) Selected for use according to suitability, and accuracy and precision required.
- b) Periodically calibrated at established intervals with traceability to any National Standards Laboratory, national, international or intrinsic standards or other acceptable natural physical standards.
- c) Clearly labeled to indicate calibration status.
- d) Records consisting of continuous calibration history are maintained.
- e) Assessment, and action required is documented when any item of inspection, measuring and test equipment is found out-of-calibration.
- f) Removal, from use, of any Inspection, Measuring and Test Equipment found out-ofcalibration or calibration overdue, or suspected of having been subject to mishandling or damage or abuse or out-of-tolerance.
- g) Monitoring and ensuring the proper handling and storage, and safeguarding the unauthorized adjustment of Inspection, Measuring and Test Equipment, when applicable.
- h) Only approved vendors meeting the criteria set forth in Quality Assurance Manual for ISO 17025 Scope of Accreditation calibrations are used for subcontracted calibration.
- i) The system for the control of Inspection, Measuring and Test Equipment is detailed in the Precision Measurements, Inc.'s Calibration System Description.

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7.6.2 INTERVALS

Measuring and test equipment shall be calibrated at periodic intervals established and maintained to assure reliability (i.e., acceptable probability that the equipment will remain intolerance throughout the interval). (QA-1000)

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

Inspection and testing are performed in accordance with documented procedure (QA-0410) to ensure that all service quality and contractual requirements are met. The procedure specifies responsibility and includes specific work instructions.

Statistical techniques are used as part of the servicing process in order to measure servicequality conformance, identify and correct nonconformities, and to implement process improvement as part of the continuous improvement program.

Documented procedures have been established for the recording, accumulation, analysis and use of inspection data to immediately correct specific service quality deficiencies and to implement long-term service quality improvement.

Process steps include the analysis of data obtained from Quality Control Inspection Reports, which identify service quality factors. Analysis results are documented and are used to increase employee quality awareness and to identify service quality training needs.

8.2 MONITORING AND MEASUREMENT

8.2.1 CUSTOMER SATISFACTION

Total Customer Satisfaction and continual improvement in this area is the goal of Precision Measurements Inc. To achieve this goal, Statistics on renewal rate and customer returns and identified errors are used to quantify Total Customer Satisfaction and to assess effectiveness of training of personnel. On a quarterly basis, this statistic is calculated and then reviewed by the President to see if it meets the goal of continuous improvement. If the goal of continuous improvement is not met, a more in-depth analysis of the results is performed to determine a course of Preventative and/or Corrective Action. Actions may include policy or procedure modification, or possibly additional training or retraining of personnel.

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8.2.2 INTERNAL AUDIT

Precision Measurements, Inc. conducts audits of all activities within the organization that affect calibration and services quality. The audits are conducted at appropriate intervals not exceeding one (1) year. The objective of the audits is to determine that all quality-related activities are in compliance with the requirements of Codes and Standards identified in 2.0, References, to measure the effectiveness of each activity and to correct deficiencies and improve the quality system.

8.2.2.1 AUDIT PROGRAM

Audits are scheduled and carried out within stated time schedules according to the importance of each functional activity that affects service quality.

Audits are planned, conducted, carried out, and the audit results recorded according to the documented Internal Audit procedure (QA-0417) and Laboratory and Site Audits (QAP-1417) by personnel independent of those with direct responsibility for the activity or area being audited. Any corrective action required is also documented.

Audits are objective, conducted internally or under contract, and include both general criteria (documents, records and policies) and technical compliance (calibration methods, practices and calibration procedures) at permanent and on-site locations.

In addition to periodic audits described and measurement assurance practices, the laboratory ensures the quality of results through one or more of the following:

- a) Internal quality control schemes using statistical techniques such as measurement assurance techniques to control the measurement process and consistently provide the highest quality measurements.
- b) Participation in proficiency testing.
- c) Regular use of certified reference materials and/or in-house quality control using secondary reference materials.
- d) Replicate testing using the same or different methods.
- e) Retesting of retained items.
- f) Correlation of results for different characteristics of an item.

Both permanent laboratory and on-site calibration activities are audited periodically to ensure the continuing effective implementation and compliance to all Quality System and ISO 17025 Scope of Accreditation criteria, and to investigate valid customer complaints of a nature warranting audit as described in the Quality Assurance Manual.

8.2.2.2 **REVIEW**

Audit reports and related Internal Corrective Action Requests (ICARs) are made available for review with the applicable personnel audited; and forwarded to QA for review and follow-up action, if indicated, during the Management Review process. Where audit results cast doubt on the correctness of validity of the laboratory's calibrations results, immediate corrective action shall be taken, including providing written notice to any customer whose work has been affected.

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The management personnel responsible for the activity or area where service nonconformities are found are required to take timely corrective action on the deficiencies reported and recorded as a result of the audit as specified in QA-0417 and/or QAP-1417, as applicable.

The QA Department is responsible for the audit program including planning, scheduling, reporting, effective implementation, verification, and closure of any ICAR(s) and ensuring customer notification has occurred where necessary.

8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

Statistical techniques are used as part of the servicing process in order to measure servicequality conformance, identify and correct nonconformities, and to implement process improvement as part of the continuous improvement program.

8.2.3.1 PROCEDURES

Documented procedures have been established for the recording, accumulation, analysis and use of inspection data to immediately correct specific service quality deficiencies and to implement long-term service quality improvement.

Process steps include the analysis of data obtained from Quality Control Inspection Reports, which identify service quality factors. Analysis results are documented and are used to increase employee quality awareness and to identify service quality training needs.

8.2.4 MONITORING AND MEASUREMENT OF PRODUCT

Incoming customer equipment is inspected and verified as received to establish accurate identity, and the type and level of service to be performed to ensure compliance with customer service requirements.

All incoming purchased parts and material required for the repair and servicing, including consumable materials that affect calibration of customer equipment, are inspected or otherwise verified as conforming to specifications prior to release for use according to documented procedures.

Procurement requirements for subcontracted calibration services, or outside services and supplies furnished under the ISO 17025 Scope of Accreditation are verified for compliance to ISO 17025 accreditation criteria.

The extent of incoming inspection activity required is determined according to the degree of control necessary to ensure that product requirements are met and according to the supplier's quality history for the purchased parts, materials or service provided. The extent and nature of incoming inspection is also determined on the basis of control exercised at the subcontractor's (supplier's) premises.

Incoming parts and materials released for urgent use prior to routine incoming inspection and verification activities are inspected for compliance by the Metrology Laboratory personnel. Any nonconformity is recorded, and the nonconforming product is identified and segregated.

Equipment received from subcontracted calibration source is inspected for physical condition. Accompanying documents are inspected and verified according to all specified requirements. Any discrepancy or nonconformance is referred to purchasing for resolution. The item is marked and segregated pending resolution.

8.2.4.1 IN-PROCESS INSPECTION AND TESTING

Data Management as part of the service record creation and data entry process verifies incoming equipment identity and customer service requirements.

Each employee involved in the service process is responsible for ensuring the quality and the accuracy of his/her own work; and that the service has been performed according to all requirements.

Repair parts and materials are tested as an integral part of the repair and recalibration process.

8.2.4.2 FINAL INSPECTION AND TESTING

The final inspection of Precision Measurements, Inc. product (serviced equipment and related service documentation) is the responsibility of Quality Assurance and is performed by QC Inspectors according to documented procedure (QA-0410).

Nonconformities are segregated (where practical), tagged, recorded, referred to appropriate personnel for correction, and re-inspected (also see 8.3) following rework.

8.2.4.3 INSPECTION AND TEST RECORDS

Records indicating incoming and in-process inspection status are maintained. The initialed and dated Receiver Form is the evidence indicating that review (inspection) has taken place and that the inspection criteria have been met.

Calibration Certificates, Service Reports and Data Reports provide records that customer equipment has passed calibration and/or has been serviced according to all service requirements. The person performing the test or inspection is indicated on the document(s).

Certificates prepared under the ISO 17025 Scope of Accreditation are signed by the responsible authorized signatories.

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Final inspection of Precision Measurements, Inc. product (service and service documentation) is performed according to specific customer service quality and Calibration System Standards requirements. Service nonconformities identified in the Final Inspection process are documented on the QC/Nonconformance Report. Charts and graphs generated from the report are used for nonconformance trend analysis leading to corrective and preventive action. Closure of the service documentation(s) and input of a "Release Date" together with the QC Inspector's name (in Precision Measurements, Inc. database) is evidence the product has passed inspection, and has been released for return to the customer.

Nonconforming product (rejects) are processed for correction and re-inspected following rework. Any re-inspection is documented on the nonconformance report (8.3 of the Quality Assurance Manual).

Copies of manually generated and subcontractor supplied service documents are filed for future reference and retrieval.

Statistical techniques are used as part of the servicing process in order to measure servicequality conformance, identify and correct nonconformities, and to implement process improvement as part of the continuous improvement program.

8.2.4.4 PROCEDURES

Documented procedures have been established for the recording, accumulation, analysis and use of inspection data to immediately correct specific service quality deficiencies and to implement long-term service quality improvement.

Process steps include the analysis of data obtained from Quality Control Inspection Reports, which identify service quality factors. Analysis results are documented and are used to increase employee quality awareness and to identify service quality training needs.

8.3 CONTROL OF NONCONFORMING PRODUCT

Precision Measurements, Inc. defines a nonconforming product as a service; including related documentation, not provided, or that cannot be provided according to applicable specifications, standards and/or customer requirements, and repair material not meeting specified requirements for its intended application. Incoming customer equipment that cannot proceed through the technical service process due to a lack of key information or tender to cover the service required is considered nonconforming product.

A documented procedure (QA-0413) has been established describing the process to prevent the unintended or unauthorized use, installation and release of a nonconforming product. Precision Measurements, Inc.'s control procedures provide for identification, documentation, evaluation, segregation (where practical), disposition and promptly reporting, to concerned functions, and customers in writing, of nonconforming products.

Nonconforming repair material and parts, the use of which could affect service quality, are handled according to procedure (QA-0413) to prevent unauthorized use.

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8.3.1 REVIEW AND DISPOSITION OF NONCONFORMING PRODUCT

Nonconformance items are identified and recorded as part of the in-process Quality Control Inspection.

Responsibility and authority for review and disposition of nonconforming product rests with the control function where the nonconformance is detected and identified; specifically:

- a) Incoming repair material and equipment: Shipping/Receiving Personnel.
- b) Defective repair material: Metrology Personnel.
- c) Nonconforming equipment, service or consumable materials that impact calibration: Metrology Manager/Supervisor.
- d) Equipment performance nonconformities: Metrology Personnel and Customer Service

Designated qualified Quality Assurance Personnel are responsible for review of nonconforming product issues where documented patterns of nonconformance require formal follow-up action.

Nonconforming products are reviewed and disposition according to documented procedures.

8.4 ANALYSIS OF DATA

Statistical techniques are used as part of the servicing process in order to measure servicequality conformance, identify and correct nonconformities, and to implement process improvement as part of the continuous improvement program.

8.4.1 PROCEDURES

Documented procedures have been established for the recording, accumulation, analysis and use of inspection data to immediately correct specific service quality deficiencies and to implement long-term service quality improvement.

Process steps include the analysis of data obtained from Quality Control Inspection Reports, which identify service quality factors. Analysis results are documented and are used to increase employee quality awareness and to identify service quality training needs.

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8.5 IMPROVEMENT

8.5.1 CONTINUAL IMPROVEMENT

The Management Review Process is carried out at least annually by a team consisting of the President and the Quality Assurance Manager, to determine overall effectiveness of the system in meeting management's objectives and commitments, customer requirements, corrective action(s) to be taken; and to identify opportunities for improvement. The functional area managers/ supervisors support and participate in the management review process as appropriate for their areas of responsibility.

Conclusions and recommendations of the review team in the review process are documented for record and necessary action initiated to implement Quality Improvement actions.

8.5.2 CORRECTIVE ACTION

A corrective action program has been implemented, and is maintained at Precision Measurements, Inc. to identify and correct quality deficiencies, including deficiencies resulting from departures from documented policies and procedures, as well as potential nonconformities relative to all service and customer requirements.

Documented procedures (QA-1414, QA-2414, QAP-0314 and QA-0242) are in place to identify and determine the cause(s) of any quality related discrepancy or nonconformity; (including the assessment of impact on the results of measurements for discrepancies or unplanned departures from normal operation) and implement necessary near term corrective action and long term preventive action in proportion to the magnitude of the problem and the level of the risks encountered.

Records of all corrective actions, including investigation of causes are maintained on file.

Corrective and preventive action can occur at any level of the Precision Measurements, Inc.'s operation and can be initiated by any employee who identifies a discrepancy or nonconformity, which affects or has the potential for affecting quality of service.

Any changes in procedures resulting from corrective action are recorded as part of the preventive action process.

The effectiveness of any corrective and preventive action is measured through one or more of the processes outlined in the Quality Assurance Manual.

Service nonconformities may be detected and identified at any step in the service process. Precision Measurements, Inc.'s corrective action procedures include:

a) Methods for the effective handling of customer complaints and reports of product nonconformities.

- b) Investigation of the cause of nonconformities as related to the service process and quality system, and the documentation of the investigation results.
- c) Determination of the action needed to correct and eliminate the cause of nonconformities.
- d) The application of controls and follow-up measures to ensure that corrective action has been implemented and is effective.

8.5.3 PREVENTATIVE ACTION

Corrective and preventive action can occur at any level of the Precision Measurements, Inc.'s operation and can be initiated by any employee who identifies a discrepancy or nonconformity, which affects or has the potential for affecting quality of service.

Precision Measurements, Inc.'s preventive action procedures are incorporated in its corrective action process, and include:

- a) The use of information from the service process, nonconformance records, audit results, quality records and customer feedback/complaints to detect, analyze and eliminate causes of potential nonconformities.
- b) Determination of the method and steps for dealing with problems requiring preventive action.
- c) Initiation of preventive action and applying controls to ensure effectiveness.
- d) Providing relevant information on actions taken for management review.
- e) Documenting opportunities for improvement of the Quality System as well as processes for implementing new capabilities and services to meet customer needs.

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APPENDIX A

APPLICABLE PRIMARY PROCEDURES

4.0 QUALITY MANAGEMENT SYSTEM

QA-0042 Quality System	
QA-0045 Document and Data Control	
QA-0142 Protecting Customer Confidentiality and Proprieta	y Rights
QA-0242 Departures from Established Policy and Procedure	
QA-0416 Quality Records	
QAP-0145 Calibration Procedure Development	

5.0 MANAGEMENT RESPONSIBILITY

QA-0041	Management Responsibility
QA-0141	Management Review

6.0 **RESOURCE MANAGEMENT**

QA-0418	Training
QAP-1418	Technician Proficiency Testing

7.0 PRODUCT REALIZATION

QA-0043	Contract Review
QA-0143	Contract Review - Quotation/Contract Bid Process
QAP-1043	Customer Service – Customer Request Form
QAP-1143	Quotation/Bid Preparation – New
QAP-2143	Quotation / Bid Preparation – Renewals
QAP-3143	Contract Addition and Deletion Process
QA-0046	Purchasing – General
QA-0146	Vendor Qualification and Registration
QAP-1046	Purchase Order Generation and Processing
QA-0048	Product Identification and Traceability
QA-0049	Process Control
QAP-0149	Data entry: In House Service
QAP-0249	Field Service Data Process
QAP-0349	Field Service Scheduling And Coordination
QAP-0649	Field Service
QAP-0749	Customer Service
QAP-1049	In-House Equipment Service (Electronic)
QAP-2049	In-House Equipment Service (Mechanical)
QAP-1249	Quality Control Process
QAP-1349	Equipment Warranty Return Process
QAP-2149	Measurement Standards Calibration and Control

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7.0 PRODUCT REALIZATION (cont.)

QAP-2349	Calculation of Measurement Uncertainty
QAP-3049	PMI Technical Library Maintenance
QAP-4049	Processing Subcontracted Calibration
QA-0410	Inspection and Testing
QA-0412	Inspection and Test Status
QAP-1411	Disposal of Standards/Standard Reference Materials
QAP-2411	Interlaboratory Comparisons
QA-0415	Handling, Storage and Preservation
QA-1415	Packaging, Shipment and Delivery
QAP-1415	Receiving Customer Equipment
QAP-2415	Delivery/Shipment of Customer Equipment
QAP-3415	Receiving Purchased Repair Material and Parts
QAP-4415	Shipping/Receiving Subcontractor Serviced Equipment
QAP-5415	Printing Transportation and Shipping Documents
QAP-6415	Calibration-Aid Processing and Handling
QAP-7415	ESD Monitor and Control
QAP-2145	Computers and Automated Test Equipment (ATE) Systems
QAP-4143	Processing Scope of Accreditation Orders

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

QA-0413	Control of Nonconforming Product
QA-1414	Internal Corrective and Preventive Action
QAP-1114	Internal Corrective Action Request
QA-2414	Supplier Corrective and Preventive Action
QAP-1214	Supplier Corrective Action Request
QAP-0314	Customer Feedback Process
QA-0417	Internal Quality Audits
QAP-1417	Laboratory and Site Audits
QA-0420	Statistical Techniques
QAP-0821	Customer Satisfaction

NOTE: Additional supplemental Operational Procedures (QAPs) in the form of individual work instructions are in place, which address the quality issues referenced in the above procedures. Calibration Procedures used to perform calibrations are identified in the Controlled Documents Master List (Latest Revision).

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