



# QUALITY MANUAL

<b>Quality Manager:</b>	<b>Abner De Leon</b>
<b>Technical Manager:</b>	<b>Cesar (Jun) Bautista Jr.</b>
<b>President/CEO:</b>	<b>Allen Ganner</b>
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<b>DRAFT</b>	

Primary Instruments Inc. is organized and operates under a Quality System in compliance with the following established standards, as applicable.

ISO/IEC Guide 17025:1999  
ISO 9001: 2000  
ANSI/NCSL Z540-1-1994  
MIL STD 45662A  
10CFR21  
10CFR50 appendix B  
ASME NQA-1-1997  
ISO 10012-1:1992(E)

This Quality Manual has been developed, reviewed, approved and issued to document Primary Instruments Quality System.

Developed by: Primary Instruments Quality Assurance

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
Cesar D. Bautista Jr.  
Senior Vice President for Operations &  
Technical Manager

Issued by: \_\_\_\_\_ Date: \_\_\_\_\_  
Abner U. de Leon  
Quality Manager

Authorized and Approved by: \_\_\_\_\_ Date: \_\_\_\_\_  
Allen Ganner  
President / Chief Executive Officer

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# QUALITY MANUAL

Primary Instruments, Inc.

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1.0

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## 1. Scope

This Quality Manual facilitates:

- recognition of technical competence for standardized methods, non-routine methods, and laboratory-developed methods we perform
- inspection and product certification capabilities and/or services we provide
- total quality for our administrative and technical systems
- audits by clients, regulatory authorities and accreditation bodies
- meeting the requirements of ISO 17025 and ISO 9001
- client satisfaction

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**2. Normative References**

**Reference List**

ISO/IEC Guide 2 - General terms and their definitions concerning standardization and related activities.

VIM: 1993 - International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

ISO 9001:2000 – Quality Management Systems – Requirements.


ISO 17025:1999 – General Requirements for the Competence of Testing and Calibration Laboratories.

**Cross-references (helpful during audits!)**

This manual is numerically aligned with the international standard ISO 17025. It is expected that this will prove useful during accreditation audits and expedite the process.

Furthermore, each section cross-references the ISO 9001 standard to assist the laboratory during the ISO 9001 registration process (if applicable).

For ease of use, each section starts with a brief summation of what the section addresses and a listing of the quality terminology and key words.

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### 3. Terms and Definitions

For the purposes of this manual, the following relevant definitions apply: ISO/IEC Guide 2; ISO/IEC Guide 30; ISO Council Committee on Conformity Assessment (CASCO); ISO 8402; ISO 10015; ISO 5725-1; ISO 17025; the Food Laboratory Accreditation Working Group (FLAWG); AOAC; American Chemical Society (ACS); and International Vocabulary of Basic and General Terms in Metrology (VIM).

**Accreditation** – formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests (CASCO).

*Accuracy* – the closeness of agreement between a test result and the accepted reference value (ISO 5725-1, ISO Guide 30).

**Calibration** - a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by the standard (VIM).

Notes

1. The result of a calibration permits either the assignment of values or measurands to the indications or the determination of corrections with respect to indications.
2. A calibration may also determine other metrological properties such as the effect of influence quantities.
3. The result of a calibration may be recorded in a document sometimes called a calibration certificate or a calibration report.

**Certification** - procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements (ISO 8402).

**Certified Reference Material** – a reference material, one or more of, whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (ISO Guide 30).


**Client** – an entity (customer, agency, company, person, etc.) who receives a test result done according to specified requirements (FLAWG).

**Competence** – ability consisting of theoretical knowledge, practical skills, and attitudes (ISO 10015).

**Corrective Action** – action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence (ISO 8402).

**Inspection** - evaluation for conformity by measuring, observing, testing, or gauging the relevant characteristics (ISO/IEC Guide 2). Activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic. (ISO 8402)

**Linearity** – is determined by the analysis of samples with analyte concentrations spanning the claimed range of the method. The results are used to calculate a regression line against analyte calculation using the least squares method. It is convenient if a method is linear over a particular range but it is not an absolute requirement. Where linearity is unattainable for a particular procedure, a suitable algorithm for calculations should be determined (AOAC).

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**Measurement Uncertainty** - parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand (International Vocabulary of Basic and General Terms in Metrology).

**Precision** – the closeness of agreement between test results obtained under stipulated conditions (ISO 5725-1, ISO Guide 30).

**Preventive Action** – action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence (ISO 8402).

**Proficiency Testing** – determination of the laboratory calibration or testing performance by means of inter-laboratory comparisons (ISO/IEC Guide 2).

**Quality Assurance** – all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO 8402).

**Quality Control** – the operational techniques and activities that are used to fulfill requirements for quality (ISO 8402).

**Quality Manual** – a document stating the quality policy, quality system, and quality practices of an organization (ISO 8402).

**Quality System** – the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management (ISO 8402).

**Range** – the difference between the largest and smallest observed value of a quantitative characteristic. For quantitative analysis the working range for a method is determined by examining samples with different analyte concentrations and determining the concentration range for which acceptable accuracy and precision can be achieved. The working range is generally more extensive than the linear range. The working range is determined by the analysis of a number of samples of varying analyte concentrations and calculating the regression from the results, usually using the method of least squares. The relationship of analyte response to concentration does not have to be perfectly linear for a method to be effective (AOAC).

**Reference Material** – a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (ISO Guide 30).


**Reference Standard** – a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are, derived (VIM). Generally, this refers to national traceable standards such as those from the National Institute of Standards and Technology (NIST).

**Repeatability (r)** – precision under the *same conditions* (same method, same test item, same operator, same apparatus, same laboratory, short interval of time) (ISO 5725-1).

**Reproducibility (R)** – precision using the *same method* on identical items obtained by operators in different laboratories using different equipment (ISO 5725-1).

**Ruggedness** – the ruggedness of a method is tested by deliberately introducing small changes to the method and examining the consequences. A large number of factors may need to be considered, but because most of these will have a negligible effect, it will normally be possible to vary several at once (AOAC).

**Selectivity** – the extent that a specific analyte can be determined from a complex mixture without interference from the other components in the mixture. A method that is perfectly selective for an analyte or group of analytes is said to be specific. The applicability of the method should be studied using various samples, ranging from pure standards to mixtures with complex matrices. In each case the recovery of the analyte(s) of interest should be determined and the influ-

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ences of suspected interference duly stated. Any restrictions in the applicability of the technique should be documented in the method (AOAC).

**Sensitivity** – the difference in analyte concentration corresponding to the smallest difference in the response of the method that can be detected. It is represented by the slope of the calibration curve and can be determined by a least squares procedure, or experimentally, using samples containing various concentrations of the analyte (AOAC).

**Skill** – ability to apply knowledge effectively and readily in performance (ISO 10015).

**Soak Time** – elapsed time between unit induction and either unit preparation or calibration, as appropriate.

**Specific** – see selectivity.

**Standard Operating Procedure** – a document that specifies or describes how an activity is to be performed. It may include methods to be used and sequence of operations (FLAWG).

**Test** - technical operation that consists of the determination of one or more characteristics of a given product, process, or service according to a specified procedure (ISO Guide 2: 1991).


**Traceability** – the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons (VIM).

**Training** – a process to provide and control competence to meet requirements (ISO 10015).

**Validation** - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled (ISO 8402).

**Verification** - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (ISO 8402).



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## 4.1 Organization

### The Ten Second Tutorial



*This section tells you our laboratory has:*

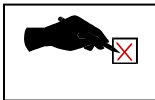
1. Appointed a Quality Manager
2. Organized the workforce to achieve quality
3. Provided adequate resources to ensure quality

### Key Words




Quality Manager  
Organizational Chart  
Authority  
Resources  
Confidential Information  
Proprietary Rights  
Responsibilities  
Undue Pressure

### Cross-references



ISO 17025:1999 Section 4.1  
ISO 9001:2000 Section 5.1, 5.3, 5.4.1, 5.5.1, 5.5.2, 6.1, 6.2.1, 6.3

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#### 4.1.1 Legal Identification / Registration

Primary Instruments Inc.  
9553 Vassar Ave Chatsworth, CA 91311  
Tel: (818) 993-4971  
Fax (818) 701-5516

#### 4.1.2 Laboratory Requirements

The executive offices / departments / units / laboratories / work areas of Primary Instruments Inc. have been organized to satisfy the needs of the client and regulatory authorities and to operate to the international standards ISO 17025 and ISO 9001. Primary Instruments Inc. is composed of the following executive offices and their respective subordinate department / units / laboratories / work areas:

President / CEO's Office (General Management)  
Executive Vice-President (Comptroller / Accounting Dept. / Administrative Support Unit / Information Management Systems.  
Senior Vice-President, Operations (Corp. Metrologist / Technical Manager / Metrology Engineering / Laboratory Operations / Shipping & Receiving Area.  
Vice- President, Marketing and Sales (Sales Dept. / Marketing & Advertising Unit)  
Vice-President, Business Development (Internet Business Unit / Alliances & Affiliations)  
Quality Manager (Total Quality & Continuous Process Improvement Dept.)

#### 4.1.3 Scope of Management System

The management system covers activities in the laboratory's permanent facility and field service (customer site) calibration. The fields of activities include:

Calibration, Verification & Repair Services [Permanent facility / Field (customer site) calibration]  
Metrology Engineering Consultation.  
Test & Measurement Equipment Sales, Distribution & Service.


The laboratory's scope of tests is listed in but not limited to the Measurement parameters declared in *Appendix B, Scope of Accreditation*.

#### 4.1.4 Potential Conflicts of Interest

The laboratory reports to the Senior Vice- President in charge of Operations. This ensures the independence of the laboratory from the rest of the organization. Potential conflicts and/or adverse influences against the laboratory's ability to operate in an independent manner are reduced by random independent checks and/or scheduled internal audits conducted by the Quality Manager and/or his/her appointed representative(s).

The responsibilities of the Senior Vice-President include:

- developing, managing, and guiding the larger organizations' policies and procedures

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- serve as a member of the executive committee which organizes and administers the relationship between the organization and the laboratory
- providing focus and coordinating functions regarding technical capabilities, resource acquisition / distribution, quality of services, technician competence, and over-all customer satisfaction
- Participates in all senior-level administrative functions/committees of the organization as appointed by the President / CEO.

#### 4.1.5 Organization

##### A) Management and Technical Personnel

**Policy:**

The laboratory managerial and technical personnel have the necessary authority and resources needed to meet the mandates assigned to their areas.

**Details:**

Responsibilities are detailed in 4.1.5 (F).

Departures from the organizational and management policies in this manual can only be approved by President / CEO.

Departures from quality system procedures can only be approved by Quality Manager.

Departures from calibration methods or technical standard operating procedures (SOPs) can only be approved by the Senior Vice-President, Operations in his role as the Technical Manager and Corporate Metrologist.

See also section 5.2.

##### B) Undue Pressure


**Policy:**

Management and personnel are to be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. The integrity of test results is the responsibility of all personnel. Management ensures that employees are never instructed or forced to alter or falsify data.

**Details:**

The following list provides some guidelines on how employees avoid conflict of interest situations. Employees shall not:

- falsify records, prepare fraudulent reports, or make false claims
- seek or use privileged or confidential company information, or data from any client, for any purpose beyond the scope of employment
- conduct non-laboratory business on laboratory time, or use company facilities or equipment to conduct outside interests in business, unless prior approval has been obtained
- solicit business on their own behalf (rather than the laboratory) from a client
- be employed by, or affiliated with, organizations whose products or services compete with laboratory products or services
- have employment that negatively affects or interferes with their performance of laboratory duties
- compete with the laboratory in the purchase, sale, or leasing of property or goods

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- allow association, family, or friends to influence business decisions to their benefit - decisions must be made on a strictly business basis, always in the best interest of the laboratory
- make any decision that provides gains or benefits to the employee and/or others
- have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal. All employees are required also to sign a "Standards of Conduct" agreement prior to employment.

### C) Client Confidentiality

**Policy:**

It is the policy of our laboratory to protect the confidential information and proprietary rights of our client including the electronic storage and transmission of results.

**Details and Procedures:**

All employees sign an *Employee Confidentiality Agreement*. The signed agreement is retained in each employee's Human Resources file.

Test results are only released to the client. Release to someone other than the client requires the express permission of the client, except when the situation contravenes Municipal, State or Federal Legislation and the results must be provided to the appropriate agency. The release of test results to anyone other than the client requires the permission of management. Laboratory reports are reviewed for accuracy prior to release.

### D) Operational Integrity

**Policy:**

The laboratory will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

**Details and Procedures:**

To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through check sample programs. Impartiality is assessed through audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading and improving his or her skills. Operational integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through corrective action procedures.

### E) Organizational Structure

**Policy:**

The organization and management structure of the laboratory and the relationships between management, technical operations, support services, and the quality system is defined through the aid of an organizational chart as illustrated in *Appendix A, Primary Instruments Inc. Organizational Line & Staff Chart*.

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**Details:**

Senior management keeps the most current organizational chart on file. An organizational chart is available with this manual as a reference record and is considered the official record on the date it is marked.

**F) Responsibility and Authority**

**President / CEO**

- develops primary goals, operating plans, policies, and short and long range objectives for the laboratory; implementing these following Board of Director's approval
- directs and coordinates activities to achieve profit and return on capital
- establishes organizational structure and delegating authority to subordinates
- leads the laboratory towards objectives, meets with and advises other executives, and reviewing results of business operations
- determines action plans to meet the needs of stakeholders
- represents organization to major clients, government agencies, shareholders and the public

**Senior Vice-President (Technical Manager)**

- is/are knowledgeable of the scope of all processes under their supervision
- provides the necessary resources (personnel, equipment, supplies) for the quality assurance program, in order to ensure confidence in the laboratory's results
- ensures equipment is maintained and calibrated, reporting all deficiencies (e.g., equipment malfunctions) in the appropriate manner
- ensures personnel are trained for the duties they perform - includes substitutes when regular personnel are absent
- maintains current job descriptions
- maintains records and manage all aspects of calibration and/or testing activities
- hiring personnel
- maintains standard pricing and customized quotation

**Quality Manager**

- ensures that the Quality System is established, implemented and maintained in accordance with the ISO 9001 and ISO 17025 standards
- manages the internal audit program
- coordinates laboratory accreditation activities
- handles the maintenance and distribution of the Quality Manual and associated documents
- maintains a master list of current versions of quality documentation
- trains personnel on Quality System activities
  
- monitors the Quality System
- reports on the performance of the Quality System to senior management for review and as a basis for improvement of the Quality System
- supervises the laboratory's inter-laboratory proficiency testing program
- determines technical training needs of personnel.
- oversees quality

**Supervisors**

- responds to client inquiries and providing professional advice

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- orients new personnel
- conducts employee performance reviews
- scheduling vacation and coverage
- ensures that all health and safety regulations are followed
- ensures that all Human Rights Legislation are complied with
- prioritizes workload
- facilitates operational concerns in their area
- ensures accurate and consistent calibration procedures through the validation of all current procedures and by de-veloping, validating and implementing new procedures
- coordinates purchasing requests
- ensures that the operational needs are within budget and advising management of any discrepancies

**Technicians**

- maintains records of all quality activities as documented in SOPs and test methods
- handles samples and performing analyses according to SOPs and test methods
- writes calibration methods as needed
- signs reports when designated with signing authority
- maintains and calibrates equipment
- reports deficiencies or malfunction to the supervisor
- identifies and records nonconformances on *Corrective Action Requests*
- identifies and records potential nonconformances on *Preventive Action Requests*
- corrects nonconformances and potential nonconformances
- improves laboratory and/or quality activities on a continuous basis

**Client Representatives and Administrative Personnel**

- performs work functions and keeping records as per approved SOPs and/or laboratory policies
- identifies and records nonconformances on *Corrective Action Requests*
- identifies and records potential nonconformances on *Preventive Action Requests*
- corrects nonconformances and potential nonconformances
- improves laboratory and/or quality activities on a continuous basis

**G) Laboratory Supervision**

**Policy:**

Adequate supervision is provided in each area of the laboratory for all testing and calibration personnel, including trainees, by persons familiar with the methods and procedures.


**Details:**

Adequate supervision is ensured through designated supervisors as well as through documentation such as this Quality Manual, test methods and SOPs. A thorough orientation and training program is adhered to for all new employees. On-going training for regular personnel is required.

**H) Technical Management**

**Policy:**

A technical manager is tasked with the overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.

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**Details:**

While the technical manager may at times delegate duties to other personnel, the technical manager is accountable for any nonconforming activities.

**I) Quality Manager**

**Policy:**

The Quality Manager is appointed by the highest level of management. The Quality Manager, who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the quality system is implemented and followed. The Quality Manager has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

**Details:**

This statement notifies all laboratory personnel that ABNER DE LEON is the Quality Manager as authorized below by the President/CEO. Any change in this position requires the re-issue of this section to all holders of controlled copies of the Quality Manual. The following signature also serves as approval for this Quality Manual and affirms senior management's commitment to the policies and procedures set forth in this manual.

---

*Allen Ganner*  
President/CEO

**J) Managerial Substitutions**

**Policy:**

Deputies for key personnel are appointed to fulfill the key personnel's duties in their absence.

**Details:**

In the absence of the Quality Manager, the Technical Manager will assume his/her responsibilities.


In the absence of the Technical Manager, the President/CEO will assume his/her responsibilities.

Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent.

If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

**Revision History.**

Revision 0

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## 4.1 Organization

### The Ten Second Tutorial



*This section tells you our laboratory has:*

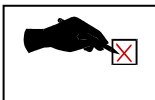
1. Appointed a Quality Manager
2. Organized the workforce to achieve quality
3. Provided adequate resources to ensure quality

### Key Words




Quality Manager  
Organizational Chart  
Authority  
Resources  
Confidential Information  
Proprietary Rights  
Responsibilities  
Undue Pressure

### Cross-references



ISO 17025:1999 Section 4.1  
ISO 9001:2000 Section 5.1, 5.3, 5.4.1, 5.5.1, 5.5.2, 6.1, 6.2.1, 6.3



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### 4.2.1 Policies and Procedures

**Policy:**

The Quality System is established, implemented, and maintained by management. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

This policy incorporates in its intent all the requirements mandated by A2LAs' Calibration Program for ISO/IEC 17025 accredited laboratories.

**Details:**

The purpose of our Quality System is to ensure that all services and products satisfy the client's requirements and have been designed, manufactured, and delivered under controlled conditions and are in conformance with the mandate of ISO/IEC 17025 and compliant to ANSI/NCSL Z540-1-1994.

The effectiveness of the Quality System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality system
- by regular management reviews of the suitability and effectiveness of the quality system
- by analysis of potential and actual problems as shown by client complaints and supplier and subcontractor assessments
- by other methods approved from time to time by the President/CEO

This Quality Manual and associated documents (including procedures) and records serve as the quality plan for the laboratory. Other documents and records include:

- standard operating procedures
- quality control plans in test methods
- organizational charts
- proposals
- project management schemes

### 4.2.2 Quality Policy Statement


**Policy:**

The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement. The Quality Policy Statement is issued under the authority of the **President/CEO** on the effective date. This Policy shall be reviewed on an annual basis by the management, or as required for continuing suitability.

**Quality Policy Statement:**

*Primary Instrument Inc. is committed to providing total customer satisfaction through accurate, zero defects and on time deliveries of our calibration, testing and other services and to continually meet and/or exceed our clients' quality requirements.*

*The Management is committed in achieving our goals:*

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- a. Through good professional practice and quality services to client by carrying out calibration and testing in accordance to stated standardized methods and client's requirements.
- b. By communicating the quality policy and the whole quality system to all employees and demonstrating how it will affect their roles within the company by implementing the policies and procedures in their work.
- c. By creating a work environment to all employees that promotes teamwork and problem solving.
- d. By providing continuous training to our employees in order to implement our quality and technical programs.
- d. By maintaining compliance of our Quality System with ISO/IEC Guide 17025-1999 and ANSI /NCSL Z540-1-1994, the purpose of which is to be able to manage our business by meeting the needs of our clients.

### 4.2.3 Quality Manual

#### Policy:

This Quality Manual outlines the structure of the documentation used in the quality system. This Quality Manual makes reference to supporting procedures including technical procedures and is maintained up to date.

#### Details:

This quality system is structured in three tiers of documentation. The tiers are as follows:


- I. Quality Manual
- II. Quality System Procedures (Operational Procedures or SOPs)
- III. Work Instructions, Calibration Procedures and Quality Documents (e.g. Forms, Records)

For most clients, this Quality Manual and the associated documents form a general Quality Plan. If necessary, specific Quality Plans will be prepared on a 'per-client' basis. These Quality Plans will modify the general requirements stated in the Manual and associated documents.

All of the above documents are controlled documents.

The following records and directive documents are referenced in the Quality Manual, but maintained separately:

- organizational chart (section 4.1.5.E)
- copies of the Quality Policy Statement posted in the laboratory (section 4.2.2)
- identification of resources and management review (section 4.14.1)
- job descriptions (section 5.2.4)
- statistical techniques (section 5.9)
- test reports (section 4.12.2)
- identification of the laboratory's approved signatories (section 5.10.2)
- laboratory's scope of tests (section 4.1.3)
- equipment inventory and records (sections 5.5.4 and 5.5.5)
- calibration status indicators (section 5.5.8)
- reference standards inventory (section 5.6.3)
- verification records (section 5.9)
- quality control plan / criteria for workmanship (section 5.4.1)
- corrective action records (section 4.10)
- preventive action records (section 4.11)
- client complaint records (section 4.8.1)

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- audit schedule and records (section 4.13.3)
- procurement and subcontracting records (sections 4.6 and 4.5.4)
- training records (section 5.2.5)
- master list of documentation (section 4.3.2)
- confidentiality agreements (section 4.1.5 C)
- contract review (section 4.4.2)
- validation of test methods (section 5.4.5)
- facility floor plan (section 5.3.1)

#### 4.2.4 Technical Management and the Quality Manager

The roles and responsibilities for technical management and the Quality Manager are outlined in section 4.1.4 (F) of this manual.

The Technical Manager ensures that section 5 of this manual is implemented and maintained. The Quality Manager ensures that section 4 of this manual is implemented and maintained.

#### 4.2.5 Site Testing and Calibration

Policy:

Primary Instruments also performs onsite calibration. Such services are available as annotated in Appendix B, Scope of Accreditation. The test and calibrations in which Primary Instruments are capable are specified.

Details:

The Quality System described in this chapter also applies to onsite calibration. Records of onsite calibration are maintained together with all the permanent laboratories records.

The organizational chart, Appendix A, of Primary Instruments also applies to onsite calibration arrangement. Technicians assigned in the laboratory are the ones assigned to perform onsite calibration. Supervision is still under their respective supervisor and/or managers. (See QM Section 4.1)

The qualifications of personnel performing onsite calibration still follows the policy outlined in QM Section 5.2 and identification of signatories follows the policy outlined in QM Section 5.10, Reporting the Results.

All relevant parts of the quality manual are available to personnel assigned onsite.

#### Revision History

Revision 2.0  
 Revision 1.0

## 4.3 Document Control

### The Ten Second Tutorial



This section tells you that Document Control involves:

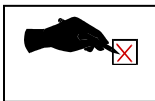
1. Writing good procedures
2. Getting them to the users
3. Keeping procedures good

### Key Words




Controlled Document  
Master List  
Unique Identification  
Revise  
Revision Number  
Effective Date  
Review and Approval  
Obsolete  
Archive  
Hand-written changes

### Cross-references



ISO 17025:1999 Section 4.3

ISO 9001:2000 Section 4.2.1, 4.2.3

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### 4.3.1 Policies and Procedures

**Policy:**

The OP# QSP 4-3-1 is used to control all quality system documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, specifications, instructions, and manuals.

**Details:**

Document means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:

- Quality Manual
- Operational Procedures
- Work Instructions
- Calibration/Test methods
- Forms
- Standards

The control of data related to testing and calibration is covered in section 5.4.7. The control of records is covered in section 4.12.

### 4.3.2 Document Approval and Issue

#### 4.3.2.1 Review / Approval / Master List

**Policy and Details:**


All documents issued to personnel in the laboratory as part of the quality system are reviewed by the Quality Manager and approved for use by President/CEO. A master list identifying the current revision status and distribution of documents in the quality system is readily available in order to preclude the use of invalid and/or obsolete documents (see OP# QSP 4-3-1). A revision history of documents is also maintained. Documents are formally reviewed on a biennial basis to ensure their continuing suitability.

#### 4.3.2.2 Availability and Obsolete Documents

**Policy and Details:**

The master list shows the current status of all controlled documents. The master list document is organized with the following information:

- Document #
- Title
- Revision #
- Date of issue
- Date of last review
- Locations

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Controlled documents are approved before issue.

The OP# QSP 4-3-1 for document control ensures that:

- authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed
- documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements
- invalid or obsolete documents are promptly removed from all points of issue or use to assure against unintended use
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked (i.e., stamped "OBSOLETE" and dated)

#### 4.3.2.3 Identification

##### Policy and Details:

All quality system documentation is identified by:

- date of issue and/or revision number
- page numbering
- total number of pages (e.g., page 5 of 5)
- issuing authority (i.e., approval signature)

#### 4.3.3 Document Changes

##### 4.3.3.1 Review / Approval

##### Policy:

Changes to documents are reviewed and approved by the same function (i.e., personnel or position) that performed the original review

##### Details:

Developments in policies and procedures require documents to be changed from time to time. Changes to documents receive the same level of review and approval as the originals.

The Quality Manual is reviewed annually by the Quality Manager. Records are kept of this review.

Test methods and OPs are reviewed on a biennial basis. Procedures for this are outlined in OP# QSP 4-3-1.

Obsolete documents are withdrawn, but are retained for archive purposes and clearly labeled as obsolete.

##### 4.3.3.2 Identification of Changes

##### Policy:

The nature of document changes is identified in the document.

##### Details:

As outlined in OP# QSP 4-3-1.

In general, the nature of changes is identified in the document with a black vertical bar in the left-hand margin. Revision history is recorded at the end of the document.

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#### 4.3.3.3 Amendments by Hand

**Policy and Details:**

Hand-written amendments to documents are permitted only by those personnel authorized to do so (see section 4.1.5 A). Amendments are clearly marked, initialed, and dated. A revised document is formally re-issued at the time of the biennial review. For further details refer to OP# QSP 4-3-1.


#### 4.3.3.4 Computerized Documents

**Policy and Details:**

The OP# QSP 4-3-1 details how changes in documents maintained in computerized systems are made and controlled.

#### Revision History

Revision 1.0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2002/11/22</p>	<p>Rev.: <b>1.0</b></p>
<p align="center"><b>Section 4.4 - Review of Requests, Tenders, and Contracts</b></p>			<p>Page #: <b>1 of 3</b></p>

## 4.4 Review of Requests, Tenders, and Contracts

### The Ten Second Tutorial



This section tells you that you must:

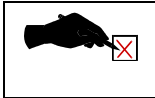
1. Clearly understand client requirements

### Key Words



Requirements  
Subcontractor  
Request  
Tender  
Contract  
Review


### Cross-references



ISO 17025:1999 Section 4.4

ISO 9001:2000 Section 5.2, 7.2.1, 7.2.2, 7.2.3



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<b>Section 4.4 - Review of Requests, Tenders, and Contracts</b>			Page #: <b>2 of 3</b>

#### 4.4.1 Policies and Procedures

**Policy:**

The OP# QSP 4-4-1 is used to review requests, tenders, or contracts. This procedure ensures that:

- a) the client requirements including the methods to be used are adequately defined, documented and understood (see section 5.4.2)
- b) the laboratory has the capability and resources to meet the requirements
- c) the appropriate calibration (or test) method is selected and capable of meeting the client's requirements (see section 5.4.2)

Any differences between the request or tender and the contract are resolved before any work commences. Each contract must be acceptable by both the laboratory and the client.

**Details:**

The request, tender and contract review is conducted in a practical and efficient manner, and the effect of financial, legal, and time schedule aspects are taken into account.

The review of capability establishes that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the calibration [and/or test] in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial test [or calibration programs] using samples or items of known value in order to determine uncertainties of measurement, limits of detection, and confidence limits.

The contract review ensures that each client's requirements are adequately defined and documented before the service or product is ordered or dispatched. This should ensure that any order, once accepted, can be completed without delay, and that the client's requirements including delivery date, technical specification, and cost can be met.

If the contract review highlights any ambiguities or uncertainties then the client will be contacted and the problem resolved before the order is accepted.

The OP# QSP 4-4-1 also describes the activities that take place should there be a subsequent amendment to a client's order.


Typical types of contracts include:

- approved service quotations
- confidentiality agreements
- non-disclosure agreements
- sample submission requests
- memorandum of agreement
- memorandum of understanding
- research proposals and contracts
- verbal orders (oral agreements)
- activity plans

#### 4.4.2 Records of Review

**Policy:**

Records of request, tender and contract review, including significant changes, are maintained. Records of pertinent discussions with a client relating to the client's requirements or the work during the period of execution of the contract are also maintained.

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**Details:**

For review of routine and other simple tasks, the date and the identification (e.g., initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on grant of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced calibration [and/or test] tasks, a more comprehensive record is maintained.

**4.4.3 Review of Subcontracted Work**

**Policy:**

Request, tender, and contract review also includes work that is subcontracted by the laboratory.

**Details:**

Subcontractor laboratories are reviewed as described in section 4.5.

**4.4.4 Notification of Client**

**Policy and Details:**

Clients are informed of deviations from the contract. This is typically communicated to the client prior to the performance of the deviation.


**4.4.5 Contract Amendment**

**Policy and Details:**

If a contract needs to be amended after the work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel.

**Revision History**

Revision 0

	<p><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2003/04/14</p>	<p>Rev.: <b>3.0</b></p>
<p><b>Section 4.5 - Subcontracting of Tests and Calibrations</b></p>			<p>Page #: <b>1 of 3</b></p>

## 4.5 Subcontracting of Tests and Calibrations

### The Ten Second Tutorial



*This section tells you that we must:*

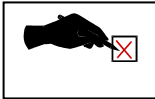
1. Know what tests and calibrations need to be done by another laboratory
2. Check out the other laboratories

### Key Words




Competence  
Register of Subcontractors  
Assessment

### Cross-references



ISO 17025:1999 Section 4.5

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2003/04/14	Rev.: <b>3.0</b>
<b>Section 4.5 - Subcontracting of Tests and Calibrations</b>			Page #: <b>2 of 3</b>

#### 4.5.1 Subcontractor Competence

**Policy:**

Work that must be subcontracted due to:

- unforeseen circumstances
- workload
- large contracts
- contracts requiring some extra technical expertise

is subcontracted to a technically competent laboratory in conformance to ISO/IEC 17025.

**Details:**

The subcontracted laboratory demonstrates technical competence by possession or receipt of an accredited certification of conformance to ISO/IEC Guide 17025 from A2LA or its Mutual Recognition Agreement (MRA) affiliation such as NVLAP, ICBO among others.

It is the responsibility of the Quality Manager to assess and approve the competence level of subcontractor laboratories.

#### 4.5.2 Client Approval

**Policy:**

Clients are advised of work (or any portion thereof) that is being subcontracted to another laboratory and their approval is obtained in writing.

**Details:**

Clients are advised of subcontracted work through fee schedules or any type of contract listed in section 4.4.1.

#### 4.5.3 Assurance of Subcontractor Competence

**Policy:**


The laboratory is responsible to the client for the subcontractor's work. Technical competence of subcontractor laboratories is demonstrated through various records.

**Note** – there may be circumstances where the client specifies which subcontractor is to be used. In such cases we may not be able to demonstrate the competence of the subcontractor and therefore are not responsible for the results.

**Details:**

Records of subcontractor competence include, but are not limited to, the following:

- accreditation certificates or documentation
- registration certificates
- check sample results
- audit results
- approval by the Quality Manager

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#### 4.5.4 Subcontractor Register

**Policy:**

A register of all subcontractors performing tests and calibrations is maintained.

**Details:**

The approved register of subcontractors and all assessment records are maintained by the Quality Manager.

#### 4.5.5 Non-Accredited Subcontractor

**Policy:**


Subcontractors not accredited to ISO/IEC Guide 17025 by A2LA or any of its MRA affiliates may be used as supply resource only if it is allowed by A2LA.

**Details:**

State metrology laboratory directly traceable to NIST are allowed by A2LA by the time of this revision. This section shall be updated if there will be any policy change from A2LA regarding this matter.

#### Revision History

Revision 2.0

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2003/06/25	Rev.: <b>2.0</b>
<b>Section 4.6 - Purchasing Services and Supplies</b>			Page #: <b>1 of 2</b>

## 4.6 Purchasing Services and Supplies

### The Ten Second Tutorial



This section tells you that we must:

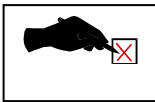
1. Know what we want
2. Check out our suppliers

### Key Words




Selection  
 Verify  
 Specifications  
 History

### Cross-references



ISO 17025:1999 Section 4.6  
 ISO 9001:2000 Section 7.4, 8.2.4

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<b>Section 4.6 - Purchasing Services and Supplies</b>			Page #: <b>2 of 2</b>

#### 4.6.1 Policies and Procedures

The laboratory will ensure that equipment, supplies and services purchased in support of our calibration services will conform to specified requirements. Procedures will exist for the purchase, reception and storage of equipment, materials and supplies relevant to the tests and calibrations. QSP 4-6-1 is used for the purchasing, reception and storage of supplies and equipment.

When it is necessary to purchase calibration services from other calibration laboratories only vendors approved by the laboratory will be engaged. The laboratory will ensure that such external laboratories conform to requirements as specified in QM 4.5.1.

#### 4.6.2 Inspection

The laboratory will ensure that purchased equipment, materials and supplies that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with specified requirements.

Records of such actions to check compliance will be maintained.

#### 4.6.3 Purchasing Documents


Purchasing documents for items that affect quality are reviewed to ensure that the requirements of the quality system are met.

#### 4.6.4 Approved Suppliers

The laboratory will evaluate suppliers of equipment, critical consumables, supplies and services which affect the quality of calibration. Records of approved suppliers are kept on file.

#### Revision History

Revision 1.0

	<p><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2002/11/22</p>	<p>Rev.: <b>1.0</b></p>
<p><b>Section 4.7 - Service to the Client</b></p>			<p>Page #: <b>1 of 2</b></p>

## 4.7 Service to the Client

### The Ten Second Tutorial



This section tells you that we must:

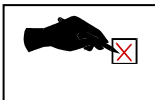
1. Facilitate clarification of the client's request
2. Give client access to relevant testing area
3. Maintain client contact
4. Inform client of delays or deviations
5. Utilize client surveys

### Key Words




Clarification  
Deviations  
Delays  
Client Satisfaction Survey

### Cross-references



ISO 17025:1999 Section 4.7  
ISO 9001:2000 Section 7.2.1, 7.2.3, 7.4.3, 7.5.1



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<b>Section 4.7 - Service to the Client</b>			Page #: <b>2 of 2</b>

#### 4.7.1 Policies and Procedures

##### Policy:

Client requests are clarified for the clients or their representatives. Furthermore the client or their representative will be afforded the right to monitor the performance of the laboratory in relation to the work performed. Web / online services are offered to clients to afford them real time monitoring of their equipment status.


##### Details and Procedures:

Service to the client includes:

- Affording the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of work performed for the client; it is understood that such access should not conflict with rules of confidentiality of work for other clients or with safety.
- Preparing, packaging, and dispatching of calibration items needed by the client for verification purposes.
- Maintaining of open contacts. The client values advice and guidance in technical matters, and opinions and interpretations based on results. Contact with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the calibration .
- Obtaining feedback from the client. Positive and negative feedback can be obtained passively through ongoing communications with the client or actively through client satisfaction surveys. The feedback is used to improve the quality system, calibration activities, and client service. Such feedback may be communicated to Primary Instruments Inc. through its website.

##### Revision History

Revision 0

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2002/11/22	Rev.: <b>1.0</b>
<b>Section 4.8 - Complaints</b>			Page #: <b>1 of 2</b>

## 4.8 Complaints

### The Ten Second Tutorial



This section tells you that you must:

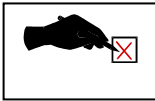
1. Maintain records of Complaints
2. Maintain records of Corrective Action

### Key Words



Resolving  
 Investigation  
 Corrective Action  
 Follow-up Verification


### Cross-references



ISO 17025:1999 Section 4.8

ISO 9001:2000 Section 7.2.3

#### 4.8.1 Policies and Procedures

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<b>Section 4.8 - Complaints</b>			Page #: <b>2 of 2</b>

**Policy:**

The OP# QSP 4-8-1 is used for resolving complaints received from clients or other parties. Records are maintained of all complaints and follow-up.

**Details:**

Records of complaints include the following information:


- details of the complaint
- investigation
- corrective action
- follow-up verification

See also section 4.10.

All personnel are responsible for recording and responding to complaints.

**Revision History**

Revision 0

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2002/11/22	Rev.: <b>1.0</b>
<b>Section 4.9 – Control of Nonconforming Testing and Calibration Work</b>			Page #: <b>1 of 3</b>

## 4.9 Control of Nonconforming Testing and Calibration Work

### The Ten Second Tutorial



This section tells you that you must:

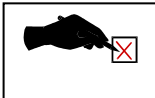
1. Stop testing when nonconforming work is identified
2. Figure out what is causing nonconforming work

### Key Words



Nonconforming  
 Root Cause


### Cross-references



ISO 17025:1999 Section 4.9

ISO 9001:2000 Section 5.5.1, 7.4.3, 7.5.1, 8.2.4, 8.3

### 4.9.1 Procedures to Control Nonconforming Work

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<b>Section 4.9 – Control of Nonconforming Testing and Calibration Work</b>			Page #: <b>2 of 3</b>

**Policy:**

The OP# QSP 4-9-1 is used to control any aspect of testing and/or calibration work, or the results of this work, when they do not conform with the test methods or the agreed requirements of the client.

**Details:**

The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of calibration certification certificate as necessary) are defined and taken into consideration when nonconforming work is identified
- an evaluation of the significance of the nonconforming work is made
- remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work
- where necessary, the client is notified and the work is recalled
- the responsibility for authorizing the resumption of work is defined

Identification of nonconforming work or problems with the quality system or with calibration activities can occur at various locations within the quality system and technical operations such as:

- client complaints
- quality control
- instrument calibration
- check all of consumable materials
- staff observations or supervision
- calibration certificate check
- management reviews
- internal or external audits

**4.9.2 Root Cause Analysis**

**Policy:**


Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 are followed to identify the root cause(s) of the problem and to eliminate this (these) cause(s).

**Details:**

The OP# QSP 4-10-1 outlines recording the root cause analysis for investigating nonconforming work.


Situations warranting corrective action investigation include:

- failure to comply with test method including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- presentation of uncertain knowledge as to compliance with calibration methods including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- failure or suspected failure in method performance as demonstrated by results provided by quality control samples
- lack of relevant evidence provided by quality audit, proficiency testing, or client feedback
- lack of relevant evidence provided by data validation
- neglect to check the inherent property of the item that compromises the calibration.

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<b>Section 4.9 – Control of Nonconforming Testing and Calibration Work</b>			Page #: <b>3 of 3</b>

**Revision History**

Revision 0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2002/11/22</p>	<p>Rev.: <b>1.0</b></p>
<p align="center"><b>Section 4.10 – Corrective Action</b></p>			<p>Page #: <b>1 of 3</b></p>

## 4.10 Corrective Action

### The Ten Second Tutorial



This section tells you that you must:

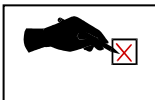
1. Identify problems
2. Determine why the problem occurred
3. Fix the cause of the problem
4. Verify that your changes worked

### Key Words




CAR  
Root Cause  
Monitor  
Audit  
Nonconforming work

### Cross-references



ISO 17025:1999 Section 4.10

ISO 9001:2000 Section 5.5.1, 8.1, 8.2.2, 8.2.3, 8.4, 8.5.2, 8.5.3

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<b>Section 4.10 – Corrective Action</b>			Page #: <b>2 of 3</b>

#### 4.10.1 General

**Policy:**

The OP# QSP 4-10-1 is utilized for implementing corrective action when nonconforming work or departures from policies and procedures in the quality system or technical operations have been identified. The procedure requires that appropriate authority be designated for the implementation of corrective actions. The procedure includes cause analysis, selection and implementation of corrective action, and monitoring of actions.

**Details:**

Problems with the quality system or technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feed-back from clients, or staff observations.

Corrective action investigations are documented and required changes to operational procedures are implemented. The corrective action request (CAR), investigation and resolution are recorded on a CAR form.

#### 4.10.2 Cause Analysis

**Policy:**

Corrective action always begins with an investigation to determine root cause(s) of the problem (see OP# QSP 4-10-1).

**Details:**

Potential causes of the problem could include client requirements, the item for calibration, item specifications, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration.

#### 4.10.3 Selection and Implementation of Corrective Actions

**Policy and Details:**

After determining the cause(s) of the problem, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the problem and to prevent recurrence. It should be noted that any corrective actions taken to eliminate the cause(s) of nonconformances or other departures are to an appropriate degree to address the magnitude of the problem and commensurate with the risks encountered (Note – in plain language, this means determine whether the benefit outweighs the cost). Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

#### 4.10.4 Monitoring of Corrective Action


**Policy:**

After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

**Details:**

Monitoring is assigned to an appropriate individual such as the originator of the CAR or the originator's supervisor. Changes resulting from corrective action are documented.



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<b>Section 4.10 – Corrective Action</b>			Page #: <b>3 of 3</b>

#### 4.10.5 Additional Audits

**Policy:**


Where the identification of nonconformances or departures casts doubts on compliance of policies, procedures, regulations, international quality standards, the appropriate areas of activity are promptly audited in accordance with section 4.13.

**Details:**

Special audits follow the implementation of corrective actions to confirm their effectiveness. A special audit is only necessary when a serious issue or risk to the business is identified. Special audits are carried out by trained and qualified personnel who are [whenever resources permit] independent of the activity to be audited. See section 4.13 for more details.

#### Revision History

Revision 0

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2002/11/22	Rev.: <b>1.0</b>
<b>Section 4.11 – Preventive Action</b>			Page #: <b>1 of 2</b>

## 4.11 Preventive Action

### The Ten Second Tutorial



This section tells you that you must:

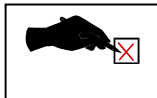
1. Identify potential problems
2. Determine why the problem could occur
3. Fix the cause of the potential problem
4. Verify that your changes worked

### Key Words




PAR  
 Potential Nonconformance  
 Action Plan

### Cross-references



ISO 17025:1999 Section 4.11

ISO 9001:2000 Section 8.4, 8.5.2, 8.5.3

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<b>Section 4.11 – Preventive Action</b>			Page #: <b>2 of 2</b>

#### 4.11.1 Preventive Action Identification

**Policy:**

Opportunities for needed improvement and potential sources of nonconformances, either technical or with the quality system shall be identified. If action is required, action plans are developed, implemented and monitored, to reduce the likelihood of occurrence of such nonconformances and to take advantage of the improvement opportunities.

**Details:**

Records of preventive action include the following information:

- details of potential nonconformances
- investigation
- preventive action
- follow-up verification

These records are maintained in the [Preventive Action Request (PAR) form/binder].

#### 4.11.2 Preventive Action Plans

**Policy:**

The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective.


**Details:**

Preventive action may result from the review of operational procedures and analysis of data. Analysis of data includes trend analysis, analysis of proficiency testing results, and risk analysis.

The OP# QSP 4-11-1 is utilized to implement opportunities for needed improvement and prevent potential sources of nonconformances.

#### Revision History

Revision 0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2003/4/14</p>	<p>Rev.: <b>3.0</b></p>
<p align="center"><b>Section 4.12 – Control of Records</b></p>			<p>Page #: <b>1 of 4</b></p>

## 4.12 Control of Records

### The Ten Second Tutorial



This section tells you that you must:

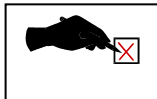
1. Identify the records to be kept
2. Keep identified records in a useful state
3. Destroy records when they are no longer needed

### Key Words




Collection  
Indexing  
Access  
Storage  
Maintenance  
Disposition  
Legible  
Traceable  
Retrievable  
Secure

### Cross-references



ISO 17025:1999 Section 4.12

ISO 9001:2000 Section 4.2.4, 6.3, 6.4, 7.1, 7.5.1, 7.5.2, 7.5.3, 8.1, 8.2.2, 8.2.3, 8.2.4

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<b>Section 4.12 – Control of Records</b>			Page #: <b>2 of 4</b>

#### 4.12.1 General

##### 4.12.1.1 Procedures

**Policy:**

The OP# QSP 4-12-1 is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. Quality records include reports from internal audits and management reviews, corrective and preventive action records as well as results obtained from calibration performed in the laboratory and performed onsite.

**Details:**

Records are available to demonstrate conformance to requirements and effective operation of the Quality System. Quality records from suppliers are also controlled.

All records, including test reports, are safely stored and held secure in locked areas, and in confidence to the client. Records are maintained in the designated archival area for 7 years.

The master list of records is organized with the following information:

- Record No. / Form No.
- Record Name
- Filing Method (loose forms filed monthly, quarterly, semi-annual, annual or electronic)
- Active Files (files referred to within the work area) / Retention Period / Location
- Inactive Files (files referred to but not often and kept in storage) / Retention Period / Location
- Persons / Positions Responsible / Users

##### 4.12.1.2 Record Integrity

**Policy:**

All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

**Details:**

The retention times for records are generally set at 7 years.

Records may be in the form of any type of media, such as hard copy or electronic media.

##### 4.12.1.3 Record Security


**Policy:**

All records are held secure and in confidence.

**Details:**

Access to records is secured through locked rooms and filing cabinets.

##### 4.12.1.4 Record Backup

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<b>Section 4.12 – Control of Records</b>			Page #: <b>3 of 4</b>

**Policy:**

The OP# QSP 4-12-1 is followed to protect and backup data/records held on computers at all times and to prevent unauthorized access to or amendment of data/records on computers.

**Details:**

Data is password protected.

Backups ensure integrity and availability of data / information in the event of a system / power failure.

**4.12.2 Technical Records**

**4.12.2.1 Record Information**

**Policy:**

Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records, personnel records and a copy of each calibration certificate issued are retained for 7 years.

The records for each calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for performing each calibration and checking of results.

**Details:**

Technical records are accumulations of data (see 5.4.7) and information that result from carrying out calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, note books, instrument printouts, magnetic media, check sheets, work notes, control graphs, test reports, calibration certificates, client's notes, papers and feedback, and calibration certificate to clients.

The records for each calibration contain sufficient information to permit its repetition. Records include:

- date of calibration
- handling, storage, and disposal
- identification of personnel
- technical proficiency (training records)
- equipment identification and performance
- calibration records
- media performance, where appropriate
- reports (mailed, faxed)
- review


*Note* – the above records may be stored in separate locations. They are cross-referenced for easy retrieval.

**4.12.2.2 Recording**

**Policy:**

Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific job at the time they are made, as needed.

**Details:**

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Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected and/or after calculations are made.

#### 4.12.2.3 Corrections to Records

**Policy:**

Changes to test data are made so as not to obscure or delete the previous data entry.


**Details:**

Mistakes are crossed out and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records are signed or initialed by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.

Note: Integrity of electronic signature complies with the provisions found in 21 CFR, Part 11.

#### Revision History

Revision 1.0

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2003/02/14	Rev.: <b>2.0</b>
<b>Section 4.13 – Internal Audits</b>			Page #: <b>1 of 3</b>

## 4.13 Internal Audits

### The Ten Second Tutorial



This section tells you that:

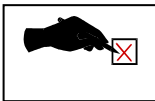
1. Trained internal auditors examine your internal operations for quality
2. Auditors report the results to those in charge
3. You must correct any areas that need fixing

### Key Words



Schedule  
 Elements  
 Independent  
 Nonconformance  
 CAR


### Cross-references



ISO 17025:1999 Section 4.13  
 ISO 9001:2000 Section 8.1, 8.2.2, 8.2.3

#### 4.13.1 Internal Audit Program



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**Policy:**

The internal audit program involves periodic audits conducted according to a predetermined schedule for each year. This program is defined on an annual basis and conducted as outlined in this section with further details found in OP# QSP 4-13-1. All elements of this Quality Manual will be audited each year and all relevant laboratory records are available to personnel conducting the audit. All areas are audited including the onsite calibration activities and similar procedures are used for both the in-house calibration activities and onsite calibration activities. These audits are performed to verify operations continue to comply with the requirements of this Quality Manual and are effective. In case of onsite calibration, the designated internal auditor visits the site as part of the internal audit process.

**Details:**

The Quality Manual, test procedures, and laboratory results are verified for compliance. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are carried out by trained and qualified personnel who are [wherever resources permit] independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.10.5). Audits are performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit.

Generally, the types of audits include:

- quality management system
- processes and procedures
- products, services, and reports

#### 4.13.2 Corrective Action

**Policy:**

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken and clients are notified if investigations show that laboratory results may have been affected.

**Details:**

Nonconformances that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformances that require a more involved resolution are recorded on a CAR and resolved as described in section 4.10.


Corrective actions and client modifications must be kept on record for each audit deviation that casts doubt as described in this section.

#### 4.13.3 Records and Management

**Policy:**

Records are made of the activity being audited, the audit findings, and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.

**Details:**

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A report is prepared by the auditors and distributed to those audited and/or the area manager/supervisor within an appropriate and agreed timeline. The audit report may include the following sections, as appropriate:

- audit objective and scope
- area or section audited
- personnel involved – auditors and auditee
- date of audit
- reference documents
- observations including nonconformances and commendations
- opening and closing meetings
- recommendations
- audit report distribution

The appropriate manager is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are kept in the laboratory.

#### **4.13.4 Follow-up Audits**

**Policy:**


Follow-up audits are performed to verify and record the implementation and effectiveness of the corrective action taken.

**Details:**

The follow-up audit is performed at a mutually acceptable time between the area implementing corrective action and the auditor. This time is determined when the CAR is issued.

#### **Revision History**

Revision 1.0

	<b>QUALITY MANUAL</b> Primary Instruments, Inc.	Issue Date: 2003/2/14	Rev.: <b>2.0</b>
<b>Section 4.14 – Management Reviews</b>			Page #: <b>1 of 2</b>

## 4.14 Management Reviews

### The Ten Second Tutorial



This section tells you that management must:

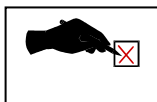
1. Periodically review technical competence and client satisfaction
2. Keep records of reviews
3. Ensure follow-up is executed
4. Measure progress

### Key Words




Supervisor Reports  
 Audit Reports  
 CAR / PAR  
 Proficiency Results  
 Client Satisfaction Survey  
 Resources

### Cross-references



ISO 17025:1999 Section 4.14

ISO 9001:2000 Section 5.1, 5.4.2, 5.6, 6.2.1, 7.1, 8.5.1

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<b>Section 4.14 – Management Reviews</b>			Page #: <b>2 of 2</b>

#### 4.14.1 Review of Quality System and Testing

**Policy:**

Management annually and in accordance with a predetermined schedule and OP# QSP 4-14-1, conduct a review of the laboratory’s quality system and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

**Details:**

The review takes account of:

- suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal audits
- corrective and preventive actions
- assessments by external bodies
- results of inter-laboratory comparisons or proficiency tests
- changes in the volume and type of work undertaken
- feedback from clients, including complaints and client satisfaction surveys
- review of onsite calibration activities
- other relevant factors, such as quality control activities, resources and personnel training

A minimum period for conducting a management review is once a year. Results of the review feed into the laboratory planning system and include goals, objectives and action plans for the coming year.

A management review can be supplemented by consideration of related subjects at regular management meetings.


#### 4.14.2 Findings, Actions, and Records

**Policy and Details:**

Findings from management reviews and the actions that arise are recorded in the minutes of the meeting. Management will ensure that the actions are discharged within an appropriate and agreed timeline.

#### Revision History

Revision 1.0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2002/11/22</p>	<p>Rev.: <b>1.0</b></p>
<p align="center"><b>Section 5.1 - General</b></p>			<p>Page #: <b>1 of 2</b></p>

## 5.1 General

### The Ten Second Tutorial



This section informs you that:

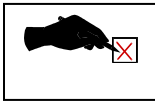
1. Many factors contribute to the correctness and reliability of tests and/or calibrations
2. The laboratory must account for these factors

### Key Words




Correctness  
Reliability  
Uncertainty

### Cross-references



ISO 17025:1999 Section 5.1  
ISO 9001:1994 Section N/A  
ISO 9001:2000 Section N/A

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<b>Section 5.1 - General</b>			Page #: <b>2 of 2</b>

### 5.1.1 Correctness and Reliability

**Policy and Details:**

Correctness and reliability of the measurement and/or calibrations performed have many contributing factors including:

- human factors (see section 5.2)
- accommodation and environmental conditions (see section 5.3)
- test and calibration methods and method validation (see section 5.4)
- equipment (see section 5.5)
- measurement traceability (see section 5.6)
- sampling (see section 5.7)
- handling of test and calibration items (see section 5.8)

### 5.1.2 Measurement Uncertainty

**Policy:**

When developing measurement and calibration methods and procedures, total measurement uncertainty must be accounted for in the training and qualification of personnel, and in the selection and calibration of equipment.


**Details:**

The extent to which the factors contribute to total measurement uncertainty differs between (types of) tests and between (types of) calibrations.

See section 5.4.6 for more details.

### Revision History

Revision 0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2003/02/14</p>	<p>Rev.: <b>2.0</b></p>
<p align="center"><b>Section 5.2 - Personnel</b></p>			<p>Page #: <b>1 of 3</b></p>

## 5.2 Personnel

### The Ten Second Tutorial



This section tells you that management:

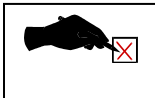
1. Analyzes training needs
2. Provides training to employees for them to do their jobs
3. Qualifies people performing specific tasks

### Key Words



Competence  
Qualification  
Authorize  
Training Needs  
Job Description  
Registry of Skills

### Cross-references



ISO 17025:1999 Section 5.2

ISO 9001:2000 Section 5.5.1, 6.2.1, 6.2.2, 7.5.1

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<b>Section 5.2 - Personnel</b>			Page #: <b>2 of 3</b>

### 5.2.1 Competence and Qualification

**Policy:**

Management ensures the competency of all specific equipment operators, those performing measurement and/or calibration in the laboratory and/or onsite, those evaluating results and sign test reports and calibration certificates of accredited tests and/or calibration. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in test reports also have:

- relevant knowledge of the technology used for the manufacturing of the items, materials, products tested, or the way they are used or intended to be used and of the defects or degradation that may occur during or in service
- knowledge of the general requirements expressed in the legislation and standards
- an understanding of the significance of deviations found with regard to the normal use of the items, materials, or products concerned

**Details:**

Management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. In some technical areas (e.g. gowning in clean rooms) it may be required that the personnel performing certain tasks be certified. The laboratory is responsible for fulfilling specified certification requirements of personnel. The requirements for personnel certification might be regulatory, might be included in the standards for the specific technical field, or required by the client.

Continued competence is monitored and where this is not achieved, the need to retrain personnel is considered. Where a method or technique is not in regular use, verification of personnel performance before they undertake tests, may be necessary.

### 5.2.2 Training Policies and Procedures

**Policy:**

Management will formulate the goals with respect to the education and the skills of the laboratory personnel. The training program is relevant to the present and anticipated tasks of the laboratory. OP# QSP 5-2-1 is utilized to identify training needs and providing the necessary training for personnel.

**Details:**

The skills and knowledge are defined in the job description for each job function as described in section 5.2.4. Management compares the job description to the skills and knowledge of the new incumbent to determine the training needs.

Training in the laboratory must include all methods or parts of methods and techniques that personnel are asked to perform. Minimally, the technician must demonstrate competency by observation by management and verification using replicate and calibration procedure. For technicians who perform only parts of the method, confirmation of competency may be verified by observation only. Re-verification of all personnel must be performed annually on all methods or techniques pertinent to their job description.

### 5.2.3 Employees

**Policy:**

Competent permanent or contractual employees are employed in the laboratory. The technical manager ensures that contractual, additional technical employees, and key support personnel are supervised and work in accordance to the policies and procedures of this Quality Manual.

**Details:**



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<b>Section 5.2 - Personnel</b>			Page #: <b>3 of 3</b>

Calibration and measurement must be either performed or supervised by an experienced person qualified to degree level. Personnel have relevant practical work experience (at least 3 years) before being allowed to perform accredited work.

Personnel not employed or sub-contracted by the laboratory are not allowed to perform or assist in both in-house calibration activities and onsite calibration under any circumstances. Trainees are allowed to perform or assist in performance of accredited calibration only under the supervision of a trained staff employed or subcontracted by the laboratory.

#### 5.2.4 Job Descriptions

##### Policy:

Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained centrally in the administration area of the laboratory.

##### Details:

Minimum contents of job descriptions include:

- the duty of performing tests and/or calibrations
- the act of planning tests and/or calibrations and evaluation of results
- the responsibility of developing and validating new methods as / when requested
- expertise and experience
- qualifications and training programs
- managerial duties

Job descriptions are dated and signed to demonstrate that each incumbent has read it and is in agreement. They are maintained current.

#### 5.2.5 Authorized Personnel

##### Policy:

Management authorizes specific personnel to perform particular types of measurement and/or calibration in the laboratory and/or onsite, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. Records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel and contracted personnel are maintained. This information is readily available and includes the date on which authorization and/or competence was confirmed and the criteria on which the authorization is based and the confirming authority.

##### Details:

The purpose of these records is to provide evidence that personnel have been adequately trained and their competence to perform particular tests has been assessed. In some cases it may be pertinent to state any particular limitations to competence. The records are maintained in a registry of skills and include:

- academic and professional qualifications
- external and internal courses attended
- relevant on-the-job training and retraining as necessary (i.e., demonstration of competence)
- skills and experience (i.e., resume)
- relevant authorizations

Records are held centrally in the administration area.

#### Revision History

Revision 1.0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2003/06/23</p>	<p>Rev.: <b>3.0</b></p>
<p align="center"><b>Section 5.3 - Accommodation and Environmental Conditions</b></p>			<p>Page #: <b>1 of 3</b></p>

## 5.3 Accommodation and Environmental Conditions

### The Ten Second Tutorial



This section tells you:

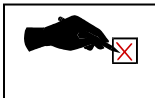
1. That laboratory facilities are suitable for attaining correct performance of tests and calibrations
2. Critical environmental conditions are monitored, controlled and recorded
3. Incompatible activities are separated
4. Access to laboratories is controlled
5. Good housekeeping is practiced

### Key Words



Incompatible activities  
Prevent cross-contamination  
Controlled access

### Cross-references



ISO 17025:1999 Section 5.3

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.5.1, 7.5.2, 7.6, 8.2.3

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<b>Section 5.3 - Accommodation and Environmental Conditions</b>			Page #: <b>2 of 3</b>

### 5.3.1 Facility

**Policy and Details:**

Laboratory facilities are appropriate to attain correct performance of tests and/or calibrations. This may include, but not limited to, energy sources, lighting, heating, ventilation and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when calibration and/or tests are undertaken at sites e.g. onsite calibration, other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented.

**Details:**

This section deals with the laboratory areas and premises for support such as item receipt and storage. All of these are made sure to be appropriate to facilitate proper performance of calibration.

### 5.3.2 Monitoring

**Policy:**

Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Due attention is paid, for example, to biological sterility, dust, air quality, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations. This shall be true for both calibration performed in the laboratory and onsite facilities.

**Details:**

Laboratories are ventilated to reduce the levels of contamination, lower humidity, and control temperature. Laboratories' test areas are air-conditioned. The relative humidity in test areas is 20-55% and the temperature is  $20 \pm 1^\circ\text{C}$  for the Physical/Dimensional Laboratory,  $20 \pm 3^\circ\text{C}$  for the Pressure/Torque Laboratory and  $23 \pm 3^\circ\text{C}$  for the Electrical and Electronics Laboratory.

Bench tops and floors are made of impervious, smooth easily cleaned materials. There is at least two linear meters work-space per analyst while working. Walls and ceilings are made of materials that are smooth and easily cleaned.

OP# QSP 5-3-1 is the procedure used for accommodation and environmental conditions for the laboratory and onsite calibration.


### 5.3.3 Separation of Incompatible Activities

**Policy:**

Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

**Details:**

Items for calibration and calibrated and certified items are separated from each other as well as serviceable and non-serviceable equipments. Laboratories are also separated from each other i.e. Physical/Dimensional Lab, Electrical and Electronics Lab and Pressure and Force Lab are separated from each other.

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<b>Section 5.3 - Accommodation and Environmental Conditions</b>			Page #: <b>3 of 3</b>

#### 5.3.4 Controlled Access

**Policy:**

Access to and use of areas affecting quality of the measurement and/or calibrations is defined and controlled.

**Details:**

Access to the laboratory is restricted to authorized personnel. The authorized personnel are made aware of the following items:

- the intended use of the area
- the restrictions imposed on working within such areas
- the reasons for imposing the restrictions

#### 5.3.5 Good Housekeeping

**Policy:**

Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary. Work Instruction WI5-3-1 is used for good housekeeping of the laboratories.


**Details:**

Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements.

#### Revision History

Revision 1.0 -Initial Release

Revision 2.0 – Added onsite calibration into the policy and details in 5.3.1

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## 5.4 Tests and Calibration Methods and Method Validation

### The Ten Second Tutorial



This section tells you:

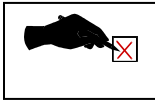
Preference is given to the use of a standard method when selecting procedures  
 All methods must be validated before use  
 Measurement uncertainty is estimated  
 Data is controlled

### Key Words




Standard Methods  
 Laboratory-Developed Methods  
 Non-standardized Methods  
 Validation  
 Uncertainty of Measurement  
 Data Checks

### Cross-references



ISO 17025:1999 Section 5.4

ISO 9001:2000 Section 4.2.1, 4.2.3, 6.3, 6.4, 7.1, 7.2.1, 7.3, 7.4.3, 7.5.1, 7.5.2, 7.6, 8.1, 8.2.3, 8.2.4

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### 5.4.1 General

**Policy:**

Methods and procedures used for all calibrations are appropriate as per:

- handling, transport, storage, and preparation of items to be calibrated
- an estimation of the measurement of uncertainty as well as statistical techniques for analysis of calibration data where appropriate

Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for and calibration are available. All instructions, standards, manuals and reference data relevant to the work of the laboratory are maintained current and readily available to personnel. Deviation from calibration procedures must be documented, technically justified, authorized, and accepted by the client.

**Details:**

There are Operational Procedures for item handling, transport, storage, preparation of calibration items, QA procedures, and standards for approving / rejecting results. These may be combined with or separate from the procedures. The content of a calibration procedure includes:

- scope
- description of calibration/test items
- soak time
- materials and equipment required
- physical environmental conditions required (temperature and humidity requirements)
- description of procedures
- method of recording observations and results
- safety measures
- documentation
- method for data analysis and presentation
- sensitivity of method
- quality control plan

International, national, or regional standards or other recognized specifications that contain sufficient and concise information on how to perform the calibrations are not necessarily supplemented or rewritten as an internal procedure when they are written in a way that can be used as published by laboratory staff. Consideration may need to be given to providing additional documentation for optional steps in the method.

### 5.4.2 Selection of Methods

**Policy:**

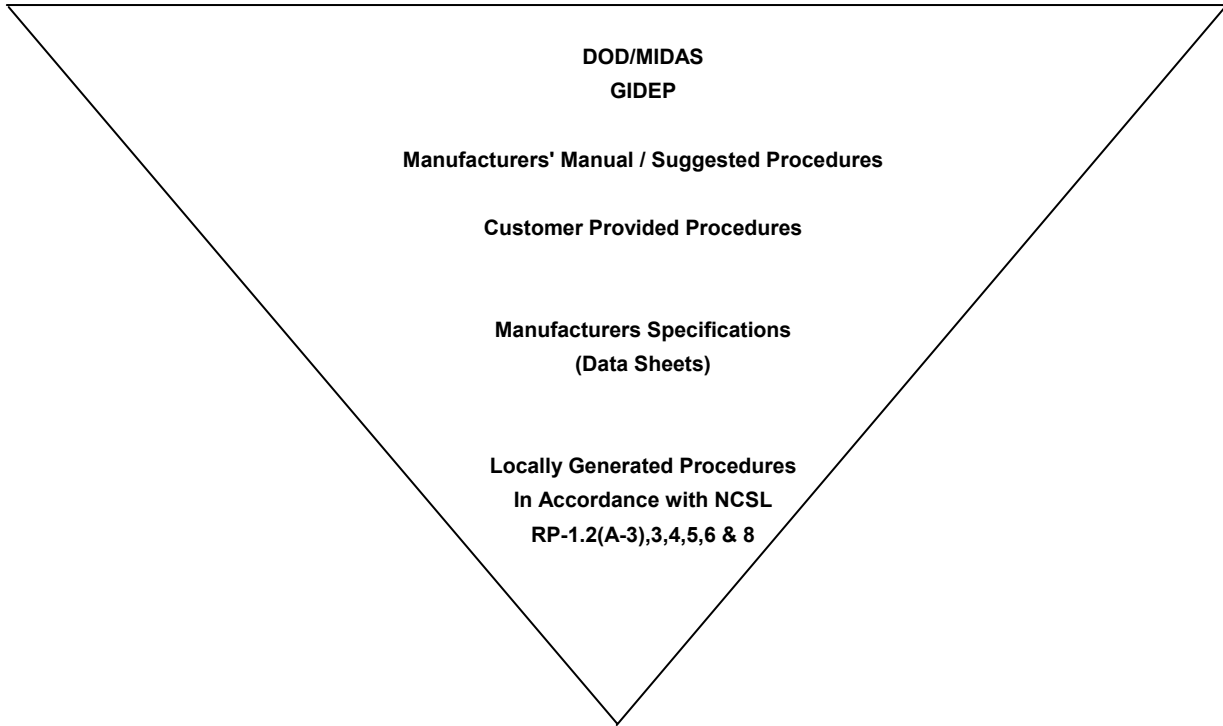
Calibration procedures meet the needs of the client and are appropriate for the calibrations it undertakes. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application. See QSP 5-4-3

The laboratory ensures that the latest procedures are used during the calibration process. In case of onsite calibration, up to date calibration procedures are available to personnel performing onsite calibration activities. The OP# QSP 5-5-2 is utilized in performing onsite calibration activities and includes the procedure used in the supply and updating of test and calibration methods used by staff working onsite.

**Details:**

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The following diagram illustrates the hierarchy of calibration procedure/methods that Primary Instruments employ:



### 5.4.3 Laboratory-Developed Methods

**Policy:**

Introduction of calibration procedures developed internally is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and ensure effective communication amongst all personnel involved.


**Details:**

Procedures developed in-house are validated and authorized before use. Where available, Certified Reference Standards are used to determine any systemic bias, or where possible results are compared with other techniques, preferably based on different principles of measurement and/or calibration. Determination of uncertainty must be part of this validation process and is essential for ongoing quality control.

### 5.4.4 Non-Standard Methods

**Policy:**

Utilization of non-standard methods is subject to agreement with the client and includes a clear specification of the client's requirements and the purpose of the calibration. The developed procedure is validated appropriately before use.

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**Details:**

Discussion and agreement for the use of non-standard methods is recorded as part of contract review procedures (see section 4.4).

All non-standard and new tests are validated for their intended purpose. Qualitative test methods must be validated to demonstrate estimated sensitivity and specificity, relative accuracy to official methods (if appropriate), positive and negative deviation, limit of detection, matrix effect, repeatability, and reproducibility.

Quantitative test methods are validated to demonstrate specificity, sensitivity, relative accuracy, positive and negative deviation, repeatability, reproducibility, and limit of determination.

For new methods where procedures are developing rapidly, especially for emergency situations, it may be necessary to circumvent normal validation procedures.

New test and/or calibration methods are documented prior to providing test and/or calibration results to clients and contain at least the following information:

- appropriate identification
- scope
- description of the type of item to be tested or calibrated
- parameters or quantities to be determined
- apparatus and equipment, including technical performance requirements
- reference standards and reference materials required
- environmental conditions required and any stabilization period needed
- description of the procedure, including
  - affixing identification marks, handling, transporting, storing and preparing of items
  - ensuring checks are made before the work is started
  - checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use
  - listing method of recording the observations and results
  - indicating any safety measures to be observed
- criteria and/or requirements for approval/rejection (quality control plan)
- data to be recorded and method of analysis and presentation
- uncertainty or procedure for estimating uncertainty

**5.4.5 Validation of Methods**

**5.4.5.1 Performance Characteristics**

**Policy:**

Validation of a method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the test results.

**Details:**

The performance characteristics of a validation plan includes, as applicable:

- selectivity and specificity
- range
- linearity
- sensitivity
- ruggedness
- accuracy
- precision





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- reporting limit
- repeatability
- reproducibility
- recovery
- confirmation techniques
- criteria for the number of calibrations performed to validate method as per defined scope of method
- action levels where defined by regulation
- quality control incorporating statistics as applicable
- interpretation of population results as applicable

Performance characteristics that are selected take into account the intended use of the method, whether for screening, confirmatory analysis, or quantization.

The design, verification of the method and documentation procedures for validation are planned and conducted by qualified personnel, equipped with adequate resources.

Records are kept on all validation activities. The records include any of the performance characteristics chosen, reference procedures or guidance documents followed to validate the method or custom validation procedure, and a final confirmation (memo to file) that the method validation results are acceptable for continued use of the method. An example statement would be "This memo serves as record that the validation of the XYZ Calibration Method has been approved for use by [Quality/Technical Manager]".

#### 5.4.5.2 Fit for Use

##### Policy:

The laboratory validates non-standardized methods, laboratory-designed/developed methods, standardized methods used outside their intended range, and amplifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs in the given application or field of application (may include procedures for sampling, handling, and transportation). The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

##### Details and Procedure:


Validation records are kept as in section 5.4.5.1. Included in these records is the validation procedure. The procedure used for the validation is likely to vary between different methods. Therefore, the procedures included in the laboratory records are not as detailed as a typical calibration procedure, but are sufficient enough to re-create how the method was validated.

The techniques used for the determination of the performance of a method, are one of, or a combination of, the following:

- calibration using reference standards or reference materials
- comparison of results achieved with other methods
- inter-laboratory comparisons
- systematic assessment of the factors influencing the result
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When changes are made in the validated non-standard method, the influence of such changes carried out is documented and if appropriate a new validation is performed.

#### 5.4.5.3 Client's Needs

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**Policy:**

The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use is relevant to the client's needs.

**Details:**

Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

As method development proceeds, regular review is required to verify that the needs of the client are still being fulfilled. Changing requirements requiring modifications to the development plan are approved and authorized.

Validation is always a balance between costs, risks, and technical possibilities.

## 5.4.6 Uncertainty of Measurement

### 5.4.6.1 Calibration

**Policy:**

The OP# QSP5-4-1 is utilized to estimate uncertainties of measurement in calibration except when the calibration method precludes such rigorous calculations. In certain cases it is not possible to undertake metrologically and statistically valid estimations of uncertainty of measurement. In these cases the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope and makes use of previous experience and validation data.

**Details:**

The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- requirement of the test method
- requirement by the client
- if there are narrow limits on which decisions on conformance to a specification are based

In cases where a well-recognized calibration method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the reporting instructions (see section 5.10).


### 5.4.6.2 Testing

**Policy and Details:**

When the company performs testing, measurement services other than calibration, calculation of uncertainties if warranted shall follow the policy above, Section 5.4.6.1 and OP#QSP 5-4-1

### 5.4.6.3 Uncertainty Components

**Policy:**

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When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

**Details:**

Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested or calibrated and the operator.

The predicted long-term behavior of the tested and/or calibrated item is normally not taken into account when estimating the measurement uncertainty.

For further information, see ISO 5725 and the Guide to Expression of Uncertainty in Measurement.

**5.4.7 Control of Data**

**5.4.7.1 Calculations and Data Transfers**

**Policy:**

Calculations and data transfers are subject to appropriate checks in a systematic manner.

**Details:**

Test data are validated through the following arrangements by the Quality Manager:

- checks to determine accuracy of calculations, conversions, and data transfers
- checks for transcription errors, omissions, and mistakes
- checks to determine consistency with normal or expected values

For those analyses where manual data reduction is required, it is performed according to the instructions provided in the calibration procedures.

**5.4.7.2 Computers and Automated Equipment**

**Policy:**

When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

- computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use
- procedures are established and implemented for protecting the integrity of data; such procedures include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing (see section 4.12.1.4). OP#QSP 5-4-2 is utilized in this case.
- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data
- data is securely maintained by preventing unauthorized access to, and unauthorized amendment of, computer records

**Details and Procedures:**

Data generated using computer software programs that are interfaced directly to instruments incorporates all dilutions and calculations, thereby eliminating the need for manual data reduction.

Commercially developed software in general use within its designed application range may be considered sufficiently validated. Laboratory software configuration / modifications are validated as outlined in OP# QSP 5-5-1.

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Electronic records, electronic signatures, and handwritten signatures executed to electronic records must be equivalent to proper records and handwritten signatures to paper and are validated by procedures in 21 CFR. Part II (Docket No. 92NO251) RIN0910-AA29; Federal Register: March 20, 1997, Volume 62, Number 54), Rules and Regulations, pages 13429-13466. For further details see: <http://www.fda.gov/cder/esig/index.htm>

**Revision History**

Revision 1.0

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## 5.5 Equipment

### The Ten Second Tutorial



This section tells you to:

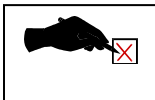
1. Identify information needs for accept / reject decisions
2. Install equipment capable of providing that information
3. Use the equipment in the proper environment
4. Periodically check the equipment calibration

### Key Words



Required Equipment and Accuracy  
 Authorized Personnel  
 Unique Identification  
 Inventory  
 Maintenance  
 Procedures  
 Out of Service  
 Calibration Status  
 Re-verification  
 Checks  
 Correction Factors  
 Safeguards against Adjustment

### Cross-references



ISO 17025:1999 Section 5.5

ISO 9001:2000 Section 4.2.1, 4.2.3, 5.1, 7.1, 7.4, 7.5.1, 7.5.2, 7.5.3, 7.6, 8.1, 8.2.3, 8.2.4

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### 5.5.1 Required Equipment

**Policy:**

The laboratory is furnished with all measurement and test equipment required for the correct performance of calibration services. When equipment is used outside the laboratory's permanent control such as equipments used on onsite calibration activities, it ensures that the requirements of this Quality Manual are met.

**Details:**

Equipment is used in an environment appropriate to its proper performance. All equipment required by a calibration is described in each method, including the equipment's tolerances.

### 5.5.2 Required Accuracy

**Policy:**

Equipment and software used for calibration are capable of achieving the accuracy required and comply with specifications relevant to the calibration concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant affect on the results. When received, equipment is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with section 5.6 before use.

**Details:**

The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement, which may include calibration procedures already used by the laboratory for such equipment.

### 5.5.3 Authorized Personnel

**Policy:**

Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel.

**Details:**

Access to laboratory equipment is controlled to ensure that only authorized personnel use equipment.

### 5.5.4 Unique Identification

**Policy:**

Each item of equipment used for measurement and calibration is uniquely identified as appropriate.

**Details:**

Measuring and calibration equipment is uniquely identified through an asset number. Measuring and calibration equipment includes any instrument that could affect the quality of test results.

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### 5.5.5 Inventory and Maintenance Records

**Policy:**

Records are maintained of each item of equipment significant to the measurement and/or calibrations performed. The records include the following:

- identity of the item of equipment (and its software)
- manufacturer's name, type identification, and serial number and/or other unique identification
- checks that equipment complies with the specification (see section 5.5.2)
- current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)
- damage, malfunction, modification or repair to the equipment

**Details:**

A database is used to capture the above inventory information. The above information related to service and maintenance is kept in individual equipment files and/or binders. Other information kept in these files and/or binders may include:

- date received and date placed in service, where possible
- Traceability and A2LA status
- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification
- performance history, where appropriate (e.g., response time, drift, noise level)

### 5.5.6 Equipment Procedures

**Policy:**

The OP# QSP 5-5-1 is utilized as an established plan for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and in order to prevent contamination or deterioration.

**Note** – additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations, or sampling (currently not applicable at our laboratory).

**Details and Procedures:**

The procedures for each piece of measuring equipment are located in the appropriate room where the equipment is located. These procedures detail any information for safe handling, transport, storage, use, and maintenance of measuring equipment.


### 5.5.7 Out of Service Equipment

**Policy:**

Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly.

**Details:**

Routine testing work is completely discontinued on equipment that even shows minor nonconformances. Not only do we do this for ethical reasons in support of our client, but minor nonconformances are often indicative of major breakdowns in expensive equipment. These breakdowns need to be avoided wherever possible.

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Out of service equipment is clearly marked as outlined in section 5.5.8.

The laboratory examines the effect of the defect or departure from specified limits on previous test and/or calibrations and institutes the “Control of Nonconforming Work” procedure as outlined in section 4.9.

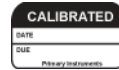
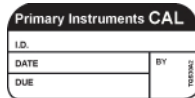
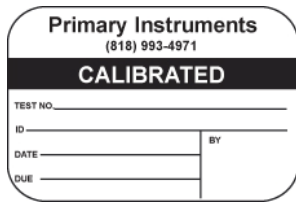
**5.5.8 Calibration Status**

**Policy:**

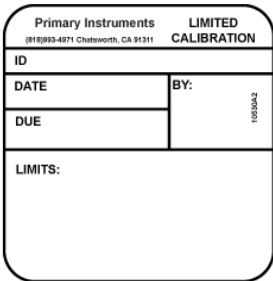
Equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate. See QSP 5-8-1 Section 3.7 for details when each of the labels is used.

**Details:**

Calibration labels have a write-on surface and a pressure sensitive adhesive. The areas that are filled out include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, and the equipment’s identification number.



Equipment that has been calibrated for limited use only is labeled as follows:




Measuring equipment that has failed calibration or is deemed out of service is labeled with one of the following labels:



A piece of equipment that does not need calibration is labeled with the following label:





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Equipment that is not calibrated however function check was performed and is used for verification only is labeled with the following label:



### 5.5.9 Return to Service

**Policy:**

When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

**Details and Procedures:**

The procedures used to check and ensure that the function and calibration status of the equipment are satisfactory before the equipment is returned to service are outlined in the calibration procedures used by the laboratory for such equipment. See Section 5.4.2

### 5.5.10 Periodic Checks

**Policy:**

When intermediate checks (cross checks) are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedure. Appropriate checks are also made for equipments brought to onsite calibration. (see QSP 5-5-2)

**Details and Procedures:**

As stated in section 5.5.6, the procedures for each piece of measuring equipment are located in the appropriate room where the equipment is located. OP# QSP 5-5-1 outlines a general maintenance plan for equipment and includes various checks. Internal quality control checks are specified in individual test methods that are located in the appropriate laboratory areas thereby providing procedures for intermediate checks.

For equipments brought to onsite calibration, appropriate checks shall be made before calibration begins. For equipments whose performance is not sensitive to movement, calibration status and fitness to use shall be performed before and after onsite calibration. If equipment is sensitive to movement, it shall be verified onsite. If equipment is found to be unfit for use, it is withdrawn from the service and the laboratory shall examine any effects of such equipment on previous calibrations (see QSP 5-5-2)

### 5.5.11 Correction Factors

**Policy**

Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software).

**Details and Procedures:**

The updating of correction factors including all copies is assured by following the appropriate calibration method or OPs . It is the responsibility of the Quality Manager to ensure that all copies are updated.

### 5.5.12 Safeguards against Adjustments

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**Policy:**

Measurement and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate measurement and/or calibration results/status.

**Details:**

Safeguards against adjustment for laboratory equipment include:

- detailed OPs and manufacturer’s manuals on the operation of the equipment
- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel
- “calibration void” seal



Safeguards against adjustment for software include:

- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel

**5.5.13 Onsite Calibration**

**Policy:**

There are procedures for operating, maintaining, storing and calibrating equipment used in onsite calibration. QSP 5-5-2 is the procedure that is utilized for onsite calibration.

**Details:**

Equipment record contains record of maintenance and/or calibration and also includes location, date and operator for all maintenance and/or calibration as well as details of storage between use.

Equipment brought to onsite calibration is listed before being transported. A full list of all the equipments is made by the onsite personnel as specified in QSP 5-5-2. For each parameter, the laboratory shall define the Best Uncertainty that it can achieve with that transported equipment.

If equipment other than that owned by Primary Instruments is used, the provider of such equipment shall be considered as a supplier of outside services/supplies subject to the requirements specified in QM Section 4.6. The laboratory shall document and archive calibration certificates (where appropriate) and other relevant details of the “borrowed” equipment. Borrowed or rented equipment are inspected for damage or malfunction before use. It is the supervisor of the personnel onsite responsibility to ensure that borrowed or rented equipment receives the same checks/calibration and other controls as laboratory owned equipment, prior to and during use.

**Revision History**

Revision 2.0

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## 5.6 Measurement Traceability

### The Ten Second Tutorial



This section tells you:

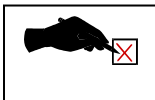
1. Measurements are traceable to SI units (when applicable)
2. Reference Standards and Reference Materials are used

### Key Words



System International  
Reference Standard  
Reference Material  
Traceability

### Cross-references



ISO 17025:1999 Section 5.6

ISO 9001:2000 Section 7.1, 7.6

#### 5.6.1 General

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**Policy:**

Measurement and/or calibration equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the measurement or calibration are calibrated before being put into service. All measurement and calibration equipment having an effect on the accuracy or validity of results are calibrated and/or verified before being put into service. As mentioned in section 5.5, the OP# QSP 5-5-1 outlines an established program for the maintenance of equipment and includes calibration.

**Details:**

The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform tests and calibrations

Procedures are documented where appropriate. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained for each standard. These records include, as applicable:

- supplier, grade, class
- dates of calibration
- accuracy specifications
- relevant parameters
- calibration results
- identification of personnel involved
- geographic locations of laboratory standards
- ISO/IEC Guide 17025 accreditation status
- Non ISO/IEC Guide 17025 accreditation status waiver

**5.6.2 Specific Requirements**

**5.6.2.1 Calibration**

**Policy:**

The program for calibration equipment is designed and operated to ensure that calibration measurements are traceable to the Système International (SI) units of measurement.

**Details:**

Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also section 5.10.4.2).

Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard or by reference to a natural constant the value of which in terms of the relevant SI unit is known.

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The term “identified metrological specification” means that it must be clear from the calibration certificate against which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

When the terms “international standard” or “national standard” are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

Maintain certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability. Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

Reference standards, such as platinum resistance thermometers, gage blocks and weights are traceable to a national or international standard (e.g., NIST).

### 5.6.2.2 Testing

#### 5.6.2.2.1

**Policy:**

The requirements given in section 5.6.2.1 apply to measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that equipment used can provide the accuracy of measurement needed.

**Details:**

The extent to which the requirements in section 5.6.2.1 are followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements are strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in section 5.6.2.2.2.

#### 5.6.2.2.2

**Policy:**

Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:

- the use of suitable reference materials certified to give a reliable characterization of the material
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned
- participation in a suitable program of inter-laboratory comparisons or proficiency testing

**Details:**

Reliable characterization involves an estimate of recovery.

The laboratory participates in proficiency testing and/or check sample programs. The list of programs is maintained by the Quality Manager.

### 5.6.3 Reference Standards and Reference Materials

#### 5.6.3.1 Reference Standards

**Policy:**

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The OP# QSP 5-6-1 outlines the program for the calibration of reference standards. Reference standards are obtained or calibrated by a body that can provide traceability as described in section 5.6.2.1. Such reference standards of measurement held by the laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

**Details:**

Reference standards are traceable to National Institute of Standards and Technology (NIST).

**5.6.3.2 Reference Materials**

**Policy:**

Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

**Details:**

Reference materials, including calibration standards, used in measurement are prepared so that the point of measurement is similar or equivalent to that of the unit under test (UUT).

**5.6.3.3 Intermediate Checks**

**Policy:**

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

When it is necessary to utilize reference standards for onsite calibration, adequate measures are taken to ensure that the necessary calibration status is maintained during transportation and while onsite. The response of such reference standards to environmental changes or relevant parameters shall be known and documented. (see QSP 5-5-2)

**Details and Procedures:**

The primary standards used to verify the accuracy of all the other standards are prepared independently from all the other standards used to establish the original calibration. It is the responsibility of the Laboratory Supervisor to establish and maintain the individual schedule for each intermediate check.

**5.6.3.4 Transport and Storage**

**Policy:**

The OP# QSP 5-8-2 outlines safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity as well as to ensure that the calibration status is not invalidated.

**Details:**


Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations, or sampling. (see QSP 5-5-2)

Proper conditions are established for housing, handling, and care of reference standards and reference materials. All information needed to properly identify references appears on their housing or containers.

**Revision History**

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### 5.7 Sampling

Primary Instruments Inc. is a calibration laboratory and sampling does not apply because the laboratory typically calibrates every item that is sent to it. There is a note in ISO 17025 that defines sampling as the removal of physical material. Therefore, the requirements for sampling are not applicable to calibration laboratories and to Primary Instruments Inc.

This section is intentionally left blank.



## 5.8 Handling of Test and Calibration Items

### The Ten Second Tutorial



This section tells you to:

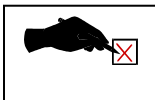
1. Keep samples in good condition.

### Key Words




Identification  
Receipt  
Protection

### Cross-references



ISO 17025:1999 Section 5.8

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.4.3, 7.5, 8.2.4

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<b>Section 5.8 - Handling of Test and Calibration Items</b>			Page #: <b>2 of 2</b>

### 5.8.1 Procedures

#### Policy & Details:

The OP# QSP 5-8-2 outlines the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of calibration items, including all provisions necessary to protect the integrity of the calibration item, and the interests of the laboratory and the client.

### 5.8.2 Identification of Test and/or Calibration Items

#### Policy:

Calibration items are systematically identified as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

#### Details:

The laboratory has a documented system for uniquely identifying the items to be calibrated. OP#QSP 5-8-1 states the procedure to be used in this case and the content of the label to be used by the laboratory to identify an item

### 5.8.3 Receipt

#### Policy:

Upon receipt of the calibration item, any abnormalities or departures from normal or specified conditions, as described in the relevant calibration method, are recorded. When there is any doubt as to the suitability of an item for calibration, or when an item does not conform to the description provided, or calibration required is not specified in sufficient detail, the laboratory consults the client for further instructions before proceeding and keeps a record of the discussion.

#### Details:

Upon receipt of an item, the laboratory communicates to the client any significant abnormalities including:

- a. Departures from required standard conditions and necessary preparations;
- b. Doubt as to the items' suitability for calibration or test;
- c. Nonconformance of the test item with the description provided by the client; and
- d. Unspecified calibration or test requirements.

### 5.8.4 Protection


#### Policy & Details

The OP# QSP 5-8-1 outlines the procedures and appropriate facilities for avoiding deterioration, loss or damage to the calibration item during storage, handling and preparation and calibration; instructions provided with the item are followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded. Where a calibration item is to be held secure (e.g., for reasons of record, safety or value, or to enable complementary test and/or calibrations to be performed later), the laboratory has arrangements for storage and security that protect the condition and integrity of the secured item concerned.

For items that are calibrated onsite, appropriate precautions are taken during the storage, handling, transportation and preparation to prevent damage. (see QSP 5-5-2)

### Revision History

Revision 1.0

	<p align="center"><b>QUALITY MANUAL</b> Primary Instruments, Inc.</p>	<p>Issue Date: 2002/11/22</p>	<p>Rev.: <b>1.0</b></p>
<p align="center"><b>Section 5.9 - Assuring the Quality of Test and Calibration Results</b></p>			<p>Page #: <b>1 of 2</b></p>

## 5.9 Assuring the Quality of Test and Calibration Results

### The Ten Second Tutorial



This section tells you:

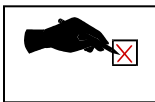
1. That results are monitored
2. There is a plan for monitoring

### Key Words




Internal Quality Control  
Statistical Techniques  
Inter-laboratory Comparisons  
Proficiency Testing  
Certified Reference Materials  
Secondary Reference Material  
Replicates  
Re-testing  
Correlation

### Cross-references



ISO 17025:1999 Section 5.9

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.4.3, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 8.1, 8.2.3, 8.2.4, 8.4

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## 5.9 Assuring the Quality of Test and Calibration Results

### Policy:

Quality control procedures are utilized to monitor the validity of calibration results. These procedures are for each test method utilized in the laboratory. The resulting data are recorded so that trends are detectable (and where practicable, statistical techniques are applied to the reviewing of the results. This monitoring is planned and reviewed and may include, but not limited to, the following:

- regular use of certified reference standards and/or internal quality control using secondary reference materials
- participation in inter-laboratory comparisons or proficiency testing programs
- replicate tests or calibrations using the same or different methods
- re-testing or re-calibration of retained items
- correlation of results for different characteristics of an item

### Details:

The methods utilized from the above list will be appropriate for the type and volume of the work undertaken. Records are maintained of assurance activities and any actions taken.

Internal quality control schemes using statistics include:

- design of experimental / factorial analysis
- variation/regression analysis
- safety evaluation/risk analysis
- tests of significance
- quality control charts
- statistical sampling inspection

Proficiency testing helps to highlight not only repeatability and reproducibility performance between laboratories, but also systematic errors such as bias. It is important to monitor proficiency testing results as a means of checking quality assurance and take action as necessary.

The Quality Manager maintains a list of all the current proficiency testing programs the laboratory participates in, monitors the results, and notifies the appropriate personnel of both problematic and successful results.

Technical personnel use certified reference standards and reference materials to evaluate test performance on a daily basis and include daily process control checks. These data are used to evaluate the validity of the test results.

Replicate tests may be used if suitable reference material is available. These materials and proficiency test materials are available for improving repeatability.

Re-testing of test items is performed occasionally at the discretion of the supervisor or when test results seem anomalous.

### Revision History

Revision 0

**Section 5.10 - Reporting of Results**

**5.10 Reporting of Results**

The Ten Second Tutorial



This section tells you:

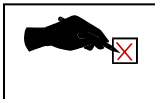
1. What needs to be on a report
2. How to handle amendments to reports

Key Words



Specific Information  
Required Information  
Interpretation  
Opinion  
Subcontractor  
Electronic Transmission of Results  
Format  
Amendments

Cross-references



ISO 17025:1999 Section 5.10

ISO 9001:2000 Section 7.1, 7.4.3, 7.5.1, 7.5.4, 8.2.4

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<b>Section 5.10 - Reporting of Results</b>			Page #: <b>2 of 5</b>

### 5.10.1 General

**Policy:**

The results of each measurement, calibration, or series of measurement or calibrations are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results are reported, normally in a calibration certificate and include all the information requested by the client and necessary for the interpretation of the calibration results and/or all information required by the method used. This information may include what is outlined in section 5.10.2, 5.10.3 and 5.10.4.

**Details:**

Calibration reports and/or test reports are issued as either hard copy or by electronic data transfer.

### 5.10.2 Calibration Certificates and Test reports

**Policy:**

Calibration certificates and/or test reports include the following information, as appropriate:

- a title (e.g. "Calibration Certificate")
- name and address of laboratory, and location where tests and/or calibrations were carried out if different from the address of the laboratory
- unique identification of the calibration certificate and/or test reports (e.g. test number), and on each page an identification in order to ensure that the page is recognized as a part of the calibration certificate and/or test reports, and a clear identification of the end of the calibration certificate and/or test certificate.
- name and address of the client
- identification of the method used
- description, condition, and unambiguous identification of the item(s) calibrated and/or tested.
- date of receipt of calibration and/or test items (where this is critical to the validity and application of the results) and date(s) of performance of the calibration and/or test.
- calibration and/or test results, if needed and where appropriate, units of measurement
- the name(s), function(s) and signature(s) or equivalent of person(s) authorizing the certificate.
- where relevant, a statement to the effect that the results relate only to the items calibrated.

**Details:**

Signing authority for calibration certificate and/or test reports is the responsibility of the Quality /Technical Manager/President. Records for individuals with signing authority for calibration certificate and/or test reports are approved by the President/CEO and maintained by the Quality Manager.

Hard copies of calibration certificates and/or test reports include the page number and total number of pages.

A statement is included specifying that the calibration certificate and/or test report is not to be reproduced except in full, without written approval of the laboratory. Data reported to the client contains the appropriate significant digits for each test method. Low level data are identified as being below specified limits.

### 5.10.3 Calibration Certificate/ Test Reports (additional requirements)

#### 5.10.3.1

**Policy and Details:**

In addition to the requirements listed in section 5.10.2, calibration certificate and/or test reports include the following, where necessary for the interpretation of results:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions



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- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in test reports when its is relevant to the validity or application of the test results, when a client's instruction so requires, or when uncertainty affects compliance to a specification limit
- where appropriate and needed opinions and interpretations (see section 5.10.5)
- additional information required by specific methods, clients, or groups of clients

#### 5.10.3.2

##### Policy and Details:

Sampling is not applicable to calibration laboratory; this section of ISO/IEC 17025 is left blank.

#### 5.10.3.3

##### Policy and Details:

In addition to the requirements listed above, the calibration certificate and/or test reports shall include the following where necessary:

- Results obtained from onsite calibrations/test shall be identified as such in the Certificates/Reports, whether they form or all of the information presented.
- Any details relevant to the calibration/test such as location of calibration / test items.

Note: The test number series used for items calibrated in the laboratory is different from the test number series used on items calibrated onsite.

### 5.10.4 Calibration Certificates

#### 5.10.4.1

##### Policy and Details:

In addition to the requirements listed in 5.10.2, the calibration certificate shall include the following, where necessary for the interpretation of calibration results:

- the environmental conditions(e.g. temperature) under which the calibrations were made that have an influence on the measurement results
- the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof
- evidence of measurement traceability (see 5.6.2.1.1)

#### 5.10.4.2

##### Policy and Details

The calibration certificate relates only to metrological quantities and the results of functional tests and specifically states which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory records those results and maintains them for possible future reference. When statements of compliance are made, the uncertainty of measurement is accounted for.

The clients are notified promptly, in writing, of any significant out-of tolerance condition of their equipment found during the calibration process. (see QSP 4-9-1). When an instrument for calibration has been adjusted or repaired, the calibration results before adjustment or repair, if available, are reported.

#### 5.10.4.3

##### Policy:

A calibration certificate and/or calibration label shall not contain any recommendation on the recalibration interval except where this has been agreed with the client and does not overrule the provisions of RP1, Method A3.

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**Details:**

Refer to QSP 5-5-1 for all Primary Instruments owned calibration equipment.

Note: This policy may be superseded by legal regulations.

### 5.10.5 Opinions and Interpretations

**Policy:**

When opinions and interpretations are included in the calibration certificate and/or test report, the basis upon which the opinions and interpretations have been made is documented. Opinions and interpretations are clearly marked as such in the calibration certificate and/or test report.

**Note** - opinions and interpretations should not be mixed-up with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

**Details:**

Opinions and interpretations included in a calibration and/or test report may comprise, but not be limited to the following:

- opinion on conformity of the results with requirements
- fulfilment of contractual requirements
- recommendations on how to use the results
- guidance to be used for improvements

In many cases it is appropriate to communicate the opinions and interpretations by direct dialogue with the client. This dialogue is written down.

### 5.10.6 Calibration and/or Test Results Obtained from Subcontractors

**Policy and Details:**

Calibration and test reports containing the results of calibration and/or tests performed by subcontractors are clearly identified for the subcontracted results. The subcontractor reports the results either in writing or electronically to the laboratory.

### 5.10.7 Electronic Transmission of Results

**Policy:**

In the case of transmission of calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of the policies and procedures of this Quality Manual continue to apply (see also 5.4.7).

**Details:**

Reports that are “published” electronically contain the statement that signatures are on file.

### 5.10.8 Format of Reports


**Policy:**

The format of reports is designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse.

**Details:**

The layout of the calibration certificate is such that the presentation of the calibration data facilitates ease of assimilation by the reader.



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The headings are standardized as far as possible.

### 5.10.9 Amendments to Reports

**Policy:**

Material amendments to a calibration certificate after issue are made only in the form of a further document, or data transfer, which includes the statement “Supplement to Calibration Certificate, serial number...[or as otherwise identified]”, or an equivalent form of wording. Such amendments meet all the requirements in this Quality Manual.

**Details:**

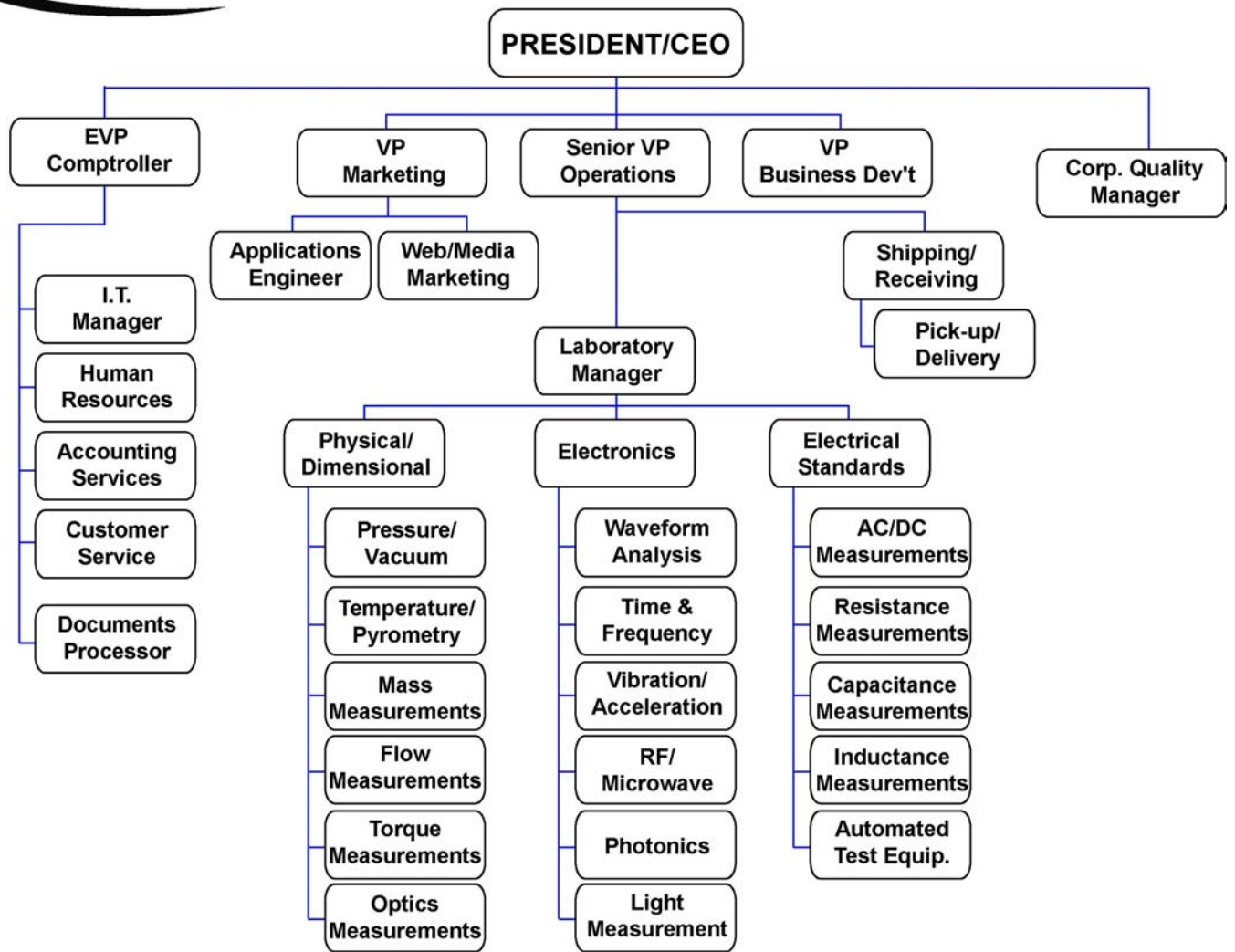
When it is necessary to issue a complete new calibration certificate, it is uniquely identified and contains a reference to the original that it replaces.

### Revision History

Revision 2.0



# Organizational Chart



SCOPE OF ACCREDITATION TO ISO/IEC 17025-1999  
& ANSI/NCSL Z540-1-1994

PRIMARY INSTRUMENTS, INC.  
 9553 Vassar Avenue  
 Chatsworth, CA 91311  
 Cesar D. Bautista, Jr. Phone: 818 993 4971

CALIBRATION

Valid To:

Certificate Number: 2011.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following calibrations<sup>1</sup>:

I. Electrical – DC/Low Frequency

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
DC Voltage – Generate	(0 – 220) mV 220 mV - 2.2 V (0 – 11) V (11 – 22) V (22 - 275) V (275 – 1000) V	15 ppm +0.5 µV 14 ppm 10 ppm +5 µV 11 ppm 13 ppm 12 ppm	Fluke 5440B
Fixed Points	1.018 V 10.0 V  Ratio: 10:1 Ratio: 100:1	0.20 ppm 0.80 ppm  0.4 ppm 1.0 ppm	Wavetek 4910  Fluke 752A
DC Voltage – Measure	100 mV 1 V 10 V 100 V 1000 V	14 ppm + 3 ppm (range) 10 ppm 8.2 ppm 12 ppm 12 ppm + [12ppm (V <sub>in</sub> /1000) <sup>2</sup> for V <sub>in</sub> > 100V]	HP 3458A, Option 2
Fixed Points	1.018 10 V	2.5 ppm 0.85 ppm	Fluke 732B

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
DC Current – Generate <sup>4</sup>	(0 - 3.3) mA (3.3 - 33) mA (33 - 330) mA 330mA - 1.0 A (1.0 - 11) A	0.016 % + 0.05 uA 0.015 % 0.016 % 0.040 % 0.074 %	Fluke 5500A
	11 – 100 A	0.07 %	Valhalla 2555
DC Current – Measure <sup>4</sup>	100 µA 1 mA 10 mA 100 mA 1 A	86 ppm 46 ppm 46 ppm 59 ppm 163 ppm	HP 3458A, Option 2
	(1 - 15) A	0.083 %	HP3458 + L&N 4360 (Shunt, 0.1 Ω)
	(1 to 100) A	0.084 %	HP3458 + L&N 4363 (Shunt, 0.001 Ω)
DC Resistance – Generate Fixed Points	0.001 Ω 0.01 Ω 0.1 Ω	3.5 ppm 3.4 ppm 3.4 ppm	L&N 4223-B L&N 4222 L&N 4221
	1 Ω	0.22 ppm	Thomas 4210
	10 Ω 100 Ω 1 kΩ 10 kΩ 100 kΩ	0.38 ppm 0.75 ppm 0.30 ppm 0.36 ppm 0.38 ppm	L&N Rosa Type L&N Rosa Type L&N Rosa Type L&N Rosa Type L&N Rosa Type
	1 MΩ 10 MΩ	0.90 ppm 2.4 ppm	L&N Rosa Type Guildline 9330-10

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
DC Resistance – Measure	0.01 Ω 0.1 Ω 1 Ω 10 Ω 100 Ω 1 kΩ 10 kΩ 100 kΩ 1 MΩ 10 MΩ	6 ppm 3 ppm 2 ppm 3 ppm 3 ppm 3 ppm 3 ppm 3 ppm 6 ppm 20 ppm 150 ppm	Guildline 9975 Current comparator
DC Resistance – Measure	10 Ω 100 Ω 1 kΩ 10 kΩ 100 kΩ 1 MΩ 10 MΩ 100 MΩ	33 ppm + 5 ppm range 26 ppm 18 ppm 18 ppm 20 ppm 36 ppm 90 ppm 625 ppm	HP3458A, with option 2
Inductance – Generate  Fixed Values (@ 1 kHz)	100 μH 1 mH 10 mH 100 mH 1 H 2 H	0.78 % 0.27 % 0.22 % 0.21 % 0.21 % 0.22 %	GenRad 1482B GenRad 1482E GenRad 1482H GenRad 1484L GenRad 1482P GenRad 1482Q
Inductance – Measure (@1 kHz)	10 mH – 10 H	0.058 %	GenRad 1689M (Inductance Bridge)
Capacitance – Generate (@1 kHz)	1 pF – 1μF	0.10 % + 0.5 pF	GenRad 1413
Fixed Values (@ 1 kHz)	1 pF 10 pF 100 pF 1000 pF	5.6 ppm 5.1 ppm 5.1 ppm 5.1 ppm	GenRad 1403-K GenRad 1403-C GenRad 1403-B GenRad 1403-A
Fixed Values (@ 1 kHz)	10, 100 μF 1 mF 10 mF	0.30 % 0.30 % 0.37 %	GenRad 1417

Parameter/Range	Frequency	Best Uncertainty <sup>2</sup> (±)	Comments
Capacitance – Measure (@1 kHz)	10 pF – 100 µF	0.58 %	GenRad 1689M (Capacitance Bridge)
AC Voltage – Generate <sup>4</sup>	<u>(1 - 33) mV</u> (10 - 45) Hz 45Hz - 10 kHz (10 - 20) kHz (20 - 50) kHz (50 - 100) kHz (100 - 500) kHz  <u>(33 - 330) mV</u> (10 - 45) Hz 45Hz - 10 kHz (10 - 20) kHz (20 - 50) kHz (50 - 100) kHz (100 - 500) kHz  <u>330mV - 3.3V</u> (10 - 45) Hz 45Hz - 10 kHz (10 - 20) kHz (20 - 50) kHz (50 - 100) kHz (100 - 500) kHz  <u>(3.3 to 33) V</u> (10 Hz - 45) Hz 45Hz - 10 kHz (10 - 20) kHz (20 - 50) kHz (50 - 100) kHz  <u>(33 - 330) V</u> 45Hz - 1 kHz (1 - 10) kHz (10 - 20) kHz  <u>(330 to 1000) V</u> 45Hz - 1 kHz (1 - 10) kHz (10 - 20) kHz	0.55 % 0.35 % 0.40 % 0.45 % 0.68 % 1.6 %  0.30 % 0.070 % 0.12 % 0.20 % 0.41 % 1.3 %  0.18 % 0.036 % 0.086 % 0.17 % 0.41 % 0.83 %  0.18 % 0.046 % 0.11 % 0.24 % 0.41 %  0.057 % 0.080 % 0.098 %  0.058 % 0.20 % 0.20 %	Fluke 5500A w/ SC600

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments	
AC Voltage – Measure <sup>4</sup>	<u>10 mV</u>		HP 3458A w/ Opt 002	
	(1 - 40) Hz	0.087 %		
	40 Hz - 1 kHz	0.064 %		
	(1 - 20) kHz	0.066 %		
	(20 - 50) kHz	0.14 %		
	(50 - 100) kHz	0.60 %		
	(100 - 300) kHz	4.7 %		
	<u>100 mV</u>			
	(1 - 40) Hz	0.018 %		
	40 Hz - 1 kHz	0.017 %		
	(1 - 20) kHz	0.024 %		
	(20 - 50) kHz	0.040 %		
	(50 - 100) kHz	0.11 %		
	(100 - 300) kHz	0.38 %		
	300 kHz - 1 MHz	1.2 %		
	(1 - 2) MHz	1.8 %		
	<u>1 V</u>			
	(1 - 40) Hz	0.014 %		
	40 Hz - 1 kHz	0.012 %		
	(1 - 20) kHz	0.019 %		
	(20 - 50) kHz	0.038 %		
	(50 - 100) kHz	0.095 %		
	(100 - 300) kHz	0.36 %		
	300 kHz - 1 MHz	1.2 %		
	(1 - 2) MHz	1.8 %		
	<u>10 V</u>			
	(1 to 40) Hz	0.014 %		
	40 Hz to 1 kHz	0.013 %		
	(1 to 20) kHz	0.019 %		
	(20 to 50) kHz	0.038 %		
	(50 to 100) kHz	0.096 %		
	(100 to 300) kHz	0.36 %		
	300 kHz to 1 MHz	1.2 %		
	(1 to 2) MHz	1.8 %		
	<u>100 V</u>			
	(1 - 40) Hz	0.029 %		
40 Hz - 1 kHz	0.026 %			
(1 - 20) kHz	0.026 %			
(20 - 50) kHz	0.044 %			
(50 - 100) kHz	0.14 %			
(100 - 300) kHz	0.48 %			
300 kHz - 1 MHz	1.8 %			

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
AC Voltage – Measure <sup>4</sup>	<u>1000 V</u> (1 - 40) Hz 40 Hz - 1 kHz (1 - 20) kHz (20 - 50) kHz (50 - 100) kHz	0.51 % 0.049 % 0.072 % 0.14 % 0.35 %	HP 3458A w/ Opt 002
AC Current – Generate <sup>4</sup>	<u>(0.03 - 0.33) mA</u> (10 - 20) Hz (20 - 45) Hz 45 Hz - 1 kHz (1 - 5) kHz (5 - 10) kHz  <u>(0.33 - 3.3) mA</u> (10 - 20) Hz (20 - 45) Hz 45 Hz - 1 kHz (1 - 5) kHz (5 - 10) kHz  <u>(3.3 - 33) mA</u> (10 - 20) Hz (20 - 45) Hz 45 Hz - 1 kHz (1 - 5) kHz (5 - 10) kHz  <u>(33 - 330) mA</u> (10 - 20) Hz (20 - 45) Hz 45 Hz - 1 kHz (1 - 5) kHz (5 - 10) kHz	0.40 % 0.38 % 0.38 % 0.55 % 1.4 %  0.23 % 0.13 % 0.13 % 0.23 % 0.63 %  0.23 % 0.13 % 0.12 % 0.23 % 0.63 %  0.23 % 0.13 % 0.12 % 0.23 % 0.63 %	Fluke 5500A w/ SC600



Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
AC Current – Generate <sup>4</sup>	<u>330 mA - 2.2 A</u>		Fluke 5500A w/ SC600
	(10 - 45) Hz	0.23 %	
	45 Hz - 1 kHz	0.13 %	
	(1 - 5) kHz	0.78 %	
	<u>(2.2 - 11) A</u>		
	(45 - 65) Hz	0.08 %	
	(65 - 500) Hz	0.12 %	
	500 Hz - 1 kHz	0.35 %	
	<u>(11 - 100) A</u>		
	(0.4 - 1) kHz	1.1 %	
AC Current – Measure	<u>100 μA</u>		HP 3458A w/ Opt 002
	(10 - 20) Hz	0.43 %	
	(20 - 45) Hz	0.21 %	
	(45 - 100) Hz	0.11 %	
	100 Hz – 1 kHz	0.11 %	
	<u>1 mA</u>		
	(10 - 20) Hz	0.49 %	
	(20 - 45) Hz	0.20 %	
	(45 - 100) Hz	0.094 %	
	100 Hz – 5 kHz	0.060 %	
	(5 - 20) kHz	0.94 %	
	(20 - 50) kHz	0.51 %	
	(50 - 100) kHz	0.81 %	
	<u>10 mA</u>		
	(10 - 20) Hz	0.49 %	
	(20 - 45) Hz	0.20 %	
	(45 - 100) Hz	0.094 %	
	100 Hz – 5 kHz	0.064 %	
	(5 - 20) kHz	0.096 %	
	(20 - 50) kHz	0.51 %	
	(50 - 100) kHz	0.81 %	

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
AC Current – Measure	<u>100 mA</u>		HP 3458A w/ Opt 002
	(10 - 20) Hz	0.49 %	
	(20 - 45) Hz	0.20 %	
	(45 - 100) Hz	0.12 %	
	100 Hz – 5 kHz	0.14 %	
	(5 - 20) kHz	0.094 %	
	(20 - 50) kHz	0.51 %	
	<u>1 A</u>		
	(10 - 20) Hz	0.49 %	
	(20 - 45) Hz	0.20 %	
	(45 - 100) Hz	0.12 %	
	100 Hz – 5 kHz	0.14 %	
	(5 - 20) kHz	0.37 %	
(20 - 50) kHz	1.3 %		
<u>10 mA - 2 A</u>		0.024%	Fluke A40 shunts
100 Hz - 20 KHz			

II. Electrical – RF / Microwave

Parameter/Range	Frequency	Best Uncertainty <sup>2</sup> (±)	Comments
RF Power Diode Sensors			
1 μW – 100 mW	50 MHz – 26.5 GHz	5.3 %	HP 436A Power Meter with 8485A Sensor
1 μW – 100 mW	(33 to 50) GHz	5.3 %	HP 436A Power Meter with Q8486A Sensor
0.3 μW – 100 mW	DC – 4.2 GHz	5.1 %	HP 436A Power Meter with 8482A Sensor
1 μW – 100 mW	(0.01 – 18) GHz	4.7 %	HP 436A Power Meter with 8481A Sensor
100 pW – 100 μW	(0.05 – 16) GHz	5.8 %	HP 436A Power Meter with 8485D Sensor
0.3 nW – 10 μW	(0.01 - 18) GHz	5.5 %	HP 436A Power Meter with 8484A Sensor
RF Power Thermistor	10 MHz – 10 GHz	2.5 %	HP 432A Power Meter with HP 478A Sensor
Tuned RF Power Level – Measure			
0 dB Reference	2.5 MHz - 1.3 GHz	0 dB	HP 8902A 11722A
-0.0 to -10 dB		0.02 dB	
-10 to -20 dB		0.04 dB	
-20 to -30 dB		0.06 dB	
-30 to -40 dB		0.08 dB	
-40 to -50 dB		0.14 dB	
-50 to -60 dB		0.16 dB	
-60 to -70 dB		0.18 dB	
-70 to -80 dB		0.20 dB	
-80 to -90 dB		0.26 dB	
-90 to -100 dB		0.28 dB	
-100 to -110 dB		0.30 dB	
-110 to -127 dB		0.40 dB	

Parameter/Range	Frequency	Best Uncertainty <sup>2</sup> (±)	Comments
RF Fixed Coaxial Attenuation – Measure			
3 dB	DC – 12.4 GHz 12.4 – 18 GHz	0.35% 0.46%	HP 8491B Attenuator Set
6 dB	DC – 12.4 GHz 12.4 – 18 GHz	0.35% 0.46%	
20 dB	DC – 12.4 GHz 12.4 – 18 GHz	0.69% 1.2%	
Network Analysis		From Cal Kit Report	
Reflection S <sub>11</sub> /S <sub>22</sub> Rho = 0.6 lin	45 MHz – 26.5 GHz	(0.00136 to 0.00843)lin	HP 8510B Analyzer HP 8340B Sweeper HP 8515A S Point Test Set
Transmission S <sub>12</sub> /S <sub>21</sub> 20 dB Attenuator 40 dB Attenuator	45 MHz – 26.5 GHz	(0.038 to 0.054) dB (0.053 to 0.331) dB	HP 85053A Cal Kit

### III. Time & Frequency

Parameter/Range	Frequency	Best Uncertainty <sup>2</sup> (±)	Comments
Frequency – Fixed Points	1, 5, 10 MHz	1 part in 10 <sup>11</sup> (mfg specs)	HP 5601A Cesium Beam
Generate	10 MHz 10 MHz – 26.5 GHz	0.5 parts in 10 <sup>9</sup> (24 hrs mfg specs) 1 part in 10 <sup>9</sup> (24 hrs mfg specs)	HP 8564E Spectrum Analyzer HP 8340B Sweeper
	10 MHz - 20 GHz 20 GHz - 40 GHz	± 10 MHz ± 20 MHz (Army procedure)	Wiltron 6669M
Frequency – Measure	10 Hz – 26.5 GHz	1 part in 10 <sup>8</sup> (1 year mfg specs)	EIP Counter Option 5 Model 548A

IV. Thermodynamic

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Temperature – Generate <sup>4</sup> Dry Blocks	(-30 to +93) °C (0 to 600) °C	1°C (From mfg) 1°C (from mfg)	Ametek DB 35L Jofra 601
Temperature – Generate <sup>4</sup> Baths	(-30 to 125) °C (-10 to 110) °C	0.8°C (From mfg) 1°C (From mfg)	Hart 7103 Hart 5023
Temperature – Measure Triple Point of Water	0.01°C @ 25°C	0.003K (From mfg)	Hart 5901C Hart 1590 Tinsley 268101 SPRT
Infrared Black Body – Generate	(33 to 400) °C  (100 to 982) °C	(From mfg) 2°C (33 to 250°C) 3°C (251 to 400°C)  25% of rdg	Hart 9131  Vanzetti 1560

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Relative Humidity – Generate			
Fixed Points – Probe Kit	11.3% RH@25 °C 32.8% RH@25 °C 52.9% RH@25 °C 75.3% RH@25 °C	2% 2% 2% 2%	Lithium Chloride Magnesium Chloride Magnesium Nitrate Sodium Chloride
Fixed Points – Salt Chamber	11.3% RH@25 °C 32.8% RH@25 °C 52.9% RH@25 °C 75.3% RH@25 °C	4% 4% 4% 4%	Lithium Chloride Magnesium Chloride Magnesium Nitrate Sodium Chloride
Relative Humidity – Measure	(10 – 90) % RH	0.5% (From Mfg)	M5.1MP Psychrometer
Dew Point Measure	(0 - 50) °C	0.1% (From Mfg)	M5.1MP Psychrometer

#### V. Dimensional

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Gage Blocks	(0.05 – 0.9) in  (1 – 4) in  (0.5 – 5) mm (5 – 20) mm (20 – 25) mm (25 – 50) mm (50 – 75) mm (75 – 100) mm	(2.0 + 4.0L) µin  (0.7 + 5.0L) µin  0.07 µm 0.12 µm 0.14 µm 0.26 µm 0.37 µm 0.48 µm	Federal Comparator 130B-24
Calipers <sup>4</sup>	(0 - 40) in	0.6R	Comparison to reference gage blocks
Micrometers (Outside) <sup>4</sup>	(0 - 40) in	0.6R	Comparison to reference gage blocks

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Height Gages <sup>4</sup>	(0.4 – 40) in	0.0013 μin	Comparison to reference gage blocks  Mitutoyo 516-402 Mitutoyo 515-359
Dial/Digimatic Indicators <sup>4</sup>  Resolution: 50 μin Resolution: 100 μin Resolution: 1000 μin	0 - 2 in	0.6R  0.6R  0.6R	Pratt & Whitney Universal Measuring Machine, Model B
Indicator Calibrator  Resolution: 10 μin Resolution: 50 μin Resolution: 100 μin	0 – 1 in	10 μin  30 μin  60 μin	Comparison to master gage blocks
Mu-Checker / Electronic Height Gage	± 0.00015 in ± 0.0005 in ± 0.0015 in ± 0.005 in ± 0.015 in ± 0.05 in	6.2 μin 12.0 μin 58.0 μin 116 μin 577 μin 1160 μin	Comparison to Reference Gage Blocks
Inside Diameter	0-7 in	0.6R	Master Ring Gages
Height Masters	(1 – 12) in  (12 – 24) in	60 μin  116 μin	Comparison to reference gage blocks  Mitutoyo 516-402 Mitutoyo 515-359

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Ring Gages (Best is Class X)	(0.06 – 1) in (1 - 4) in (4 - 7) in (7 - 12) in	10 µin (10 +4L) µin (5 + 4L) µin (10 + 4L) µin	Pratt & Whitney Internal Supernicrometer Model U36334

VI. Mechanical

Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Scale and Balances <sup>4</sup>	1 mg – 200 g	0.2 mg	Class 1 weights
	2 oz – 200 lbs	0.26 lbs	Class F weights
Low Pressure	Up to 2 in H <sub>2</sub> O	0.003 in H <sub>2</sub> O	Dwyer Microtector 1430
Pressure – Measure			
Pneumatic Pistons	0.5 – 5 psig 1.5 – 100 psig 15 – 1000 psig	0.14% 0.14% 0.14%	Volumetric 7-201
Hydraulic Pistons	6 – 15140 psig	0.14%	Ruska 2400HL
Torque (For calibration of Transducers)	0.5 in oz to 200 in lbs	1.0 %	CDI System 2000-400-0
	37.5 ft-lbs to 2000 ft-lbs	1.0 %	CDI System 2000-1-0
Torque (For calibration of Wrenches and Screwdrivers)	0.5 in oz to 200 in lbs	2.4 %	CDI System 2000-400-0
	37.5 ft-lbs to 2000 ft-lbs	2.4 %	CDI System 2000-1-0



Parameter/Equipment	Range	Best Uncertainty <sup>2</sup> (±)	Comments
Pipettes			
Spectrophotometric	0.1 – 5 000 µL	1 % (From Mfg.)	Artel PCS 3
Gravimetric	100 µL 500 µL 1000 µL 2000 µL 3000 µL 4000 µL 5000 µL	0.2 µL 1 µL 1 µL 2 µL 2 µL 2 µL 3 µL	Mettler HK 60

<sup>1</sup> This laboratory offers commercial and on-site calibration services.

<sup>2</sup> Best Uncertainties represent expanded uncertainties using a coverage factor of  $k = 2$  which provides a level of confidence of approximately 95%.

<sup>3</sup> L is the nominal length of the device in inches.

<sup>4</sup> Calibration also performed onsite (client facility). Uncertainties obtained from on site calibrations are generally larger than the uncertainties obtained in the permanent laboratory environment.

*"DISCLAIMER - The uncertainties achievable on a customer's site can normally be expected to be larger than the Best Measurement Capabilities (BMC) that the accredited laboratory has been assigned as Best Uncertainty on the A2LA Scope. Allowance must be made for aspects such as the environment at the place of calibration and for other possible adverse effects such as those caused by transportation of the calibration equipment. The usual allowance for the uncertainty introduced by the item being calibrated, (e.g. resolution) must also be considered and this, on its own, could result in the calibration uncertainty being larger than the BMC."*



Maintained by:  
Approved by:

**APPENDIX C  
LIST OF COMPANIES REQUIRING SITE CALIBRATION**

<b>No.</b>	<b>Company</b>	<b>City</b>	<b>Purpose (Equipments Calibrated)</b>
1	Alpha Therapeutics	Los Angeles, CA	Electrical/Mechanical, Temp/RH etc
2	Avica Aerospace	Simi Valley, CA	Mechanical
3	Axsys Tecnologies	San Diego, CA	Electrical/Mechanical, Temp/RH etc
4	Canyon Engineering	Valencia, CA	Mechanical
5	Coorstek	El Segundo, CA	Mechanical, Temp/RH
6	Dayton Rogers	Van Nuys, CA	Mechanical, Temp/RH
7	International Rectifier	El Segundo, Ca	Electrical/Mechanical etc
8	Janco Corp.	Burbank, CA	Mechanical, Temp/RH
9	Kavlico	Moorpark, CA	Mechanical
10	L3 Trexcom	Simi Valley, CA	Electrical/Mechanical
11	Medtronic Minimed	Northridge, CA	Electrical/Mechanical, Temp/RH etc
12	Moog	Chatsworth, CA	Electrical/Mechanical
13	Newport Corp	Irvine, CA	Electrical/Mechanical
14	Ontic Corp	Chatsworth, CA	Electrical/Mechanical
15	Qlogic	Aliso Viejo, CA	Electrical/Mechanical
16	Reinhold Industries	Santa Fe Springs, Ca	Mechanical, Temp/RH
17	Sabeus	Chatsworth, CA	Optical
18	Samco Scientific Corp	San Fernando, CA	Mechanical
19	SGL Technics Polycarbon Division	Valencia, CA	Mechanical, Temp
20	TA Mfr	Valencia, CA	Temp
21	Technicolor	Camarillo, CA	Electrical/Mechanical
22	Universal Plastic Mold	Baldwin Park, CA	Mechanical/Dimensional
23	Valley-Todeco	Sylmar, CA	Mechanical/Dimensional
24	Wilshire Precision Products	North Hollywood, CA	Mechanical/Dimensional
25	Xerox	El Segundo, CA	Mechanical / Temp
26	JMR Electronics	Chatsworth, CA	Electrical/RF
27	EDO Communications	Simi Valley, CA	Electrical/RF
28	Hydrodyne	Burbank, CA	Mechanical/Dimensional
29	Corlund Electronics	Camarillo, CA	Electrical/Mechanical
30	Johansson Dielectric	Sylmar, CA	Mechanical/Dimensional
31	Viking Electronics	Moorpark, CA	Electrical/Mechanical/Temp
32	Savacor	Los Angeles, CA	Electrical

<b>No.</b>	<b>Company</b>	<b>City</b>	<b>Purpose (Equipments Calibrated)</b>
33	TAVCO	Chatsworth, CA	Mechanical
34	NMB	Chatsworth, CA	Electrical
35	TECOM	Thousand Oaks, CA	Electrical

# *Quality Policy Statement*

*Primary Instrument Inc. is committed to providing total customer satisfaction through accurate, zero defects and on time deliveries of our calibration, testing and other services and to continually meet and/or exceed our clients' quality requirements.*

*The Management is committed in achieving our goals:*

- a. Through good professional practice and quality services to client by carrying out calibration and testing in accordance to stated standardized methods and client's requirements.*
- b. By communicating the quality policy and the whole quality system to all employees and demonstrating how it will affect their roles within the company by implementing the policies and procedures in their work.*
- c. By creating a work environment to all employees that promotes teamwork and problem solving.*
- d. By providing continuous training to our employees in order to implement our quality and technical programs.*
- e. By maintaining compliance of our Quality System with ISO/IEC Guide 17025-1999 and ANSI /NCSL Z540-1-1994, the purpose of which is to be able to manage our business by meeting the needs of our clients.*

**Cesar D. Bautista Jr.**  
Sr. Vice President/Technical Manager

**Allen Ganner**  
President/CEO