**CALIBRATION SYSTEM CONTROLS & PROCESSES**

**1.0 PURPOSE AND SCOPE**

This procedure establishes the system for operating, controlling and maintaining a calibration laboratory at Larson Davis a division of PCB Piezotronics, Inc. (LD). The quality system portions of the ISO 17025-2017 standard are addressed in the Quality Management System (QMS), D0001.0001; this document addresses those requirements of the standard not addressed in the QMS.

This procedure applies to Measurement Standards (MS) used to calibrate, confirm and/or certify Measurement and Test Equipment (M&TE). This procedure also includes the controls necessary for using the MS and M&TE in calibrating, confirming and/or certifying product manufactured by LD or within the LD calibration scope.

**2.0 AFFECTED DEPARTMENTS**

Engineering

Logistics

Manufacturing

Quality

**3.0 REFERENCE DOCUMENTS**

ISO 9001: 2015

ISO/IEC 17025-2017

ANSI Z540-1

D0001.0001 Larson Davis Quality Management System

D0002.0001-1 Measurement and Evaluation Method Matrix

D0002.0001-2 Proficiency Testing Schedule

D0002.0002 LD ISO 17025 Scope of Accreditation

D0002.0004 - M&TE and MS Maintenance, Handling & Protection

D0001.1012 Customer Communication

D0001.1020 Corrective / Preventive Action Process

D0001.1021 Document Change Order

D0002.0018 Writing an Uncertainty Budget

Fluke Calibration – Implementing 17025 Measurement Uncertainty Requirements in Software

D0001.4037 – METTEAM Asset Management

**4.0 RESPONSIBILITIES & AUTHORITY**

**4.1 Responsibilities of the Calibration System Organization**

Larson Davis is a division of PCB Piezotronics, Inc., a New York corporation, and is a legal entity and accountable for its actions. The LD Division will maintain its own ISO17025-2017 accreditation, which in no way reduces or limits its legal responsibilities.

The LD Management organization is detailed in the Larson Davis Quality Management System, D0001.0001. The individuals with control of the calibration system report to the Director of LD Operations. The responsibilities of the reporting individuals may include but are not limited to:

* Preparation of the calibration system description in compliance with international standards listed previously, customers, and regulatory organizations.
* Preparation of calibration procedures
* Training and adherence to calibration and system procedures
* Control of the system
* Specification of M&TE to be used
* Calibration of measuring & test equipment
* Coordination of measurement standards calibration by independent labs
* Identification and correction of out-of-tolerance conditions
* Performance of calibration audits
* Control and maintenance of company designed measuring equipment
* Maintenance of calibration records
* Compliance with established calibration frequencies
* Proper storage and handling of MS and M&TE

**4.2 Function and Responsibility by Position**

Accountability for the oversight of the Calibration System is controlled by the Director of LD Operations. The Engineering Manager, Logistics Manager, Production Manager and Quality Assurance Manager (QA) report to the Director of LD Operations and the Metrology Engineer reports to the Engineering Manager.

The **Engineering Manager** has the responsibility to appoint a member of the Engineering Department with the responsibility of Metrology Engineer. The **Metrology Engineer** has the responsibility to:

* Specify the Measurement Standards and the Measurement & Test Equipment to be used for the parameters and/or product being tested.
* Specify the calibration interval of Measurement Standards and Measurement & Test Equipment based on industry practices and observed stability.
* Approve certification / calibration test procedures and systems.
* Evaluate tolerance budgets and determine measurement uncertainties.
* Review MS and M&TE out-of-tolerance occurrences and determine corrective action.
* Specify the scope of the calibration / test / certification system.
* Act as a resource to all other managers regarding their responsibilities as they relate to the LD Calibration System.
* Approves all purchase requests for external 17025 certifications or services on metrology equipment.
* Review and sign-off on yearly proficiency testing with QA Manager.

The **Logistics Manager** is responsible to do the following:

* Order review for lead time prior to order acceptance
* Ensuring on-time shipment and delivery of orders to customers

Daily control of the system is the responsibility of the **Production Manager**, or a designated representative, who reports to the Production Manager. The daily control of the system includes but is not limited to:

* Calibration of in-house certified M&TE
* Control of released product undergoing certification
* Control of company designed M&TE
* Supervision of Calibration Technician(s) including training and adherence to documented procedures
* Control of M&TE Calibration Stickers
* Customer Interface (as requested by Customer or Sales)
* Scheduling customer calibration orders
* Control of customer furnished equipment
* Protection, storage and handling of equipment
* Maintenance of Customer records in database

The **QA Manager**, or a designated representative, reports to the Director of LD Operations and is responsible but not limited to the listed functions:

* Policy / procedures / system description
* Oversight of the Quality components of the Calibration System
* Correction of out-of-tolerance conditions
* Coordination of 3rd party / customer audits
* Oversight of the audit team for internal audits of the Quality System
* Send out and track instruments sent to NIST traceable calibration sources (independent lab)Maintenance of MS and M&TE records
* Review of the Calibration System as part of Management Reviews per D0001.1164, of the Quality Management System.
* Manage the yearly proficiency testing process and submit results to accrediting body.

The **Sales Manager** or a designated representative has the responsibility to meet the needs of customers.

**5.0 DEFINITIONS**

See Appendix A—Vocabulary and Definitions at the end of this document

**6.0 SAFETY PRECAUTIONS**

Employees are required to observe safety precautions as detailed in the individual test and calibration procedures.

**7.0 EQUIPMENT & MATERIALS**

Equipment and materials are specified in the individual test instructions.

**8.0 GENERAL BACKGROUND**

LD designs and manufactures precision analytical instrumentation for noise, sound, and vibration. LD markets its measurement instrumentation to private industry, education and government agencies for both industrial and military applications. Additionally, LD provides technical support, repair, and calibration / certification services for its equipment. In order to provide these services, LD complies with the standards required under ISO/IEC 17025-2017, ANSI Z-540-1, and associated Accreditation Bodies that govern the control of Calibration and Test Laboratories. Some Accreditation Bodies impose requirements above and beyond other regulatory standards. Larson Davis adheres to these additional requirements as outlined in D0002.0005.

LD designs and manufactures instrumentation to meet industry standards established by ANSI, IEC, ISO and other controlling organizations. To ensure compliance with these standards, LD has established test procedures for each product. LD products are verified to the applicable standards for their intended use. Test procedures may include bench tests and/or automated computer controlled tests. These are used to verify compliance of the product to the specified standards.

The tests may use a variety of M&TE from other manufacturers as well as instruments manufactured, for test purposes, by LD. In order to maintain the integrity of the test procedures, LD requires that test equipment used in the confirmation process be calibrated or certified to the manufacturer’s original equipment standards or as specified by the Metrology Engineer.

Measurement standards used for confirmation are traceable to **NIST** (U.S. National Institute of Standards and Technology), a recognized international standards organization or to a physical constant.

**9.0 CALIBRATION SYSTEM TECHNICAL REQUIREMENTS**

 **9.1 General**

Larson Davis recognizes that many factors contribute to the correctness and reliability of measurements made in the laboratory. LD controls or accounts for variations to the extent necessary to ensure customer confidence that the product meets or is better than the specifications for the product being tested or certified.

Variations are considered when developing test and/or calibration procedures, determining uncertainty budgets and the impact of the variations is lessened through ongoing personnel training, equipment selection and test development.

LD products are sufficiently sensitive to deviations in M&TE and MS that failures or unusual test results trigger an automatic evaluation of the test system. Technicians are trained and have the experience necessary to troubleshoot and evaluate causes of failure, and appropriate actions are taken to mitigate the effect of M&TE and MS that have fallen out of calibration. The act of performing calibrations on LD products is an effective tool in maintaining confidence in the calibration status of M&TE and MS such that scheduled intermediate checks are not required in this laboratory.

 **9.2 Personnel**

Larson Davis/PCB has an Employee Guide (Handbook) which describes many aspects of the work environment, management expectations and requirements of all employees who work for the company. Among these general policies for employee conduct are those that govern confidentiality of customer and company information; a code of ethics; electronic communication policy; general positions on honesty and deportment including accepting and giving monetary items that would promote undue influence over another person; and policies governing the improper influence of other employees with the company.

Organizational Structure—Larson Davis is a division of PCB Piezotronics, Inc. LD maintains its own registration certificates for ISO9001:2015 and accreditations to other ISO standards. As a division the departments of accounting, human resources, legal, IT, sales and marketing are shared with the corporate entity and housed at the corporate headquarters in Depew, New York. LD does maintain its own Quality Management System and procedures with oversight from corporate Quality personnel.

An Organizational Chart is maintained for LD by Human Resources and it shows the job titles and relationships within the division. Job descriptions are approved and maintained for all positions within the company. The key positions in management of the division are backed up by other department heads. These people may also use as resources others with similar positions from other divisions of PCB.

**9.2.1 Personnel Competence & Training**

Employees involved in calibration and/or certification activities are trained in the products, processes and techniques included in their specific areas of responsibility.

* As new product designs or versions are released by Engineering, the Project Engineer, or other qualified individual trains the assigned technician. Training includes repairing, troubleshooting, testing and/or certifying of the product.
* Product or process changes are communicated through the ECO Process (Engineering Change Order) or the DCO Process (Document Change Order).
* Employees are trained by product or process, which includes the applicable work instructions for that product or process.
* Training is planned and documented per the Training System procedure (D0001.1005).
* Employee competence at the time of hire is documented by Human Resource per the Job Description procedure (D0001.1004) and the New Hire Process.
* Employees, responsible for opinions and/or interpretations that may be included as part of a test report, are knowledgeable in the manufacturing technology for the instrumentation and have an understanding of the significance of deviations with regard to normal use of the product. When opinions and/or interpretations are shared with a customer, a record of the dialogue is reported to appropriate individuals to document in business systems database (BSD).

**9.2.2 Contract Personnel**

Individuals involved in testing, evaluating and/or certifying products are employed by or under contract to Larson Davis. Contracted employees are supervised to the extent necessary to ensure compliance to LD quality and technical procedures.

**9.2.3 Continuing Education**

The Training System, D0001.1005, contains the processes used at Larson Davis to evaluate an employee’s level of education or training and to allow the supervisor to formulate a training program for that employee. The employees doing repair and/or calibration functions are members of the Production Department. The Production Manager evaluates the training needs of the employees and then plans how to meet those needs.

Employees receive ongoing training in their departments through departmental training, on-the-job cross-training, training taught by a product design engineer, seminars, etc.

**9.2.4 Competence and Authorization**

Competence to perform the tasks are determined at the time of hire through interviews and review of past work performance. Competence is also observed during on the job training and performance evaluations. When tasks are learned authorizations to perform the tasks are granted.

**9.3 Environmental Conditions**

Larson Davis’s facilities are maintained with adequate energy sources, lighting, housekeeping, and environmental controls necessary to facilitate the correct performance of tests and/or calibrations.

LD calibration, repair, and/or certification work is performed at LD in an indoor environment unless the customer requires field-calibration or repair.

* Calibration of measurement and test equipment is conducted in an environment that does not adversely affect the function of the instrument being used as a reference or as the instrument under test.
* LD facilities are maintained at temperatures that are suitable as a comfortable work environment for the employee (18-28oC). The measured relative humidity is at levels that are normal for the season of the year with a minimum of 25% RH and not to exceed 70% RH.
* Calibrations are performed only during times when a normal working environment is maintained.
* Incompatible activities are separated as necessary.
* Policies governing access to the testing areas are determined by the Production Manager and the Metrology Engineer.

Temperature and humidity measurements are recorded on an ongoing basis and in the certification program each workday. These same measurements are recorded at the beginning and end of each instruments certification process.

**9.4 Test and Calibration Methods & Method Validation**

Calibration of measurement and test equipment is performed using methods that follow the standards to which the device or equipment is stated to conform. For such cases where measurement and test equipment do not express conformance to an applicable standard, the test methods used are generally practiced in industry. If a decision rule for conformity to a specification or industry standard for our products is not inherent, the decision rule shall be communicated to and agreed upon with the customer.

Document D0002.0001-1 provides a matrix of measurement and test equipment calibrated at Larson Davis, and the calibration methods used for each. Proficiency testing from accredited laboratories ensures that all calibration and test methods are valid and consistent with industry standards.

The Metrology Engineer, Project Engineer(s), and Test Engineer(s) are responsible for developing, verifying, and validating the test methods through the Verification Test Plan specified in D0001.1009. Any changes to the test methods are documented through a Document Change Order, D0001.1021 or ECO process.

**9.4.1 Decision Rule Flow Chart**

Decision Rule Flow Chart for Calibration

Calibration Process

\*\*Note: pass/fail and decision rule criteria for all LD product is inherent to the standards for our industry

Quote Repair/Cal

Send product to customer

Metrology Engineer approves reinstatement of equipment

Metrology Engineer approves reinstatement of equipment

Repair

External/Internal Developed

Customer Rejection

Recalibrate – All test procedures incorporate root difference square guardband method for decision rule

Tolerance = $\sqrt{Spec^{2}-U^{2}}$

Send out for repair and recalibration

Internal

External

LD Product

Pass

Fail

Laboratory

Laboratory Test Equipment or LD Product

Certify product and send to customer

Pass/Fail

Customer Approval

Repair if Needed

**9.5 Equipment**

 **9.5.1 Equipment Identification**

The LD Quality Manager or designated employee maintains a list of the equipment used for the calibration of released product, customer instrumentation, and calibration system test instrumentation. The information maintained on the list includes:

* Equipment Description
* Manufacturer
* Model
* Serial Number or other unique identifier
* Current interval of calibration
* Certificate number
* Cal Due date
* Calibration Supplier (if outside calibration source)
* Location of the test instrumentation
* Equipment that is permanently removed from use will show the date of last use.

The test equipment configuration and software for specific test processes are defined and approved by the Metrology Engineer. The test equipment configuration and its associated test software or instructions are capable of achieving the required accuracy for the specification, instrument or product being tested.

Work instructions and/or training are provided to ensure adherence to the testing process by the employee. Equipment reference manuals for operation of non-LD test equipment are available in Document Control and in the Production Area for use by employees.

The list of tracked equipment is added to as needed. Instrument replacement or addition to the list is approved by the Metrology Engineer, Logistics Manager or Quality Manager, according to D0001.4037.

The added or replacement instrument is accompanied by the required certificates of calibration prior to being approved or placed into service. Once the instrument is approved, the equipment list is edited by the Quality Manager or designated employee as indicated in D0001.4037 to includethe date the equipment was placed into service or removed from the list and the calibration due date.

The measurement standards and other test equipment are maintained in good order by the production staff. The Production Manager, or a designated employee, ensures that the equipment is working properly and that each piece is calibrated within the assigned calibration interval. The Production Manager has the authority to designate an employee to perform the daily tasks and oversee the general maintenance of the equipment.

Any employee who uses and /or monitors the measurement standards and test equipment has the responsibility to be observant for equipment malfunction. Employees are required to report any deviation or malfunction to the Production Manager or an appointee. It is the responsibility of the employee to tag the defective equipment as “out-of-order”. The Production Manager or an appointee is responsible to see that the piece of defective or past due equipment is removed from use and the equipment list is updated to mark the equipment as “inactive” which prevents its use in automated tests. The equipment is calibrated and/or repaired before being returned to the line for use in the testing processes. The Quality Manager, Production Manager, or Metrology Engineer are authorized to restart work in the lab.

There are instruments that appear on the Measurement and Test Equipment list that are not used for traceability. These instruments are used for a number of purposes including but not limited to troubleshooting, bench testing, and/or engineering development. These instruments are tracked as a convenience to ensure adequate performance levels and a record of routine maintenance. The QA Manager adds this type of instrument to the equipment list as needed.

The records and histories of calibration for units removed from use are maintained for at least three years after the date of last use.

Equipment that is calibrated and/or certified, at LD, to a measurement standard and used for calibration and/or certification purposes is labeled with a red label. The label indicates the date of calibration, date for next calibration, and the certifying technician’s initials.

Equipment that is calibrated and/or certified, at LD, to a measurement standard, but is not used for calibration and/or certification purposes is labeled with a green label. The label indicates the date of calibration, date for next calibration, and the certifying technician’s initials.

Test instruments that use limited parameters of the equipment and are not calibrated for the full capability of the instrument include the notation "NIST Traceable, Limited Cal.” on the yellow calibration status labels.

The yellow label is placed in a visible location on the test instrument. In the case of microphones, small or difficult to label equipment the label is placed on the instrument’s storage box or location.

Instruments verified / calibrated by an external calibration supplier may have that supplier’s calibration sticker on the instrument. If the Larson Davis interval of calibration is different than the interval specified by the supplier, the QA Manager will note the variation on the calibration certificate and enter the correct interval in the database and equipment list. Red, green, or yellow stickers are not placed on these instruments. The Logistics Manager attaches an electronic copy of the calibration report to the equipment list and notes any corrections, adjustments, or other information pertinent to the equipment’s calibration history. Purchase requests for external 17025 certifications or service work on metrology equipment shall be approved by the metrology engineer.

**9.5.2 ADEQUACY OF MEASUREMENT EQUIPMENT**

Engineering (Metrology Engineer) specifies the M&TE that is used as Measurement Standards and the M&TE will be calibrated or verified using any of the specified measurement standards.

The Metrology Engineer determines:

* The adequacy of each model of equipment used for the calibration of new, released, customer and in-house test instrumentation.
* The scope of tests, performed on the measuring equipment manufactured by LD and non-LD equipment, to verify accuracy, stability, range, and resolution for the specified use. The parameters for each instrument are defined such that performance to those parameters can be documented and demonstrated.
* Which specifications non-LD equipment is required to meet. Typically the OEM specifications for the instrument are specified unless noted otherwise by engineering.
* When or if corrections must be applied to measurements or if any specific environmental conditions are required for achieving the specified degree of accuracy. Engineering maintains records of the specified corrections and/or conditions and ensures that associated test procedures and/or software are updated as necessary. Records include the date corrections were released to Manufacturing, the details as to why the corrections were needed and any procedures required to make the corrections. These would be documented through the ECO/DCO procedures.

Measurement equipment that is designated as a measurement standard(s) is certified by a third party calibration source. The third party calibration source certifies the measurement standard(s) with NIST traceable standards to the original equipment manufacturers (OEM) specifications or to industry accepted specifications for the type of instrumentation being tested. The Metrology Engineer approves purchases requests for 17025 certifications from third party laboratories.

Traceable Measurement Standards are used to verify, certify, or calibrate LD and non-LD measurement equipment used for the calibration and certification of LD products. Limited calibration of the test equipment is allowed when the equipment is used for testing over a limited range or using specific parameters of that instrument in a defined process.

The Metrology Engineer specifies the accuracy and uncertainty required for the tests and test equipment.

**9.5.3 Handling & Protection**

The M&TE and MS Maintenance, Handling & Protection procedure, D0002.0004, provides the guidelines necessary to ensure the continued suitability of the equipment governed by this document.

 **9.6 MEASUREMENT TRACEABILITY**

**9.6.1 Reference Standards**

Reference standards are calibrated at outside sources and are directly traceable to national or international measurement standards or constants of nature. All reference standards are controlled and stored separately to prevent damage that may adversely affect their accuracy.

**9.6.2 Transfer Standards**

Transfer standards (used to transfer the basic value of the reference standard to lower echelon transfer standards or measuring and test equipment) may be calibrated at Larson Davis or sent to an outside source.

**9.6.3 Inspection and/or Measuring Equipment**

Inspection and/or measuring equipment (hardware acceptance) for mechanical measurement may be calibrated internally or sent to an outside source.

**9.6.4 Documented Evidence**

Documented evidence indicating the person attesting to the correctness of the results exists indicating the chain of traceability.

**9.7 PLANNING**

The materials and time necessary for calibration and verification of released product is anticipated and planned into the manufacturing cycle. Planning includes maintenance functions for the MS and M&TE, new product manufacturing and calibration /certification /repair of customer instrumentation.

Instruments received at LD for calibration, verification or repair are evaluated and the time required to complete the work is determined and communicated to the Sales Customer Service Representative (CSR) for communication to the customer.

A customer may request calibration or verification of outdoor systems on-site. The Production Manager provides the CSR with a cost estimate and possible dates for the work to occur. The CSR works with the customer to finalize the order. Service and/or calibration contracts are handled through the "Contract Review" procedure.

**9.8 CALIBRATION PROCEDURES**

The writing and updating of calibration procedures is an ongoing process. Engineering, Manufacturing and Quality will review new and edited procedures prior to release or approval of changes to existing documentation. Changes to documentation are per the Document Change Order Procedure (D0001.1021).

* Calibration procedures that are written for verifying test instrumentation in-house will be validated and approved by Engineering and maintained by Document Control.
* Test procedures for the calibration of released product or customer instrumentation may be written by Engineering and/or the Production Technicians. Procedures are then approved and released through the ECO/DCO procedure (D0001.1021). Released procedures are maintained in Document Control.
* Procedures will specify the equipment to be used and the required results of the calibration or certification. Procedures will include instructions to be followed by the technician to adequately calibrate or certify the instrument.

LD utilizes test equipment and measurement standards from other manufacturers as well as equipment manufactured by LD. When appropriate, instruments will be calibrated and/or certified using automated test programs and procedures. If automated programs are not available documented bench test procedures may be used and the results verified by the technician.

All automated and bench test procedures will be specified and detailed by the LD Engineering Department to ensure adequate reliability of the test instruments. Copies of the test procedures will be on file and readily available to authorized employees. Technicians will have access to test procedures as required. The Production Manager and the QA Manager will have access to copies of the test procedures. Access to test procedures may be in the form of paper copies or online in an electronic format.

Measurement standards may be sent to LD approved calibration laboratories for NIST traceable certification. These laboratories should have ISO 17025 revision 2008 or newer accreditations. In the case where ISO 17025-2017 accredited laboratories are not possible for the type of equipment being re-certified the equipment will be sent to multiple laboratories and the results compared.

**9.9 CALIBRATION SOURCES**

Measurement standards used by LD will be calibrated and certified by LD approved calibration facilities with documented traceability to NIST standards and ISO17025-2017 accreditation. The measurement standards will then be used to calibrate test equipment for LD calibration and certification test procedures.

Measurement standards with traceability to NIST will be returned to LD with supporting documentation of traceability as attested by official certificates, reports and/or data sheets. The supporting documentation will list the following:

* Interval of Calibration
* Unique calibration certificate or report number
* Calibration Source (facility that did calibration)
* Description and unique identification of the item (serial number)
* Calibration Status as received (in or out-of-tolerance)
* Environmental conditions
* Statement of corrections made due to environment (if applicable)
* Date of calibration
* Statement of Traceability to NIST or other applicable standards
* Statement of compliance to ISO17025 and/or ANSI Z540
* List of measurement standards used and their traceability
* Calibration Statement of uncertainty and cumulative effect
* Test data showing standard value, instrument value and deviation
* Details of maintenance, adjustment, repair or modification
* Calibration test procedure identification
* Any limitations for use
* Identification of person performing calibration or certification
* Identification of person responsible for ensuring correctness of recorded information

**9.10 RECORDS**

Records of calibration and certification will be maintained and stored in Document Control electronically. The Quality Assurance Manager will maintain the calibration schedule and supervise the calibration process. The records of any instrument used in the calibration system will be maintained while the instrument is in use and at least three years after it has been removed from service. The equipment list will indicate the date each instrument was placed into service and the date when it is removed.

* Records will include the make, model, type and serial number (or other unique identification), of the relevant measurement equipment.
* Calibration results will contain sufficient detail so that traceability of the measurements can be demonstrated. Detail must be adequate to allow reproduction of the measurements under conditions similar to those of the original.

From time to time, amended certificates may need to be issued to customers. MET/TEAM has an amendment process that permits changes or corrections to be made when necessary. However, there are circumstances when an amended certificate cannot be issued and a replacement certificate is generated instead. A note will be made on replacement certificates that states “(#xxxxxxxxxx) is a replacement for a certificate that has been found to have errors (#yyyyyyyyyy)”.

**9.11 SUBCONTRACTOR CONTROLS**

Measurement standards used by LD will be calibrated and certified by LD approved calibration facilities with documented traceability to NIST standards.

LD approved facilities will be audited and inspected to the requirements of ISO/IEC 17025 and ANSI-Z540 by the QA Manager or his qualified designee. Audits will be conducted as often as necessary to ensure compliance to the standards, typically every 12 - 18 months. Copies of government inspection audits or certificates issued by a recognized accreditation organization (i.e. A2LA) may also be acceptable as a proof of compliance. Audits may be conducted on-site or through the mail. The type of audit will be determined by the past performance and/or reputation of the supplier.

The QA Manager or designee will maintain the LD audit reports and copies of other applicable audits of LD approved calibration facilities. The QA Manager reports the results of audits to the Director of LD Operations.

**9.12 CALIBRATION SYSTEM ADEQUACY**

LD will maintain a documented program for compliance with the requirements of ISO/IEC 17025-2017 and ANSI-Z540-1. The QA Manager or designee will oversee the audit of the performance and status of the system on a regular basis with reports written for each audit.

The results of each audit will be presented to the Director of LD Operations. The audit may include observing calibration procedures to ensure that procedures are followed.

Calibration Supplier audits may be scheduled on a 12 to 18 month interval and will be by appointment.

The Quality Manager will supervise and ensure that each instrument requiring calibration in the equipment list is calibrated on time and according to documented procedures. Records of audits will be maintained as electronic or hard copies for at least three years.

**9.13 PROFICIENCY TESTING**

LD follows ISO 17025-2017 and ISO 17043 and maintains a proficiency test schedule that ensures that its entire scope of accreditation is covered every four years, and at least two proficiency testing activities are performed per year, except in the case where the lab has fewer than four disciplines and then only one proficiency test activity per year will be required. The schedule is found in the Proficiency Testing Schedule (D0002.0001-2).

LD will perform PT using commercially available PT programs and through inter-laboratory comparison (ILC).

Where commercially available, LD will contract with a PT provider to perform proficiency testing. LD will submit the PT provider's report containing En values to the Accrediting Body with any corrective action responses within 30 days, regardless of the resulting En values.

Prior to sending equipment for ILC, LD will perform a calibration and generate a report for the equipment being tested using the normal procedure used for calibration/verification of customer product.

Upon receipt of the ILC’s calibration results, the Metrology Engineer and Quality Manager or designee will review the results of the tests, comparing the results of each laboratory.

In the case where an ILC is used because commercially available PT is not available, the Quality Manager or designee has the responsibility of generating a report of the ILC analysis, and any corrective action responses to the Accrediting Body. This report shall be sent to A2LA within 30 days of generating the report and according to the process outlined by said Accrediting Body, including submission forms, policies, and procedures.

If LD’s PT results and the inter-laboratory comparison results differ such that the result of Equation 1 is greater than 1, LD will initiate a Corrective Action to investigate the root cause of the measurement discrepancy. Detailed corrective action responses, including root cause analysis, for any outlying or unacceptable final results related to testing/calibration on LD’s Scope of Accreditation will also be submitted in the report to the Accreditation Body.

$$ E\_{n}= \frac{\left|Lab-Ref\right|}{\sqrt{\left(U\_{95}Lab\right)^{2}+ \left(U\_{95}Ref\right)^{2}}} (1)$$

where *Lab* and *Ref* indicate the laboratory and reference measurement values respectively for the attribute in question. U95Lab and U95Ref represent the expanded uncertainties expressed at the 95% confidence level for the laboratory and reference laboratory respectively.

**9.14 CORRECTIVE ACTION**

Customer feedback and suggestions are an integral part of the LD Quality and Product Support groups. Comments or complaints from customers are reviewed and an appropriate individual will be assigned to address the concerns of the customer. Customer communication that requires an action by LD to resolve are addressed through the Corrective / Preventive Action (D0001.1020) procedure. Records of corrective action or customer feedback are maintained as indicated in those procedures.

**10.0 INSPECTION**

There are inspection points throughout the process. The inspection points include but are not limited to:

* monitoring instrument calibration due dates
* monitoring instrument performance
* verification of supplier qualifications to perform instrument calibration
* inspecting certificates for NIST compliance and declaration
* examining test results for accuracy and compliance to specifications

**11.0 RECORDS**

The records maintained are specified in the process and include but are not limited to:

* Equipment calibration and repair history
* Employee Training
* Interval changes
* Reasons for equipment replacement (other than rotation out for interval based calibration)
* Documentation of calibration extensions granted

Records are maintained for a minimum of one year or the minimum interval specified by the process / procedure documentation.

**12.0 DISTRIBUTION**

* Engineering
* Production
* Repair and Calibration
* Quality Assurance

**APPENDIX A – VOCABULARY / DEFINITIONS**

**Accuracy of measurement:** Agreement of a measured value with an external standard.

**Accreditation Body:** An organization that evaluates and audits laboratories for conformance to International Standards, such as A2LA, NVLAP, etc.

**Adjustment (of a measuring instrument):** The operation of bringing a measurement instrument into a state of performance suitable for its use.

**Calibration:** The set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measurement instrument or system. The values represented by a material measure or a reference material, and the corresponding values realized by standards.

**Certified Reference Material (CRM):** 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.

**Conformity:** Fulfillment of specified requirements.

**Control of Measurement Process:** Monitoring and analysis of data from a measurement process, together with corrective actions, intended to maintain the process of measurement continuously within a specification.

**Corrective Action:** Action taken to eliminate the causes of an existing nonconformity defect or other undesirable situation in order to prevent recurrence.

**LD:** Larson Davis a division of PCB Piezotronics, Inc.

**Laboratory:** The portion of the organization that calibrates and/or tests.

**Limits of permissible error (of a measuring instrument):** Extreme values of error permitted by specifications, regulations, etc. for a given measuring instrument.

**Maximum permissible errors (of a measuring instrument):** Extreme values of error permitted by specifications, regulations, etc. for a given measuring instrument.

**Measurand:** Particular quantity subject to measurement.

**Measurement:** Set of operations having the object of determining the value of a quantity.

**Measurement Procedure:** Set of operations, described specifically, used in the performance of particular measurements according to a given method.

**Measurement Process:** Set of interrelated resources, activities, and influences that produce a measurement.

**Measurement Standards (MS):** A material measure, measuring instrument, reference material, or system intended to define, conserve, or reproduce a unit or one or more values of a quantity values in order to transmit them to other measuring instruments by comparison.

**Measuring Equipment:** All of the measuring instruments, measurement standards, reference materials, auxiliary apparatus and instructions that are necessary to carry out a measurement.

**Metrology:** The science of measurements.

**M & TE:** Measurement and Test Equipment

**Objective Evidence:** Information that can be proved true, based on facts obtained through observation, measurement, tests or other means.

**Quality Audit:** Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**Stability:** Ability of a measuring instrument to maintain constant its metrological characteristics with time.

**Test:** A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

**Traceability:** The ability to show that a standard or an instrument has been calibrated or certified by a higher order standard which is then calibrated or certified by a still higher-order, and on and on, thus the standard or instrument is eventually related back to the established national standards.

**Uncertainty of Measurement:** An indication of the variability associated with a measured value that takes into account two major components of error: 1) bias and 2) random error attributed to the impression of the measurement process.

**Verification:** Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

**14.0 REVISIONS**

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| --- | --- | --- | --- | --- |
| **DCO #** | **REV** | **DATE** | **INITIAL** | **CHANGES** |
|  | B | 3/15/95 | JEB | Complete rewrite and evaluation of revision A. |
|  | C | 4/11/95 | JEB | Added section 3.13 - Personnel Training Records Added section 3.14 - Complaint RecordsAssigned section 3.15 to Amendments & RevisionsAssigned section 3.16 to Attachments Section |
|  | D | 4/29/96 | DR/JEB | Removed references to Mil-Std 45662ADeleted calibration procedures as attachments and assigned a location instead. Specified that extensions must be approved in writing from Director of Operations.Clarified 4:1 accuracy statement in section 3.1Changed specification number to correspond to the ISO9001 Quality Manual numbering system. |
|  | E | 1/20/98 | JEB | Re-wrote the document to compliance to the currentISO-10012 Standard, (re-write) and the ISO Procedure outline |
|  | F | 5/7/00 | JEB | Edited the Calibration System Organization Chart |
|  | G | 9/28/00 | JEB | Edited and corrected titles, department names, clarified responsibilities for training and records, removed the requirement to double sticker instruments with intervals assigned by the calibration supplier but not matching the current interval defined for the instrument. Emphasized the replacement standard for Guide 25 and added ANSI-Z540. Removed ISO 10012 which is not an auditable standard. |
|  | H | 7/3/08 | DAR | Rewrote to complement the new ISO 17025-2005 standard. |
|  | I | 7/13/12 | DAR | Make additional changes to bring up to date. |
| 1467 | J | 12/4/13 | SJA | Complete rework of document. Changed sections 3.0, 4.2, 9.1,9.3-9.6, added section 9.13 |
| 1490 | K | 4/25/14 | SJA | Added mention of Accreditation Body and D0002.0005 in section 8.0 |
| 1550 | L | 3/16/2015 | DAR | Update proficiency testing requirement to bring in line with standard. |
| 1629 | M | 6/10/2016 | SJA | Update PT providers and ILC reporting policy |
| 1630 | N | 7/1/2016 | SJA | Amended and Replacement certificate policy, section 9.10 |
| 1870 | O | 1/22/2019 | DPW | Added decision rule information and documentation information for opinions and interpretations of data. Updated policy to comply with the new revision of ISO 17025-2017 |
| 1885 | P | 4/30/19 | TLB | Amended section 9.13 |
| 1892 | Q | 6/3/19 | TLB | Amended section 9.13 to add Corrective Action statement |
| 1943 | R | 3/6/20 | DAR | Redistribute responsibilities with the addition of QA Manager. Amended Section 4.2. |