



## QUALITY ASSURANCE MANUAL

Revision F  
Revision Date 03-28-2025

In conformance with:  
ISO/IEC 17025:2017



### PI TAPE TEXAS, LLC

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In Conformance with:

ISO/IEC 17025:2017

ISO 10012-1, 10 CFR, part 21 & 10 CFR, part 50, Appendix B

## **1.0 Introduction**

Pi Tape Texas, LLC specializes in manufacturing and calibration of precision diameter, circumference and linear measurement tapes. It is our goal to provide quality service at a reasonable price with customer requirements in mind. We pride ourselves in meeting the requirements contained in the ISO/IEC 17025:2017 quality system and quality assurance standards.

Our calibration system is traceable through N.I.S.T. to the international system of units and in conformance with ISO/IEC 17025:2017, ISO/IEC 10012-1, 10 CFR, part 21, 10 CFR, part 50, Appendix B.

This manual serves as our Calibration System description as well as our Quality Assurance Manual. It describes how we will maintain good laboratory practices and outlines our policies as required to keep the highest level of quality during the performance of the calibration services we provide.

On behalf of all of us at Pi Tape Texas, LLC

Harold "Skip" Phillips, Jr. and Carrie Phillips, Owners

Harold "Skip" Phillips, Jr. Quality Assurance Manager

## **2.0 References**

Reference to the following standards has been evaluated in developing our quality system for guidance.

ISO/IEC 17025:2017

ISO/IEC 10012-1

10 CFR, part 21

10 CFR, part 50, Appendix B

## **3.0 Terms**

For any relevant terms or definitions concerning this Quality Manual or any quality function, please consult management of Pi Tape Texas, LLC.

## **4.0 General Requirements**

### **4.1 Impartiality-**

4.1.1 Pi Tape Texas, LLC's top management is committed to implementing a quality program that ensures impartiality in all aspects of our business.

4.1.2 We have identified the following relationships that could have a potential for affecting our impartiality related to relationships:

4.1.3 We will not allow commercial, financial or other pressures to impact our impartiality.

4.1.4 If we identify a potential conflict, we will evaluate the conflict and we will notify any affected customer to determine the appropriate resolution.

4.1.5 Ownership, management, employees, vendors, contractors, customers and banking institutions. Risk relate to activities includes meeting customer delivery schedules, failure to calibrate standards at set intervals, and performing to specific customer requirements. If a risk to opportunity is identified, at a minimum, we will demonstrate how will eliminate or minimize such risk. We will also review and update as necessary during our annual management review. See form 405 Risk Assessment.

### **4.2 Confidentiality-**

4.2.1 Pi Tape Texas, LLC is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 When the Pi Tape Texas, LLC is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2.3 Information about the customer shall be confidential to the laboratory and shall not be shared, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.

## **5.0 Structural Requirements**

5.1 Our facility and all the functions of our laboratory are a legally identifiable business which operates as: Pi Tape Texas, LLC located at 10235 Robinson Drive, Tyler, TX USA 75703.

5.2 Harold "Skip" Phillips Jr. is the Quality Assurance Manager and the owner of Pi Tape Texas, LLC and has the overall responsibility of the laboratory.

5.3 Pi Tape Texas, LLC has established, implemented and maintains a quality system appropriate to the scope of activities to be perform. We have documented our policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the calibration results we provide to our customers. Our quality system's documentation is to be communicated, understood by, available to and implemented by the appropriate personnel of our laboratories.

The scope of calibration performed at this laboratory is as follows:

- Calibration of precision diameter tapes
- Calibration of precision circumference tapes
- Calibration of precision linear measurement tapes
- Calibration of digital tapes
- Calibration of Pi Tape linear machines
- Calibration of Pi Tape master tapes (to calibrate ring gages)
- Calibration of Pi Tape ring gages
- Calibration of tension scales up to 10 pounds

5.4 Our quality systems, policies and procedures in their entirety covers all work performed in our permanent facility. The primary responsibility of the QA Manager is the development, implementation, monitoring and documenting compliance of our quality system to the requirements as stated in ISO/IEC 17025:2017 and to satisfy the needs of our customers as requested by them.

Audits covering quality, calibration and management system review are performed on an annual basis, at minimum. The primary documents used during an audit are the Quality and Management System Review form 401 and the Internal Audit Checklist form 600.

It is the vision and responsibility of Pi Tape Texas, LLC to carry out calibration activities in such a way as to meet the requirements set forth by ISO/IEC 17025:2017 and to satisfy the needs of our customers, the regulatory authorities or organizations providing recognition.

Arrangements have been made to ensure that management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

Personnel are to avoid involvement in any activities that would diminish confidence in competence, impartiality, judgment or operational integrity of any function of this laboratory.

All personnel at Pi Tape Texas, LLC are aware of the relevance and importance of their activities and how they contribute to the achievement and the objectives of the management system.

In the event of extended absence of the Owners, the Quality Assurance Assistant will be appointed deputy until the return of the Owners or until a replacement is made.

All records and documentation, including electronic storage, will be stored safely and held secure and in confidence for customers. All records and documentation are kept on file for ten years. Any personnel found violating this policy can be punished up to and including dismissal.

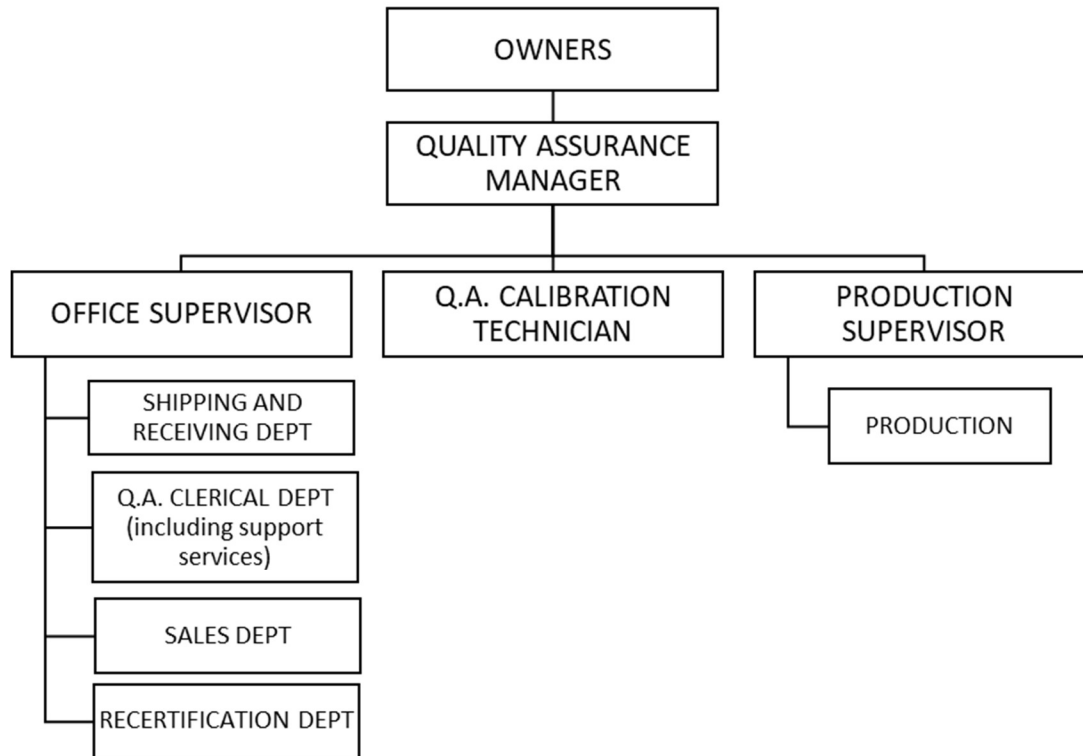
Our Quality Policy is as follows:

“Pi Tape Texas, LLC provides the most accurate measuring tapes in the world. Our commitment is supported by a single-minded dedication to strict adherence of calibration and production accuracy protocol, with constant focus on innovation and improvement. This attention to detail is ingrained in all levels of our business, from the initial contact to the certification, packing and shipping of the final product. Since 1944, the reliability and reputation of Pi Tape Texas, LLC products continues to be evidenced by our unequalled longevity and success in our industry.”

—Harold “Skip” Phillips, Jr. and Carrie Phillips, Owners

## 5.5 Organizational Structure

- a) The Organizational Chart below illustrates the responsibilities, interrelationships and authorities within Pi Tape Texas, LLC.



- b) Our facility is organized in such a way as to define, identify and eliminate potential conflicts of interest. The Quality Assurance Manager and the Quality Assurance Assistant will collaborate to develop and enforce Pi Tape's Quality Policy.
- c) Our quality system includes written technical procedures and is used by technical personnel when carrying out our technical functions. These procedures are indicated in our procedure manual titled "Quality Assurance Procedures Calibration Information". The procedures are indicated with titles "Procedure 1" thru "Procedure 17".

5.6 The Quality Assurance and managerial staff are granted the authority and resources needed to discharge their duties, including:

- a) The Quality Assurance Manager will be responsible for implementing and maintaining the quality and management system. The Quality Assurance Manager has the responsibility and authority to ensure that proper operations, plans and procedures are written to provide a standard approach to quality assurance throughout Pi Tape Texas, LLC and to provide continuous monitoring and improvement by means of internal audits and management reviews of the quality system;

- b) Any departures from normal operations must be approved by the responsible manager. The responsible manager must report to the appropriate tier of management;
- c) Initiation of actions to prevent or minimize such deviations;
- d) Reporting to management of the performance of the management system and any need for improvement;
- e) Ensuring the effectiveness of laboratory activities.

5.7 The laboratory management shall ensure that:

- a) Communication takes place regarding effectiveness of the management system and the importance of meeting customers' and other requirements;
- b) The integrity of the management system is maintained when changes the management system are planned and implemented.

## **6.0 Resource Requirements**

6.1 Pi Tape Texas, LLC is committed to have the necessary resources to effectively manage and perform the calibrations within our scope. This includes the following resources: personnel, facilities, equipment, systems and support services.

### **6.2 Personnel-**

6.2.1 Our laboratory management ensures the competence and impartiality of all who operate specific equipment, perform calibrations, evaluate results and sign calibration reports. When using staff that is undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified based on appropriate education, training, experience and/or demonstrated skills, as required.

6.2.2 Current job descriptions are maintained for managerial, technical and key support personnel involved in calibrations. As a minimum, these job descriptions include the responsibilities with respect to performing calibrations, with respect to the planning of calibration and evaluations of results, reporting opinions and interpretations, to method modifications and development and validation of new methods, expertise and experience required, qualifications and training programs and managerial duties.

6.2.3 Management formulates the goals with respect to education, training and skills of technical personnel. It is the policy of Pi Tape Texas, LLC to identify training needs and to provide training to our personnel. Our training program is relevant to the present and anticipated functions of our laboratory. Pi Tape Texas, LLC uses only personnel that are trained and competent in the requirements necessary to perform activities for which they are responsible.

6.2.4 Management shall communicate to personnel their duties, responsibilities and authorities.

6.2.5 Records are maintained of the relevant authorization, competence, education and professional qualifications, training, skills and experience of all technical personnel. This information is readily available and includes the date on which the authorization and/or competence is confirmed.

6.2.6 Management authorizes specific personnel to perform types of calibration, issue calibration reports, give opinions and interpretations, develop and verify methods and operate particular types of equipment.

Vision examinations shall be administered annually by a medically qualified/trained person and documented. All documentation will be kept on file for 10 years.

Vision requirements are as follows:

Near vision: Snellen Jaeger Type 1 with one eye, natural or corrected, not less than 12" – examination is required annually.

Color Vision: Testing for color vision is required at least one time for dimensional inspectors. Individuals shall be capable of adequately distinguishing the differentiating colors used in the method for which certification is required, the process being performed or inspection activity.

### **6.3 Facilities and environmental conditions-**

6.3.1 Our facilities for calibration, including but not limited to energy sources, lighting and environmental conditions, are such to facilitate correct performance of our calibrations. We ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of our calibration are documented. Calibrations are not performed outside of our permanent facility.

6.3.2 Laboratory activities are performed in environmental conditions of:

Temperature: 68 degrees F +/- 2 degrees F

Humidity: 45% +/- 15%

6.3.3 Monitoring, controlling and recording of environmental conditions are required by the relevant specifications, methods and procedures or where they influence the quality of results are performed. Due attention is given to dust, humidity, electrical supply, temperature, vibration levels, as appropriate to the technical activities concerned. Calibrations are stopped immediately when environmental conditions jeopardize the results of our calibrations.

6.3.4 Measures to control facilities and environmental conditions shall be implemented, monitored and reviewed and shall include:

- a) Access to and uses of areas affecting the quality of our calibrations are controlled to the extent of particular circumstances;
- b) Measures are taken to prevent cross-contamination in the laboratory and measures are taken to ensure good house-keeping;
- c) Separation between neighboring areas in which there are incompatible activities are a priority.

6.3.5 Pi Tape Texas, LLC does not perform laboratory activities outside our permanent facility.

### **6.4 Equipment-**

6.4.1 All measurement and test equipment required for the correct performance of calibrations (including preparation of calibration items, processing and analysis of calibration data) are furnished to personnel.

6.4.2 In those cases where the need to use equipment is outside our permanent control, the requirements of our quality system and the requirements of ISO/IEC 17025:2017 are still met.

6.4.3 Procedures are developed for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. See form 306, Safe Shipping & Handling.

6.4.4 Before being placed into service, equipment is calibrated and checked to establish that it meets the specification requirements and complies with the relevant standard specifications.

6.4.5 Equipment and its software used for calibration shall achieve the accuracy required and comply with specifications relevant to the calibrations concerned.

6.4.6 A system requiring mandatory recall of M&TE's has been established. On the first day of each month, our M&TE list is checked to verify any standards that need to be recalled for that month. Laboratory M&TE and measurement standards may have the Calibration Due Dates extended for scheduling or workload backlog reasons. A new calibration label will be placed on the item extended, showing the original calibration Due Date and the new Due Date. A memo showing the details of the extension will be



placed on the calibration report with the either the Quality Manager or QA Assistant's signature indicating approval for the extension.

6.4.7 Calibration programs have been established which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

Equipment is operated by authorized personnel only. Employees are trained 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 technical personnel.

6.4.8 Wherever practical, all equipment under our control requiring calibration is labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due. Equipment shall be calibrated at periodic intervals. The length of the interval will be based on the stability, calibration history, purpose and the degree of usage for each individual item. All equipment calibration intervals are kept of file. A listing of all Pi Tape Texas, LLC equipment used for calibration and reference material will be maintained and updated quarterly, at a minimum. This list will show the item description, the unique identification number assigned to the item, calibration source, date calibrated, date due for recalibration and evidence that the equipment is traceable. All historical M&TE calibration reports will be kept on file in the QA department.

6.4.9 Equipment that has been subject to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. It is isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration to perform correctly. The effects of previous calibrations are examined. If any changes occur which have no impact to the quality system, a notation is documented. If any out of tolerance conditions are found, the customer is notified in writing.

6.4.10 A procedure is carried out when intermediate checks are needed to maintain confidence in the calibration status of our equipment, along with a procedure to update computer software where calibrations give rise to a set of corrective factors.

6.4.11 Calibration equipment, including both hardware and software, are safeguarded from adjustment, which would invalidate the calibration results.

6.4.12 If any item becomes damaged or gives suspect results, it shall be taken out of service, clearly identified until it has been repaired and shown by calibration or verification to perform satisfactorily. Tamper resistant seals are applied on M&TE's, where appropriate. These seals are checked, and verification of inspection is recorded each workday. If these seals are disturbed, the M&TE is re-adjusted to its original position and calibrated to conform to the original accuracy. The Laboratory shall examine the effect of any discrepancies on previous calibrations.

6.4.13 Records are maintained on each item of equipment and its software significant to the calibrations performed. These records include, at a minimum:

- a) The identity of the item and its software;
- b) The manufacturer's name, type identification and serial number or other unique identification;
- c) Checks that equipment complies with the specification, any limitations, or items not calibrated to their full capacity are identified to that condition;
- d) The current location, where appropriate;
- e) Dates, results and copies of reports and/or calibration reports, adjustments acceptance criteria and the due date of next calibration;
- f) The manufacturer's instructions (if available), acceptance criteria and period of validity;
- g) The maintenance plan, where appropriate, and the maintenance carried out to date;
- h) Any damage, malfunction, modification or repair to the equipment;

## **6.5 Metrological Traceability-**

6.5.1 All equipment used for calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the calibration is calibrated

before being put into service. A program and procedure have been established for the calibration of our equipment to ensure an unbroken chain of traceability.

6.5.2 Our program for calibration of equipment is designed and operated to ensure that calibrations and measurements made by us are traceable to the international system of units (SI). We establish traceability of our own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to a national measurement standard. National measurement standards are our primary standards, which are primary realizations of the SI units or agreed representations of the SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, we ensure traceability of measurement using calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration reports issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. Calibration laboratories fulfilling the requirements of ISO/IEC 17025:2017 are considered to be competent.

6.5.3 Where traceability of measurements to SI is not possible, confidence is achieved by requiring and establishing traceability to appropriate measurement standards such as the use of

- a) certified reference materials provided by a competent supplier to give reliable physical or chemical characterization of a material and/or the use of specified methods or consensus standards that are clearly described and agreed on by all parties concerned.
- b) A program and procedure are in place for the calibration of our reference standards. Reference standards are clearly marked "Reference Only". Procedures are maintained and followed for safe handling, transport, storage and use of reference standards in order to prevent contamination or deterioration and in order to protect their integrity.

All products manufactured are calibrated during final inspection in accordance with our quality system.

## **6.6. Externally provided products and services-**

6.6.1 All external providers must comply with all requirements of Pi Tape Texas, LLC Purchase orders.

6.6.2 It is the policy of Pi Tape Texas, LLC to purchase services and supplies that affect the quality of our calibrations from approved sources. Procedures are developed and maintained for the purchase, reception and storage of reagents and laboratory consumable materials relevant for calibration. We ensure that these purchased goods and supplies are not used until they have been inspected or otherwise verified and complying with specifications or requirements defined in the purchase order. Records of actions taken to check compliance are recorded. See Master Vendor PO templates in Purchasing folder on server.

6.6.3 The purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered and are reviewed and approved for technical content by proper authority prior to issuing the purchasing document. Pi Tape Texas, LLC performs technical checks of critical consumables and supplies that are received. The required specifications are verified prior to usage. Pi Tape Texas, LLC performs vendor survey audits on critical supplies and services which directly affect the quality of products and calibration services we provide. Records of these vendor survey audits and a list of those approved are maintained utilizing forms 701, 702 and 703 in our QA System Document folder.

## **7.0 Process Requirements**

### **7.1 Review of tenders, offers and contracts-**

7.1.1 Pi Tape Texas, LLC has developed and maintains procedures for the review of requests, tenders and contracts that are adequately documented, understood and fall within the scope of our capabilities. Where external providers are used, requirements of section 6.6 are applied, with our customers approval.

7.1.2 Pi Tape Texas, LLC shall inform the customer when the method requested by the customer is

considered inappropriate. Every contract is to be acceptable to both Pi Tape Texas, LLC and the customer. 7.1.3 Decision Rules are clearly defined and listed below. Decision Rules can be found on our Calibration Reports, this Quality Manual after section 7.1.8, Offer to Sell forms, invoices and on our website at the Services tab on the Calibration & Recertification Lab section. Records of reviews, including any significant changes are maintained including pertinent discussions with the customer relating to the client's requirements of the results of the work during the period of the execution of the contract.

This calibration was performed on location at Pi Tape Texas, LLC and completed in accordance with ISO/IEC 17025 requirements. All calibration standards are traceable to the National Institute of Standards and Technology (NIST) or other signatory to the CIPM mutual recognition agreement. The expanded uncertainties were calculated using the principles of the GUM and expressed at a 95% confidence interval and a coverage factor of k=2. Statements of conformance are based on measurement results being within the specified tolerances, which are unmodified by the measurement uncertainties. The Decision Rule used is a Simple Acceptance as defined in ILAC G8 with a TUR of 2:1 or greater. Decision Rules are as follows:

- Acceptable – Results within specification
- Unacceptable – Results exceed specification

7.1.4 Any differences between the customer request and the contract shall be resolved before any work is to begin. This review is performed in a practical manner and can be done verbally. A review of our capabilities has been performed on all instruments listed on our price guide, therefore eliminating further review of these items unless the customer requests a special requirement.

7.1.5 The client is informed in writing of any deviation from the latest revision of the contract.

7.1.6 If the contract needs to be amended after work has begun, the same contract review process is to be repeated and any amendments are to be communicated to all affected personnel at our facility.

7.1.7 Pi Tape Texas, LLC shall cooperate in clarifying requests from customers.

7.1.8 All records regarding customer requirements are retained for a period of 10 years.

## **7.2 Selection, Verification and Validation of Methods-**

### **7.2.1 Selection and verification of methods**

7.2.1.1 Appropriate methods and procedures are used for all calibrations within our scope. Method validation is documented on an annual basis.

7.2.1.2 All instructions, standards manuals, and reference data relevant to the work of Pi Tape Texas, LLC is kept up to date and is readily available to our personnel. Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for calibration are available where the absence of such instructions could jeopardize the results of our calibrations.

7.2.1.3 Calibration methods which meet the needs of our customers and which are appropriate for the calibrations we undertake are used. Methods published in international, regional, or national standards are used as the choice instructions. Steps are taken to ensure that we use the latest valid edition of a method. When necessary, the method is supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, appropriate method will be selected that has been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. The customer is informed of the method chosen.

7.2.1.5 Internally developed methods or methods adopted may also be used if they are appropriate for the intended use and have been verified. Standard operating methods are confirmed before introducing a calibration. This method is repeated for confirmation should the standard change. Records of verification

are kept on file. Our customers are notified when the proposed method by the customer is inappropriate or out of date.

7.2.1.6 New methods are verified by competent personnel and are approved and authorized before being implemented.

7.2.1.7 Deviation from calibration methods can occur only if the deviation has been documented, technically justified, authorized and accepted by the customer.

## 7.2.2 Validation of Methods

7.2.2.1 Laboratory developed methods of calibration are planned and assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and communicated amongst all personnel involved. When it is necessary to use methods not covered by standard methods, these methods are subject to agreement with the customer and will include a clear specification of the customer's requirements and the purpose of the calibration. All non-standard methods used are validated prior to use. These include handling, transport, storage and preparation of items to be calibrated, and where appropriate, an evaluation of the measurement uncertainty as well as techniques for analysis of the calibration data.

Validation is the confirmation by examination and the provision of objective evidence that the requirements for a specific intended use are fulfilled. Non-standard methods, laboratory-designated/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods are validated to confirm that the methods are fit for intended use. This validation process is extensive as is necessary to meet the needs of a given application or field of application. The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limits, 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 object), as assessed for the intended use are relevant to the customers' needs.

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The results obtained, the procedure used for the validation, and a statement as to whether the method is fit for intended use is recorded.

7.2.2.4 Internally developed methods of calibration include information as a minimum, appropriate identification, scope, description of the type of item to be calibrated, parameters or quantities and ranges 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, criteria and/or requirements for approval or rejection, data to be recorded and method of analysis and presentation, and the uncertainty or the procedure for estimating uncertainty, results obtained and a statement on the validity of the method.

## 7.3. Sampling- Lab does not currently perform sampling.

## 7.4 Handling of Calibration Items-

7.4.1 Procedures are in place for the transportation, receipt, handling, protection, storage, retention and/or disposal of calibration items, including provisions necessary to protect the integrity of the calibration item, and to protect the interests of the laboratory and our customers.

7.4.2 A system is in place for identifying calibration items. This identification is retained throughout the life of the item in the laboratory and is designed and operated to ensure that items cannot be confused physically or when referred to in records or other documents. This system also accommodates a sub-division group of items, if applicable, and the transfer of items within and from the laboratory.

7.4.3 Upon receipt of the calibration item, abnormalities or departures from normal or specified conditions, as

described in the calibration method, are recorded. The customer is notified in writing when there is doubt as to the suitability of an item for calibration, or when an item does not conform to the description provided, or the calibration required is not specified in enough detail.

7.4.4 Procedures are implemented along with appropriate facilities for avoiding deterioration, loss or damage to the calibration item during storage, handling and preparation. Conditions are maintained, monitored and recorded when items must be stored or conditioned under specified environmental conditions. We have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned where a calibration item or a portion of an item is to be held secure.

## **7.5 Technical Records-**

7.5.1 Pi Tape Texas, LLC will ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

7.5.2 Pi Tape Texas, LLC will ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

## **7.6 Evaluation of Measurement Uncertainty-**

7.6.1 Sources contributing to the combined uncertainty include, but are not limited to, the reference standards and reference material used, methods and equipment used, environmental conditions, properties and condition of the item being calibrated, and the operator. The predicted long-term behavior of the calibrated item is not normally considered when estimating the combined measurement uncertainty.

7.6.2 Methods are developed and are applied to estimate the uncertainty of measurement for all calibrations and types of calibrations within our scope. When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation are considered using appropriate methods of analysis. If any doubts exist on the validity of calibration and/or uncertainty results, our laboratory shall notify, in writing, any customer whose work may have been affected. Items that are not calibrated to their full capacity, or have other limitations, are identified to that condition.

7.6.3 Pi Tape Texas, LLC evaluates all measurement uncertainties used in our calibration laboratory.

## **7.7 Ensuring the validity of results-**

7.7.1 Quality control procedures for monitoring the validity of calibrations undertaken have been developed and implemented. The resulting data is recorded in such a way that trends are detectable and where practical, statistical techniques are applied to the reviewing of the results. This monitoring is planned and reviewed and includes, but not limited to:

- a) regular use of certified reference materials;
- b) internal quality control using secondary reference materials;
- c) participation in interlaboratory comparison or proficiency testing programs;
- d) Internal checks are used to verify the accuracy of our engraving machine lead screws. The procedures are carried out and recorded at predetermined intervals. All precautionary measures are kept on file. If calibration operation of item or any process therein is interrupted or distraction occurs, then such operation or process will be repeated to ensure calibration results are not compromised;
- e) Intermediate checks on measuring equipment;
- f) replicate calibrations using the same or different methods;
- g) recalibration of retained items;

- h) correlation or results for different characteristics of an item;
- i) review of reported results;
- j) perform intra-laboratory comparisons;
- k) testing of blind samples, if applicable;

7.7.2 Pi Tape Texas, LLC participates in interlaboratory comparisons.

7.7.3 Data from monitoring activities is analyzed and used to control and improve the laboratories activities.

## **7.8 Reporting the Results-**

7.8.1 The results of each calibration or series of calibrations carried out by Pi Tape Texas, LLC is reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration methods.

The results are reported on a calibration report and include all the information requested by the customer and necessary for the interpretation of the calibration results and all information required by the method used.

7.8.2 Each calibration report includes at least the following information, unless we have written authorization from the customer:

- a) A title;
- b) The name and address of the laboratory;
- c) The location where the calibrations were carried out;
- d) Unique identification of the calibration report;
- e) The name of the customer, if required by customer;
- f) Identification of the method used;
- g) A description of the condition of, and unambiguous identification of the item(s) calibrated;
- h) The date of receipt of the calibration item(s) where this is critical to the validity and application of the results;
- i) Date(s) of the performance of the calibration, if different than the date of issue;
- j) Date report was issued;
- k) Sampling is not performed;
- l) Reference to the item being tested;
- m) The calibration results with, where appropriate, the units of measure;
- n) Additions, deviations or exclusions from the method are not applicable;
- o) Identification of the person(s) authorizing the report;
- p) External providers are not used.

Specific requirements for the calibration certificates:

- a) The uncertainty of measurement and/or statement of compliance with an identified metrological specification or clause there of;
- b) The conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;
- c) Evidence that the measurements are traceable;
- d) No adjustments are made;
- e) End of Report.

The calibration report relates only to quantities and the results of functional tests.

A calibration report or calibration label does not contain any recommended calibration intervals except where this has been agreed with the customer. This may be superseded by legal requirements.

When it is not possible to apply a calibration label directly to an item, the calibration label may be affixed to

the instrument container.

When opinions and interpretations are included, we document the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such on the report.

In case of transmission of the calibration result by telephone, telex, fax or other electronic or electromagnetic means, the requirements of ISO/IEC 17025:2017 are met.

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

Amendments-Material amendments to a calibration report after issue are made only in the form of a further document which includes a statement "Amendment to (prior revision report number)". When it is necessary to issue a completely new calibration report, the new report number is uniquely identified and with reference to the original it replaces.

## **7.9 Complaints-**

7.9.1 It is the policy of Pi Tape Texas, LLC to record and resolve to the best of our ability any complaint received from our customers or other parties. Records are maintained of all complaints and of the investigation and corrective actions taken by Pi Tape Texas, LLC and are kept on file in the QA department.

7.9.2 A description of the handling process for complaints shall be available to any interested party upon request.

7.9.3 The process for handling complaints includes the following elements and methods:

- a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
- b) tracking and recording complaints, including actions undertaken to resolve them;
- c) ensuring that any appropriate action is taken.

7.9.4 Pi Tape Texas, LLC shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, Pi Tape Texas, LLC will acknowledge receipt of the complaint, and provide the customer with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the customer shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7 Whenever possible, Pi Tape Texas, LLC shall give formal notice that the complaint has been resolved.

## **7.10 Non-Conforming Work-**

It is the policy of Pi Tape Texas, LLC to follow procedures when any aspect of our calibration work, or the result of these calibrations, do not conform to our own procedures or the agreed requirements of our customers. Work is to be halted immediately and equipment to be identified. An evaluation of the significance of the nonconforming work is to be made by management and the issuance of a corrective action. Where necessary, the customer is to be notified and the work recalled. No work can be resumed with the suspected issue until authorized by the QA Manager or designee. Records are kept on file for 10 years.

Where the evaluation indicates that the nonconforming work could reoccur or that there is doubt about the compliance of our operations with our policies or procedures, a corrective action will be issued.

## **7.11 Control of Data and Information Management-**

7.11.1 The laboratory has access to data and information needed to perform laboratory activities.

7.11.2 Calculations and data transfers are subject to appropriate checks in a systematic manner, when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, we ensure that computer software developed by the user is documented in enough detail and is suitably validated as being adequate for use. Procedures are established and implemented for protecting the data: such procedures include, but are not limited to, integrity and confidentiality of data entry and collection, data storage, data transmission and data processing. Computers and automated equipment are maintained to ensure proper functioning and are provided with environmental and operating conditions necessary to maintain the integrity of the calibration data.

7.11.3 Pi Tape Texas, LLC's Information Management System will:

- a) be protected from unauthorized access;
- b) be safeguarded against tampering and loss;
- c) be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
- d) be maintained in a manner that ensures the integrity of the data and information;
- e) include recording system failures and the appropriate immediate and corrective actions.

Any requests from customers to audit our facilities need to be submitted in writing. Once the request is received, we will verify the request comes from a company with which we do (or plan to do) business.

7.11.4 When Pi Tape Texas, LLC's information management system is managed and maintained off-site or through an external provider, Pi Tape Texas, LLC shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 Pi Tape Texas, LLC will ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

## **8.0 Management System Requirements**

### **8.1 Options-**

8.1 Option A & Option B (See ISO/IEC 17025:2017 page 19 for Management System Options)

For our initial ISO/IEC 17025:2017 assessment we will follow option A but future assessment we will consider option B.

### **8.2 Management System Documentation (Option A)-**

8.2.1 Pi Tape Texas, LLC has developed and maintains procedures to control all documents that form part of our quality system whether internally generated or from an external source, such as regulations, standards, other normative documents, calibration methods, as well as drawings, software, specifications, instructions and manuals.

8.2.2 Policies and objectives shall address competence, impartiality and consistent operation of the laboratory.

8.2.3 Management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.

8.2.4 All documentation, processes, records related to the fulfillment of the requirements of this document



shall be included in, referenced from or linked to the management system.

8.2.5 All personnel involved in the laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

### **8.3 Control of management system documents-**

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of our quality management system.

8.3.2 We will ensure that:

a) All documents issued to personnel in the laboratory as part of our quality system is reviewed and approved for adequacy by the Quality Assurance Manager or designee prior to use. A master list identifying the current revision status and distribution of documents in the quality system is established and is available to preclude the use of invalid and/or obsolete documents. Please reference our document file titled "Quality Assurance System Document File" and our procedure manual titled "Calibration Procedures". The procedures are indicated with titles "Procedure 1" through "Procedure 17". Current revisions are kept in the system document file (Server/F/QA documents);

b) documents are periodically reviewed, and updated as necessary;

c) Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval. Where practicable, the altered or new text shall be identified in the document or the appropriate attachments. Amendments done by hand are not allowed. Changes made to computerized documents are noted on the revision page of the document;

d) 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 otherwise assured against unintended use. Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked and placed in the historical file. Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) Management system documents generated by this laboratory are uniquely identified. These identifications include the date of issue, and/or revision identification, page numbering, the total number of pages or a mark to signify the end of a document, and the issuing authority;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

### **8.4 Control of Records-**

8.4.1 Pi Tape Texas, LLC developed and maintains procedures for identification, collection, indexing, accessing, filing, storing, maintaining and disposing of quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective and preventive actions.

All records are stored and retained in such a way that they are readily retrievable when Pi Tape Texas, LLC is provided a Report Test number (or name of company that purchased items, along with the date of such purchase) in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of these records are 10 years.

Records are held secure and in confidence and procedures have been established to protect back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

8.4.2 Pi Tape Texas, LLC retains records of original observations (where practical) derived data and

enough information to establish an audit trail, calibration record, staff records and a copy of each calibration report issued, for a period of ten years. The records for each calibration contain enough 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. These records include the identity of the personnel responsible for performance of each calibration and checking of the result (sampling is not performed at this laboratory). Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.

When mistakes occur in records, each mistake is crossed out, not erased, made illegible or deleted, and correct value entered alongside. All such alterations to these records are signed or initialed by the person making the correction. When records are stored electronically, equivalent measures are taken to avoid loss or change in original data.

## **8.5 Actions to address risk and opportunities-**

8.5.1 Pi Tape Texas, LLC will consider the risks and opportunities associated with the laboratory activities in order to:

- a) give assurance that the management system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the laboratory;
- c) prevent or reduce undesired impacts and potential failures in the laboratory activities;
- d) achieve improvement.

8.5.2 Pi Tape Texas, LLC will plan:

- a) actions to address these risks and opportunities;
- b) how to:
  - integrate and implement the actions into its management system;
  - evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

## **8.6 Improvements-**

8.6.1 Our laboratory shall continually improve the effectiveness of its management system using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.6.2 Pi Tape Texas, LLC affords our customers or their representatives the cooperation to clarify the customer's request and to monitor the performance in relation to the work performed, provided it does not jeopardize the confidentiality of other customers. We provide our customers or their representatives reasonable access to relevant areas of our laboratory for the witnessing of calibrations performed for the client as well as preparation, packaging and dispatch of calibrated items. The performance of service to our customers is monitored by keeping a file on all customer feedback. Customer feedback is reviewed at the time it is received and again during our management review in order to gauge customer satisfaction.

## **8.7 Corrective Action-**

8.7.1 It is the policy of Pi Tape Texas, LLC to implement corrective action when non-conforming work or departure from our policies or procedures in the quality system or technical operations have been found, however the method.

A corrective action starts with the investigation into the root cause of the problem. When a corrective action is deemed necessary, actions most likely to eliminate the problem and prevent reoccurrence are implemented to a degree appropriate to the magnitude and risk of the problem by:

- a) reacting to the nonconformity, take action, address the consequences;
- b) evaluate the need for action to eliminate the cause(s) in order that it does not recur or occur elsewhere by reviewing the nonconformity, determining the cause and identifying if similar nonconformities exist;
- c) implement any actions needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if needed;
- f) make changes to the management system, if needed.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 Documentation and implementation of any required changes resulting from corrective action investigations are performed and records retained. Results are reviewed to ensure that the corrective actions taken have been effective. The corrective action is closed once deemed satisfactory.

Where the identification of nonconforming or departure casts doubt on the compliance to our policies or procedures or compliance to ISO/IEC 17025, the appropriate areas of activity are audited as soon as possible.

## **8.8 Internal audits-**

8.8.1 Pi Tape Texas, LLC periodically, and in accordance with predetermined schedule and procedure, conducts internal audits of our activities to verify that our operations continue to comply with:

- a) the requirements of our quality system and to the requirements of ISO/IEC 17025:2017. This internal audit addresses all elements of our quality system, including the calibration activities.
- b) It is effectively implemented and maintained

8.8.2 The laboratory shall:

- a) The Owners are responsible for planning and organizing these audits as required by the schedule or at any time requested by management. Trained and qualified personnel, who are independent of the activity to be audited, carry out such audits;
- b) Define the audit criteria and scope for each audit;
- c) Ensure the results are reported to management;
- d) Implement appropriate corrective actions without delay;
- e) Retain records as evidence of the implementation of the audit program and results.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of our calibration results, corrective action is taken in a timely manner and customers are notified in writing if investigations show that the result of calibration may have been affected. The area of activity audited, the audit findings and corrective actions taken that arise from these internal audits are recorded and retained. Follow up audits are performed to verify and record the implementation and effectiveness of any corrective action taken.

## **8.9 Management reviews-**

8.9.1 In accordance with a predetermined schedule and procedure, Pi Tape Texas, LLC upper management periodically conducts a review of our quality system and calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes in improvements.

8.9.2 The inputs to management review shall be recorded and shall include the following:

- a) As a minimum, changes in internal & external issues relevant to laboratory activities;
- b) Fulfillment of objectives;
- c) This review includes the suitability of policies and procedures;
- d) Status of actions from previous management reviews;
- e) The outcome of recent internal audits;
- f) Corrective actions;
- g) Assessments by external bodies, the results of interlaboratory comparisons or proficiency tests;
- h) Changes in volume and type of work;
- i) Customer feedback;
- j) Any and all complaints;
- k) Effectiveness of improvements;
- l) Adequacy of resources;
- m) Results of risk identification;
- n) Outcomes of the assurance of the validity of results;
- o) Other relevant factors, such as monitoring activities and training.
- p) Opportunities for improvement.

8.9.3 The outputs from the management review shall record all decisions and related actions to address the following:

- a) the effectiveness of the management system and its processes;
- b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- c) provision of required resources;
- d) any need for change.

Management reviews are conducted once a year as a minimum. Findings from management reviews and the actions that arise from them are recorded and retained. Management ensures that actions are carried out within an appropriate and agreed timescale.

An extension of this requirement can be made up to 90 days for the purpose of making changes in the systems or to accommodate other work load conditions. Each review will be documented and kept on file, with the date and signature of the person performing the review.

(Internal notes: update website and Calibration Report template when QA manual is updated)

Revision Page:

<u>Date</u>	<u>Revision</u>	<u>Page</u>	<u>Section</u>	<u>Description</u>	<u>Initials of person updating this revision</u>
10/08/2020	B	3-4		Removed Gen Mgr, added QA Assistant	DDB
03/22/2021	C	2	4.1.5	added form #	DDB
		2-3	5.3	expanded scope	
		3	5.4	paragraph 2, added form #, updated audit document name	
		4	5.5c	updated procedure #	
		5	6.2.3	updated paragraph	
		6	6.4.3	added form #	
		6	6.4.6	updated qualified signatures for extensions	
		7	6.4.7	updated wording	
		7	6.4.8	updated historical M&TE calibration report location	
		8	6.6.2	added form #	
		9	7.1.3	listed locations of decision rules	
		9	7.1.4	updated wording on first sentence	
		11	7.7.1d	updated wording	
		15	8.3.2a	updated procedure #	
10/22/2021	D	18	8.9.2	Added item p) Opportunities for improvement	DDB
03/04/2025	E	9	7.1.3	New Statement for Calibration Certificate	CP
		Cover page		Updated Accreditation to A2LA & removed original published date to follow revision date	
03/28/2025	F	8	6.6.2	Revised location of PO requirements	CP
		8	6.6.3	Added location of Vendor Survey Audit requirements	
		9	7.1.3	New Statement for Calibration Certificate	

End of manual.