Quality Assurance Manual

January 2008

Revision O
Revision date of 05/22/18

Pi Tape Texas, LLC

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Tyler, TX 75703 USA

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In conformance with:

ISO/IEC 17025:2005
excluding section 5.4.6.2-3
reference Z540-1-1994 section 10.2B

ANSI/NCSL Z540-1-1994

ANSI/NCSL Z540-3-2006

The former MIL STD 45662A

ISO 10012-1, 10 CFR, part 21

10 CFR, part 50, Appendix B

PI TAPE® precision measuring products
Quality since 1944

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Contents Page

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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 quality system and quality assurance standards excluding section 5.4.6.2-3.

Our calibration system is traceable to N.I.S.T. in conformance with ISO/IEC 17025:2005 excluding section 5.4.6.2-3, ANSI/NCSL Z540-3-2006, ANSI/NCSL Z540-1-1994, ISO/IEC 10012-1, 10 CFR, part 21, 10 CFR, part 50, Appendix B and the former MIL STD 45662A. 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., President

Jerry Mathis, QA Manager

2.0 References

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

ISO/IEC 17025:2005(E)

ANSI/NCSL Z540-3-2006 (American National Standards Institute/National Conference of Standards Laboratories Z540-3-2006)

ANSI/NCSL Z540-1-1994 (American National Standards Institute/National Conference of Standards Laboratories Z540-1-1994)

The former MIL STD 45662A

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 Management requirements

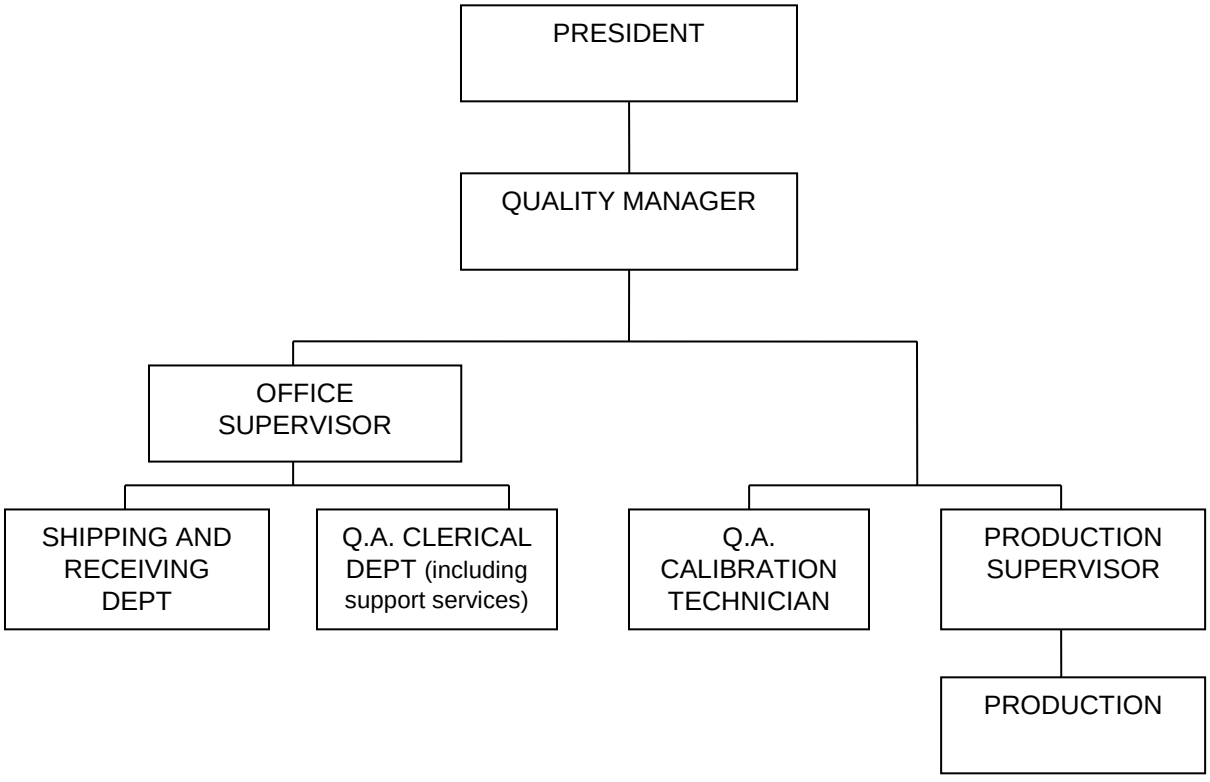
4.1 Organization

4.1.1 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.

4.1.2 It is the vision and responsibility of Pi Tape to carry out calibration activities in such a way as to meet the requirements set forth by ISO/IEC 17025 (excluding section 5.4.6.2-3) and to satisfy the needs of our customers, the regulatory authorities or organizations providing recognition.

4.1.3 Our quality systems, policies and procedures in their entirety covers all work performed in our permanent facility. We do not operate any temporary or mobile facilities.

4.1.4 Our facility is organized in such a way as to define, identify and eliminate potential conflicts of interest. The President and Quality Assurance Manager will collaborate to develop and enforce Pi Tape's Quality Policy. The Organizational Chart below illustrates the responsibilities, interrelationships and authorities within Pi Tape.



4.1.5 The Quality Assurance and managerial staff are granted the authority and resources needed to discharge their duties. The President and the QA Manager will be responsible for implementing and maintaining the quality system. The President has the responsibility and authority to ensure that proper operations, plans and procedures are written so as to provide a standard approach to quality assurance throughout Pi Tape and to provide continuous monitoring and improvement by means of internal audits and management reviews of the quality system. Any departures from normal operations must be approved by the responsible manager. The responsible manager must report to the appropriate tier of management. Job descriptions are on file.

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.

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 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 President, the QA Manager will be appointed deputy until the return of the President or until a replacement is made. In the event of extended absence of the QA Manager, the President will be appointed deputy until the return of the QA Manager or until a replacement is made.

4.2 Management System

4.2.1 Pi Tape 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 tension scales up to 10 pounds
Calibration of digital tapes

4.2.2 Our Quality Policy is as follows: "Pi Tape Texas, LLC is dedicated to providing 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 products continues to be evidenced by our unequalled longevity and success in our industry."

—Harold "Skip" Phillips, Jr., President

Our quality system includes written technical procedures and is used by technical personnel when carrying 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 14”.

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 (excluding section 5.4.6.2-3) 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 Calibration System Audit form and the Quality and Management System Review form.

The primary responsibility of the Quality Assurance Manager is to assure competence that our calibration department meets or exceeds the requirements stated in section 4.2.1 in addition to meeting our customer’s expectations, staying abreast of current methods and technology of metrology and to oversee all technical functions of our laboratories.

4.3 Document Control

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

4.3.2 All documents issued to personnel in the laboratory as part of our quality system is reviewed and approved 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 procedure manual titled “Quality Assurance Procedures Calibration Information”. The procedures are indicated with titles “Procedure 1” thru “Procedure 14”. Current revisions are kept in the system document file (Server/F/QA docs).

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.

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.

4.3.3 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.

4.4 Review of requests, tenders and contracts

4.4.1 Pi Tape has developed and maintains procedures for the review of requests, tenders and contracts. Every contract is to be acceptable to both Pi Tape and the customer. Any differences between the two 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.

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. Work is not outsourced by Pi Tape Texas.

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

4.5 Subcontracting of Tests and calibrations.

Pi Tape does not subcontract tests and/or calibrations.

4.6 Purchasing services and supplies

It is the policy of Pi Tape 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.

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 performs technical checks of critical consumables and supplies that are received. The required specifications are verified prior to usage. Pi Tape performs audits on critical services which directly affect the quality of calibration services we provide. Records of these audits and a list of those approved are maintained.

4.7 Service to our customers

Pi Tape affords our customers or their representatives' 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 gage customer satisfaction.

4.8 Complaints

It is the policy of Pi Tape 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 and are kept on file in the QA department.

4.9 Control of nonconforming calibration work

It is the policy of Pi Tape 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.

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.

4.10 Improvement

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

4.11 Corrective action

It is the policy of Pi Tape 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. Documentation and implementation of any required changes resulting from corrective action investigations are performed. 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.

4.12 Preventive action

Needed improvements and potential sources of nonconformance, either technical or concerning our quality system, are identified. If preventive action is required, an action plan is developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformance and to take advantage of the opportunity for improvement. Procedures for preventive action include the initiation of actions and application of controls to ensure that they are effective.

4.13 Control of records

4.13.1 Pi Tape 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 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.

4.13.2 Pi Tape retains records of original observations (where practical) derived data and sufficient 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 contains sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. 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.

4.14 Internal audits

Pi Tape periodically, and in accordance with predetermined schedule and procedure, conducts internal audits of our activities to verify that our operations continue to comply with the requirements of our quality system and to the requirements of ISO/IEC 17025. This internal audit addresses all elements of our quality system, including the calibration activities. The President is 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.

When audit finding 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.

4.15 Management reviews

In accordance with a predetermined schedule and procedure, Pi Tape 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. As a minimum, this review includes the suitability of policies and procedures, reports from managerial and supervisory personnel, the outcome of recent internal audits, corrective and preventive actions, assessments by external bodies, the results of interlaboratory comparisons or proficiency tests, changes in volume and type of work, customer feedback, any and all complaints, recommendations for improvement and other relevant factors such as quality control activities, resources and staff training.

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 our 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. If audit findings cast doubt on the validity of calibration results, the Laboratory shall immediately notify, in writing, any customer whose work may have been affected.

5 Technical Requirements

5.1 General

Many factors determine the correctness and reliability of our calibrations performed. These factors include contributions from human factors, accommodation and environmental conditions, calibration methods and method validation, equipment measurement traceability and the handling of calibration items (sampling is not performed). The extent to which these factors contribute to the total uncertainty of measurement can differ considerably between (types of) calibrations. Pi Tape has taken account of these factors in developing calibration methods and procedures, in the training and qualifications of personnel and in the selection and calibration of our equipment.

5.2 Personnel

Our laboratory management ensures the competence 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 on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

Management formulates the goals with respect to education, training and skills of technical personnel. It is the policy of Pi Tape 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 uses only personnel that are employed by us for all activities of our laboratory. We do not use contract employees or non-permanently employed personnel.

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.

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

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.

5.3 Accommodation and environmental conditions

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 insure 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.

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.

Separation between neighboring areas in which there are incompatible activities are priority and measures are taken to prevent cross-contamination. Access to and uses of areas affecting the quality of our calibrations are controlled to the extent of particular circumstances. Measures are taken to ensure good house keeping and special work instructions are prepared when necessary.

5.4 Calibration methods and method validation

5.4.1 Appropriate methods and procedures are used for all calibrations within our scope. These include handling, transport, storage and preparation of items to be calibrated, and where appropriate, an estimation of the measurement uncertainty as well as techniques for analysis of the calibration data. Method validation is documented on an annual basis.

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. All instructions, standards manuals, and reference data relevant to the work of Pi Tape is kept up to date and is readily available to our personnel. Deviation from calibration methods can occur only if the deviation has been documented, technically justified, authorized and accepted by the customer.

5.4.2 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 standard unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

5.4.3 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. Internally developed methods or methods adopted may also be used if they are appropriate for the intended use and have been validated. The customer is informed of the method chosen. Standard operating methods are confirmed before introducing a calibration. This method is repeated for confirmation should the standard change. Our customers are notified when the proposed method by the customer is considered to be inappropriate or out of date.

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.

5.4.4 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.

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.

5.4.5 Validation is the confirmation by examination and the provision of objective evidence that the particular 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 results obtained, the procedure used for the validation, and a statement as to whether the method is fit for intended use is recorded.

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.

5.4.6 Estimation of uncertainty of measurement

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 taken into account using appropriate methods of analysis.

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 taken into account when estimating the combined measurement uncertainty. The combined uncertainty will have at least a 3 to 1 ratio between the combined uncertainty and the item being calibrated.

The accuracy of the standards used to calibrate laboratory measurement and test equipment will have at least a 4 to 1 ratio between the standard and the item being calibrated. If the 4 to 1 ratio is not obtainable, the calibration cycle will be shortened. If the same standard is found out of tolerance a second time, the standard will be removed and/or labeled "Reference Only". If any doubts exist on the validity of calibration 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.

5.4.7 Control of data

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 sufficient detail and is suitably validated as being adequate for use. Procedures are established and implemented for protecting the data: such procedures include, nor 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.

5.5 Equipment

5.5.1 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. 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 excluding section 5.4.6.2-3 are still met.

5.5.2 Equipment and its software used for calibration are capable of achieving the accuracy required and comply with specifications relevant to the calibrations concerned. Calibration programs have been established for key quantities or values of the instruments where these properties have a significant effect on the results. 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.

5.5.3 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.

5.5.4 Each item of equipment and its software used for calibration and significant to the result, when practical, is uniquely identified.

5.5.5 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;
d) The current location, where appropriate;
e) The manufacturer's instructions (if available);
f) Dates, results and copies of reports and/or calibration reports, adjustments acceptance criteria and the due date of next calibration;
g) The maintenance plan, where appropriate, and the maintenance carried out to date;
h) Any damage, malfunction, modification or repair to the equipment;
i) Any limitations, or items not calibrated to their full capacity are identified to that condition.

5.5.6 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.

5.5.7 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.

5.5.8 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 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 calibration reports will be kept on file in the calibration department.

A system requiring mandatory recall of M&TE's has been established. On the first day of each month, our standards list (rolodex system) is checked to verify any standards that need to be recalled for that month.

5.5.9 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.

5.5.10 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.

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

5.5.12 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 Quality Manager's signature indicating approval for the extension.

5.6 Measurement traceability

5.6.1 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 has been established for the calibration of our equipment.

5.6.2 Our program for calibration of equipment is designed and operated so as 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 by the use of 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 are considered to be competent.

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 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.

5.6.3 Reference standards

A program and procedure is in place for the calibration of our reference standards. Reference standards are clearly marked “Reference Only”.

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

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.

5.7 Sampling

Sampling is not performed at this laboratory. All items are calibrated during final inspection.

5.8 Handling of test and calibration items

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.

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 so as 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.

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 sufficient detail.

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 have to 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.

5.9 Assuring the quality of test and calibration results

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, regular use of certified reference materials and/or internal quality control using secondary reference materials, participation in interlaboratory comparison or proficiency testing programs, replicate calibrations using the same or different methods, recalibration of retained items, and correlation or results for different characteristics of an item.

5.9.1 As a precautionary measure to insure the highest quality of accuracy, master tapes are used to verify the accuracy of our lead screws. This procedure is carried out and recorded at four month intervals. Master tapes are for manufactures use only. All precautionary measures are kept on file in the calibration department. 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.

5.10 Reporting the results

The results of each calibration or series of calibrations carried out by Pi Tape 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.

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 and the location where the calibrations were carried out;
c) Unique identification of the calibration report;
d) The name of the customer;
e) Identification of the method used;
f) A description of the condition of, and unambiguous identification of the item(s) calibrated;
g) The date of receipt of the calibration item(s) where this is critical to the validity and application of the results, and the date(s) of the performance of the calibration;
h) The calibration results with, where appropriate, the units of measure;
i) The names, functions and signatures or equivalent identification of the person(s) authorizing the calibration report;
j) The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
k) The uncertainty of measurement and/or statement of compliance with an identified metrological specification or clause there of;
l) Evidence that the measurements are traceable;
m) 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 are met.

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

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 complete new calibration report, the new report number is uniquely identified and with reference to the original it replaces.

Date	Revision	Page/Section	Description	Initials of person updating this revision
12/12/08	A	6	updated 4.13.1 Accessing records	DDS
01/29/09	B	12	updated 5.7 Added informational statement under Sampling section	DDS
02/05/09	C	11	updated 5.5.7 Changed wording regarding non-conforming work procedures	DDS
02/18/09	D	Cover, Index 1, 2, 4, 10	added “excluding section 5.4.6.2-3” where ISO/IEC 17025:2005 is referenced	DDS
		10	updated 5.4.6 paragraph 1 Changed Procedures to Methods	
		10	updated wording 5.5.3 Employee training	
		11	updated wording 5.5.12 Due Date extension memo	
		12	updated wording 5.6.3 Reference Standards	
07/15/10	E	5	updated 4.6 updated wording regarding checking the thickness of steel	DDS
12/23/10	F	5	updated 4.6 paragraph 2, changed the word *evaluate* to *audit* on 2 occurrences	DDS
07/29/11	G	3	updated 4.2.1 added digital tapes to scope	DDS
09/20/12	H	8	added annual eye examination requirements	DDS
01/17/13	I	1	added ANSI/NCSL Z540-3-2006 standard	DDS
03/27/14	J	Cover 13	added Texas location 5.9.1 added corrective action procedure	DDS
06/25/15	K	Cover	Change of Administration address in CA	DDS
04/07/16	L	Cover, 1, 2, 3, 5	change company name, added wording to specify Admin & Mfg locations	DDB

Date	Revision	Page/Section	Description	Initials of person updating this revision
04/07/16	L	2	change address, when referring to Identifiable business	DDB
04/03/17	M	Cover	Update manufacturing plant phone number. Changed Admin. Office name to Remit to.	CMP
05/02/17	N	QA Manual	Reset margins to match Index page numbering.	DDB
		3 / 4.2.2	Replaced Quality Policy	DDB
05/22/18	O	Cover	deleted Remit to address; removed the words "Manufacturing Plant:"	DDB
		4	added the full title of Procedures along with adding a 14th procedure (2 places).	DDB
		4	removed the word "share" at end of para. 5	DDB
		5 / 4.6	added wording to clarify information regarding critical consumables, supplies, services.	DDB
		8	fixed typographical error at end of 4th para.	DDB

End of manual.