Cal-Tek Company

An ATS Company

# Quality Management System

# Chapter 2

# Quality Manual

**UNCONTROLLED DOCUMENT IF PRINTED**

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# 1. Purpose, Scope, and Responsibilities

The purpose of this manual is to provide a document that defines the basis for the Quality Management System that is used at Cal-Tek Company (Cal-Tek). Our Quality Management System is designed to meet the requirements of ISO/IEC 17025:2017 and ANSI/NCSL Z540-1-1994 (R2002) and is used to promote customer satisfaction by preventing nonconformity at all stages of providing calibration and repair services to our customers.

This manual and the system it defines applies to all activities within the company that have an effect on calibration or repair service quality.

It is the paramount responsibility of the Quality Manager under the direct supervision of the Operations Director to implement and dynamically supervise all aspects of the Cal-Tek quality system to ensure that the requirements of the Quality Manual are being met, and to ensure that the client and regulatory authorities or organizations are satisfied. Effective quality control is not a task-specific function; it is an integral part of all management activity and process planning.

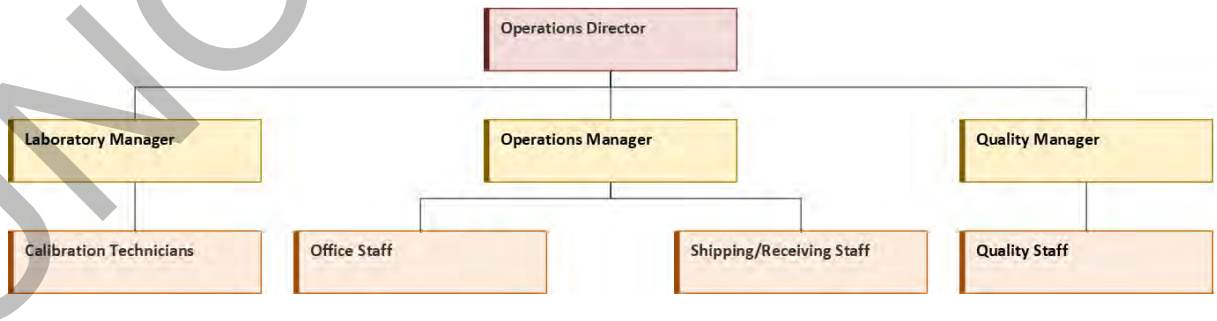
## 1.1. Quality Manual Approval

The Cal-Tek Quality Manager, under the authority of the Operations Director, is responsible for the preparation, approval, revision, and distribution of this document. Initial release and revision of this document requires approval by the Operations Director and Quality Manager.

| Name | Title | Signature |
|---|---|---|
| Tim Cooke | Operations Director | Tim Cooke<br>Digitally signed by Tim Cooke<br>Date: 2025.08.05 11:35:27 -04'00' |
| Steven Donovan | Quality Manager | Steven Donovan<br>Digitally signed by Steven Donovan<br>Date: 2025.08.05 11:07:59 -04'00' |

## 1.2. Organization Chart

A full organization chart with the names of management as well as Cal-Tek's place in its parent organization (ATS) can be found in **Chapter 7 (Addendum)**.



## 1.3. Quality Policy Statement

Quality and continuous improvement are the basic operating principles for Cal-Tek Company. Knowing and understanding the requirements of our customers and suppliers and consistently meeting or exceeding those requirements is our main objective and the responsibility of every Cal-Tek employee. All Cal-Tek employees are required to read and understand the quality documentation and implement the policies and procedures in their work. The management of Cal-Tek is committed to compliance with ISO/IEC 17025:2017 and ANSI/NCSL Z540-1-1994 (R2002) and to continually improve the effectiveness of the management system.

## 1.4. Quality Objectives

Cal-Tek Company is committed to a Quality Management System that will ensure customer satisfaction and provide continuous improvement and value for its customers.

Measurable objectives are:

- Provide our customers with exceptional services.
- Provide these services on time in the best possible way.
- Provide totally open communications with our customers in order to better understand and meet their needs.
- Provide our customers with services that contribute to a safer and more reliable world.

# 2. References

- **ISO/IEC 17025:2017**: General requirements for the competence of testing and calibration laboratories.
- **ISO/IEC 17000:2020**: Conformity assessment – Vocabulary and general principles.
- **ISO/IEC Guide 99:2007**: International vocabulary of metrology – Basic and general concepts and associated terms (VIM).
- **ANSI/NCSL Z540-1-1994 (R2002)**: Calibration Laboratories and Measuring and Test Equipment – General Requirements.
- **A2LA R205**: Specific Requirements – Calibration Laboratory Accreditation Program.
- **A2LA P102**: Policy on Metrological Traceability.
- **A2LA R103**: General Requirements – Proficiency Testing for ISO/IEC 17025 Laboratories.
- **A2LA R105**: Requirements When Making Reference to A2LA Accredited Status.
- **ILAC P14:09/2020**: Policy for Uncertainty in Calibration.

# 3. Terms and definitions

3.1. **Assessment**: An evaluation process including a documented review, an on-site audit and an analysis and report.

3.2. **ATS**: Applied Technical Services, LLC. Cal-Tek's parent company.

3.3. **Audit**: An on-site verification activity based upon a sample used to determine the effective implementation of a supplier's documented quality system.

3.4. **Calibration**: A set of operations which compare values taken from a piece of inspection, measuring and test equipment or a gage to a known standard under specified conditions.

3.5. **Calibration Procedure**: A defined process for the review and adjustment of equipment. Synonymous with "Method" as defined by ISO 17025.

3.6. **Client**: A company or organization that is provided with a product and/or service. May also be referred to as "Customer" in this document.

3.7. **Corrective Action**: The reactive process used to identify and resolve deficiencies in the product, process or Quality Management System.

3.8. **Customer Property**: It is any tooling, fixturing and/or measuring and test equipment that are owned by the customer. It is any product that is provided by the customer that may be modified and/or assembled into the final product. Customer supplied products may be items that are used to carry and/or protect the final product through the process and on to the final destination. Customer Property may include intellectual property information that is provided in confidence.

3.9. **Documents**: Material (typically paper or electronic) defining the process to be followed.

3.10. **Environment**: Environment is all the process conditions surrounding or affecting the manufacture and quality of a part or product. The environment will vary for each site, but generally it includes housekeeping, lighting, noise, HVAC, ESD control and safety hazards relating to housekeeping.

3.11. **Impartiality**: Objectivity (freedom of bias) regarding the outcome of laboratory activities. *[ISO/IEC 17000:2020]*

3.12. **Internal Quality Audit**: An audit of those portions of the company's Quality Management System retained under its direct control and within its structure.

3.13. **Management Representative**: A member of management who, irrespective of other responsibilities has been appointed to manage and maintain the Quality Management System.

3.14. **Management Review**: The period review, by top management, of the Quality Management System.

3.15. **Nonconforming Product**: Any product that does not meet the defined acceptance criteria.

3.16. **Preventive Action**: The proactive process used to identify and resolve potential and/or suspect deficiencies in the product, process, or Quality Management System.

3.17. **Procedure**: Documented processes that are normally used when work affects more than one function or department of an organization. Procedures are considered to be Level II Quality Management System documents.

3.18. **Quality Management System**: The organizational structure, responsibility, procedures, processes and resources for implementing quality management.

3.19. **Quality Manual**: The document that describes the clauses of the Quality Management System used to assure customer requirements, needs, and expectations are met.

3.20. **Raw Data**: Test data that is generated or taken by the technician/analyst at the time the test is being run. It is generally not edited or manipulated in any fashion.

3.21. **Records**: Any record or data that is generated in accordance with the Quality Management System.

3.22. **Repair**: action taken on nonconforming product so that the product will fulfill the intended usage although the product may not conform to the original requirements.

3.23. **Rework**: Action taken on nonconforming product so that it will meet the specified requirements.

3.24. **Site**: A supplier, subcontractor, or client's location at which value-added production processes occur.

3.25. **Supplier**: An organization that provides product and/or service.

3.26. **CAPA**: Acronym for Corrective Actions and Preventive Actions.

3.27. **Met/Team**: Asset management software developed by Fluke Calibration.

3.28. **Service Level**: The level of documentation required by the customer.

3.28.1. **ISO 9001 Service**: Includes a certificate of calibration with a listing of SI traceable standards used. As found and as left data is only provided for items that are received out of tolerance.

3.28.2. **Calibration with Data**: As found and as left data is provided for all calibrations performed at this service level.

3.28.3. **Accredited Calibration with Data**: Meets all requirements of ISO/IEC 17025:2017. Measurement uncertainties are reported and the certificate displays the accreditation symbol provided by our accrediting body.

# 4. General requirements

## 4.1. Impartiality

4.1.1. Cal-Tek's calibration activities are undertaken impartially and structured and managed to safeguard impartiality.

4.1.2. The management of Cal-Tek is committed to impartiality. Examples of this include the **Confidentiality and Impartiality Form (F320-1)**, as well as ATS's Purpose, Mission, and Values ("Do What's Right").

4.1.3. Cal-Tek is responsible for the impartiality of its calibration activities and does not allow commercial, financial or other pressures to compromise impartiality.

4.1.4. Cal-Tek identifies risks to its impartiality on an on-going basis as part of the **Management Review procedure (QP105)**. This includes those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present Cal-Tek with a risk to impartiality.

4.1.5. If a risk to impartiality is identified, Cal-Tek is able to demonstrate how it eliminates or minimizes such risk. This may be achieved through means such as the **Management Review procedure (QP105)** or **the Corrective Action/Preventive Action procedure (QP190)**.

4.1.6. Cal-Tek Company is a subsidiary of Applied Technical Services, LLC (ATS). Cal-Tek's day-to-day operations and quality management system are managed autonomously from ATS. This allows key personnel total freedom and eliminates any form of real or potential conflict of interest.

## 4.2. Confidentiality

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

4.2.2. When Cal-Tek is required by law or authorized by contractual arrangements to release confidential information, the customer or individual will, unless prohibited by law, be notified of the information provided.

4.2.3. Information about the customer obtained from sources other than the customer (e.g. complainant regulators) will be confidential between the customer and Cal-Tek. The provider (source) of this information will be confidential to Cal-Tek and will not be shared with the customer unless agreed by the source.

4.2.4. Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on Cal-Tek's behalf, will keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

4.2.4.1. Cal-Tek personnel are required to read and sign **F320-1 (Confidentiality and Impartiality Agreement)**.

# 5. Structural requirements

5.1. CALTEK-2000, LLC dba Cal-Tek Company can be held legally responsible for all actions taken. Cal-Tek is located at 20 Republic Rd, North Billerica, MA 01862. Cal-Tek is a subsidiary of Applied Technical Services, LLC, headquartered at 1049 Triad Ct, Marietta, GA 30062.

5.2. Cal-Tek has identified management that has overall responsibility for the laboratory in its Organization Chart (see 1.2 or **Chapter 7 (Addendum)**).

5.3. The range of calibration services for which Cal-Tek conforms with ISO/IEC 17025:2017 is documented in the Scope of Accreditation provided by A2LA. Cal-Tek only claims conformity with ISO/IEC 17025:2017 for this range of calibration services, which excludes externally provided calibration services on an ongoing basis.

5.4. Calibration activities are carried out in such a way as to meet the requirements of the Quality Manual, ISO/IEC 17025:2017, A2LA requirements, and the laboratory's customers. This includes calibration activities performed in Cal-Tek's laboratory and at customer facilities.

5.5. Cal-Tek has:

(a) Defined the organization and management structure of the laboratory, its place in its parent organization (ATS), and the relationships between management, technical operations and support services in its Organization Chart (see 1.2 or **Chapter 7 (Addendum)**).

(b) Specified the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of calibrations in **Chapter 6 (Job Descriptions)**.

(c) Documented its procedures in **Chapters 3 (Quality Procedures) and 5 (Calibration Procedures)**, to the extent necessary to ensure the consistent application of its laboratory activities and the validity of its results.

5.6. Cal-Tek has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

(a) Implementation, maintenance, and improvement of the quality management system.

(b) Identification of deviations from the management system or from the procedures for performing calibration activities.

(c) Initiation of **Corrective or Preventive Actions (QP190)** to prevent or minimize such deviations.

(d) Reporting to Cal-Tek management on the performance of the management system and any need for improvement.

(e) Ensuring the effectiveness of calibration activities.

5.7. Cal-Tek management ensures that:

(a) Communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements. Management review meetings (**QP105**) are the primary method of achieving this.

(b) The integrity of the management system is maintained when changes to the management system are planned and implemented.

# 6. Resource requirements

## 6.1. General

Cal-Tek ensures that it has the personnel, facilities, equipment, systems, and support services necessary to manage and perform its calibration activities.

## 6.2. Personnel

6.2.1. All personnel of Cal-Tek that could influence its calibration activities act impartially (see 4.1), are competent and work in accordance with Cal-Tek's quality management system.

6.2.2. Cal-Tek documents the competence requirements for each function influencing the results of calibration activities in **Chapter 6 (Job Descriptions)**, including requirements for education, qualification, training, technical knowledge skills, and experience.

6.2.3. Cal-Tek ensures that personnel have the competence to perform calibration activities for which they are responsible and to evaluate the significance of deviations.

6.2.4. Cal-Tek's management communicates to personnel their duties, responsibilities, and authorities.

6.2.5. Cal-Tek has a **Training Procedure (QP270)** and retains records on **F270-1 (Training Record)** for:

(a) Determining the competence requirements.

(b) Selection of personnel.

(c) Training of personnel.

(d) Supervision of personnel.

(e) Authorization of personnel.

(f) Monitoring competence of personnel.

6.2.6. Cal-Tek authorizes personnel to perform specific calibration activities, including but not limited to, the following:

(a) Development, modification, verification and validation of calibration procedures.

(b) Analysis of results, including statements of conformity.

(c) Report, review and authorization of results.

6.2.7. Our training effectiveness is evidenced by the use of Appraiser Variation Studies, Intermediate Testing and Proficiency Testing.

## 6.3. Facilities and environmental conditions

6.3.1. The facilities and environmental conditions at Cal-Tek's laboratory (20 Republic Road, North Billerica, MA 01862) are suitable for calibrations and do not adversely affect the validity of results.

6.3.2. The requirements for facilities and environmental conditions necessary for the performance of calibrations are documented in **QS400 (Environment)**.

6.3.3. Cal-Tek monitors, controls, and records environmental conditions in accordance with relevant specifications, methods, or procedures or where they influence the validity of results.

6.3.4. Measures to control facilities are implemented, monitored, and periodically reviewed and include, but are not limited to:

(a) Access to and use of areas affecting calibration activities.

(b) Prevention of contamination, interference or adverse influences on calibrations.

(c) Effective separation between areas with incompatible calibration disciplines.

6.3.5. When Cal-Tek performs calibrations at sites or facilities outside its permanent control, it ensures that the requirements related to facilities and environmental conditions of ISO/IEC 17025 and Cal-Tek's quality management system are met. At customer sites or facilities that do not meet the requirements of **QS400 (Environment)**, Cal-Tek receives written consent from the customer to proceed with calibrations via **Report R215-1 (Conditions Waiver)**.

## 6.4. Equipment

6.4.1. Cal-Tek has access to equipment (including but not limited to measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) that is required for the correct performance of calibration activities and that can influence the results.

6.4.2. When Cal-Tek uses equipment outside its permanent control, such as rental equipment, it ensures that the requirements for equipment of ISO/IEC 17025 and Cal-Tek's quality management system are met.

6.4.3. Cal-Tek has a **Handing and Storage procedure (QP230)**, for handling, transport, storage, use and planned maintenance of equipment to ensure proper function and to prevent contamination or deterioration.

6.4.4. Cal-Tek verifies that equipment conforms to specified requirements before being placed or returned into service.

6.4.5. Cal-Tek verifies that the equipment used for measurements are capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6. Measuring equipment is calibrated when:

- The measurement accuracy or measurement uncertainty affects the validity of the required results, and/or
- Calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7. Cal-Tek has established a calibration program in accordance with **QP220 (Calibration of Cal-Tek Equipment)**, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8. All equipment requiring calibration or which has a defined period of validity is labelled to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.9. Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, will be taken out of service. It will be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. Cal-Tek examines the effect of the defect or deviation from specified requirements and initiates the **Nonconformance procedure (QP225)** (see 7.10).

6.4.10. When intermediate checks are necessary to maintain confidence in the performance of equipment, these checks are carried out according to the **Intermediate Testing procedure (QP440)**. Our interval for this testing is every 90 days for most items.

6.4.11. When calibration and reference material data include reference values or correction factors, Cal-Tek ensures that the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12. Cal-Tek utilizes **Void Seals (QP460)** to prevent unintended adjustments of equipment from invalidating results.

6.4.13. Records are maintained in Met/Team for equipment which can influence the results of calibrations. The records include the following, where applicable:

(a) The identity of equipment, including software and firmware version.

(b) The manufacturer's name, type identification, and serial number or other unique identification.

(c) Evidence of verification that equipment conforms with specified requirements.

(d) The current location.

(e) Calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval.

(f) Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity.

(g) The maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment.

(h) Details of any damage, malfunction, modification to, or repair of, the equipment.

## 6.5. Metrological traceability

6.5.1. Cal-Tek establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty linking them to an appropriate reference.

6.5.2. Cal-Tek ensures through our **Metrological Traceability procedure (QP530)** that measurement results are traceable to the International System of Units (SI) through one of the following:

(a) A calibration provided by a competent laboratory (e.g. accredited to ISO/IEC 17025).

(b) Certified values of certified reference materials provided by a competent producer (e.g. accredited to ISO 17034) with stated metrological traceability to the SI.

(c) Direct realization of the SI units ensured by comparison, directly or indirectly with national or international standards.

6.5.3. When metrological traceability to the SI units is not technically possible, Cal-Tek demonstrates metrological traceability to an appropriate reference, e.g.:

(a) Certified values of certified reference materials provided by a competent producer.

(b) Results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

## 6.6. Externally provided products and services

6.6.1. Cal-Tek ensures that only suitable externally provided products and services that affect calibration activities are used when such products and services:

(a) Are intended for incorporation into Cal-Tek's own activities.

(b) Are provided, in part or in full, directly to the customer by Cal-Tek, as received by the external provider.

(c) Are used to support the operation of the calibration laboratory.

6.6.2. Cal-Tek has a procedure, **QP310 (Supplier Assessment)**, and retains records on **F310-1 (Supplier Assessment Questionnaire)** and **R140-1 (Approved Supplier List)** for

(a) Defining, reviewing, and approving Cal-Tek's requirements for externally provided products and services.

(b) Defining the criteria for evaluation, selection, monitoring of performance, and re-evaluation of external providers.

(c) Ensuring that externally provided products and services conform to Cal-Tek's established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025 and ANSI/NCSL Z540-1, before they are used or directly provided to the customer.

(d) Taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3. Cal-Tek communicates its requirements to external providers for:

(a) The products and services to be provided.

(b) The acceptance criteria.

(c) Competence, including any required qualification of personnel.

(d) Activities that Cal-Tek or its customer intends to perform at the external provider's premises.

6.6.4. It is the policy of Cal-Tek Company that materials (reagents) be sourced from recognized suppliers and be appropriately labeled for the safety of our employees (as further defined in **QP310**).

# 7. Process requirements

## 7.1. Review of requests, tenders and contracts

7.1.1. Cal-Tek has a procedure, **CP100 "Contract Review"**, for the review of requests, tenders, and contracts. This procedure ensures that:

(a) The requirements are adequately defined, documented, and understood.

(b) That Cal-Tek has the capability and resources to meet the requirements.

(c) Where external providers are used, the requirements of 6.6 are applied and Cal-Tek advises the customer of the specific calibrations or other services to be performed by the external provider and gains the customer's approval.

(d) The appropriate calibration procedures are selected and are capable of meeting the customers' requirements.

7.1.2. Cal-Tek informs the customer when the calibration procedure requested by the customer is considered to be inappropriate or out of date.

7.1.3. When the customer requests a statement of conformity to a specification or standard for the calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected is communicated to, and agreed with, the customer.

7.1.4. Any differences between the request or tender and the contract will be resolved before calibration work commences. Each contract will be acceptable both to Cal-Tek and the customer. Deviations requested by the customer will not have an impact on the integrity of Cal-Tek or the validity of results.

7.1.5. The customer will be informed of any deviation from the contract.

7.1.6. If a contract is amended after work has commenced, the contract review will be repeated, and any amendments will be communicated to all affected personnel.

7.1.7. Cal-Tek will cooperate with customers or their representatives in clarifying the customer's request and in monitoring Cal-Tek's performance in relation to the work performed.

7.1.8. Records of reviews, including any significant changes, are retained on **Form F100D "Contract Review Data Sheet"**. Records are also retained of pertinent discussions with a customer relating to the customer's requirements or the results of calibrations.

## 7.2. Selection, verification and validation of methods

### 7.2.1. Selection and verification of methods

7.2.1.1. Cal-Tek uses appropriate methods and procedures for all calibrations and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

7.2.1.2. All methods, procedures, and supporting documentation, such as instructions, standards, manuals and reference data relevant to performing calibrations, are kept up to date and are made readily available to personnel in accordance with **QP120 "Document Control"**.

7.2.1.3. Cal-Tek ensures that it uses the latest valid version of a calibration procedure unless it is not appropriate or possible to do so. When necessary, the application of the calibration procedure is supplemented with additional details to ensure consistent application.

7.2.1.4. When the customer does not specify the calibration procedure to be used, Cal-Tek selects an appropriate calibration procedure and informs the customer of the calibration procedure chosen. Calibration procedures 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, are recommended. Cal-Tek developed or modified methods can also be used.

7.2.1.5. Cal-Tek verifies that it can properly perform calibration procedures before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the calibration procedure is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.6. When calibration procedure development is required, it is a planned activity and is assigned to competent personnel equipped with adequate resources. As calibration procedure development proceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan are approved and authorized.

7.2.1.7. Deviations from calibration procedures 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. Cal-Tek validates non-standard calibration procedures, internally developed calibration procedures, and standard calibration procedures used outside their intended scope or otherwise modified. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.2. When changes are made to a validated calibration procedure, the influence of such charges is determined and where they are found to affect the original validation, a new validation is performed.

7.2.2.3. The performance characteristics of validated calibration procedures, as assessed for the intended use, are relevant to the customers' needs and consistent with specified requirements.

7.2.2.4. Cal-Tek retains the following records of validation:

(a) The validation procedure used (**QP470 "Validation of Procedures"**).

(b) Specification of the requirements.

(c) Determination of performance characteristics of the calibration procedure.

(d) Results obtained.

(e) A statement on the validity of the calibration procedure, detailing its fitness for the intended use.

## 7.3. Sampling

Cal-Tek does not presently perform sampling of substances, materials or products as defined by this term.

## 7.4. Handing of calibration items

7.4.1. Cal-Tek has a procedure, **CP230 "Handling and Storage"**, for the transportation, receipt, handling, protection, storage, retention, and disposal or return of calibration items, including all provision necessary to protect the integrity of the calibration items, and to protect the interests of Cal-Tek and the customer. Precautions are taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for calibration. Handling instructions provided with the item are followed.

7.4.2. Cal-Tek has a system for the unambiguous identification of calibration items. The identification is retained while the item is under Cal-Tek's responsibility. The system ensures that items are not confused physically or when referred to in records or other documents. If necessary, the system can accommodate a sub-division of an item or groups of items and the transfer of items.

7.4.3. Upon receipt of a calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for calibration, or when an item does not conform to the description provided, Cal-Tek consults with the customer for further instructions, as defined in procedure **QP340 "Control of Customer Property"**, before proceeding and records the results of this consultation. When the customer requires the item to be calibrated acknowledging a deviation from specified conditions, Cal-Tek includes a disclaimer in the report indicating which results may be affected by the deviation.

7.4.4. When items need to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded.

## 7.5. Technical records

7.5.1. Cal-Tek ensures that technical records for each calibration 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 calibration under conditions are close as possible to the original. The technical records include the date and identity of personnel responsible for each calibration and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

7.5.2. Cal-Tek ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files are retained, 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. Cal-Tek identifies the contributions to measurement uncertainty in accordance with **QP350 "Estimation of Measurement Uncertainty"**. When evaluating measurement uncertainty, all contributions that are of significance are taken into account using appropriate methods of analysis. Calibrations resulting in TURs of less than 4:1 will be reported to the customer.

7.6.2. Cal-Tek evaluates measurement uncertainty for all calibrations performed at the "Accredited Calibration with Data" service level. This includes all calibrations of Cal-Tek owned equipment.

## 7.7. Ensuring the validity of results

7.7.1. Cal-Tek has a procedure, **QP440 "Intermediate Testing / Process Monitoring and Verification"**, for monitoring the validity of results. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but is not limited to:

(a) Use of reference materials or quality control materials.

(b) Use of alternative instrumentation that has been calibrated to provide traceable results.

(c) Function check(s) of measuring equipment.

(d) Use of check or working standards with control charts, where applicable.

(e) Intermediate checks on measuring equipment.

(f) Replicating calibrations using the same or different procedures.

(g) Recalibration of retained items.

(h) Correlation of results for different characteristics of an item.

(i) Review of reported results.

(j) Interlaboratory comparisons.

7.7.2. Cal-Tek monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but may not be limited to, either or both of the following:

(a) Participation in proficiency testing.

(b) Participation in interlaboratory comparisons other than proficiency testing.

7.7.2.1. Proficiency testing (PTs) is performed in accordance with **QP445 "Proficiency Testing"**.

7.7.3. Data from monitoring activities is analyzed, used to control and, if applicable, improve Cal-Tek's calibrations. If the results or the analysis of data from monitoring activities is found to be outside pre-defined criteria, appropriate action is taken to prevent incorrect results from being reported.

## 7.8. Reporting of results

### 7.8.1. General

7.8.1.1. Results are reviewed and authorized per **QP490** prior to release.

7.8.1.2. Results are provided accurately, clearly, unambiguously, and objectively, usually in a certificate of calibration, and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the calibration procedure used. All issued calibration certificates are retained as technical records.

7.8.1.3. When agreed with the customer, the results may be reported in a simplified way. Any information listed from 7.8.2 to 7.8.7 that is not reported to the customer is readily available.

7.8.1.4. Cal-Tek has controls in place to include reviewing and signing of all calibration reports by quality personnel. Quality personnel have been trained in the analyses of calibration reports and calibration data to ensure results are not reported outside pre-defined criteria. The calibration reporting software currently in use also has built in report criteria and will not print reports with data outside the pre-defined criteria as having passed calibration.

### 7.8.2. Common requirements for calibration certificates

7.8.2.1. Each calibration certificate includes at least the following information, unless Cal-Tek has valid reasons for not doing so, thereby minimizing any possibility of understanding or misuse.

(a) A title (e.g. "Certificate of Calibration").

(b) The name and address of the laboratory.

(c) The location of the performance of the calibration, including when performed at a customer facility or at sites away from Cal-Tek's permanent facility, or in associated temporary or mobile facilities.

(d) Unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end.

(e) The name and contact information of the customer.

(f) Identification of the calibration procedure used.

(g) A description, unambiguous identification, and, when necessary, the condition of the unit under test.

(h) The date of receipt of the unit under test, where this is critical to the validity and application of the results.

(i) The date of performance of the calibration.

(j) The date of issue of the report.

(k) A statement that the certificate shall not be reproduced except in full, without the written approval of Cal-Tek.

(l) A statement to the effect that results relate only to the items calibrated.

(m) The results with, where appropriate, the units of measurement. This excludes items calibrated to the "ISO 9000" service level that are received in tolerance. The results are supported by tables, graphs, sketches and photographs as appropriate and any failures identified.

(n) Additions to, deviations, or exclusions from the calibration procedure.

(o) Identification of the person(s) authorizing the calibration certificate.

(p) Clear identification when results are from external providers.

7.8.2.2. Cal-Tek is responsible for all information provided in the calibration certificate, except when information is provided by the customer. Data provided by a customer is clearly identified. In addition, a disclaimer will be put on the report when the information is supplied by the customer and can affect the validity of results.

7.8.2.3. When calibration certificates include the A2LA symbol, they shall comply with the requirements of **A2LA R105**. Prior to issuance, such certificates shall be reviewed per **QP400** or **QP410**.

7.8.2.3.1. When forms are designed to include the A2LA symbol, such forms shall be designed with Quality Manager supervision to ensure proper symbol usage per **A2LA R105**.

7.8.2.4. It is the policy of Cal-Tek Company not to perform accredited calibrations or use an accrediting body symbol on calibrations that do not have measurement uncertainty reported on accredited parameters.

### 7.8.3. Specific requirements for test reports

Cal-Tek does not issue test reports.

### 7.8.4. Specific requirements for calibration certificates

7.8.4.1. In addition to the requirements listed in 7.8.2, calibration certificates include the following:

(a) For calibration performed at the "Accredited Calibration with Data" service level, the measurement uncertainty of the measurement result presented in the

same unit as that of the measurand or in a term relative to the measurand (e.g., percent).

(b) The conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results.

(c) A statement identifying how the measurements are metrologically traceable.

(d) The results before and after any adjustment or repair, if available.

(e) Where relevant, a statement of conformity with requirements or specifications.

(f) Special limitations of use.

7.8.4.2. A calibration certificate or calibration label does not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

7.8.4.3. When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, will be reported. In cases where adjustment is not possible a *"Limited Calibration"* certificate and calibration label will be issued.

### 7.8.5. Reporting sampling – specific requirements

Cal-Tek does not perform sampling.

### 7.8.6. Reporting statements of conformity

7.8.6.1. When a statement of conformity to a standard is provided, Cal-Tek documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and applies the decision rule.

7.8.6.2. Cal-Tek reports on the statement of conformity, such that the statement clearly identifies:

(a) To which results the statement of conformity applies.

(b) Which specifications, standards or parts thereof are met or not met.

(c) The decision rule applied (unless it is inherent in the requested specification or standard).

### 7.8.7. Reporting opinions and interpretations

Cal-Tek does not provide opinions and interpretations on its calibration certificates.

### 7.8.8. Amendments to calibration certificates

7.8.8.1. When an issued calibration certificate needs to be changed, amended or re-issued, any change of information is clearly identified and, where appropriate, the reason for the change included in the calibration certificate.

7.8.8.2. Amendments to a calibration certificate after issue are made only in the form of a further document, or data transfer, which includes the statement "Amendment to Calibration Certificate, certificate number…", or an equivalent form of wording. Such amendments meet all the requirements of ISO/IEC 17025.

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

## 7.9. Complaints

7.9.1. Cal-Tek has a documented process, **QP480 "Complaints"**, to receive, evaluate and make decisions on complaints. It is the policy of Cal-Tek Company that complaints received from customers and other parties be reviewed and addressed per **QP480** or **QP190**, and that appropriate preventative and/or corrective action be taken consistent with our objectives outlined in our Quality Policy Statement (see 1.3), and **QP225**.

7.9.2. A description of the handling process for complaints will be made available to any interested party on request. Upon receipt of a complaint, Cal-Tek confirms whether the complaint relates to calibrations that it is responsible for and if so, deals with it. Cal-Tek is responsible for all decisions at all levels of the handling process for complaints.

7.9.3. The process for handling complaints includes at least 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. Cal-Tek is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5. Whenever possible, Cal-Tek acknowledges receipt of the complaint, and provides the complainant with progress reports and the outcome.

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

7.9.7. Whenever possible, Cal-Tek gives formal notice of the end of the complaint handling process to the complainant.

## 7.10. Nonconforming work

7.10.1. Cal-Tek has a procedure, **QP225 "Nonconformance"**, that is implemented when any aspect of its calibration activities or results of this work do not conform to its

own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are outside of specified limits, results of monitoring fail to meet specified criteria). This procedure ensures that:

(a) The responsibilities and authorities for the management of nonconforming work are defined.

(b) Actions (including halt or repeating of work and withholding reports, as necessary) are based upon the risk levels established by Cal-Tek.

(c) An evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results.

(d) A decision is taken on the acceptability of the nonconforming work.

(e) Where necessary, the customer is notified **promptly**, and work is recalled.

(f) The responsibility for authorizing the resumption of work is defined.

7.10.2. Cal-Tek retains records of nonconforming work and actions on **R190-1 "Nonconformance log"**.

7.10.3. Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of Cal-Tek's operations with its own management system, Cal-Tek implements corrective action.

7.10.4. It is the policy of Cal-Tek Company that any nonconformance shall be addressed per **QP225**, and that appropriate action is taken consistent with our objectives outlined in our Quality Policy Statement (see 1.3). When a nonconformance is observed by any Cal-Tek employee (including but not limited to environmental conditions outside limits specified in **QS400**), that employee has the responsibility to notify a supervisor and/or the Quality Manager and to halt further calibration work until the nonconformance has been addressed by the Quality Manager or Operations Director. Work may only be resumed with the permission of the Quality Manager or Operations Director.

## 7.11. Control of data and information management

7.11.1. Cal-Tek has access to the data and information needed to perform calibrations.

7.11.2. The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data is validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by Cal-Tek before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they are authorized, documented, and validated before implementation.

7.11.3. The laboratory information management system(s) are:

(a) Protected from unauthorized access.

(b) Safeguarded against tampering and loss.

(c) Operated in an environment that complies with provider or laboratory specifications, or in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription.

(d) Maintained in a manner that ensures the integrity of the data and information.

(e) Capable of recording system failures and the appropriate immediate and corrective actions.

7.11.4. When a laboratory information management system is managed and maintained off-site or through an external provider, Cal-Tek ensures that the provider or operator of the system complies with all applicable requirements of ISO/IEC 17025.

7.11.5. Cal-Tek ensures 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 are checked in an appropriate and systematic manner.

## 7.12. Out of Tolerance conditions

7.12.1. Client out-of-tolerance conditions will include the size of error, and an out-of-tolerance report will be issued to the client. This report will be **written** in the form of a service report with the error conditions noted and **promptly provided to the customer**.

# 8. Management system requirements

## 8.1. General

8.1.1. Cal-Tek has established, documented, and maintains a management system that can support and document the consistent achievement of the requirements of ISO/IEC 17025, ANSI/NCSL Z540-1 as well as A2LA requirements. The management system is also capable of assuring the quality of calibration results.

8.1.2. Cal-Tek's management system addresses the following:

- Management system documentation (see 8.2).
- Control of management system documents (see 8.3).
- Control of records (see 8.4).
- Actions to address risk and opportunities (see 8.5).

- Improvement (see 8.6).
- Corrective actions (see 8.7).
- Internal audits (see 8.8).
- Management reviews (see 8.9).

8.1.3. Cal-Tek's management system complies with "Option A" as defined by ISO/IEC 17025:2017.

## 8.2. Management system documentation

8.2.1. Cal-Tek's management has established, documented, and maintains policies and objectives for the fulfillment of ISO/IEC 17025 and ensures that the policies and objectives are acknowledged and implemented at all levels of the organization.

8.2.2. The policies and objectives address the competence, impartiality and consistent operation of the laboratory.

8.2.3. Cal-Tek's management will provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4. All documentation, processes, systems, records, related to the fulfillment of the requirements of ISO/IEC 17025, are included in, referenced from, or linked to the management system.

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

## 8.3. Control of management system documents

8.3.1. Cal-Tek controls the documents (internal and external) that relate to the fulfillment of ISO/IEC 17025, A2LA requirements, and Cal-Tek's management system. **QP120** defines Cal-Tek's Document Control procedure.

8.3.2. Cal-Tek ensures that:

(a) Documents are approved for adequacy prior to issue by authorized personnel.

(b) Documents are periodically reviewed and updated as necessary.

(c) Changes and the current revision status of documents are identified.

(d) Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled.

(e) Documents are uniquely identified.

(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. Cal-Tek establishes and retains legible records to demonstrate fulfillment of the requirements of ISO/IEC 17025 and the management system. **QP130** defines Cal-Tek's Records Control procedure.

8.4.2. Cal-Tek has implemented the controls needed for the identification, storage, protection, back-up, archive-, retrieval, retention time, and disposal of its records. Cal-Tek retains records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality commitments, and records are readily available.

## 8.5. Actions to address risks and opportunities

8.5.1. Cal-Tek considers the risks and opportunities associated with its calibrations 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 performing calibrations.

(d) Achieve improvement.

8.5.2. Cal-Tek plans:

(a) Actions to address these risks and opportunities.

(b) How to:

- Integrate and implement these actions into its management system.
- Evaluate the effectiveness of these actions.

8.5.3. Actions taken to address risks and opportunities are proportional to the potential impact on the validity of calibration results.

## 8.6. Improvement

8.6.1. Cal-Tek identifies and selects opportunities for improvement and implements any necessary actions.

8.6.2. Cal-Tek seeks feedback, both positive and negative, from its customers. The feedback is analyzed and used to improve the management system, calibration services, and customer service.

## 8.7. Corrective actions

8.7.1. When a nonconformity occurs, Cal-Tek in accordance with **QP190**:

(a) Reacts to the nonconformity, and as applicable:

- Takes action to control and correct it.
- Address the consequences.

(b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

- Reviewing and analyzing the nonconformity.
- Determining the causes of the nonconformity.
- Determining if similar nonconformities exist or could potentially occur.

(c) Implement any action needed.

(d) Review the effectiveness of any corrective action taken.

(e) Update risks and opportunities determined during planning, if necessary.

(f) Make changes to the management system if necessary.

8.7.2. Corrective actions taken are appropriate to the effects of the nonconformities encountered.

8.7.3. Cal-Tek retains records as evidence of:

(a) The nature of the nonconformities, cause(s) and any subsequent actions taken.

(b) The results of any corrective action.

## 8.8. Internal audits

8.8.1. Cal-Tek conducts internal audits in accordance with **QP250** at planned intervals to provide information on whether the management system:

(a) Conforms to:

- Cal-Tek's own requirements for its management system, including performing calibration services.
- The requirements of ISO/IEC 17025.
- The requirements of Cal-Tek's accreditation body (A2LA).

(b) Is effectively implemented and maintained.

8.8.2. Cal-Tek:

(a) Plans, establishes, implements, and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the calibration services concerned, changes affecting Cal-Tek and the results of previous audits.

(b) Defines the audit criteria and scope for each audit.

(c) Ensures that the results of the audits are reported to relevant management.

(d) Implements appropriate correction and corrective actions without undue delay.

(e) Retains records as evidence of the implementation of the audit program and the audit results.

## 8.9. Management reviews

8.9.1. Cal-Tek's management reviews the management system in accordance with **QP105** at planned intervals, which do not exceed 12 months, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of the requirements of the Quality Manual.

8.9.2. The inputs to and outputs from the management review, as defined in **QP105**, are recorded.

# 9. Revision History

| Date | Revision | Description |
|---|---|---|
| 12/20/2005 | A | Released at Rev. A against ISO/IEC 17025:2005. - JS |
| 03/13/2006 | B | Updated Quality Policy to reflect changes per audit finding NCR#2 by PJLA. - JS |
| 03/13/2008 | C | Updated Quality Manual to reflect requirements of ISO/IEC 17025:2005 and ANSI/NCSL Z540-1-1994 (R2002). - JS |
| 02/20/2013 | D | Updated for date established, 4.1.3 statement, title, and grammatical corrections. - TC |
| 03/13/2013 | E | Policy statements updated. Statement regarding accreditation body symbol usage. - TC |
| 03/31/2014 | F | 4.14.2 updated to reflect customer notification clause in 5.10.9.Z.1 (Z540-1 requirement). 5.4.6.3 updated to include TUR reporting. Clauses added to 5.10.4.1 to reflect Cal-Tek Company policies on MU reporting and statements of compliance. - TC |
| 04/21/2014 | G | 4.8 updated to include customer complaint policy. - TC |
| 04/25/2015 | H | Wording revised in section 4.14.2 and 5.10.10 (prompt notification of customer). - TC |
| 07/31/2017 | I | Complaint procedure revised. - TC |
| 02/22/2018 | J | Reference to ANSI/NCSL Z540-1-1994 (R2002). - TC |
| 11/25/2018 | K | Updated to ISO/IEC 17025:2017. - TC |
| 09/30/2019 | L | 5.7.1 definition clarified. - TC |

| Date | Revision | Description |
|---|---|---|
| 10/15/2024 | M | Reformatted to use modern Microsoft Word features. Refreshed organization chart. Reflects acquisition of Cal-Tek by ATS at the beginning of 2024. “Inc.” removed from all references to “Cal-Tek Company”. References to NIST traceability updated to refer to SI. Merged section 2 into section 1 and created new section 2 for external document references. Many grammatical corrections. Removed several unused terms. Renamed “sections” of the QMS to “chapters” (e.g. Chapter 3 – Quality Procedures). Replaced mentions of “this International Standard” with “the Quality Manual”. - SD |
| 08/05/2025 | N | Rewrite to follow structure of ISO/IEC 17025:2017. - SD |