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.

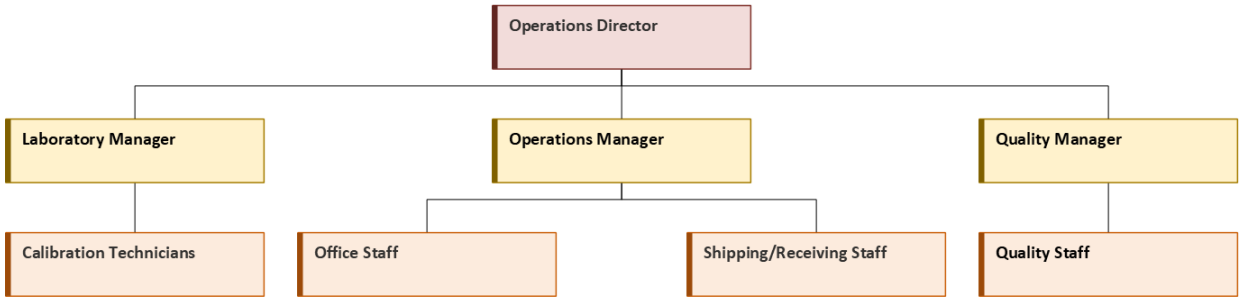
This manual and the system it defines applies to all activities within the company that have an effect on calibration or repair service quality.

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 Digitally signed by Tim Cooke Date: 2024.10.15 09:46:31 -04'00'
Steven Donovan	Quality Manager	Steven Donovan Digitally signed by Steven Donovan Date: 2024.10.15 09:27:55 -04'00'

1.2. Organization Chart



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 the highest quality 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 the best pricing and value for our services.

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 9000:2015**: Quality management systems – Fundamentals and vocabulary.
- **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.
- **ANAB AR 2251**: Accreditation Requirements: ISO/IEC 17025 Calibration Laboratories.
- **ANAB SR 2401**: ANSI/NCSL Z540-1 Calibration Laboratories.

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

3.3. **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.

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

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

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

3.7. **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.

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

3.9. **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.

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

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

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

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

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

3.15. **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.

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

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

3.18. **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.

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

3.20. **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.

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

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

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

4. Management requirements

4.1. Organization

4.1.1. CAL-TEK 2000, LLC dba Cal-Tek Company can be held legally responsible for all actions taken.

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.

4.1.2. We carry out calibration activities in such a way as to meet the requirements of the Quality Manual and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.

4.1.3. Our quality management system covers the work carried out in our permanent facility (20 Republic Rd, North Billerica, MA 01862), as well as at our customers' facilities.

4.1.4. 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. Management is committed to identifying or eliminating risks to impartiality, including risks from internal or external relationships.

4.1.5. Cal-Tek Company:

(a) Has managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departure from the quality system or from the procedures for performing calibrations, and to initiate actions to prevent or minimize such departures.

(b) Has made arrangements to ensure that its 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.

(c) Has policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.

(d) Has defined policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

(e) Has defined the organization and management structure of the laboratory, and the relationships between quality management, technical operations and support services.

(f) Has specified the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations.

(g) Has provided adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the calibration results.

(h) Has technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.

(i) Has appointed a member of staff as Quality Manager who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the Quality Manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

(j) Has appointed deputies for key managerial personnel.

(k) Has conveyed the relevance and importance of all activities and how they contribute to the achievement of the management system objectives.

4.1.6. Cal-Tek's top management has put in place internal audits (**QP250**) and management review meetings (**QP105**) to ensure and review the effectiveness of communications and the management system.

4.2. Quality system

4.2.1. We have established, implemented and maintain a quality system appropriate to the scope of our activities. The laboratory has documented its quality policy, quality system, quality procedures and calibration instructions to the extent necessary to assure the quality of the calibration results. The Quality and Management system's documentation has been communicated to, understood by, available to, and implemented by the appropriate personnel.

When required by law or authorized by contractual arrangements to release confidential information, Cal-Tek Company will notify the customer or individual concerned of the information provided, unless Cal-Tek is legally prohibited from doing so.

Information obtained about the customer from sources other than the customer (e.g., complainant, regulators) is confidential between the customer and Cal-Tek. Further, the provider (source) of this information shall be confidential to the Cal-Tek and will not be shared with the customer, unless agreement to do so is made with the source.

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

4.2.2. Our quality system policy and objectives are defined in the Quality Manual. The overall objectives are documented as part of our Quality Policy Statement (see 1.3).

4.2.3. The quality policy statement has been issued under the authority of the Operations Director. It includes the following:

(a) The management's commitment to good professional practice and to the quality of its calibrations in servicing its clients.

(b) The management's statement of the laboratory's standard of service.

(c) The objectives of the quality system.

(d) A requirement that all personnel concerned with calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policy and procedures in their work.

(e) The management's commitment to compliance with requirements of ISO/IEC 17025:2017 and ANSI/NCSLI Z540-1-1994 (R2002).

(f) This Quality Manual includes or makes references to the supporting procedures in **Chapters 3 (Quality Procedures) and 5 (Calibration Procedures)**. It outlines the structure of the documentation used in the quality system.

4.2.4. The roles and responsibilities of technical management and the Quality Manager, including their responsibility for ensuring compliance with the Quality Manual, are defined in **Chapter 6 (Job Descriptions)**.

4.2.5. The Quality Manual makes references to **Quality Procedures "QPXXX"** and **Calibration Procedures "CPXXX"**. The structure of the documentation used in the management system is outlined in document **MI100 "Master Index"**.

4.2.6. The roles and responsibilities of technical and quality management are defined in **Chapter 6 (Job Descriptions)**, including their responsibilities for ensuring compliance.

4.2.7. The integrity of the management system is maintained through the continued implementation of management and quality system review and any changes to the system will be planned and impact studies will be performed before implementation.

4.3. Document control

4.3.1. General

We have established and maintain procedure **QP120 "Document Control"** to control all documents that form part of the quality system (internally generated or from external sources, such as regulations, standards, other normative documents, calibration methods, as well as drawings software, specifications, instructions, and manuals).

4.3.2. Document approval and issue

4.3.2.1. The procedures **QP120** and **QP130** control all documents that form part of the quality system. This includes documents that are internally generated or are form external sources, such as regulations, standards, other normative documents, calibration methods, as well as drawings, software, specifications, instructions, and manuals.

4.3.2.2. All documents issued to personnel as part of the quality system have been reviewed and approved for use by authorized personnel prior to issue. A **Master List "MI100"** that identifies the current revision status and distribution of documents in the quality system has been established and is readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.3. The procedures ensure that:

(a) Authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed.

(b) Documents are periodically reviewed and where necessary, revised to ensure continuing stability and compliance with applicable requirements.

(c) Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.

(d) Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.4. Our quality system documents are uniquely identified. Such identification includes the date of issue and the identification, page numbering, the total number of pages, and the issuing authority.

4.3.3. Document changes

4.3.3.1. Cal-Tek Company is a small operation so all changes to documents will be reviewed and approved by the same function that performed the original review. The designated personnel will have access to pertinent background information upon which to base their review and approval.

4.3.3.2. Where practicable, the altered or new text will be identified in the document or the appropriate attachments.

4.3.3.3. Our documentation control system does not allow for the amendment of documents by hand pending the re-issue of the documents.

4.3.3.4. The procedure also describes how changes in documents maintained in computerized system are made and controlled.

4.4. Review of requests, tenders, and contracts

4.4.1. We have procedure **QP100 "Contact Review"**, for the review of requests, tenders, and contracts. The policies and process for these reviews leading to a contract for calibration will ensure that:

(a) The requirements, including the methods to be used, are adequately defined, documented, and understood.

(b) The capability and resources to meet the requirements are available.

(c) The appropriate calibration method is selected and capable of meeting the clients' requirements.

(d) Any differences between the request or tender and the contract will be resolved before any work commences. Each contract will be acceptable both to the laboratory and client.

4.4.2. Records of reviews, including any significant changes, will be maintained. Records will also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

4.4.3. The review will also cover any work that is subcontracted (should we in the future choose to use such).

4.4.4. The client will be informed of any deviation from the contract.

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

4.5. Subcontracting of calibrations

4.5.1. Cal-Tek Company will use only appropriately accredited subcontractors when needed. Calibration subcontracting will only be awarded to a calibration laboratory that has demonstrated through the accreditation process competency in the scope of work to be performed.

4.5.2. Whenever a subcontractor is used a Cal-Tek Company representative will inform the customer in advance that a subcontractor will be used and obtain the customer's written approval.

4.5.3. Cal-Tek Company recognizes a responsibility to our customers for the work performed by subcontractors contracted by us on behalf of a customer.

4.5.4. Cal-Tek Company maintains an approved vendor log to track all vendors/subcontractors, this log includes a column for accreditation and/or compliance with applicable standards for the work to be performed.

4.6. Purchasing services and supplies

4.6.1. We have procedure **QP310, "Supplier Assessment"**, for the selection and purchasing of services and supplies we use that affect the quality of calibrations. **QP140 "Purchasing"** exists for the purchase, reception and storage of reagents and laboratory consumable materials relevant for calibrations.

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**).

4.6.2. We will ensure that purchased supplies and reagents and consumable materials that affect the quality of calibrations are not used until they have been inspected or otherwise verified as complying with standards specifications or requirements defined comply with specified requirements. Records of actions taken to check compliance will be maintained. We have **QP280 "Receiving Inspection"** to ensure compliance with this requirement.

4.6.3. Purchasing documents for items affecting the quality of our output will contain data describing the services and supplies ordered. These purchasing documents will be reviewed and approved for technical content prior to release.

4.6.4. We will evaluate suppliers of critical consumables, supplies and services that affect the quality of calibration, and shall maintain records of these evaluations and list those approved.

4.7. Service to the customer

4.7.1. We will cooperate with clients or their representatives to clarify the client's requests and to monitor Cal-Tek Company's performance in relation to the work performed, provided that Cal-Tek ensures confidentiality to other clients. **QP300 "Servicing"** defines how service is provided to the client.

4.7.2. Cal-Tek Company maintains a system of **"Report Cards", Form F300-1**, to request feedback from our clients. **Form F300-1** requests and encourages both positive and negative comments about our services. This information is used with our management system and during our management meetings to improve client relations and service.

4.8. Complaints

Customer complaints are covered as part of procedure **QP480 "Complaints"**. Records will be maintained of all complaints and of the investigation and corrective actions taken by the laboratory.

4.9. Control of nonconforming calibration work

4.9.1. We have procedure **QP225 "Nonconformance"**, it will be implemented when any aspect of our calibration work, or the results of this work, do not conform to our

procedures or the agreed requirements of the client. 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**. The policy and procedure ensures that:

(a) The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of calibration certificates, as necessary) are defined and taken when nonconforming work is identified.

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 Quality Manual Section 5.1.1), 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.

(b) An evaluation of the significance of the nonconforming work is made.

(c) Corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work.

(d) Where necessary, the client is notified, and work is recalled.

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

4.9.2. Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures will be promptly followed.

4.10. Improvement

Cal-Tek Company has systems in place to monitor the effectiveness of its management system through the use of quality policies, quality objectives, management reviews, corrective actions, preventative actions and through the use of customer report cards.

4.11. Corrective action

4.11.1. General

The procedure **QP190 "Corrective and Preventive Action"** designates the appropriate authorities for implementing corrective action when nonconforming work or departure from the

policies and procedures in the quality system or technical operations has been identified. 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**.

4.11.2. Cause analysis

The procedure for corrective action starts with an investigation to determine the root cause(s) of the problem.

4.11.3. Selection and implementation of corrective actions

Where corrective action is needed, our laboratory will identify potential corrective actions. We will select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions will be to a degree appropriate to the magnitude and the risk of the problem.

We will document and implement any required changes resulting from corrective action investigations.

4.11.4. Monitoring of corrective actions

We will monitor the results to ensure that the corrective actions taken have been effective.

4.11.5. Additional audits

Where the identification of nonconformance or departures casts doubt on the compliance with set policies and procedures, or in compliance with the Quality Manual, we will ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

4.12. Preventive action

4.12.1. Needed improvements and potential sources of nonconformance, either technical or concerning the quality system, will be identified. If preventive action is required, action plans will be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformance and to take advantage of the opportunities for improvement. Quality Procedure **QP190** quality forms **F190-1**, **F200-1** and quality logs **R190-1**, **R190-2** and **R190-3**.

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

4.13. Control of records

4.13.1. General

4.13.1.1. We have procedure **QP130 "Records Control"** for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical

records. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.13.1.2. All records will be legible and will be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records have been established and documented in **QP130 "Records Control"**.

4.13.1.3. All records will be held secure and in confidence.

4.13.1.4. As part of **QP130** a system exists to protect, and back-up records stored electronically and to prevent unauthorized access to or amendment of these records, virus scanning software is used weekly to ensure electronic media integrity.

4.13.2. Technical records

4.13.2.1. We will retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each calibration will contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the calibration to be repeated under conditions as close as possible to the original. The records will include the identity of personnel responsible for the performance of each calibration and checking of results.

4.13.2.2. Observations, data and calculations will be recorded at the time they are made and will be identifiable to the specific task

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

4.14. Internal audits

4.14.1. We will periodically, and in accordance with a predetermined schedule and procedure **QP250 "Internal Audits"**, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit program will address all elements of the quality system, including the calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Trained and qualified personnel, who are, wherever resources permit, independent of the activity to be audited, will carry out such audits. An **"Internal Audit"** checklist has been created to aid in performing this task and is designated as **F400** in **Chapter 4 (Forms and Reports)**.

4.14.2. When audit findings, or an event such as identification of defective laboratory calibration equipment, cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's calibration results, we will take timely corrective action and will **promptly** notify clients in writing if investigations show that the laboratory results may have been affected.

4.14.3. The area of activity audited, the audit findings and corrective actions that arise from them will be recorded.

4.14.4. Follow-up audit activities will verify and record the implementation and effectiveness of the corrective action taken.

4.15. Management reviews:

4.15.1. In accordance with a predetermined schedule and procedure **QP105 "Management Review",** our executive management will periodically conduct a review of our quality system and calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- The suitability of policies and procedures
- Reports from managerial and supervision personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- The results of inter-laboratory comparisons or proficiency tests
- Changes in the volume and type of the work
- Client feedback and Complaints
- Identifying and eliminating risks to impartiality,
- Other relevant factors, such as quality control activities, resources and staff training and goal assessment.

4.15.2. Findings from management reviews and the actions that arise from them will be recorded. The management will ensure that those actions are carried out within an appropriate and agreed upon timescale.

5. Technical requirements

5.1. General

5.1.1. Many factors determine the corrections and reliability of the calibrations performed by a laboratory. These factors include contributions from:

- Human factors (5.2).
- Accommodation and environmental conditions (5.3).
    - Temperature: **65 to 75 °F**. Relative Humidity: **25 to 55 %RH**.
- Calibration methods and method validation (5.4).

- Equipment (5.5)
- Measurement traceability (5.6)
- The handling of calibration items (5.8)

5.1.2. The extent to which the factors contribute to the total uncertainty of measurement differs considerably between types of calibrations. We will take account of these factors in developing calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment we use.

5.2. Personnel

5.2.1. Our management will ensure the competence of all who operate specific equipment, perform calibrations, evaluate results, and calibration certificates. When using staff that is undergoing training, appropriate supervision will be provided. Personnel performing specific tasks will be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

5.2.2. Our management will formulate the goals with respect to the education, training and skills of the laboratory personnel. We have procedure **QP270 "Training"** that identifies the training needs and providing training of personnel. The training program will be relevant to the present and anticipated tasks. Our training effectiveness is evidenced by the use of Appraiser Variation Studies, Intermediate Testing and Proficiency Testing.

5.2.3. We will only use personnel who are employed by, or under contract to Cal-Tek Company. Where contracted and additional technical and key support personnel are used, Cal-Tek will ensure that such personnel are supervised, competent and that they work in accordance with the laboratory's quality system.

5.2.4. We maintain current job descriptions for managerial, technical and key support personnel involved in calibrations.

5.2.5. The management has authorized specific personnel to perform particular types of calibrations, to issue calibration certificates, and to operate particular types of equipment. We maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contract personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.

5.3. Accommodation and environmental conditions

5.3.1. Our facilities for calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the calibrations.

We will ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care will be taken when calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of calibrations will be documented.

5.3.2. It is the policy of Cal-Tek Company that we will monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention will be paid to temperature and humidity as appropriate to the technical activities concerned.

Per **QP220**, when an environmental non-conformance is observed by any Cal-Tek employee (including but not limited to environmental conditions outside limits specified in Quality Manual Section 5.1.1), that employee has the responsibility to notify a supervisor and/or the Quality Manager and to halt further calibration work until the non-conformance has been addressed by the Quality Manager or Operations Director. Calibrations can be performed outside the environmental limits specified in Quality Manual Section 5.1.1 only with the permission of a supervisor, the Quality Manager or Operations Director.

In the case of On-Site Calibrations, customer approval may be obtained for calibration work outside the specified temperature limits. This approval shall be documented on **Form R215-1, Conditions Waiver**.

Resumption of work can be approved only by Quality Manager or Operations Director.

5.3.3. There is effective separation between neighboring areas in which there are incompatible activities. Should there be a need, measures will be taken to prevent cross-contamination.

5.3.4. Access to and use of areas affecting the quality of the calibrations is controlled. The laboratory has determined the extent of control based on its particular circumstances.

5.3.5. Measures have been taken to ensure good housekeeping in the laboratory. Special procedures will be prepared where necessary.

5.4. Calibration methods and method validation

5.4.1. General

5.4.1.1. We have procedure **QP150 "Process Control"**, 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 statistical techniques for analysis of calibration data.

We have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for calibration, or both, where the absence of such instructions could jeopardize the results of calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory will be kept up to date and will be made readily available to personnel. Deviation from calibration methods will occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

5.4.2. Selection of methods

We will calibrate to the original manufacturer's specifications. We will use calibration methods which meet the needs of the client, and which are appropriate for the calibrations it undertakes. Methods published in international, regional or national standards will preferably be used. We will ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard will be supplemented with additional details to ensure consistent application.

When the client does not specify the method to be used, we will select appropriate methods that have 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. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client will be informed as to the method chosen. We will confirm that we can properly operate standard methods before introducing the calibrations. If the standard method changes, the confirmation will be repeated.

We will inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3. Laboratory-developed methods

5.4.3.1. The introduction of calibration methods developed by Cal-Tek Company for its own use is a planned activity and will be assigned to qualified personnel equipped with adequate resources. This process is defined in procedure **QP110 "Methods Development"**.

Plans will be updated as development proceeds and effective communication amongst all personnel involved will be ensured.

5.4.4. Non-standard methods

5.4.4.1. When it is necessary to use methods not covered by standard methods, these will be subject to agreement with the client and will include a clear specification of the client's requirements and the purpose of the calibration. The method developed will have been validated appropriately before use.

5.4.5. Validation of methods

5.4.5.1. Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2. We validate non-standard methods, laboratory-designed / developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation will be as extensive as is necessary to meet the needs of the given application or field of application. We will record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

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

5.4.6. Estimation of uncertainty of measurement

5.4.6.1. Cal-Tek Company has and applies a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

5.4.6.2. We have procedure **QP350 "Estimation of Measurement Uncertainty"** for estimating uncertainty of measurement, this along with **Quality Statement QS300** defines our systems for measurement uncertainty. Cal-Tek Company also uses Fluke MET/CAL & MET/TEAM software and hardware for measurement uncertainty calculations as this software has been approved for this purpose and has been validated in **VR100-1**.

5.4.6.3. Our laboratory has a procedure **QP350** and **QS300** for estimating uncertainty of measurement. Calibrations resulting in TURs of less than 4:1 will be reported to the client.

5.4.6.4. When estimating the uncertainty of measurement, all uncertainty components, which are of importance in the given situation, will be taken into account using appropriate methods of analysis.

5.4.7. Control of data

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

5.4.7.2. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, we will ensure that:

(a) Any computer software developed by our staff will be documented in sufficient detail and be suitably validated for adequacy before use.

(b) Procedures have been established and are implemented for protection of data; such procedures include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.

(c) Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of calibration data.

5.5. Equipment

5.5.1. Cal-Tek Company maintains sufficient measuring and test equipment for the correct performance of calibrations within our scope. In those cases where we use equipment outside our permanent control, only equipment with a valid accredited calibration certificate and appropriate handling will be used to ensure that the requirements of the Quality Manual are met.

5.5.2. All equipment and software used in the calibration of customer owned equipment have been validated for use and all equipment will be checked and/or calibrated before use. All of our equipment is calibrated in accordance with procedure **QP220 "Calibration".**

5.5.3. Cal-Tek Company maintains Work Instructions on the use and maintenance of our equipment. All calibration technicians are properly trained in the use of our equipment as evidenced by their respective training files. We maintain a library of manuals related to laboratory owned and client owned equipment.

5.5.4. Each item of equipment and its software used for calibration and is significant to the results will, when practicable, be uniquely identified.

5.5.5. Records will be maintained of each item of equipment and its software significant to the calibrations performed. The records will include at least the following:

(a) The identity of the item of equipment 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, or reference to their location.

(f) Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the expiration date of calibration.

(g) The maintenance plan, where appropriate, and maintenance carried out to date.

(h) Any damage, malfunction, modification or repair to the equipment.

5.5.6. We have procedure **QP230 "Handling and Storage"**, 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 subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, will be taken out of service. It will be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by performance testing and or calibration to perform correctly. We will examine the effect of the defect or departure from specified limits on previous calibrations and will institute procedure **QP340 "Customer Property"** and/or **QP330 "Identification and Traceability"**.

5.5.8. Cal-Tek Company uses calibration labels with the unique serial or asset number of the instrument to identify instruments, indicate the status of calibration, calibration date and date of expiration or calibration recall. Procedure **QP330 "Identification and Traceability"**, defines the process for controlling client equipment.

5.5.9. When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory manager will ensure that the function and calibration status of the equipment is checked, and that the equipment is not returned to service until performance testing is completed. Procedure **QP430** defines the process for performance testing.

5.5.10. Cal-Tek Company uses Intermediate Testing to maintain confidence in the calibration status of our equipment. This test is defined in **QP440** and **Form R240-1** is used for recording results. Our interval for this testing is every 90 days.

5.5.11. Cal-Tek Company records correction factors applied during a calibration on the calibration documents, **R200-1**, related to the calibrated instrument.

5.5.12. Cal-Tek Company owned test and calibration equipment is safeguarded against undocumented adjustments by the use of void seals. Our software is safeguarded against unauthorized adjustments through the use of password protection.

5.6. Measurement traceability

5.6.1. General

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 result of the calibration will be calibrated before being put into service. Cal-Tek Company has an established program and procedures for the calibration of its equipment.

5.6.2. Specific requirements

5.6.2.1. *Calibration*

5.6.2.1.1. Cal-Tek Company maintains a calibration program for our equipment that requires the use of only accredited calibration vendors to ensure that calibrations and measurements made by the laboratory are traceable to the

International System of Units (SI) via a National Measurement Institute such as NIST.

The calibration certificates issued by these laboratories will contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

5.6.2.1.2. There are certain calibrations that currently cannot be strictly made to the SI. In these cases, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material.
- The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable program of inter-laboratory comparisons is required where possible.

5.6.3. Reference standards and reference materials

5.6.3.1. *Reference standards*

Cal-Tek Company has a program and procedures for the calibration of our reference standards. Our reference standards will be calibrated by an accredited source that can provide traceability. Cal-Tek's reference standards are not used for any other purpose outside of calibration, (e.g. "no standard is used as a voltage supply to a device under test"). Our policy is that any reference standard needing adjustment will be sent for full re-calibration.

5.6.3.2. *Reference materials*

Reference materials will, where possible, be traceable to the SI, or to certified reference materials. Internal reference materials will be checked as far as is technically and economically practicable.

5.6.3.3. *Intermediate checks*

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials will be carried out according to defined procedures and schedules using **QP440**.

5.6.3.4. *Transport and storage*

Cal-Tek Company maintains quality procedure **QP230** for the proper handling, transport and storage of our calibration standards.

5.7. Sampling

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

5.8. Handling of calibration items

5.8.1. We have a procedure **QP230 "Handling and Storage"**, for the transportation, receipt, handling, protection, storage, retention and/or disposal of calibration items, including all provisions necessary to protect the integrity of the calibration item, and to protect the interests of the laboratory and the client.

5.8.2. We have a system for unique identification of calibration items. The identification will be retained throughout the life of the item in the laboratory. The system is designed and operates so as to ensure that the items cannot be confused physically or when referred to in records or other documents. The system will, as appropriate, accommodate a sub-division of groups of items and transfer of items within and from our facility.

5.8.3. Upon receipt of the calibration item, abnormalities or departures from normal, calibration void seals broken or specified conditions, as described in the calibration method, will be recorded. 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 calibration required is not specified in sufficient detail, we will consult the client for further instructions, as defined in procedure **QP340 "Control of Customer Property"**, before proceeding and will record the discussion.

5.8.4. The appropriate facilities and procedures provide for avoiding deterioration, loss or damage to the calibration item during storage, handling and preparation.

Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

5.9. Assuring the quality of calibration results

5.9.1. We have quality control procedures for monitoring the validity of calibrations undertaken. The resulting data will be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring will be planned and reviewed and may include, but not be limited to, the following:

(a) Regular use of certified reference materials and/or internal quality control using secondary reference materials and intermediate testing.

(b) Participation in inter-laboratory comparison or proficiency-testing programs.

(c) Replicate calibrations using the same or different methods.

(d) Recalibration of retained items.

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

5.9.2. Cal-Tek Company 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

5.10. Reporting the Results

5.10.1. General

The results of each calibration, or series of calibrations carried out, will be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration methods.

The results will be reported, usually in a calibration certificate, and will include all the information requested by the client and necessary for the interpretation of the calibration results and all information required by the method used.

In the case of calibrations performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way.

5.10.2. Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

(a) A title (e.g., “Test Report” or “Certificate of Calibration”).

(b) The name and address of the laboratory, and the location where the calibrations were carried out, if different from the address of the laboratory.

(c) Unique identification of the calibration certificate (such as serial number), and on each page an identification in order to ensure that the page is recognized as part of the calibration certificate, and a clear identification of the end of the calibration certificate.

(d) The name and address of the client.

(e) Identification of the calibration procedure 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 performance of the calibration.

(h) Reference to the procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results.

(i) The calibration results with, where appropriate, the units of measurement.

(j) The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report.

(k) Where relevant, a statement to the effect that the results relate only to the items calibrated.

5.10.3. Test reports

Cal-Tek Company is a calibration laboratory only and does not issue test reports.

5.10.4. Calibration certificates

5.10.4.1. In addition, the calibration certificates will include the following, when necessary for the interpretation of calibration results.

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

(b) The uncertainty of measurement and/or statement of compliance with an identified metrological specification or clauses thereof.

(c) Evidence that the measurements are traceable.

5.10.4.2. 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.

5.10.4.3. The calibration certificate will relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this will identify which clause of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory will record those results and maintain them for possible future reference.

Statements of compliance are issued without considering uncertainty (MU) in determining compliance to specification(s). Our policy is that customers share the responsibility of compliance assessment of MU when considering calibration results.

5.10.4.4. 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.

5.10.4.5. A calibration certificate (or calibration label) will not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.5. Opinions and interpretations

We do not provide opinions and interpretations on our calibration certificates.

5.10.6. Calibration results obtained from subcontractors

Cal-Tek Company will evaluate and file all subcontractors' calibration certificates and issue new certificates of calibration with notes as to how the data was obtained (see 4.5.1).

5.10.7. Electronic transmission of results

In the case of the transmission of calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of the Quality Manual shall be met.

5.10.8. Format of reports and certificates

The form will be designed to accommodate each type of calibration carried out and to minimize the possibility of misunderstanding or misuse.

When forms are designed to include symbols from an accrediting company, such forms will be designed with Quality Manager Supervision to ensure proper symbol usage per the applicable guidance documentation of the accreditor.

Prior to issuance of individual calibration documents containing accrediting agency symbols, documents will be reviewed per **QP400** or **QP410**.

5.10.9. Amendments to test reports and calibration certificates

Material amendments to a calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

> Supplement to Calibration Certificate, serial number … (or as otherwise identified). Or an equivalent form of wording.

Such amendments shall meet all the requirements of the Quality Manual.

When it is necessary to issue a completely new calibration certificate, this will be uniquely identified and shall contain a reference to the original it replaces.

5.10.10. Out of Tolerance Conditions

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**.

6. 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

Date	Revision	Description
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
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