SECTION: III

QUAL TECH LABS, INC.

ISO/IEC 17025:2005

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

QUALITY MANUAL
(10/15/2015, Rev. 1)

(Tracy Williams)

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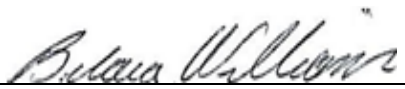
QUAL TECH LABS, INC.

ISO/IEC 17025:2005

QUALITY MANUAL

(SIGNATURE PAGE)

ORIGINATED BY:			
	Tracy A. Williams		
TITLE:	Quality Manager		
DATE:	October 15, 2015		
APPROVED BY:			
	Barbara Williams		
TITLE:	CEO		
DATE:	October 15, 2015		
ISSUED TO:	Master File	**DATE:**	October 15, 2015

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ORGANIZATIONAL CHART

(Appendix "A")

COMPANY PROFILE

Qual Tech Labs Inc. has been established since 1983, is based in Exton, Pennsylvania, and of which is legally responsible for all that takes place under the guidelines of said company. We provide calibration services, with quick turnaround times to meet all our customer's fast pace needs. Qual Tech Labs, Inc. is approved by several companies and is directly traceable to the National Institute of Standards and Technology (NIST). By utilizing the most sophisticated equipment available, you are assured minimal total measurement uncertainty.

All certifications of calibration include NIST traceable numbers, adherence to military, or federal standards, date of calibration, recalibration due date, are signed by a trained calibration technician. Copies of our comprehensive Quality Systems manual are available for your review. Customer audits and surveys of our facility are always welcome.

This manual is published and maintained by Qual Tech Labs, Inc. The manual's purpose is to set forth an easy to use procedure covering the quality management functions. The manual has been constructed to reflect a quality program in compliance with ISO/IEC Standards as well as US Government Military Specifications, Federal Aviation Administration (FAA), and non-governmental, where applicable.

This manual is the general quality requirements set forth by Qual Tech Labs, Inc. Specific quality instructions pertaining to daily operations, calibration procedures and customer requirements shall be maintained in the Qual Tech Labs, Inc. Quality Instruction Manual and filed calibration procedures.

The manual is distributed, maintained and controlled by revision and date. All manuals within the facilities of Qual Tech Labs, Inc. will be at current revision levels. Manuals that have been issued or distributed to customers are considered uncontrolled.

Qual Tech Labs, Inc. has developed and implemented the Quality System outlined in this Quality Manual to ensure that its measurement activities meet or exceed the requirements of ISO/IEC 17025:2005 and complies with ISO 9001:2000. The Quality System is an integral and essential part of all company operations.

End Section QM-1.0

POLICY STATEMENT

The objective of Qual Tech Labs, Inc. is to continually provide calibration services that meet or exceed the requirements of ISO/IEC 17025:2005, and to satisfy the needs of the customers, regulatory authorities or organizations providing recognition. We are committed to providing good professional practices and to the quality of our calibrations in servicing our customers.

The purpose of this Quality Management System is to implement and continuously maintain our commitment to these objectives through a dynamic Quality Assurance System based on the ISO/IEC 17025:2005 standard.

Quality control is an integral part of all the corporation's management. It is not a separate element or function; each aspect of the day-to-day operations and services of the corporation shall be conducted in accordance with the quality policies contained in this manual. It is designed to integrate human, technical and material resources in a manner that results in optimum production consistent with the highest possible quality standards.

The laboratory management is committed to the compliance with ISO 17025:2005 and our quality management system. We are committed to continually improve the effectiveness of the management system.

There are no exceptions to this commitment. Every employee is expected to understand and work towards our quality commitment. Success requires satisfied customers. This Quality Assurance System reflects the company's total commitment to achieving the goal of meeting the needs of our customers efficiently and safely.

The CEO and General Manager are responsible for the implementation and ongoing supervision of the procedures contained in this manual. This administrative responsibility complements but in no way, reduces or removes the technical responsibility of employees of their quality control duties. Quality is everyone's business. There are no exceptions. Any problems that cannot be resolved are to be immediately referred to me.

Barbara A. Williams, CEO

End Section QM-2.0

OVERVIEW

3.1 Scope

The Quality Manual contains the Quality System used by Qual Tech Labs, Inc. Its purpose is to provide the controls necessary to:

- Achieve the highest possible quality standards for all services provided by Qual Tech Labs, Inc.
- To recognize and implement all customer and statutory requirements.
- Motivate and control the management, technical and human resources that affect and impact quality for identifying, reducing, and ultimately preventing all quality deficiencies.

The Quality System contained in this manual is based on the requirements of ISO/IEC 17025:2005, ANSI/NSCL Z540-1, 10CFR Part, ISO 9001:2000.

3.2 Application

The Quality System applies to all methods and standards, which include customer facilities or in house, undertaken by Qual Tech Labs, Inc. If there is an identified discrepancy between the contents of this manual and any contract or customer specifications, the latter shall generally apply notwithstanding a thorough situation analysis by management.

3.3 Reference Documents:

- ISO/IEC 17025:2005; *Quality Systems – General Requirements for the Competence of Testing and Calibration laboratories.*
- *ANSI/NCSL Z540-1-1994; American National Standards for Calibration – Calibration Laboratories and Measuring and Test Equipment – General Requirements*
- *10CFR Part 2; Reporting of Defects and Noncompliance (12/31/2015)*
- *ISO 9001:2000; Quality Management Systems – Requirements*
- QUAL TECH LABS, INC., *Quality System Procedures Manual (8/22/2015) (Companion Manual to this document)*
- Manufacturer's Manuals

3.4 Definitions:

Company: QUAL TECH LABS, INC.

Product: The result or product of any activity or process. The term "product" as used throughout these manuals is not limited to only physical or material product but may also include any other process that produces a desired result including services, processed materials and/or proprietary output such as software or graphic imagery. (*"Product"* throughout these manuals is usually expressed in a singular context instead of its plural, *"products."* This is intentional; "product" is the output or result of any process and therefore a singular definition is technically appropriate. Generally, there is only one company "output" which may or may not be comprised of many items or, in its broader and non-quality assurance sense, "products.")

Quality Assurance: The combined resources of management, organizational structure, line responsibilities, procedures, processes and personnel deployed for total quality over all aspects of the production and delivery process. Quality Assurance policies are contained in this manual. Its companion Quality Systems Procedures manual contains the specific quality assurance control procedures.

Sub-Contractor: Any outside company, vendor or individual in a contractual relationship with Qual Tech Labs, Inc. for supplying materials and/or labor. Company vendors and suppliers are defined as "sub-contractors" for the purposes of interpreting quality control responsibilities contained in this manual.

End Section QM-3.0

4.1.1 It is the paramount responsibility of the CEO to implement and dynamically supervise all aspects of the Qual Tech Labs Quality System to ensure the requirements of the International Standard are being met, and to ensure the client, 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 The company management system shall cover work carried out in the company's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.3 Key personnel in the organization that have an involvement or influence on the calibration activities of the company shall be defined as required to identify potential conflicts of interest.

4.1.4 The responsibility of the company shall be, but is not limited to:

- Have managerial and technical personnel with authority and the responsibility to implement, maintain and improve the management system, irrespective of other responsibilities.
- Ensure management and personnel are free from an undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.
- Have policies and procedures to ensure the protection of its client's confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.
- Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.
- Define the organization and management structure of the company, its place in any parent organization and the relationships between quality management, technical operations and support services.
- Specify the responsibility, authority and interrelationships of all personnel who perform or verify work affecting the quality of the calibration and services provided.
- Provide adequate supervision of staff, including trainees, by person's familiar with methods and procedures, purpose of each calibration or service, and with the assessment of the measurement results.
- Have technical management, which has overall responsibility for the technical operations, and the provision of the resources needed to ensure the required quality of company operations.
- Appoint a member of staff who has the defined responsibility and authority for ensuring that quality system is implemented and followed always.
- Appoint deputies for key managerial personnel, where practical based on the function.

- Management shall ensure that personnel are aware of the relevance and importance of their activities and how activates contribute to the overall management system goals and objectives.

4.1.5 The company management will ensure communication processes be established and communications take place regarding the effectiveness of the management system.

4.1.6 The General Manager has the responsibility of the Quality Management Representative functions as they define the specific quality responsibilities. These responsibilities are defined in "Organizational Chart" (Appendix "A"). Each person has the authority to stop or modify work process on nonconforming product or services. The level of responsibility and authority for quality control need not necessarily be by individual; where appropriate it may be defined by position and/or task level.

4.1.7 Nominated personnel, in their absence, may delegate the quality responsibility to another employee if the employee has received the appropriate training and/or authority from management.

4.1.8 The relevant procedures contained in this manual, together with the Quality Descriptions and Specifications documentation, define the individual responsibility and authority of personnel for all immediate quality control remedial action. A nominated employee may:

- Initiate action to prevent and/or correct quality nonconformities on his or her own initiative;
- Identify and record any quality assurance or quality system problems;
- Initiate, suggest, recommend or provide solutions through specified channels;
- Verify the implementation of proposed solutions; and
- Continue to control the process of the nonconformance until designated quality standards are fully restored.

4.1.9 The General Manager also has the title and responsibilities as the Quality Manager. The primary responsibility of the General Manager is to monitor and coordinate the Quality Program by providing advice and pertinent input to the technical management functions. The implementation, supervision and day-to-day quality control activities is a supervisory responsibility and this responsibility is in no way reduced or alleviated by the function of the General Manager.

4.1.10 The specific duties of the General Manager include, but are not limited to, the following areas. As the company's management representative, the General Manager has the delegated authority to:

- ❖ Implement and maintain the standards contained in this manual, and additional or supplementary standards contained or promulgated in ISO/IEC 17025:2005.
- ❖ Report to members of management on the effectiveness and deficiencies of the quality control system. A formal report shall be submitted annually or more frequently if, in the opinion of the CEO, such reports are necessary and appropriate.
- ❖ Coordinate with personnel, and sub-contractors and outside vendors, as necessary to achieve and maintain the quality control objectives contained in the policy statement.

4.1.11 The General Manager has the delegated authority to stop, review and/or reject any production or service process that does not conform to the specific quality control standards contained in this manual or, in his or her judgment, does not conform with the intent of the quality control statement.

4.1.12 The Laboratory Manager also has the title and responsibilities as the Technical Manager. The Technical Manager has the responsibility and authority for technical operations, equipment evaluation/selection, technical training, technical support and traceability for Qual Tech Labs, Inc. The Technical Manager, along with the Quality Manager, is responsible for compliance with requirements of ISO/IEC 17025:2005.

4.1.13 The General Manager / Quality Manager and the Lab. Manager / Technical Manager will ensure that the integrity of the management system is maintained when changes are planned and implemented.

End Section QM-4.1

4.2.1 General

The purpose of this manual is to develop and implement an ongoing and practical ISO/IEC 17025:2005 Quality Assurance System so that products and processes meet specified and/or agreed requirements. The documentation of this commitment to quality management is contained in three levels:

4.2.2 Quality Manual (QM)

The Quality Manual is the first-level company document. It contains company Quality Policy and establishes responsibilities. It also provides organizational structure and details how each company department or function is to meets its quality objectives which are established and reviewed during the management review.

4.2.2.1 Management has set the following measurable quality objectives:

4.2.2.1.1 Customer Complaints Improvements (reduction of errors)

4.2.2.1.2 Customer Complaints Closure (root cause analysis and corrective action)

4.2.2.1.3 Customer Contact Data (data for analysis)

4.2.2.1.4 Customer Lost Business (root cause analysis)

4.2.2.1.5 Customer Satisfaction (data for analysis)

4.2.2.1.6 Customer Lead-Time Reduction & On-Time Delivery

4.2.2.1.7 Technician Efficiency & Utilization Improvement

4.2.3 Quality System Procedures Manual (QSP)

The Quality System Procedures Manual is the second-level company document. It contains detailed information on specific quality control procedures including the purpose and scope of the procedure; individual responsibilities; method and resources to be deployed; and instructions on required documentation.

4.2.4 Quality Plans/Technical Procedures and other Level 3 Documentation

The company's third level of quality control system includes, but is not limited to, all work documentation including quality plans, work orders, technical procedures, specific procedures, records, and inspection reports. Such routine documentation is used to analyze results and performance of processes and production for meeting or exceeding predetermined quality control goals. Generally, any documented policy or procedure not contained in the Quality Manual (QM) or the Quality System Procedures Manual (QSP) is classified as a third-level document.

4.2.5 Manual Use & Cross Referencing

Qual Tech Labs, Inc. recognizes that it is impractical to initially document every new work procedure as quick as one may become necessary. Where a specific task or situation arises that is not covered by the Quality Systems Procedure Manual (QSP) it is appropriate to refer to the Quality Manual (QM) for guidance as to the intent of company policy and responsibilities. If necessary, a new procedure is to be developed and included in the next manual update.

End Section QM-4.2

4.3.1 The concise and accurate documentation of all Quality Assurance procedures is essential to the effectiveness of the company Quality Program. Document control procedures are necessary to provide efficient information management at all levels. The Quality System Procedures Manual (QSP) contains specific details on the control of essential documents and data. The purpose of this section is to provide an overview of information management principles and policy.

4.3.2 Documents is defined as all relevant information generated by the company or issued by a customer or other external organization in either hard or electronic storage media. The term "Document" in both manuals refers to both information in printed form and/or in computer files. Documents generated by the company shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(is).

4.3.3 A Controlled Document is any document or data that is listed by user and current document update status. Controlled documents include Quality Manuals (QM and QSP), Quality Plans, Standards, Policy Statements, Charts, Text Books, Posters, Notices, Memoranda, Software, Specifications and other essential product or process information. The purpose of document control is to ensure that all personnel have timely access to current information. Controlled Documents are routinely reviewed by the members of management and revised when necessary to ensure continuing suitability and compliance with applicable requirements.

4.3.4 Document Approval and Issue

The General Manager approves all quality control documents, prior to issue. Master lists of controlled documents are maintained by the Quality Manager to prevent the use of invalid or obsolete procedures.

4.3.4.1 Current issues of all relevant controlled documents are to be made available to every employee. The General Manager shall ensure that employees are aware of current procedure status always.

4.3.4.2 Superseded, invalid and/or expired documents are to be removed from all issued locations or, if needed for legal purposes or knowledge preservation purposes, must be clearly marked as no longer valid and/or expired.

4.3.4.3 Withdrawn and/or superseded documents may be kept if necessary for legal, research or other legitimate purpose provided the document and/or data is clearly identified as expired.

4.3.5. Document Changes

Any proposed changes to a quality controlled document suggested through periodic reviews or audits to ensure continuing suitability and compliance must be reviewed and approved by issue. The General Manager prepares the revised document. The designated personnel shall have access to pertinent background information upon which to base their review and approval. Any line function or outside organization (including contractors, customers and, if appropriate, outside inspectors) are to be included in the review process and briefed on the reason(s) for the proposed change. Where practical, the altered or new text shall be identified in the document or the appropriate attachments.

4.3.6 Amendments to documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practical, but not to exceed a 60-day period, unless outside approval is required.

End Section QM-4.3

4.4.1 The purpose of review is to ensure the appropriate measuring methods to be used are selected, defined, documented and understood, and that the customer requirements can be met prior to any work commencing. The Marketing and Sales Departments handling the quote, and customer must agree and accept the quote or invoice to identify and resolve any differences between the customer's expectations and the company's actual calibration services before any work commences. It is also to guarantee that the company has the capability and resources to meet the specifications. The contract (quote or order) review shall also cover any work that is subcontracted by the company.

4.4.2 All requests, quotes, tenders and contracts are reviewed by the Marketing and Sales Departments before submission to the customer. This includes all orders and communications by any means (telephone, fax, mail or electronic transfer). For verbal orders, the company shall document the order and, where possible, confirm its accuracy with the customer.

4.4.3 Contract/Order Amendments

Any change orders, specification changes, amendments or delivery variations to an existing order or contract are subject to the contract review procedures as stated above. The changes or amendments received from the customer are to be clearly identified, documented and immediately forwarded to the relevant affected personnel and/or subcontractors. If work has commenced and the contract requires amendments, the contract review process shall be repeated with the new amendments communicated to all affected personnel, subcontractors, etc.

4.4.4 Records of reviews, including any significant changes, shall be maintained. Records shall 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. The review shall cover any work that is subcontracted by the company.

4.4.5 The client shall be informed of any deviation from the contract as early as possible.

End Section QM-4.4

SUBCONTRACTING OF CALIBRATION AND SERVICES (LEVEL 2 LINK QS-4.5)

4.5.1 Subcontractor of Calibration and Services

The ability of subcontractors (including suppliers and vendors) to meet approved quality requirements is essential. The evaluation and selection of any supplier or vendor of outside services relevant to measurement must include a thorough review of that company's internal quality control performance and standards to ensure consistency and full compliance with this International Standard for the work in question or should have a quality system in place. When subcontracts are used or necessary, the Customer Service Manager shall advise or request approval, in writing, to the client prior to contracting out the job when contractually required.

4.5.2 Control of Subcontractor & Vendor Standards

Company purchase orders, contract documentation and quality policy and procedures define the extent of control over subcontractors and vendors. The actual level of supervision depends on the type of subcontractors' or vendors' verifiable past performance. At no time is a quality deviation permitted in services that results in, or may result in, a standard of work that falls below the company's quality standards.

4.5.3 Approved Subcontractors & Vendors

The General Manager maintains a register of approved subcontractors, vendors and other suppliers, relevant to measurement with a record of the evidence of compliance with this International Standard for the work in question or a proven quality system in place. Where possible, a subcontractor and/or vendor shall be selected from the approved list provided the service is within its known capabilities and quality standards. Where appropriate, a quality check and reverification of acceptability shall be requested in accordance with QM-4.5.1; Subcontractor of Calibration and Services. Such a request may be made if it has been a specified amount of time since the subcontractor or vendor has worked with the company; and/or if the calibration required is new or has changed since the last subcontractor(s) or vendor(s) services.

4.5.4 Qual Tech Labs, Inc. is fully responsible for all work performed by a subcontractor, except in the case where the client or a regulatory authority specifies which subcontractor is to be used. The company is contractually accountable to the customer for its own product irrespective of subcontractor performance. The work-in-progress approval by a customer of a subcontractor's or vendor's product or process does not alleviate or remove any responsibility from the company, or its quality control standards, nor does it in any way provide a defense against any subsequent rejection of product or services delivered to the customer.

End Section QM-4.5

4.6.1 Purchasing Specifications

The selection and purchasing of services and supplies that affect the quality of calibrations is followed in QM-4.5; Subcontracting of Calibrations. Procedures shall exist for the purchase, reception and storage of reagents and company consumable materials relevant for the calibrations.

4.6.2 The Customer Service Manager shall specify all inspection criteria prior to delivery of the purchased supplies and consumable materials that affect the quality of measurement. Product or services are not released until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the calibrations concerned. Typically, such inspections would be required for purchases that must meet a critical technical standard. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 All purchasing, contract and other acquisition documentation is to clearly state, where applicable:

- The name, complete description and quantity ordered;
- The type, grade, class, and other precise identifying characteristics;
- Positive materials identification, including the product title or trade name, and all applicable specifications, drawings, process requirements, inspection instructions and necessary technical data;
- Approval and/or qualification requirements of any product, process, procedure, process equipment and personnel; and
- The Title, Number and Issue Date of any Quality System to be applied or which they were made from.

4.6.4 Purchase orders are issued by the Customer Service Manager or Controller.

4.6.5 Vendor Evaluation and Records

The General Manager shall evaluate suppliers of critical consumable supplies and services that affect the quality of measurement. This evaluation shall be followed per QM-4.5; Subcontracting of Calibrations.

4.6.6 A list of approved suppliers shall be maintained and followed per QM-4.5; Subcontracting of Calibrations. Records shall be maintained following QM-4.13; Control of Records.

End Section QM-4.6

SERVICE TO THE CLIENT (LEVEL 2 LINK QS-4.7)

4.7.1 The General Manager shall clearly identify the client's request and monitor the performance of the work being performed, while keeping the client apprised of any situations that may arise, if the company ensures confidentiality to other clients. Such cooperation may include:

- Providing the client and their representatives reasonable access to relevant areas of the company for the witnessing of measurements performed for the client;
- Preparation, packaging, and dispatch of serviceable items needed by the client for verification purposes.

4.7.2 Documented communications with the client, including guidance in technical matters, opinions and interpretations based on results, shall be maintained throughout the work being performed by the company. Delays and/or deviations shall be relayed to the client in writing or verbally for approval and/or disposition.

4.7.3 Customer surveys, including negative and positive feedback are requested by the company to improve the quality system and calibration activities and customer services.

End Section QM-4.7

4.8.1 The Company shall have a procedure for the resolution of complaints received from clients or other parties. Customer complaints are taken seriously and investigated with corrective action taken on every complaint. Customers are contacted for further information that may be needed to assess complaints and thoroughly resolve problematic areas from reoccurring. Customers are also contacted with the corrective action that was taken and its effectiveness to assure them of resolution for future business.

4.8.2 Customer complaints may be telephoned in or taken from the surveys sent out or any other means of communication. Records shall be maintained of all complaints and the investigations and corrective actions (following QM-4.11; Corrective Action) taken by the company.

End Section QM-4.8

CONTROL OF NONCONFORMING CALIBRATION WORK (LEVEL 2 LINK QS-4.9)

4.9.1 Nonconforming product is defined as any product, material or service that does not meet its specified requirements. Its failure to conform to the agreed standards might be the result of poor consumable materials or servicing by a sub-contractor; poor communications on the exact specifications required; damage in transit; or customer complaints. Policy QM-4.9; Control of Nonconforming Calibration Work does not address the possible reasons for nonconformance. It is concerned primarily with the controls necessary to prevent the inadvertent introduction of any calibration deficiencies. To achieve this objective, controls for identifying, evaluating, documenting, separating, reviewing and disposition of a nonconformance, with emphasis on preventing any accidental delivery to a client, are required.

4.9.2 The responsibility for identifying a nonconformance and the authority to order its disposition is the responsibility of the Laboratory Manager. Where nonconforming product is from a subcontractor, then its disposition and any further corrective action for future orders, shall be mutually agreed between the company's authorized representative and the subcontractor.

4.9.3 Nonconforming Review and Disposition

A nonconformance may be identified at any stage and, when identified, is corrected immediately together with any decision about the acceptability of the nonconforming work. The disposition method may be one of the following:

- Stop all further work, DO NOT APPLY STICKER
- Quote for disposition
- Notify client
- Return to supplier for replacement or re-servicing

4.9.4 When required under contract, customers are notified prior to any disposition or reworking can take place.

4.9.5 Disposition is determined by the Customer to the Customer Service Manager and administered by the Laboratory Manager and shall include the nature and the extent of the reasons are to be documented.

4.9.6 Records are to be maintained for nonconforming measurements, materials, and any re-inspection results. These records are to detail the exact occurrence, nature, extent, and disposition of the quality failure. When the evaluation indicates that the nonconformance could reoccur or there is doubt about the compliance of the company's operation with its own policies and procedures, the corrective action procedure, QM-4.10; Improvements shall be promptly followed.

End Section QM-4.9

4.10.1 Qual Tech Labs, Inc. shall continually improve the effectiveness of its management system using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

End Section QM-4.10

CORRECTIVE ACTION (LEVEL 2 LINK QS-4.11)

4.11.1 The purpose of corrective action is to identify and eliminate the quality failures that cause, or contribute to, actual and potential nonconformance. The investigation of quality failures and potential failures is a dynamic responsibility of personnel to make the decision about the acceptability of the nonconforming work. The introduction of nonconforming services and materials, or the measurement resulting in a nonconformance, may represent a systemic failure of quality management objectives or may simply indicate a temporary, and easily corrected loss of control.

4.11.2 Corrective actions depend on clearly identifying the underlying causal factors of any quality failure. The first and foremost step is investigating and identifying the root cause. Potential problems might include client requirements, methods and procedures, staff skills and training, consumable, or equipment and its calibrations. The level of any remedial action depends on the seriousness and complexity of the problem. Where an anomalous situation requires a permanent change to operating procedures, the changes are to be developed, implemented and recorded in accordance with QM-4.3; Document Control.

4.11.3 Corrective Action

Specific procedures developed for corrective action must be to a degree appropriate to the magnitude and the risk of the problem:

4.11.3.1 Promptly and effectively respond to customer complaints and other reports of product nonconformity.

4.11.3.2 Investigate and identify causative factors in any product, material, process and/or quality documentation that contribute, directly or indirectly, to any nonconformity.

4.11.3.3 Instigate corrective action (identified in 3.2 above) to eliminate any future nonconformance from the identified causal factor(s).

4.11.3.4 Monitor any corrective action taken to assess its effectiveness

4.11.4 Where the identification of a nonconformance or departure casts doubt on the company's compliance with its own policies and procedures, or on its compliance with this International Standard, the company shall ensure that the appropriate areas of activity are audited in accordance with QM 4.14 immediately or when practical as time allows. The interval or audit time may be increased as appropriate based on the evaluation from the findings when a serious issue or risk to the business is identified.

End Section QM-4.11

PREVENTIVE ACTION (LEVEL 2 LINK QS-4.12)

4.12.1 The purpose of preventive action is to take a proactive approach in eliminating or identifying areas of improvement with the quality failures that may cause, or contribute to, actual and potential nonconformity the detection of potential failures is a dynamic responsibility of management. The importance of early detection of potentially expensive quality variances is critical to the success of the company.

4.12.2 Specific procedures developed for preventive action must:

4.12.2.1 Review and, when necessary, investigate all processes and support activities that affect, directly or indirectly, quality control, process control when a nonconformance problem is detected or reported in quality records, audit reports and customer complaints.

4.12.2.2 Plan and implement specific preventive actions as determined necessary to correct actual and potential nonconformance problems.

4.12.2.3 Ensure that preventive action is initiated and understood.

4.12.2.4 Monitor any preventive action taken to assess its effectiveness.

End Section QM-4.12

4.13.1 The effectiveness of the Quality Management Systems depends on efficient record keeping. Records may be stored as hard (paper) media or electronically using computer software. The term "Quality Records" is interchangeable between the two; document storage and/or electronic storage. Secure retrieval protocols and the integrity of stored information are critical for either method to ensure back-up records are practiced and to prevent unauthorized access to, or amendment of records.

4.13.2 Quality Management Records are defined as any internal audit reports, quality plans, training records, service/scale reports, calibration records, subcontractor approval and oversight documents, management reviews, corrective and preventive action records, and all technical quality or conformance documents.

4.13.3 Technical Records

Records of original observations derived data and sufficient information to establish an audit trail; calibration records, measurement records, staff records and a copy of each calibration report or certificate must be retained. The records for each calibration or scale serviced shall 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 shall include the identity of personnel responsible for the performance of each calibration and checking of results. Technical records may include; forms, contracts, work sheets, work orders, work books, check sheets, work notes, control graphs, clients' notes, papers and feedback.

4.13.4 All quality records must be legible and contain specific tracing information for the pertinent scale serviced. Observations, data and calculations shall be recorded at the time they are made and shall identifiable to the specific task.

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

4.13.6 The General Manager is responsible for maintaining an accurate list of all quality records and shall establish specific record locations and document retention cycles. The retention times are to be established after consideration of potential product liability, litigious limitation of civil statutes and statutory requirements.

4.13.7 Quality Records are available to any customer, or the customer's representative, as requested. All records shall be held secure and in confidence. The company may, however, and at its sole discretion, voluntarily disclose proprietary quality documentation on a non-contractual basis to its customers for any legitimate purpose.

End Section QM-4.13

4.14.1 *Internal Quality Audits (IQA)* are necessary to measure the effectiveness of the company's total quality performance. Competent and qualified personnel who do not have direct responsibility for the function under audit and is knowledgeable of the function under audit, conducts *IQAs*. The General Manager selects the auditor, plans and organizes all audits. The Auditor (internal or external) has been selected based on their technical knowledge and their understanding of Quality Policy and Procedures. The purpose of any *IQA* is not punitive: it is to verify that actual procedures and results comply with the company's quality policies and procedures.

4.14.2 All elements of the quality system are audited regularly, (audits are completed within one year from the last audit), in accordance with documented procedures. The complexity and importance of the audited function determine the actual frequency of each *IQA*.

4.14.3 Emergency *IQAs* may be conducted in the event of consistent quality management failures that adversely affect the process performance of any company function. An identifiable pattern of functional quality problems that impact negatively on other functions, or have a clear and present potential to do so, usually requires an emergency *IQA*.

4.14.4 The results of any *IQA* are distributed to the General Manager. When an *IQA* Report identifies significant quality failures and/or recommends immediate remedial action, it is the responsibility of the General Manager to plan and initiate corrective action.

4.14.5 When audits findings cast doubt on the effectiveness of the operations or on the correctness or validity of the company's calibration results, the company shall take timely corrective action, and shall notify clients in writing if investigations show that the company results may have been affected.

4.14.6 Check or follow-up audits shall be performed as appropriate to verify that all necessary corrective actions have been taken. The decision to perform a check *IQA* depends on the improvement (or otherwise) of process output, the relative importance of the function under audit and its impact on other interdependent functions, and any relevant safety or environmental issues.

4.14.7 The General Manager always review *IQA* findings to identify any actions that may improve the total quality performance of the company.

End Section QM-4.14

MANAGEMENT REVIEWS (LEVEL 2 LINK QS-4.15)

4.15.1 Qual Tech Labs, Inc. has documented adequate resources for quality control and process verification activities. These resources are continuously reviewed to provide the level of control necessary to meet operational changes and/or growth and to ensure their continuing suitability and effectiveness. The review shall take account of:

- The suitability of policies and procedures;
- Reports from personnel;
- The outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- The results of intercompany comparisons;
- Changes in the volume and type of the work;
- Customer feedback;
- Complaints; and
- Recommendations for improvement;
- Other relevant factors, such as quality control activities, resources and staff training.

4.15.2 Results should feed into the company planning system and should include the goals, objectives and action plans for the coming year.

4.15.3 Findings from management reviews and the actions that arise from them shall be recorded. The General Manager shall ensure that those actions are carried out within an appropriate and agreed time scale.

4.15.4 The deployment of quality control resources is to be reviewed at least once each year. A more frequent review may be necessary if quality control deficiencies and/or experience suggest a less than adequate commitment to the policies and procedures contained in this manual. The purpose of a formal annual review is to analyze the level of resources (management, manpower and materials) committed to the quality control program. The annual review is to be formally conducted by the General Manager. A review shall also be part of any new contract or vendor relationship.

End Section QM-4.15

5.1.1 Many factors determine the correctness and reliability for the calibrations performed by the company. These factors include contributions from:

- Human factors;
- Accommodation and environmental conditions;
- Test and calibration methods and method validation;
- Equipment;
- Measurement traceability;
- Measurement uncertainty; and
- Handling of test and calibration items.

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between types and methods utilized. The company shall consider these factors in the development of methods and procedures as well as in the training and qualification of personnel and the selection and methods of the equipment being used.

End Section QM-5.1

5.2.1 The appropriate departmental managers shall ensure the competence of all personnel who operate specified equipment, perform services and evaluate results. Personnel performing specific tasks shall be qualified based on appropriate education, training, experience and/or demonstrated skills as required.

5.2.2 Where personnel may be required to hold some type of special certificate, Qual Tech Labs, Inc. is responsible for fulfilling those requirements. The requirements may be regulatory, or required by the client.

5.2.3 The General Manager shall formulate the goals with respect to the education, training and skills of personnel. The company shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the company.

5.2.4 The General Manager and/ or Laboratory Manager shall use personnel who are employed by, or under contract to, the company. Where contracted and additional technical and key support personnel are used, the General Manager shall ensure that such personnel are supervised and competent, and that they are trained and work in accordance with the company's quality system.

5.2.5 The General Manager and/or Laboratory Manager shall maintain current job descriptions for support personnel involved in the services provided. Job descriptions can be defined in many ways, as a minimum, the following should be defined:

- The responsibilities with respect to performing provided services;
- The responsibilities with respect to the planning of calibrations, services and evaluation of results;
- The responsibilities for reporting opinions and interpretations;
- The responsibilities with respect to method modification and development and validation of new methods;
- Expertise and experience required;
- Qualifications and training program; and
- Managerial duties.

5.2.6 The General Manager and/or Laboratory Manager shall authorize specified personnel to perform types of measurement, to give opinions and interpretations and to operate types of equipment. The General Manager and/or Laboratory Manager shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

End Section QM-5.2

ACCOMMODATION AND ENVIRONMENTAL CONDITIONS (LEVEL 2 LINK QS-5.3)

5.3.1 The Laboratory Manager shall ensure the calibration and service facilities and equipment including, but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of all calibration or service reports taken. The environmental conditions cannot invalidate the results or adversely affect the required quality of any measurement. Care shall be taken when calibration, construction and services are undertaken at sites other than a permanent company facility. The technical requirements for accommodation and environmental conditions that can affect the results of calibration and services shall be documented.

5.3.2 The Laboratory Manager shall 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 shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Calibrations shall be stopped when the environmental conditions jeopardize the results.

- Effective separation areas shall be identified for incompatible activities with measures taken to prevent cross-contamination.
- The Laboratory Manager shall determine the extent of control for access and use to areas affecting the quality of measurement.
- Every measure shall be taken to ensure good housekeeping practices throughout the company.
- Special procedures shall be prepared as necessary.

End Section QM-5.3

5.4.1 General

International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the calibration and provided services do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a company. It may be necessary to provide additional documentation for optional steps in the method or additional details.

5.4.2 Selection of Methods

The Laboratory Manager shall use appropriate methods and procedures for all calibrations to equipment within its scope. These including 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.

5.4.3 The Laboratory Managers shall ensure that instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for calibration, where the absence of such instructions could jeopardize the results of measurements conducted. All instructions, standards, manuals and reference data relevant to the work of the company shall be kept up to date and shall be made readily available. Deviation from calibration methods shall occur only if the deviation has been documented, technically justified, authorized and accepted by the client.

5.4.4 The company shall use measurement methods which meet the needs of the client and which are appropriate for the equipment it undertakes. Methods published in international, regional, or national standards shall preferably be used when calibrating the equipment used for measurement. The Laboratory Manager shall 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 shall be supplemented with additional details to ensure consistent application.

5.4.5. When the manufacturer does not specify the method to be used for calibration of equipment, the company shall 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. Company-developed methods, or methods adapted by the company may also be used if they are appropriate for the intended used and if they are validated. The client shall be informed as to the method chosen, if this has any effect on their measurement output. The company shall confirm that it can properly operate standard methods before introducing the calibrations. If the standard method changes, the confirmation shall be repeated.

5.4.6 The Customer Service Manager shall inform the client when a piece of equipment for the measurement method proposed by the client is considered inappropriate or out of date.

5.4.7 Company-Developed Methods

Qual Tech Labs, Inc. may develop methods and validation before use that are traceable to NIST if there are no methods have been established. The client shall agree to these methods.

5.4.8 Nonstandard Methods

Quall Tech Labs, Inc. may develop methods and validation before use that are traceable to NIST if there are no methods have been established. The client shall agree to these methods.

5.4.9 Validation of Methods

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

5.4.10 The Laboratory shall validate standard methods used outside their intended scope, and amplifications and modifications of standard methods to conform that the methods are fit for the intended used. The validation shall be as extensive as necessary to meet the needs of the given application or field of application. The Laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. Validation may include procedures for handling and transportation.

5.4.11 The techniques used for the determination of the performance of a method shall be one of, or a combination of, the following:

- Calibration using reference standards or reference materials;

- Comparison of results achieved with other methods;
- Intercompany comparisons;
- Systematic assessment of the factors influencing the result;
- Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

5.4.12 When some changes are made in the validated nonstandard methods, the influence of such changes shall be documented and, if appropriate, a new validation should be carried out.

5.4.13 The range and accuracy of the values obtainable from validated methods as assessed for the intended use, shall be relevant to the client's needs. These may include:

- 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 object.

5.4.14 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that using the method and a statement on the validity can fulfill the requirements. Some method-development proceeds, regular review shall be carried out to verify that the needs of the client are still being fulfilled. Any change in requirements requiring modifications to the development plan shall be approved and authorized. Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values can only be given in a simplified way due to lack of information.

5.4.15 Estimation of Uncertainty of Measurement

When estimating the uncertainty of measurement, all uncertainty components, which are of importance in the given situation, shall be considered issuing appropriate methods of analysis.

- ❖ Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being calibrated, and the operator.

- ❖ The predicted long-term behavior of the calibrated item is not normally considered when estimating the measurement uncertainty.
- ❖ For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement.

5.4.16 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- The requirements of the calibration method;
- The requirements of the client;
- The existence of narrow limits on which decisions on conformance to a specification are based.

5.4.17 Control of Data

The control of data transfers shall be subject to appropriate checks in a systematic manner. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of calibration data, the company shall ensure that.

- Computer software developed by the user is documented in sufficient detail and is suitable validated as being adequate for use.
- Procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing.
- 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.
- Commercial off-the-shelf software in general use within their designed application range may be sufficiently validated. However, company software configuration/modifications should be validated.

End Section QM-5.4

5.5.1 The company shall be furnished with all items of equipment required for the correct performance of the measurements taken and recorded, which include preparation, processing and analysis. In those cases, where the company needs to use equipment outside its permanent control, the requirements of this international standard are ensured to have been met.

5.5.2 Equipment and its software used for calibration shall can achieve the accuracy required and shall comply with specifications relevant to the measurements concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on measurement results. Before being placed into service, equipment shall be calibrated or checked to establish that it meets the company's specification requirements and complies with the relevant standard specifications. It shall be checked or calibrated before use.

5.5.3 Authorized personnel shall operate equipment. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate company personnel.

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

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

a) the identity (serial number) 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 due date of next calibration

g) the maintenance plan and maintenance carried out to date

h) any damage, malfunction, modification or repair to the equipment

5.5.6 The company shall have procedures for safe handling, transport, storage; use and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration. Additional procedures may be necessary when measuring equipment is used outside the permanent company for calibration.

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, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown to perform correctly. The company shall examine the effect of the defect or departure from specified limits on previous calibrations and shall institute the *"Control of nonconforming work"* procedure.

5.5.8 Whenever practicable, all equipment under the control of the company and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.9 When equipment goes outside the direct control of the company, the company shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out per a defined procedure.

5.5.11 Where calibrations give rise to a set of correction factors, the company shall have procedures to ensure that copies are correctly updated.

5.5.12 Calibration equipment, including both hardware and software, shall be safeguarded from adjustments, which would invalidate the calibration results.

End Section QM-5.5

5.6.1 All equipment used for calibration, including equipment for subsidiary calibrations, (for environmental conditions), having a significant effect on the accuracy or validity of the result of the measurements shall be calibrated before being put into service. The company shall have an established program and procedure for the calibration of its own equipment. Such a program shall include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring equipment used to perform calibrations.

5.6.2 The program for calibration of equipment shall be designed and operated to ensure that measurements made by the company are traceable to the International Systems of Units *(SI).*

5.6.3 The company established traceability of its own measurement standards and measuring instruments to the *SI* by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the *SI* units of measurement. The link to *SI* units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the *SI* units or agreed representations of *SI* units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured using calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

5.6.4 Calibration laboratories fulfilling the requirements of the International Standard ISO/IEC 17025:2005 are competent. A calibration certificate bearing an accreditation body logo from a calibration company accredited to this ISO/IEC 17025:2005 International Standard for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

5.6.5 Traceability to *SI* units of measurement may be achieved by reference to an appropriate primary standard or by reference to a natural constant, the value of which in terms of the relevant *SI* unit is known and recommended.

5.6.6 Calibration laboratories that maintain their own primary standard or representation of *SI* units based on fundamental physical constants can claim traceability to the *SI* system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

5.6.7 The term *"identified metrological specification"* means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

5.6.8 When the terms *"international standard"* or *"national standard"* are used about traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of *SI* units.

5.6.9 Traceability to national standards does not necessarily require the use of the national metrology institute of the country in which the company is located.

5.6.10 If a company wishes or needs to obtain traceability from a national metrology institute other than in its own country, this company should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

5.6.11 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

5.6.12 There are certain calibrations that currently cannot be strictly made in *SI* units. 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 reliable physical or chemical characterization of a material; or
- 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 intercompany comparisons is required, where possible.

5.6.13 Reference Standards

The company shall have a program and procedure for the calibration of its reference standards. A body that can provide traceability shall calibrate reference standards. Such reference standards of measurement held by the company shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

5.6.14 Reference Materials

Reference materials shall, where possible, be traceable to *SI* units of measurement, or to certified reference materials. Internal reference materials shall be checked to ensure it is technically and economically practicable.

5.6.15 Intermediate Checks

Checks need to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out per defined procedures and schedules.

5.6.16 Transport and Storage

The company shall have procedures for safe handling, transport, storage and use of reference standards and reference materials to prevent contamination or deterioration and to protect their integrity. Additional procedures may be necessary when reference standards and reference materials are used outside the permanent company.

End Section QM-5.6

SAMPLING (LEVEL 2 LINK QS-5.7)

5.7.1 Qual Tech Labs, Inc. does not conduct any sampling. If sampling does become a requirement or service provided by the company, procedures shall be development, implemented and followed accordingly.

End Section QM-5.7

HANDLING OF CALIBRATION ITEMS (LEVEL 2 LINK QS-5.8)

5.8.1 Qual Tech Labs, Inc. shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of items to be measured, including all provisions necessary to protect the integrity of the calibrated item, and to protect the interests of the company and client.

5.8.2 The company shall identify calibration scales and items by serial number. The identification shall be retained throughout the life of the item in the company. The system shall be designed and operated to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a subdivision of groups of items and the transfer of items within and from the company.

5.8.3 Upon receipt of the calibrated items, abnormalities or departures from normal or specified conditions, as described in the methods, shall 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 the calibration required is not specified in sufficient detail, the company shall consult the client for further instructions before proceeding and shall record the discussion.

5.8.4 The company shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items must be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where items or portions of items are to be held secure, the company shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

5.8.5 Reasons for keeping an item secure can be for reasons of record, safety or value, or to enable complementary calibrations to be performed later.

End Section QM-5.8

ASSURING THE QUALITY OF CALIBRATION RESULTS (LEVEL 2 LINK QS-5.9)

5.9.1 The company shall have quality control procedures for monitoring the validity of calibrations undertaken. The resulting data shall 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 shall be planned and reviewed and may include, but not limited to, the following:

- Regular use of certified reference materials and/or internal quality control using secondary reference materials;
- Participation in intercompany comparison or proficiency-testing programs;
- Replicate calibrations using the same or different methods;
- Recalibration of equipment used for measurement or retained items; and
- Correlation of results for different characteristics of an item.

The selected methods should be appropriate for the type and volume of work undertaken.

The company will ensure quality control data is analyzed and, where it is found outside pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.

End Section QM-5.9

REPORTING THE RESULTS (LEVEL 2 LINK QS-5.10)

5.10.1 General

The results of each calibration or series calibrations carried out by the company shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the calibration and service methods. The results shall be reported Certificate of Calibration with a detailed work order included, and shall include all the information requested by the client and necessary for the interpretation of the 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. The reports may be issued as hard copy or by electronic data transfer if the requirement has been met.

5.10.2 Any information listed in the report, which is not reported to the client, shall be readily available in the company and contain the personnel or subcontractor, which carried out the calibration or service.

5.10.3 Measurement Reports

Each report shall include at least the following information, unless the company has valid documented reasons for not doing so:

- A title (“Calibration Certificate Number”);
- The name and address (work order) of the company, and the location where the calibration or services were carried out, if different from the address of the company;
- Unique identification of the report (such as a serial number), and on each page an identification to ensure that the page is recognized as a part of the report, and a clear identification of the end of the report;
- The name and address of the client (work order);
- Identification of the method used;
- A description of, the condition of, and unambiguous identification of the item(s) calibrated or serviced;
- The date of receipt of the item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the calibration or provided service;
- Reference to the procedures used by the company or other bodies where these are relevant to the validity or application of the results;
- The results with, where appropriate, the units of measurement; and
- The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the report.

Hard copies of reports should also include the page number and total number of pages. A statement specifying that the report shall not be reproduced except in full, without written approval from the company.

5.10.4 Calibration Reports shall include the following, where necessary for the interpretation of results in addition to the above items mentioned:

- ❖ The conditions under which the measurements were made that have an influence on the calibration or service results, (e.g. environmental);
- ❖ The uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof; and
- ❖ Evidence that the measurements are traceable.

5.10.5 The Certificate of Calibration Report shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses 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 company shall record those results and maintain them for possible future reference. When statements of compliance are made, the uncertainty of measurement shall be considered.

5.10.6 When an instrument or scale for calibration or servicing has been adjusted or repaired, the results before and after adjustment or repair, if available, shall be reported.

5.10.7 The Certificate of Calibration shall not contain any recommendation on the intervals except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.8 Opinions and Interpretations

When opinions and interpretations are included, the company shall document the basis upon which they have been made.

5.10.9 Calibration Results Obtained from Subcontractors

Where calibration/Service functions have been subcontracted, the company performing the work shall issue the Certificate of Calibration to the contracting company.

5.10.10 Electronic Transmissions of Results

In the case of transmission of results by telephone, telex, e-mail, facsimile or other electronic or electromagnetic means, the requirements of the ISO/IEC 17025:2005 International Standard shall be met.

5.10.11 Format of Reports

The report shall be designed to accommodate each type of service carried out and to minimize the possibility of misunderstanding or misuse. The reader should give attention to the layout of the report, especially about the presentation of the data and ease of assimilation. The headings should be standardized as far as possible.

5.10.12 Amendments to Calibration Reports

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

- *"Supplement to Certificate of Calibration, serial number [or as otherwise identified]"*, or an equivalent form of wording.
- Such amendments shall meet all the requirements of the ISO/IEC 17025:2005 International Standard.
- When it is necessary to issue a complete new Calibration Certificate, this shall be uniquely identified and shall contain a reference to the original that it has replaced.

End Section QM-5.10

PROCEDURES CONTENTS LIST

PROCEDURES CONTENTS LIST

END OF QUALITY MANUAL