

# Quality Manual



**Matphil Technologies, Inc.**  
**dba AccuTek Laboratories**  
**dba pipette.com**

9212 Mira Este Court, Suite 100  
San Diego CA 92126

**UNCONTROLLED  
COPY**

**Issue Date:**

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## **QUALITY POLICY**

The Company recognizes that the disciplines of quality, health and safety, and environmental management, are integral parts of its management function. The Management of AccuTek Laboratories views these as a primary responsibility and fundamental to the best business practice of operating under the control of a Management System, along the lines laid down in the ISO/IEC 17025:2005 & ISO 9001:2000 standards. The Company is committed to the adoption of best professional practice in the services it offers to its Customers

It is the Company's policy to seek to operate to the highest standards continuously and to implement and operate fully the ISO/IEC 17025:2005 & ISO 9001:2000 standards, including continual improvement, through registration and annual review.

The Company will:

- ✓ have as its goal the achievement of superior external and internal Customer satisfaction levels;
- ✓ comply with all legislation relevant to the supply of new and refurbished liquid measuring instruments, accessories, supplies and the provision of liquid measuring instruments calibration services, and also the Occupational Safety and Health Administration and Environment Protection Agency regulations;
- ✓ ensure all test and calibration activity is always carried out in accordance with stated methods and customers' requirements;
- ✓ implement continual improvement initiatives to sustain Quality excellence and make best use of its management resources;
- ✓ communicate its objectives, and its performance in achieving these objectives, throughout the Company and to interested parties;
- ✓ take due care to ensure that activities are safe for employees, associates, sub-contractors, and others who come into contact with its products, services, work and other activity;
- ✓ work closely with its Customers and Suppliers in seeking to establish the highest standards for product and service quality and on-time delivery;
- ✓ adopt a forward-looking view on future business decisions which may have an impact on Quality;
- ✓ train all members of staff in the needs and responsibilities of Quality Management;
- ✓ constantly striving to meet, and where possible exceed, its customer's expectations.

Responsibility for upholding this policy is truly Company-wide under the guidance and with the assistance of the General Manager who encourages the personal commitment of all staff to address quality as part of their skills.

Signed:

(General Manager)

Date:



**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**Manual Issue Sheet**

Section: QM 1  
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**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**AccuTek Laboratories**

Controlled Issue:

This Copy: Number 1  
Copy Holder: Quality Manager

This Quality Manual cover the activities and functions performed by operating areas included in the registration scope definition:

Supply of new and refurbished liquid measuring instruments, accessories, supplies and the provision of liquid measuring instruments calibration services.

The Management System is designed to meet the requirements of:

ISO/IEC 17025:2005 & ISO 9001:2000

CA:2762



**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**Distribution Sheet**

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**Quality Manual**

**ISO/IEC 17025:2005 & ISO 9001:2000**

Controlled Distribution:

Copy: Number 1:  
Copy Holder: Quality Manager

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Copy Holder: Quality Manager



**Quality Manual**  
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**Amendment Procedure**

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**AMENDMENT PROCEDURE**

All copies of this Quality Manual must be kept under strict control to prevent the Management System from becoming unreliable. The following procedure will ensure that the system remains current and valid.

1. All copies of the Quality Manual will be clearly numbered and the holder recorded, with each page of the Quality Manual carrying its own number.
2. Changes can be suggested by any employee but will have the signed authorization of the Quality Manager at the time of being incorporated into the Quality Manual.

The Quality Manager will first ensure the proposed amendment is reviewed and approved by the Company's executive and senior management.

3. The Quality Manager will record a summary of each change on the Section Revision History for the applicable section and will amend the appropriate pages in each controlled copy of the Quality Manual, updating the issue reference and issue date accordingly.

The Quality Manager will sign off the entry. The previous authorization signature will be replaced by a typescript of the Authorizer's initials on the reprinted Section Revision History.

4. One hard copy of each superceded page will be filed in an archive file, for reference purposes, and marked as such with reference to the next issue reference and date.
5. Copies of the Quality Manual may be issued to parties outside the Company for reference purposes only, but will not be registered as a controlled distribution copy.

All requests for an uncontrolled copy will be passed to the Quality Manager for processing. The front sheet of such copies will be marked with the words "Uncontrolled Copy" with the date of issue noted.



**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000****QUALITY OBJECTIVES**

The Company is dedicated to establishing a Management System that includes the setting, measuring and monitoring of Quality objectives.

The Company will:

- Identify the needs and requirements of Customers both explicit and implicit.
- Assess the ability to meet these needs economically.
- Ensure all brought-in materials and services reliably meet the required standards of performance and efficiency.
- Identify the processes involved in providing products and services and will establish systems to ensure Quality requirements are met efficiently and economically, including customer, regulatory and other contractual requirements.
- Ensure schedules are planned and met.
- Identify new market opportunities.
- Provide clear leadership to ensure all employees are able to focus on a prevention rather than detection philosophy and that it is applied throughout the company.
- Operate a system of education and training for Quality improvement.
- Review the Management System to identify opportunities for improvement and to maintain progress and continual improvement.
- Ensure all quality objectives are measurable and consistent with the Quality Policy.

Achieving these objectives will demonstrate the Senior Management's dedication to the philosophy of applying a systematic approach to the establishment and maintenance of a Management System and to demonstrate the determination to consistently provide products and services that meet Customer and applicable regulatory requirements.

Further measurable objectives relating to any given project or process may be set. Objectives will be reviewed on a regular basis to determine levels of achievement. As objectives are achieved in their entirety, others may replace them. See also SOP01, Setting Quality Objectives, for further details on setting and monitoring quality objectives.



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**ISO/IEC 17025:2005 & ISO 9001:2000**

**Quality Policy**

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**QUALITY POLICY**

The Company recognizes that the disciplines of quality, health and safety, and environmental management, are integral parts of its management function. The Management of AccuTek Laboratories views these as a primary responsibility and fundamental to the best business practice of operating under the control of a Management System, along the lines laid down in the ISO/IEC 17025:2005 & ISO 9001:2000 standards. The Company is committed to the adoption of best professional practice in the services it offers to its Customers.

It is the Company's policy to seek to operate to the highest standards continuously and to implement and operate fully the ISO/IEC 17025:2005 & ISO9001:2000 standards, including continual improvement, through registration and annual review.

The Company will:

- ✓ have as its goal the achievement of superior external and internal Customer satisfaction levels;
- ✓ comply with all legislation relevant to the supply of new and refurbished liquid measuring instruments, accessories, supplies and the provision of liquid measuring instruments calibration services, and also the Occupational Safety and Health Administration and Environment Protection Agency regulations;
- ✓ ensure all test and calibration activity is always carried out in accordance with stated methods and customers' requirements;
- ✓ implement continual improvement initiatives and make best use of its management resources to better meet Customers' requirements;
- ✓ communicate its objectives, and its performance in achieving these objectives, throughout the Company and to interested parties;
- ✓ take due care to ensure that activities are safe for employees, associates, sub-contractors, and others who come into contact with its products, work and other activity;
- ✓ work closely with its Customers and Suppliers in seeking to establish the highest standards for product quality and on-time delivery;
- ✓ adopt a forward-looking view on future business decisions which may have an impact on Quality;
- ✓ train all members of staff in the needs and responsibilities of Quality Management;
- ✓ constantly striving to meet, and where possible exceed, its customer's expectations.

Responsibility for upholding this policy is truly Company-wide under the guidance and with the assistance of the General Manager who encourages the personal commitment of all staff to address quality as part of their skills.

Signed: \_\_\_\_\_ (General Manager)                      Date: \_\_\_ / \_\_\_ / \_\_\_





**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**Company Profile**

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**COMPANY PROFILE**

AccuTek Laboratories is located in San Diego, California and has been a quality supplier of new and refurbished pipettes supported by pipette service and calibration since 1996.

As a growing company, AccuTek strives continuously to assure customer satisfaction by providing the best possible quality and price for its products and services.

By performing calibration services in-house, the Company is able to assure state-of-the-art facilities with controlled conditions for temperature, humidity and barometric pressure, with manufacturer qualified technicians and superior precision calibration equipment.

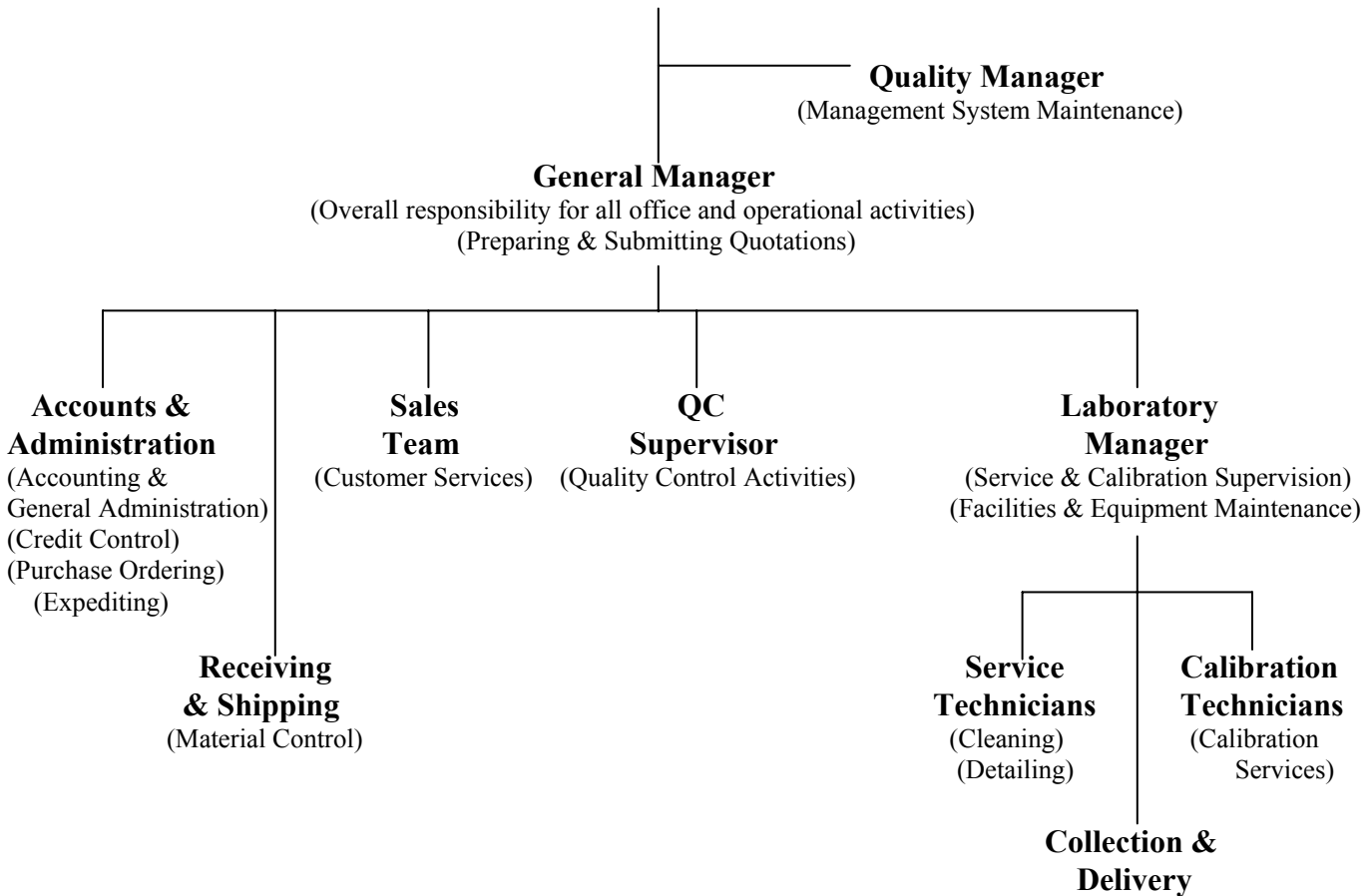
As the Company is proud to include customers in the biotech, pharmaceutical, food and chemical industries where precision and quality are paramount, an essential requirement of the continued maintenance and development of the Company's objectives is the establishment of a management system registered to the ISO/IEC 17025:2005 and ISO9001:2000 standards. The ISO/IEC 17025 standard providing specific management and technical requirements for test and calibration services. As well as satisfying the guidelines in these standards, the Company's procedures follow Good Laboratory Practice and Good Manufacturing Practice guidelines.

AccuTek Laboratories continues to be based on the wide ranging and practical blend of skills and experience of its management core and staff, and offers cost effective specialist skills and the in-depth experience across the full range of pipette applications. The Company is committed to the operation of an independently verified Management System as evidence of the excellence of the service provided to its customers.

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**ORGANIZATION AND RESPONSIBILITIES**

**The Directors of Matphil Technologies, Inc. are the Executive Management of AccuTek Laboratories**  
 (Corporate Strategy and Business Development)



Functional responsibilities, for the above Post Titles, are detailed descriptively within the text of each procedure.

**Responsibilities:**

Whilst the detailed Management System states specific Post Titles for certain actions, other persons may need to carry out the actions in the short term absence of the stated person.

This applies to the function of the Laboratory Manager. The responsibility for other defined roles will automatically pass to the Laboratory Manager or the General Manager. The General Manager will be responsible for determining who will be delegated to perform the responsibilities and authorities required. The short-term delegation of the actions to another person does not mean that the person holding the Post Title relinquishes the responsibility and will monitor actions carried out on their behalf.

For long-term absences, the General Manager will be responsible for passing the responsibilities of the Post Title to another suitable and qualified member of staff.

Quality responsibilities are described as follows:

**Executive Management:**

Responsibility for:

- corporate strategy, business development and direction, and Company profitability;
- the organization including the definition of the Quality Policy and its communication and understanding throughout the organization;
- appointing a member of the Company's management as the Quality Manager;
- presiding over management reviews of the Management System on the agenda and other recommendations of the Quality Manager.

**General Manager:**

Responsibility for:

- the co-ordination and control of quality activities and all services provided;
  - the provision of the resources necessary for the effective implementation of the Management System;
  - determining the applicable regulatory authorities whose requirements may have an impact on the Customer's requirements and their product;
  - responding to quality and other related problems that arise from customer complaints;
- ....continued



**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**Responsibilities**

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**General Manager: continued....**

- participating in the hiring or discharging of employees, and in employee meetings;
- ensuring that all personnel are adequately qualified and experienced in their relevant discipline to perform the duties of their position in a satisfactory manner;
- ensuring personnel qualification requirements are defined;
- ensuring training needs are analyzed and training and recruitment programs are established to meet identified needs;
- ensuring training programs are successfully completed in a timely manner;
- conducting market research and analyses;
- general marketing activity including advertising, the Company's web site, and other promotional tools;
- monitoring the quality of competitors;
- ensuring good relationships are established and maintained with the Company's Customers;
- ensuring the functional specifications of products and associated services are established;
- ensuring estimates and quotations are prepared for submission;
- ensuring quotations, and subsequent received orders, are reviewed and approved;
- ensuring good relationships are established and maintained with the Company's key Suppliers and Sub Contractors;
- ensuring a listing of the Company's Preferred Suppliers and Sub Contractors is maintained, with the scope of approval for each;
- ensuring suppliers and sub contractors are formally assessed, and their continuing performance monitored and reviewed, to confirm they can meet the Company's requirements;
- ensuring the purchasing requirements are determined and Purchase Orders are made with clearly defined requirements for purchased products and services;
- establishing the level of controls to be implemented and the action programs required to deal with poor Supplier performance.

**Laboratory Manager:**

Responsible for:

- ensuring all equipment maintenance requirements are scheduled and completed in a satisfactory manner;
- ensuring product and service requirements to fulfil Customer orders are planned and scheduled via regular planning meetings;
- ensuring that all established and appropriate process controls, procedures and written work instructions are adopted, particularly where their absence would affect quality;
- ensuring that criteria for workmanship are issued, that the approved processes and equipment to achieve those criteria are available, and that the work is completed in compliance with the applicable standards, industry, health and safety, and Company codes of practice such as GLP and GMP, and documented procedures;
- ensuring all in-house service requirements adhere to planned schedules;
- ensuring all variations in schedules affecting Customer orders are reported and resolved in a satisfactory and timely manner;
- ensuring that all established and appropriate process controls, procedures and written work instructions are adopted, particularly where their absence would affect quality;
- the quality of work carried out by service and calibration personnel and for providing support and guidance when the required standards are not met;
- responding to any product quality related problems that may arise during the service and calibration processes, whether within the Company's facility or at a sub-contractor.

**Service and Calibration Personnel:**

Responsible for:

- completing all assigned equipment maintenance requirements in a satisfactory manner;
- adopting all established and appropriate process controls, procedures and written work instructions, particularly where their absence would affect quality;
- following issued criteria for workmanship;
- completing work in compliance with the applicable standards, industry, health and safety, and Company codes of practice, and documented procedures.

**QC Supervisor:**

Responsible for:

- responding to any product quality related problems that may arise during the service, calibration and shipping processes, whether within the Company's facility, on-site or at a sub-contractor;
- ensuring all equipment and gauging required for use in QC inspection is fit for use prior to its release;
- planning, scheduling all calibration activity for measuring, monitoring and test equipment to maintain their integrity;
- monitoring all product, service and calibration work to ascertain the QC inspection needs;
- the quality of all product and services supplied by the Company, and its sub-contractors, via a planned program of QC inspection, including incoming material and components;
- the co-ordination of quality inspection activities;
- reviewing, with others as necessary, all non-conforming material received from suppliers and sub-contractors and determining the actions required.

**Quality Manager:**

Responsible to the General Manager for:

- planning and managing the Management System, including maintaining and controlling the Quality Manual and any associated procedures and documentation;
- ensuring all Company personnel have access to the Management System documentation and are aware of the Company's Quality Policy;
- preparing and implementing a program of audits and reviews of the Management System to ensure compliance with ISO/IEC 17025:2005 and ISO9001:2000 standards;
- reporting to the Executive and General management on patterns, trends and other quantifiable measurements to ascertain the effectiveness of the System in meeting the Company's Quality Policy and objectives and the requirements of Customers;
- recommending and initiating corrective and preventive action as and when necessary will have the organizational freedom and authority to resolve all quality related issues;
- aiding the determination of the applicable regulatory authorities whose requirements may have an impact on the Customer's requirements;
- liaising with interested external parties and ensuring Customers and applicable regulatory authorities have appropriate access to the Quality System documentation.

**Accounts & Administration:**



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**ISO/IEC 17025:2005 & ISO 9001:2000**

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Responsible for:

- ensuring prompt invoicing, and subsequent credit control, processes are established;
- generating and expediting purchase orders;
- co-ordinating office and administration activities.

**All Personnel:**

Responsible for:

- the prompt identification and reporting of any non-conformance;
- for the compliance to, and maintenance of, those aspects and requirements of the Company's Management System and associated procedures in which they are involved;
- being aware of the Company's Quality Policy and for upholding its principles;
- to carry out the specific responsibilities as defined by the applicable Post Title.

See section QM 3-2, Organization, for an organization chart providing an outline of the functional Post Titles, their inter-relationship and reporting lines, and principal responsibilities.



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**ISO/IEC 17025:2005 & ISO 9001:2000**

**Responsibilities**

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**Management System Responsibilities:**

In accordance with the procedures defined in the authorized Quality and Procedures Manuals, including the Internal Audit Procedure, PM 10, the following personnel are appointed as Quality Manager and Internal Auditors:

**Quality Manager &  
Internal Auditor:**

**Alex Spector**

Signature: \_\_\_\_\_

**Deputy Quality Manager:**

**Tatyana Dolgen**

Signature: \_\_\_\_\_

**Internal Auditor:**

**Igor London**

Signature: \_\_\_\_\_

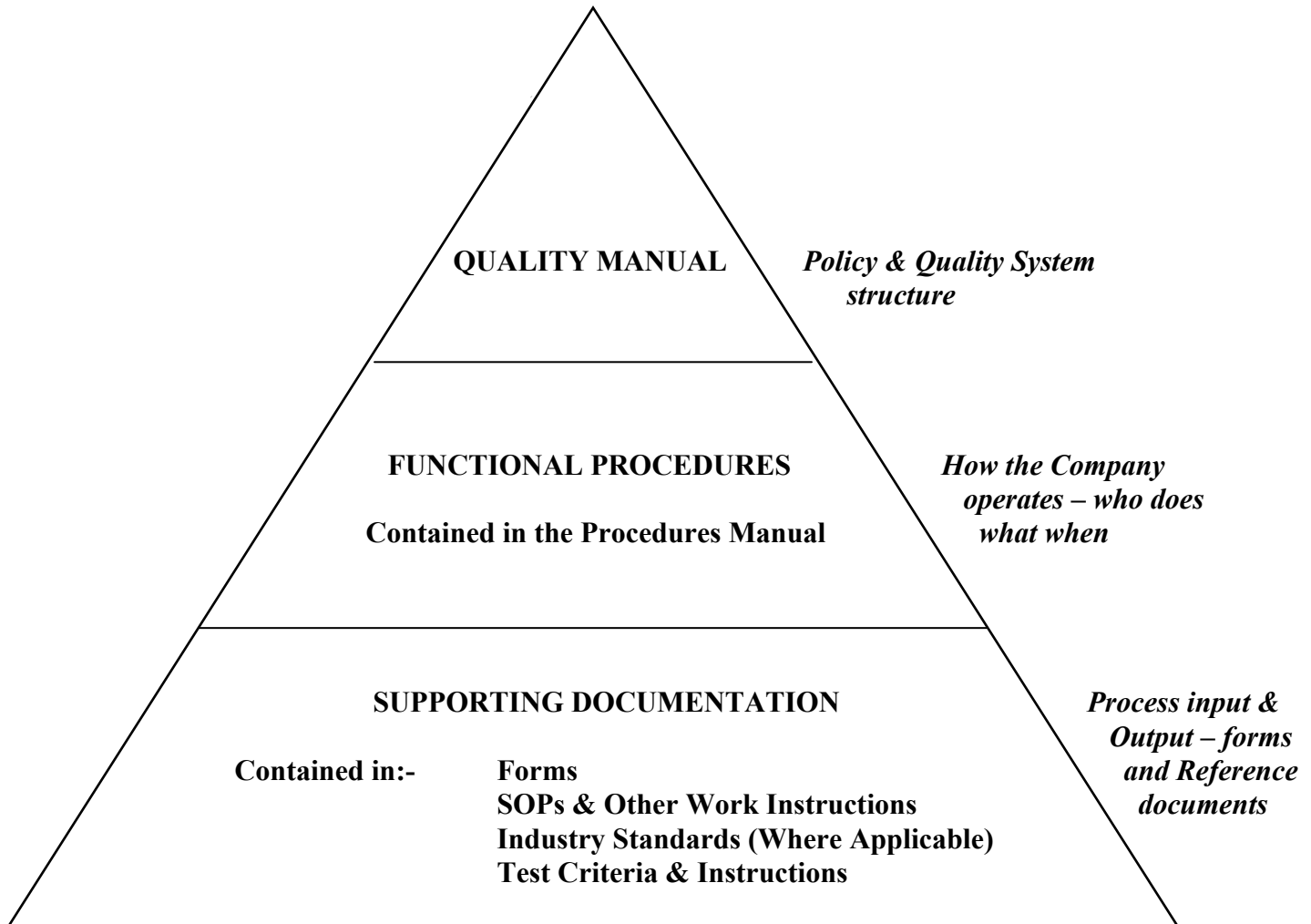
Authorized By: \_\_\_\_\_ (General Manager)      Date: \_\_\_\_\_

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

**1. Management System Structure**

The formal Management System has been developed with the following basic structure:

<b>International Standards          ISO/IEC 17025:2005 &amp;          ISO9001:2000</b>	<i>Defines International          System requirements</i>
<b>Customer Specifications          &amp; Special Quality Conditions</b>	<i>Defines Customer          Requirements</i>



Note: This is an uncontrolled copy unless the Revision History page bears an original authorizing signature or is stamped "Controlled Copy"



# Quality Manual

## ISO/IEC 17025:2005 & ISO 9001:2000

### Quality System

Section: QM 3  
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## 2. General Introduction

AccuTek Laboratories recognizes its responsibility in the supply of new and liquid measuring instruments pipettes, and the provision of liquid measuring instruments calibration services, and has developed and documented a Management System which complies with the international standards ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories, and ISO 9001:2000 - Quality management systems Requirements.

The purpose of this manual is to provide comprehensive evidence to all customers, suppliers and employees of what specific controls are implemented to ensure product and service quality. This manual also governs the creation of quality related documents. It will be revised, as necessary, to reflect the management system currently in use. It is issued on a controlled copy basis to all internal functions affected by the quality system and on an uncontrolled copy basis to customers and suppliers. It may be issued to customers on a controlled copy basis upon customer request.

This manual is divided into four main sections. Section QM 4 is modeled on the sectional organization of the ISO/IEC 17025:2005 standard with additional information from the ISO 9001:2000 standard. Sections are further subdivided into several subsections representing main management system elements or activities.

## 3. Exclusions

### 3.1 General Policy

AccuTek Laboratories' management system is tailored to the Company's operations, including all customer and regulatory requirements. Requirements of ISO/IEC 17025:2005 & ISO 9001:2000 that are not applicable to the nature of the business are excluded from the scope of the Company's quality system.



## Quality System

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# Quality Manual

## ISO/IEC 17025:2005 & ISO 9001:2000

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### 3.2 Procedure

3.2.1 Exclusion of an ISO 9001:2000 requirement is permissible only when both of the following conditions are satisfied:

- The requirement must be limited to ISO 9001:2000 Clause 7.
- Exclusion of the requirement will not affect the Company's ability or responsibility to provide product that meets customer and applicable regulatory requirements.

All elements of ISO/IEC 17025:2005 will apply with regard to the Company's pipette calibration activities.

#### 3.2.2 Responsibilities

The General Manager and the Quality Manager are responsible for identifying those requirements of ISO/IEC 17025:2005 & ISO 9001:2000 that are not applicable to the Company's business, and to recommend their exclusions from the AccuTek Laboratories quality system.

The General Manager has responsibility for evaluation and approval of the exclusions. This evaluation and approval of exclusions are normally conducted during the management review process covering Quality Policy.

#### 3.2.3 Identification

Any excluded requirements are identified in this section of the quality manual and will reference the applicable clauses in the ISO/IEC 17025:2005 & ISO 9001:2000 standard. In each case, there is also an explanation as to why the exclusion is applicable.



## Quality System

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# Quality Manual

## ISO/IEC 17025:2005 & ISO 9001:2000

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### 3.2.4 List of Exclusions for ISO9001:2000

1. Exclusion 7.3 Design and Development

Explanation: This ISO9001:2000 clause is not relevant to the Company's quality activities, as design input is limited to advice only and the selection criteria for products and material.

### List of Exclusions for ISO/IEC 17025:2005

1. Exclusion 4.5 Subcontracting of tests and calibrations

Explanation: The Company does not, and has no intention to, sub-contract any of its calibration activities.

### 3.3 Scope

AccuTek Laboratories' Management System applies to the supply of new and refurbished liquid measuring instruments, accessories, supplies and the provision of liquid measuring instruments calibration services.



**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000****INTRODUCTION**

The Company is committed to maintaining an effective Management System in pursuance of its Quality Policy objectives. The internationally recognized quality management standards ISO/IEC 17025:2005 & ISO 9001:2000 have been used as the basis for establishing this Management System.

The following sections, in sequence referencing the numbering used by the ISO/IEC 17025:2005 standard, reflect its application by the Company and serve as a guide to customers, auditors and all who are interested in how the Company ensures continued customer satisfaction. Additional guidance material from ISO9001:2000 is included where appropriate.

The numbering sequence follows Clause 4 of the standard that specifies the requirements for sound management and Clause 5 that specifies the requirements for technical competence for the type of tests and / or calibrations the Company undertakes.

ISO/IEC 17025:2005 is taken as the principal standard for its relevance to the Company's scope of providing calibration services. By complying with this standard the Company is also therefore operating in accordance with ISO9001:2000. Additional guidance from ISO:9001:2000 is taken, where appropriate, to cover the Company's scope in the supply of new and refurbished products.

The management system is based upon a "process approach" to quality management and

- identifies the processes needed for the quality system and their application throughout the organization;
- determines the sequence and interaction of these processes;
- determines criteria and methods required to ensure that both the control and effective operation and management of these processes;
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- monitors, measures, and analyzes these processes, and implements actions necessary to achieve planned results and continual improvement;
- implements actions required to achieve planned results and continually improvement of these processes.

Wherever possible, controls have been integrated with existing systems (environment, health and safety) and cross-referenced for ease of interpretation.

The effective implementation of the Management System will be verified by regular inspections, reviews and audits which will compare management practice against the requirements of the written procedures on Management System standards. Corrective action will be taken where necessary and will be subsequently reviewed for effectiveness.

For the correspondence between ISO/IEC 17025:2005 and the ISO 9001:2000 see Annex A.

#### **4. MANAGEMENT REQUIREMENTS**

##### **4.1 Organization**

**Section: QM3**

The Company can demonstrate that it is an entity that can be held legally responsible and acknowledges its responsibility to carry out inspection activities to the requirements of ISO/IEC 17025:2005 and to satisfy the needs of its Customers and other interested parties.

The management system described in these manuals covers the work carried out at the Company's permanent facility and any work that may be undertaken off site.

The Company can demonstrate that it is independent of any undue commercial, financial or other pressures and any conflicts of interest that may endanger the trust in its independence and integrity in relation to its inspection activities.

A person has been appointed as the Quality Manager who, irrespective of other duties, has the responsibility for the implementation, maintenance and improvement of the Management System and reports directly to the Executive and General Management on its effectiveness.

Other suitably experienced and qualified personnel have been appointed and are aware of their responsibilities for impartiality and confidentiality. Their interrelationships have been defined and suitably qualified and experienced personnel are appointed to act as delegates key management roles.

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000****4.2 Management system****Section QM2 and 3**

The Company has established, implemented and will maintain and continually improve a management system appropriate to the scope of its activities. Details of the system have been communicated to and are understood by all personnel. Details of the Management System have been documented in this Quality Manual and a supporting Procedures Manual.

A Quality Policy has been issued under the authority of top management that provides the framework for the setting of overall objectives. These objectives are communicated to all personnel and are subject to regular review with the intent of supporting the improvement program.

At least one copy of the Quality Policy, QM 2-2, is displayed prominently within the Company's premises. The continuing suitability of the Quality Policy will be reviewed through the Management Review process.

All personnel are aware of the importance of meeting Customer requirements and of adherence to the relevant statutory and other regulatory requirements.

All Management System documentation will be available to all members of staff and, as appropriate, to interested external parties including Customers and applicable regulatory authorities.

**4.3 Document control****Section PM 2**

Procedures have been established and are maintained to control all documents forming part of the Management System. Documents are approved for use prior to issue and a Document Register has been created from which the current revision status can be determined.

Documents are uniquely identified and authorized versions are available at all relevant locations. The documents are reviewed regularly to insure continued suitability and fitness for use. Changes to documents are controlled in such a manner so that amendments are clearly identifiable.

continued...

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000****4.3 Document control ....continued**

The Document Control & Records Procedure ensures that all documents are reviewed for adequacy by the Quality Manager and the applicable functional management. The procedure also provides for ongoing monitoring and review to control their issue and prompt distribution to affected personnel and to maintain their currency by ensuring that any obsolete material is removed.

The status of documents is identified, they are legible and retrievable, and located where required within the organization. Where documents originate from outside the organization they are identified and their distribution controlled. Obsolete documents are clearly identified to prevent unintended use.

To support the System, documentation in the form of Quality Records is established and maintained to provide evidence of conformity with requirements and effective operation of the System.

Procedures are in place for the identification, storage, retrieval, protection, retention time and disposition of Quality Records. Review is undertaken through the Management Review and Internal Audit processes.

**4.4 Review of requests, tenders and contracts****Section PM 5**

All requests to quote, tenders and contracts (including any amendments to previous agreements) are reviewed to insure that:

- The requirements, together with the methods to be used are adequately defined documented and understood;
- The laboratory has the capability and resources to meet the requirements;
- The appropriate inspection method is selected and is capable of meeting the Customer's requirements.

Records of the reviews and of any pertinent discussions are maintained and the Customer is kept informed of any deviation from the contract.

#### **4.5 Subcontracting of tests and calibrations**

The Laboratory does not sub-contract any of its inspection activities; therefore this clause is not applicable.

Any other sub-contracted work is placed with a competent sub-contractor selected from the Preferred Supplier and Sub Contractors List maintained by the Company. The Company maintains evidence of compliance with the International Standard ISO 17025 for the work in question as appropriate.

The Customer is informed in writing of any sub-contracted work and, when appropriate, approval is obtained from the Customer in writing. The Company acknowledges its responsibility for the sub-contracted work unless the Customer or a regulatory authority decides which sub-contractor is to be used.

#### **4.6 Purchasing services and supplies**

**Section PM 7**

Procedures have been established for the selection and control of goods and services that affect the quality of products and calibration activity. The Company controls its purchasing function to ensure that the purchased product or service conforms to specified requirements. Particular control is exercised on all product and service that is likely to have an impact on the subsequent Company product or service, its realization and delivery to the Customer. To this end, the Company realizes it is responsible for the quality of all products purchased from suppliers, including those designated as a source by Customers.

Purchasing documents clearly define the goods and/or services ordered and are reviewed and approved for technical content before release.

The suppliers of goods and/or services which affect the quality of the product or calibration service activity are evaluated and selected against defined criteria and are subject to planned performance review and evaluation. The results of reviews, evaluations and necessary follow up actions, are recorded in the Company's Preferred Suppliers and Sub-Contractors List (the register of approved suppliers). The scope of each supplier's approval is also recorded in the entry. Customer designated suppliers are incorporated into the approval system.

continued...

**Quality Manual****ISO/IEC 17025:2005 & ISO 9001:2000****4.6 Purchasing services and supplies ....continued**

The necessary follow up actions will include the actions to take, both internally and externally, when dealing with suppliers that do not meet requirements.

The function having responsibility for approving supplier quality systems also has the authority to disapprove the use of such sources.

Purchasing documents are reviewed before release for the adequacy of information provided covering the product / service, delivery timescales, accurate cross-referencing, associated procedures, specifications, processes, equipment, personnel, and specific quality conditions including inspection arrangements, samples and communication of concession requirements.

Where appropriate, specific instructions are in place to control order placement by verbal means.

The Company inspects or otherwise verifies purchased products and services, including documentation. Goods and/or services are not used until they have been verified as meeting the requirements of the inspections.

**4.7 Service to the Customer Section PM 5, 8, 13**

The Company is willing to cooperate with its Customers in clarifying their requests and in monitoring their performance.

Positive and negative feedback is actively sought from Customers and used as a tool for improvement of the management system and the Company's activities.

**4.8 Complaints Section PM 11**

A procedure has been established for the recording and resolution of complaints and records of investigations and corrective actions are maintained.

**Quality Manual****ISO/IEC 17025:2005 & ISO 9001:2000****4.9 Control of nonconforming testing and/or calibration work**

The responsibilities for the management of nonconforming work are defined and appropriate actions taken when necessary to halt any nonconforming work and withhold the issue any certificates until the nonconformance has been evaluated and suitable corrective action taken. Where necessary, the Customer is notified and any nonconforming work is recalled.

An evaluation as to the significance of the nonconforming work is made and appropriate corrective and preventive actions are promptly taken.

**4.10 Improvement****Section PM 13**

The Company has a policy of continual improvement in the effectiveness of its management system through the use of the quality policy and related objectives, audit results, the analysis of performance data, corrective and preventive actions and management review.

Methods have been established to monitor and gather information relating to customer satisfaction and their perception of any failure to meet their requirements.

**4.11 Corrective action****Section PM 12**

Authorities are defined for the implementing of corrective action when nonconformance has been detected.

The root cause of any nonconformance is determined and suitable corrective actions selected, documented, implemented and reviewed for effectiveness.

Appropriate problem solving techniques are utilized, and corrective action determined and taken to rectify faults and prevent their recurrence and the procedure is documented. Requirements for identifying faults, determining their cause, and implementing the program are covered and recorded, and the results reviewed for satisfactory completion.

Where necessary, additional internal audits of the area(s) or activity where the nonconformance has been detected are planned and carried out.

continued....

**Quality Manual****ISO/IEC 17025:2005 & ISO 9001:2000****4.11 Corrective action ....continued**

If it is determined that a Supplier is responsible for the root cause, there will be a flow down of the corrective action to the Supplier. If the program is not progressing in a timely manner or is shown to be ineffective, further actions are specified and expedited.

**4.12 Preventive action****Section PM 12**

Needed improvements and potential nonconformance are identified, documented, implemented and reviewed for effectiveness. The Company identifies preventive actions where necessary to eliminate potential non-conformities and to prevent their occurrence. The results of such actions are recorded and reviewed for effectiveness.

Where supplier is identified as a root cause, the action and follow up programs include the involvement of the supplier.

Improvement activity, including corrective and preventive action programs, is a formal agenda item for management review.

**4.13 Control of Records****Section PM 2, 4, 8, 9**

The Company has established and will maintain procedures for the identification, collection, indexing, access, filing, storage maintenance and disposal of quality and technical records. These include those resulting from internal audits, management reviews, corrective and preventive action.

Records are legible and are stored so that they are readily retrievable by authorized persons. Records are kept in such a way as to prevent damage or deterioration. The retention times for records are established.

All records are kept secure, in confidence and are protected against unauthorized access or amendment. Data held electronically are backed up regularly and protected from malicious code.

Records of original observations and derived data are kept so as to enable an audit trail to be established for each inspection report issued.

continued....

#### **4.13 Control of Records ....continued**

Technical records contain sufficient information to allow for the identification of factors affecting the uncertainty of the observations and to allow the inspection to be repeated under conditions as close as possible to the original. The person responsible for the observations or inspections and for the checking of any results can be identified.

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

Errors in records are not erased or otherwise made illegible, but are crossed out and the correct value entered alongside. The person making the correction is identifiable. Records held electronically are similarly protected against the loss of original data.

#### **4.14 Internal audits**

Internal audits of the Company's activities are planned and carried out to verify that its operations comply with its own procedures and of the requirements of the ISO/IEC 17025:2005 and ISO 9001:2000 Standards, and to identify any opportunities for improvement

Each element of the Management System is audited at least annually by employees who have been trained in the workings of the system, in appropriate auditing techniques and tools, and of the need for impartiality and objectivity. The intervals between audits take into account the status and importance of the processes and areas to be audited, and by reference to contractual or regulatory requirements and previous audits.

Wherever resources permit, auditors will not inspect their own principal areas of responsibility and the results of the audit, with details of any non-compliance and the determined action program, will be documented and become the subject of Management Review. The results of the audit will be conveyed to the employees responsible for the area under assessment.

Corrective and preventive actions are identified and implemented. If any corrective actions indicate that calibration results may have been affected, then Customers are informed in writing. The results of audits are recorded along with any corrective and preventive actions implemented. Follow up activities are recorded and the effectiveness of corrective and preventive actions reviewed.

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000****4.15 Management reviews****Section PM 3**

The complete Management System is subject to a multi-functional review at planned intervals sufficient to ensure its continuing suitability, adequacy and effectiveness. The results of management review activity are recorded including all actions arising.

The review includes the evaluation of information on current performance and improvement opportunities related to business plans, internal audits, audits by Customers or external bodies, customer feedback, process performance, product / service performance, follow up from previous meetings including the progress and status of action programs, and any changes that could effect the Management System. All quality matters providing input into the management review will be formal agenda items.

The results of activity arising from review meetings, the Management System and its processes and improvements to products related to customer requirements will be an essential part of the review process.

Each decision and action will relate to the improvement of the effectiveness of the Management System and its processes, and will have clear timescales with resource needs, including personnel, identified.

**5 TECHNICAL REQUIREMENTS****5.1 General****Section PM 4, 8, 9**

The factors affecting the correctness and reliability of calibrations have been identified and are taken into account when developing calibration procedures, in the selection and training of personnel and in the calibration of the equipment used.

**Quality Manual****ISO/IEC 17025:2005 & ISO 9001:2000****5.2 Personnel****Section PM 4, 8**

Job descriptions have been documented for all managerial, technical, key support staff and those carrying out calibrations. The competence of all personnel performing tasks relating to inspection has been insured on the basis of their education, training and experience. When necessary, staff are required to demonstrate specific skills and/or to hold personal certification. When staff are undergoing training, adequate supervision is provided.

Personal goals have been formulated with respect to the skills education and experience of inspection personnel and suitable training is identified, carried out and monitored for effectiveness.

All personnel are employed by or are under contract to the Company. Where contract personnel are used, adequate supervision is provided.

Specific personnel are authorized to perform inspections and to issue inspection reports. Records are maintained of such authorization together with the skills, education, experience and applicable personal certifications.

The review and identification of current and future training needs is an agenda item at the management review meetings.

**5.3 Accommodation and environmental conditions****Section PM 4, 8**

The Company insures that the environmental conditions under which measurements are made do not invalidate the results. Inspection is suspended when the environmental conditions may invalidate the results.

All aspects of human and physical factors in the work environment, that effect applicable governmental safety and environmental regulations, and / or the conformity of the product and technical actives concerned, have been identified and are managed.

These include the control of temperature, humidity, lighting, cleanliness, and any other issues likely to affect the conformity of the product.

continued...

**5.3 Accommodation and environmental conditions ....continued**

Good housekeeping practices are maintained in every department in support of an adequate and controlled work environment.

Effective separation exists between neighboring areas in which there are incompatible activities and measures are taken to prevent cross-contamination. Access to the laboratory is controlled and restricted to those having business there.

The Company provides and maintains suitable buildings and other workplaces with sufficient associated utilities, appropriate equipment, both hardware and software, with supporting transport, communication and other service needs.

**5.4 Test and calibration methods and method validation Section PM 8**

The Company uses appropriate methods for all inspections within its scope throughout the entire work process including, where appropriate, the measurement of uncertainty and statistical techniques.

Instructions are available for the use and operation of all relevant equipment and on the handling of inspection samples. These instructions are kept current and are available to the personnel concerned. Any deviations from these instructions are technically justified, documented, authorized and accepted by the Customer.

The Company uses inspection methods that meet the requirements of the Customer and are valid for the work undertaken. If no method is specified by the Customer, recognized standard methods are used or methods are developed by the laboratory in lieu. Any laboratory developed methods are developed by suitably qualified personnel equipped with adequate resources.

Any non-standard methods used are subject to agreement by the Customer and are validated as necessary before use. Validation is also carried out before any standard methods are used outside their intended scope. The range and accuracy of the values obtained from validated methods are assessed and shall be relevant to the intended needs.

continued...

**Quality Manual****ISO/IEC 17025:2005 & ISO 9001:2000****5.4 Test and calibration methods and method validation ....continued**

Procedures are used for the estimation of uncertainties in measurement based on knowledge of the capabilities and scope of the method used. When estimating the uncertainty of measurement, all relevant uncertainty components are taken into account.

Calculations and data transfers are subject to appropriate checks in a systematic manner. When computers or automated equipment are used, appropriate software is documented and validated, the security and confidentiality of data are protected at all stages and the equipment and its operating conditions are maintained to protect the integrity of the measurements.

**5.5 Equipment****Section PM 4. 8, 9**

The laboratory is furnished with all items of sampling, measuring and test equipment required, including those needed for the handling of items for inspection, calibration and measurement. The equipment is capable of carrying out the inspections and calibrations required and of meeting the requirements for accuracy.

All measuring equipment is calibrated before use and is calibrated and/or re-checked at defined intervals thereafter in order to establish that it meets the laboratory's requirements for accuracy.

Records of calibration are maintained and the equipment is identified to indicate the calibration status. Equipment is safeguarded against any adjustments which would invalidate inspection results. Where calibrations give rise to a set of correction factors, these will be documented and updated as necessary.

All measuring equipment is operated only by authorized personnel in accordance with the relevant manuals and laboratory instructions.

When measuring equipment has to be transported, stored, maintained or goes outside the direct control of the laboratory, procedures have been established to insure proper function thereafter.

continued....

**5.5 Equipment ....continued**

Measuring equipment that has been damaged or is suspect in any way, is quarantined until it has been repaired and its proper function established. The effect of the defect on any previous calibrations is evaluated and action taken, if necessary, under the procedures for the control of nonconformance (see section 4.9).

**5.6 Measurement traceability**

**Section PM 9**

A register of measuring equipment is maintained and defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. Equipment under calibrated status will include personally owned and customer supplied equipment used to provide evidence of product conformity.

The calibration program for all items of measuring equipment (including reference standards) establishes an unbroken link traceable to the International System of Units (SI) via the relevant primary national or international Standards. When using external calibration laboratories, traceability is assured by means of the calibration certificate issued by that laboratory.

Where it is not possible to make calibrations strictly in SI units or such calibrations are not relevant, other appropriate measurement standards may be used such as those provided by a competent supplier that is recognized and accepted by all parties concerned.

**5.7 Sampling**

**Section PM 8**

The Company does not conduct a sampling program of substances, materials or products for subsequent inspection or calibration.

Sampling of products during quality control activity may be carried out to sampling plans developed using appropriate statistical techniques and which address the factors to be controlled to ensure validity of the results.

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000****5.8 Handling of test and calibration items****Section PM 8**

Procedures have been established for the transportation, receipt, handling, protection and storage of items for inspection or calibration. Such items are identified throughout all stages of inspection. The identification is such that the items cannot be confused physically with other items referred to in records and reports.

Any departure from normal conditions noted upon receipt of the item(s) for inspection and / or calibration or when the item(s) does/do not conform to the description provided, the Customer is informed and further instructions sought before inspection is commenced.

Items for inspection or calibration are protected as necessary against deterioration, loss or damage while in the care of the Company.

**5.9 Assuring the quality of test and calibration results****Section PM 8**

Quality control procedures have been established for monitoring the validity of inspections undertaken. Quality control data are analyzed and, when they are found to be outside pre-defined criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.

**5.10 Reporting the results****Section PM 8**

The results of each inspection or calibration or series of inspections or calibrations are reported accurately, clearly, unambiguously and objectively in accordance with the inspection methods used and any instructions from the Customer. The results are recorded in the form of a calibration report and in a format intended to minimize the possibility of misunderstanding or misuse.

Each calibration report contains the information agreed with the Customer and is uniquely identified. Any deviations or waivers from the inspection method(s) are included in the inspection reports and, when necessary, a statement of compliance with the requirements or specifications.

When appropriate, opinions and interpretations are included and are clearly identified as such.

continued...

**Quality Manual****ISO/IEC 17025:2005 & ISO 9001:2000****5.10 Reporting the results ....continued**

Calibration reports that are transmitted electronically are done so that the security, integrity and confidentiality of transmitted data are maintained at all stages.

Any amendments to inspection reports are issued in the form of a new document clearly identifiable as an amendment to the original report

**Preservation of product (ISO 9001: 2000 Clause 7.5.5)**

The Company recognizes the need to provide an effective means of handling, preserving, storing and shipping products procured for sale.

The handling, preservation and environmental control procedures are designed to prevent damage or contamination, and cover safety, shelf life and hazardous material issues, with personnel trained in their requirements.

Storage is in designated areas under adequate control and protection and all packaging is to specified requirements. Shipping, and the associated documentation, is also recognized as part of the Company's activity that requires control and specification.

Procedures ensure adequate identification, handling, packaging, storage, and protection including:

- cleaning;
- detection and preventing foreign object damage;
- special handling for sensitive products;
- marking and labeling including safety warnings;
- shelf life and stock rotation;
- special handling for hazardous materials.

The Company will ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.



**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

<b>Nominal cross-references between ISO 9001:2000 &amp; ISO/IEC 17025:2005</b>	
ISO 9001:2000	ISO/IEC 17025:2005
4.1	4.1, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.2, 4.2.1, 4.2.2, 4.2.3, 4.2.4
4.2.1	4.2.2, 4.2.3, 4.3.1
4.2.2	4.2.2, 4.2.3, 4.2.4
4.2.3	4.3
4.2.4	4.3.1, 4.12
5.1	4.2.2, 4.2.3
5.1 a)	4.1.2, 4.1.6
5.1 b)	4.2.2
5.1 c)	4.2.2
5.1 d)	4.15
5.1 e)	4.1.5
5.2	4.4.1
5.3	4.2.2
5.3 a)	4.2.2
5.3 b)	4.2.3
5.3 c)	4.2.2
5.3 d)	4.2.2
5.3 e)	4.2.2
5.4.1	4.2.2 c)
5.4.2	4.2.1
5.4.2 a)	4.2.1
5.4.2 b)	4.2.1
5.5.1	4.1.5 a), f), h)
5.5.2	4.1.5 I)
5.5.2 a)	4.1.5 I)
5.5.2 b)	4.11.1
5.5.2 c)	4.2.4
5.5.3	4.1.6
5.6.1	4.15
5.6.2	4.15
5.6.3	4.15
6.1 a)	4.10
6.1 b)	4.4.1, 4.7, 5.4.2, 5.4.3, 5.4.4, 5.10.4
6.2.1	5.2.1
6.2.2 a)	5.2.2, 5.5.3
6.2.2 b)	5.2.1, 5.2.2
6.2.2 c)	5.2.2
6.2.2 d)	4.1.5 k)
6.2.2 e)	5.2.6
6.3.1 a)	4.1.3, 4.12.1.2, 4.12.1.3, 5.3

**Quality Manual**  
**ISO/IEC 17025:2005 & ISO 9001:2000**

<b>Nominal cross-references between ISO 9001:2000 &amp; ISO/IEC 17025:2005</b>	
ISO 9001:2000	ISO/IEC 17025:2005
6.3.1 b)	4.12.1.4, 5.4.7.2, 5.5, 5.8
6.3.1 c)	4.6, 5.5.6, 5.6.3.4, 5.8, 5.10
6.4	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5
7.1	5.1
7.1 a)	4.2.2
7.1 b)	4.1.5 a), 4.2.1, 4.2.3
7.1 c)	5.4, 5.9
7.1 d)	4.1, 5.4, 5.9
7.2.1	4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10
7.2.2	4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10
7.2.3	4.4.2, 4.4.4, 4.5, 4.7, 4.8
7.3	5, 5.4, 5.9
7.4.1	4.6.1, 4.6.2, 4.6.4
7.4.2	4.6.3
7.4.3	4.6.2
7.5.1	5.1, 5.2, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
7.5.2	5.2.5, 5.4.2, 8.4.5
7.5.3	5.8.2
7.5.4	4.1.5 c), 5.6
7.5.5	4.6.1, 4.12, 5.8, 5.10
7.6	5.4, 5.5
8.1	4.10, 5.4, 5.9
8.2.1	4.10
8.2.2	4.11.5, 4.14
8.2.3	4.11.5, 4.14, 5.9
8.2.4	4.5, 4.6, 4.9, 5.5.2, 5.5.9, 5.8, 5.8.3, 5.8.4, 5.9
8.3	4.9
8.4	4.10, 5.9
8.5.1	4.10, 4.12
8.5.2	4.11, 4.12
8.5.3	4.9, 4.11, 4.12