4 Contents

4.1 Organization

4.1.1 Legal Identification / Registration

Pitt County Sheriff's Office Forensics Services Unit
124 New Hope Road, Greenville, North Carolina 27834
Telephone #: 252-902-2680
Fax #: 252-830-4151

4.1.2 Laboratory Requirements

The work areas of Pitt County Sheriff's Office Forensics Services Unit have been organized to satisfy the needs of all entities we serve. The Pitt County Forensics Services Unit will carry out all crime laboratory services in accordance with stated methods regulatory authorities and to meet the international standards ISO 17025. Pitt County Sheriff's Office Forensics Services Unit is composed of the following work areas:

Laboratory personnel offices and workspaces
Drug Chemistry
Blood Alcohol
General Laboratory
Records Room
Supply Room
SAFIS, Unknown and Known Impression Evidence Room

4.1.3 Scope of Management System

The Pitt County Sheriff's Office (PCSO) Forensics Services Unit is committed to delivering state of the art scientific analysis, while maintaining the highest level of integrity, impartiality, and professionalism to the community in Pitt County that we serve, thereby contributing to the citizen's safety and due process of the judicial system.

The PCSO Forensics Services Unit management system covers activities in the laboratory's permanent facility. The fields of activities include:

Drug Chemistry-Analyze all drugs submitted to the agency.
Blood Alcohol-Analyze all blood alcohol samples submitted to the agency.
Latent Evidence-Analyze and Identify all Latent Evidence submitted to the agency.

4.1.4 Potential Conflicts of Interest

The laboratory reports to the Sheriff of Pitt County. The Laboratory Director serves as the Forensics Services Unit's central operating officer and authorizes policy and procedures. Adverse influence against the laboratory's ability to operate in an independent manner is monitored by independent checks and/or audits from the appropriate Quality Assurance measures.

The Pitt County Forensics Services Lab Director and staff personnel have responsibilities and authorities that are maintained and defined in folder 8_Job Descriptions. The Director organizes the Divisions to maximize operational effectiveness through proper delegation and authority.

The responsibilities of the Laboratory Director include:

- developing, managing, and guiding the larger organizations policies and procedures
- serving as a member of the executive committee which organizes and administers the relationship between the organization and the laboratory
- providing focus and coordinating functions regarding overall policy changes
- participating in all senior-level administrative functions/committees of the organization as appointed by the Sheriff of Pitt County
- Create an atmosphere in which all personnel are free from undue internal or external pressures and influences which may negatively impact the quality of work performed. Laboratory personnel shall be responsible for ensuring the integrity of the analytical process
- Provides guidance concerning any situations that could diminish confidence in its competence, impartiality, judgment, or operational integrity. Work shall be performed in an environment free from undue pressure that might influence technical judgment.

4.1.5 Organization

4.1.5.1 Management and Technical Personnel

Policy:
The laboratory managerial and technical personnel, irrespective of other responsibilities, have the necessary authority and resources needed to meet the mandates assigned to their areas.

Details:
Responsibilities are detailed in section 4.1.5.6.

Departures from the organizational and management policies in this manual can only be approved by Quality Manager or designated person per Authorizing Deviations procedure.

Departures from quality management system procedures can only be approved by Quality Manager or designated person per Authorizing Deviations procedure.

Departures from test methods or technical standard operating procedures (SOPs) can only be approved by the Technical Leader of discipline or designee and Quality Manager per SOP# *QSP 4-1-5, Authorizing Deviation*.

See also section 5.2.

4.1.5.2 Undue Pressure

Policy:
Management and personnel are to be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. The integrity of test results is the responsibility of all personnel.

Details:
The following list provides some guidelines on how employees avoid conflict of interest situations. Employees shall not:

- falsify records, prepare fraudulent reports, or make false claims
- seek or use privileged or confidential information, or data from any client, for any purpose beyond the scope of employment
- conduct non-laboratory business on laboratory time, or use laboratory facilities or equipment to conduct outside interests or business, unless prior approval has been obtained
- be employed by, or affiliated with, organizations whose products, services or purpose compete with laboratory products, services or purpose
- have employment that negatively affects or interferes with their performance of laboratory duties
- allow associations, family, or friends to influence decisions to their benefit - decisions must be made on a strictly business and legal basis, always in the best interest of the laboratory, its clients and the pursuit of justice

- make any decision that provides gains or benefits to the employee and/or others
- have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf
- engage in activities that may diminish confidence in the laboratories competence, impartiality, judgment, or operation integrity

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal.

4.1.5.3 Client Confidentiality

Policy:
It is the policy of our laboratory to protect the confidential information and rights of our client including the electronic storage and transmission of results.

Details and Procedures:
All employees sign a FORM# 4-1-5-F2, *Confidentiality Agreement*. The signed agreement is retained in Pitt County Sheriff's Office Standards Division Personnel Records.

Client, as referred to by these policies, procedures and documents, shall be defined as the submitting person/agency, relevant Attorney for prosecutorial district or other legally authorized party.

Test results are only released to the client. Release of test results to someone other than the client requires the express permission of the client, except when the situation contravenes State or Federal Legislation and the results must be provided to the appropriate agency. The release of test results to anyone other than the client requires the permission of the Laboratory Director and/or Quality Manager.

4.1.5.4 Operational Integrity

Policy:
The laboratory will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

Details and Procedures:
To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through proficiency testing programs and other measurable competency tools, such as competency tests, court testimony review, etc. Impartiality is assessed through Form # 4-1-5-L3, *audits and approvals*. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving his/her skills. Operational integrity is reviewed by management on a regular basis according to SOP#*QSP 4-15-1, Management Review* to ensure continued suitability and effectiveness of laboratory policies and procedures. Any issue is acted on immediately through the control of nonconforming work or the corrective action procedures.

4.1.5.5 Organizational Structure

Policy:
The organization and management structure of the laboratory within the Sheriff's Office and the relationships between management, technical operations, support services, and the quality management system is defined through the aid of DOC# 4-1-5-D3, *organizational chart*. The Laboratory is positioned within the Criminal Investigation Division as shown in DOC# 4-1-5-D4, *Departmental Organizational chart*.

Details:
Senior management keeps the most current organizational chart on file. An organizational chart is available with this manual.

4.1.5.6 Responsibility and Authority

4.1.5.6.1 Laboratory Director

- develops primary goals, operating plans, policies, and short and long range objectives for the laboratory
- directs and coordinates activities to achieve quality and meet client requirements
- establishes organizational structure and delegates authority to subordinates
- leads the laboratory towards objectives,
- determines action plans to meet the needs of the laboratory
- represents organization to clients, government agencies, and the public
- develops, manages, and guides the larger organizations policies and procedures

- serves as a member of the executive committee which organizes and administers the relationship between the organization and the laboratory
- provides focus and coordinating functions regarding overall policy changes
- participates in all senior-level administrative functions/committees of the organization as appointed by the Sheriff of Pitt County
- creates an atmosphere in which all personnel are free from undue internal or external pressures and influences which may negatively impact the quality of work performed. Laboratory personnel shall be responsible for ensuring the integrity of the analytical process
- provides guidance concerning any situations that could diminish confidence in its competence, impartiality, judgment, or operational integrity. Work shall be performed in an environment free from undue pressure that might influence technical judgment.
- has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

4.1.5.6.2 Technical Leader[s]

- knowledgeable of the scope of all processes under their supervision
- provides the necessary resources (personnel, equipment, supplies) for the quality assurance program, in order to ensure confidence in the laboratory's results
- ensures equipment is maintained and calibrated, reporting all deficiencies (e.g., equipment malfunctions) in the appropriate manner
- ensures personnel are trained for the duties they perform - includes substitutes when regular personnel are absent
- maintains records and manages all aspects of testing activities
- writes SOPs and test methods

4.1.5.6.3 Quality Manager

- ensures that the Quality Management System is established, implemented and maintained in accordance with ISO 17025 standards
- manages the internal audit program
- coordinates laboratory accreditation activities
- handles the maintenance and distribution of the Quality Manual and associated documents
- maintains a master list of current versions of quality documentation
- trains personnel on Quality Management System activities
- monitors the Quality Management System

- reports on the performance of the Quality Management System to other senior management members for review and as a basis for improvement of the Quality Management System
- supervises the laboratory's inter-laboratory proficiency testing program

4.1.5.6.4 Supervisors

- responds to client inquiries and provides professional advice
- orientates new personnel
- determines technical training needs of personnel
- conducts employee performance reviews
- schedules vacation and coverage
- ensures that all health and safety regulations are followed
- ensures that all Legislation's are complied with
- oversees quality, prioritizes workload
- facilitates operational concerns in their area
- coordinates purchasing requests
- ensures that the operational needs are within budget and advising management of any discrepancies

4.1.5.6.5 Analysts (Chemists, Technicians, Examiners)

- maintains records of all quality activities as documented in SOPs and test methods
- handles samples and performing analyses according to SOPs and test methods
- signs reports when designated with signing authority
- maintains and calibrates equipment
- reports deficiencies or malfunction to the supervisor
- identifies and records nonconformities on Form# 4-11-1- F1, *Corrective Action Requests* and Form# *4-8-1-F1, Nonconformity Record(NCR)*
- identifies and records potential nonconformities on Form# 4-12-1-F1, *Preventive Action Requests*
- corrects nonconformities and potential nonconformities
- improves laboratory and/or quality activities on a continuous basis

4.1.5.6.6 Safety Officer

- ensures that the health and safety program outlined in the *Safety and Chemical Hygiene Plan (SCHP)* is implemented and followed at all times

4.1.5.6.7 Administrative Personnel

- performs work functions and keeps records as per approved SOPs and/or laboratory policies
- writes/transcribes SOPs
- identifies and records nonconformities on Form# 4-11-1- F1, *Corrective Action Requests* and Form# *4-8-1-F1, Nonconformity Record(NCR)*
- identifies and records potential nonconformities on Form# 4-12-1-F1, *Preventive Action Requests*
- corrects nonconformities and potential nonconformities
- improves laboratory and/or quality activities on a continuous basis

4.1.5.7 Laboratory Supervision

Policy:
Adequate supervision is provided in each area of the laboratory for all testing personnel, including trainees, by persons familiar with the methods and procedures.

Details:
Adequate supervision is ensured through designated supervisors as well as through documentation such as this Quality Manual, test methods and SOPs. A thorough orientation and training program is adhered to for all new employees. Ongoing training for regular personnel is required.

4.1.5.8 Technical Management/Leaders

Policy:
A Technical Leader is assigned to each major discipline of the laboratory. They have overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.

Details:
While the Technical Leader may at times delegate duties to other personnel, the Technical Leader is accountable for any nonconforming activities.

4.1.5.9 Quality Manager

Policy:
The Quality Manager is appointed by the Laboratory Director. The Quality Manager, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed. The Quality Manager has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

Details:
N/A

4.1.5.10 Managerial Substitutions

Policy:
Designees for key personnel are appointed to fulfill the key personnel's duties in their absence.

Details:
In the absence of the Quality Manager, the Technical Manager/Leader will assume his/her responsibilities.

In the absence of the Technical Manager/Leader, the Quality Manager will assume his/her responsibilities.

Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent. If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

4.1.5.11 Awareness

Policy:
Management ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

Details:
Supervisors review the details of each employee's job description with the appropriate employee and how the overall Quality Policy Statement (section 4.2.2) relates to their activities to achieve the objectives of the management system.

4.1.6 Communication Processes

Policy and Details:
Top management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 Management System

4.2.1 Policies and Procedures

Policy:
The Quality Management System is established, implemented, and maintained by management. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

Details:
The purpose of our Quality Management System is to ensure that all services and products satisfy the client's requirements and have been produced and delivered under controlled conditions.

The effectiveness of the Quality Management System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality management system
- by regular management reviews of the suitability and effectiveness of the quality management system
- by analysis of potential and actual issue as shown by client complaints or complaints from internal personnel, Form# 4-11-1- F1, *Corrective Action Requests*, Form# *4-8-1-F1, Nonconformity Record(NCR)* and Form# 4-12-1-F1, *Preventive Action Requests*.
- by other methods approved by the Laboratory Director, Quality Manager, or Technical Leader.

This Quality Manual and associated documents (including procedures) and records serve as the quality plan for the laboratory. Other documents and records include:

- standard operating procedures both administrative and technical
- test method
- organizational charts
- forms
- logs
- other documents

4.2.2 Quality Policy Statement

Policy:
The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement and reviewed during management review. The Quality Policy Statement is issued under the authority of the top Management of the Pitt County Sheriff Forensic Services Unit on the effective date. The Laboratory Director and Quality Manager comprise the Top Management.

Quality Policy Statement:
Pitt County Forensic Services Unit pledges to ensure accurate and timely Drug testing, Blood Alcohol testing and Latent Print Examination. To continuously meet or exceed the stated or implied expectations of our clients.

a) *Management commitment to good professional practice and quality of services provided to the client*: tests are always carried out in accordance with stated standardized methods and client's requirements. Requests to perform tests that may jeopardize an objective result or have a low validity are rejected.

b) *Standards of service include*:

- Objective
- Accuracy
- Timely
- Client Satisfaction

Excellence in the workplace is promoted by providing all employees with the knowledge, training, and tools necessary to allow for the completion of accurate and timely work.

c) *Purpose of management system related to quality*: to manage our activities by meeting the needs of our clients through acceptable practices in the field of forensic Services.

d) *Personnel*: familiarize themselves with quality documentation and implement the policies and procedures in their work.

e) *Management is committed to complying with ISO 17025 international standards and to continually improving the effectiveness of the management system*: the objective of this Quality Manual is to document the compliant policies and

associated procedures that are integrated into our daily activities. Continual improvements are established, implemented, and locked into the management system.

Additional objectives include:

- to consistently improve laboratory performance
- to make procedural changes to improve performance
- to participate in proficiency testing or quality evaluation programs with peer laboratories
- to ensure that all personnel are trained to a level of familiarity with the quality management system appropriate to the individual's degree of responsibility
- to improve and validate laboratory methodologies and procedures
- to establish and report on quality through SOP# *QSP 4-15-1, Management Review*

4.2.3 Commitment to the Management System

Policy:
Top management is committed to the development and implementation of the management system and continually improving its effectiveness.

Details:
The results of the management system are regularly reviewed during management review (see section 4.15) and continual improvements are made as outlined in section 4.10 – Improvements.

4.2.4 Communication of Requirements

Policy:
Top management communicates to the organization the importance of meeting client requirements as well as statutory and regulatory requirements.

Details:
In general, the underlying message in all oral and written management communications involves meeting the aforementioned requirements. Meeting statutory and regulatory requirements ensures that laboratory operations will not be disrupted and the organization can continue to meet client needs.

4.2.5 Quality Manual

Policy:
This Quality Manual outlines the structure of the documentation used in the quality management system. This Quality Manual makes reference to supporting procedures including technical procedures.

Details:
This quality management system is structured in three tiers of documentation. The tiers are as follows:

I. Quality Manual
II. Laboratory Procedures
III. Forms, Documents and Logs

The following records and directive documents are referenced in the Quality Manual.

- organizational chart (section 4.1.5.5)
- copies of the Quality Policy Statement posted in the laboratory (section 4.2.2)
- identification of resources and management review (section 4.15.1)
- job descriptions (section 5.2.4)
- statistical techniques (section 5.9.2)
- test reports (section 4.13.2 and 5.10)
- identification of the laboratory's approved signatures (section 5.10.2)
- laboratory's scope of tests (section 4.1.3)
- equipment inventory and records (sections 5.5.4 and 5.5.5)
- calibration status indicators (section 5.5.8)
- reference standards inventory (section 5.6.3)
- verification records (section 5.9)
- quality control plan / criteria for workmanship (section 5.4.1)
- corrective action records (section 4.11)
- preventive action records (section 4.12)
- client complaint records (section 4.8)
- audit schedule and records (section 4.14.1)
- procurement (sections 4.6)
- training records (section 5.2.5)
- master list of documentation (section 4.3.2)
- confidentiality agreements (section 4.1.5.3)
- contract review (section 4.4.2)

- validation of test methods (section 5.4.5)
- facility floor plan (section 5.3.1)

4.2.6 Technical Management and the Quality Manager

The roles and responsibilities for technical management and the Quality Manager are outlined in section 4.1.5.6 of this manual.

The Quality Manager ensures that sections 4 and 5 of this manual are implemented and maintained.

4.2.7 Maintenance

Policy and Details:
Top management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.3 Document Control

4.3.1 Policies and Procedures

Policy:
The procedure for SOP#*QSP 4-3-1, document control* is used to control all quality management system documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, tests as well as drawings, specifications, instructions, and manuals.

Details:
Document means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:

- Quality Manual
- QSP(Quality System Procedures)
- TP's/SOP's (Technical Procedures/Standard Operating Procedures) and test methods
- Forms
- Chemical Hygiene/Safety Manual

The control of data related to testing is covered in section 5.4.7. The control of records is covered in section 4.13.

4.3.2 Document Approval and Issue

4.3.2.1 Review / Approval / Master List

Policy and Details:
All documents issued to personnel in the laboratory as part of the quality management system are reviewed and approved for use by authorized personnel prior to issuance (i.e., reviewed by personnel knowledgeable in the documented activity and then approved by management). A master list identifying the current revision status of documents in the quality management system is readily available in order to preclude the use of invalid and/or obsolete documents (see SOP# *QSP 4-3-1, document control*). A revision history

of documents is also maintained. Documents are formally reviewed annually in January to ensure their continuing suitability.

4.3.2.2 Availability and Obsolete Documents

Policy and Details:
The master list shows the current status of all controlled documents. The master list document is organized with the following information:

- Document #
- Title
- Version #
- Effective Date
- Date of Last Review

Controlled documents are approved before issue.

The SOP# *QSP 4-3-1, document control* for document control ensures that:

- authorized electronic editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed
- documents are reviewed annually and where necessary revised to ensure continuing suitability and compliance with applicable requirements
- invalid or obsolete documents are promptly removed from all points of issue or use to assure against unintended use
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked (i.e., "OBSOLETE" and dated watermarked on the document.)

4.3.2.3 Identification

Policy and Details:
All quality management system documentation is identified by:

- effective date and version number
- page numbering
- total number of pages (e.g., page 5 of 5)
- issuing authority

4.3.3 Document Changes

4.3.3.1 Review/Approval

Policy:
Changes to documents are reviewed and approved according to Procedure QSP# *QSP 4-3-1, document control*

Details:
Developments in policies and procedures require documents to be changed from time to time. Changes to documents utilizing Form# *4-3-1-F1, Document approval* receive the same level of review and approval as the originals.

The Quality Manual is reviewed annually in January by the Quality Manager. Records are kept of this review.

4.3.3.2 Identification of Changes

Policy:
The nature of document changes is identified in the document.

Details:
As outlined in SOP# *QSP 4-3-1, document control*.

In general, the nature of changes is identified in the revision history and is recorded at the end of the document.

4.3.3.3 Amendments by Hand are not permitted.

Policy and Details:
Hand-written amendments to documents are not permitted.

4.3.3.4 Computerized Documents

Policy and Details:
The SOP# *QSP 4-3-1, document control* details how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of Requests

4.4.1 Policies and Procedures

Policy:
The SOP# *QSP 4-4-1, Request Reviews* is used to review requests. This procedure ensures that:

a) the laboratory has the capability and resources to meet the requirements requested by client
b) the appropriate test method is selected and capable of meeting the client's requirements (see section 5.4.2)

Details:
A request for laboratory services is reviewed in a practical and efficient manner, and the effect of financial, legal, and time schedule aspects are taken into account.

Top management will ensure that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests requested by the client.

The FS1 form ensures that each client's requirements are adequately defined and documented before the item is accepted or service is rendered. This should ensure that any request can be completed without delay, and that the client's requirements can be met.

The SOP# *QSP 4-4-1, Request Reviews* also describes the activities that take place should there be a subsequent amendment to a client's request.
Typical types of requests/agreements include:

- confidentiality agreements
- new client request
- submission requests

4.4.2 Records of Review

Policy:
The FS1 form, including any changes to the form, is maintained. Records of pertinent discussions with a client relating to the client's requests are also maintained.

Details:
Review of submitted FS1 form by laboratory personnel for work to be performed shall be documented by completion of the chain of custody form by the person responsible for the testing.

4.4.3 Review of Subcontracted Work

N/A

4.4.4 Notification of Client

Policy and Details:
The signatures of Pitt County Forensic Services Unit employees and the client appearing on the FS1form, acknowledge agreement by the client, that laboratory personnel shall use the most appropriate and up to date methods authorized.

4.4.5 Additional or modified testing request

Policy and Details:
If additional testing or change is needed, the same review process is repeated and any changes or deviations are communicated to all affected personnel.

The signatures of Pitt County Forensic Services Unit employees and the client appearing on the FS1 form, acknowledges agreement by the client, that laboratory personnel shall use the most appropriate and up to date methods authorized.

Any written communication to include electronic that would affect the analysis of the test items or amend the Forensic Services Request (FS1) shall be retained in Master Case File.

4.5 Subcontracting of Tests and Calibrations

N/A

4.6 Purchasing Services and Supplies

4.6.1 Policies and Procedures

Policy:
The SOP# ***QSP 4-6-1, Purchasing*** is used to select and purchase services and supplies and is used for procurement, reception, and storage of supplies.

Details:
Consumable materials are stored according to the appropriate test method, SOP, or work instruction.

4.6.2 Specifications

Policy:
Only services and supplies of the required quality are used. These quality requirements are detailed in laboratory SOPs under the "*Materials Required*" section and will identify the appropriate minimum specifications when necessary.

Details:
Packing slips are checked against package content labels and matched with the Purchase Order if accepted. Certificates of analysis (COA) for those materials that require it are maintained on file after the COA (if provided) is checked to ensure the received item meets minimum specifications.

Chemicals are purchased from ISO 9001 (if possible) registered companies with manufacturer's certificates where possible. Whatever the source, the laboratory verifies the quality of the standards by comparing the new batch of standards to the old. Due regard is paid to the manufacturer's recommendations on storage and shelf life.

The grade of any reagent used (including water) is stated in the method together with guidance on any particular precautions to be observed in its preparation or use.

Where no independent assurance of the quality of procured goods or services is available or the supplier's evidence is insufficient, the laboratory ensures that purchased goods and services comply with specified requirements. Where possible and practical, the laboratory ensures that goods are inspected, calibrated, or are otherwise in compliance with any standard specification relevant to the calibrations or tests concerned.

4.6.3 Purchasing Documents

Policy:
Purchasing requests are recorded on the Purchase Order form and contain data describing the product ordered.

Details:
The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, quality required and quality management system standard under which they were produced.

The completion of the Purchase Order is the responsibility of the originator. The originator shall review the Purchase Order for accuracy.

4.6.4 Approved Suppliers

Policy:
Suppliers of critical services are evaluated and approved before use by the Quality Manager. A Log# 4-6-4-L1, *approved vendor list* is maintained.

Details:
Audits or tender evaluation is conducted to qualify suppliers of critical services prior to use. The criteria for evaluation will include the vendor evaluation form.

The records are maintained by the Quality Manager.

4.7 Service to the Customer

4.7.1 Service

Policy:
Client requests are clarified if needed. Furthermore, the client or their representative may be afforded the right to discuss laboratory functions with Lab Director or Quality Manager, provided that the laboratory ensures confidentiality to other clients.

Details and Procedures:
Service to the client includes:

- Affording the client or the client's representative the right to discuss laboratory functions with Lab Director or Quality Manager; it is understood that such discussions should not conflict with rules of confidentiality of work for other clients or with safety.
- Preparing, packaging, and dispatching of test items needed by the client for verification purposes.
- The client may receive advice and guidance in technical matters, and opinions and interpretations based on results. The laboratory should inform the client of any delays or major deviations in the performance of the tests.

4.7.2 Feedback

Policy and Details:
The laboratory seeks feedback from the client. Positive and negative feedback may be obtained passively through ongoing communications with the client (e.g., review of test reports with clients) or actively through Form# 4-4-1-F1, *Client Satisfaction Survey*. The client satisfaction survey form shall be disseminated to our clients annually in November of each calendar year. Results of the survey shall be reviewed and included in the Management Review. The feedback is used to improve the quality management system, testing activities, and client service.

4.8 Complaints

Policy:
The SOP# *QSP 4-8-1, Complaints* is used for resolving complaints received from clients or other parties. Records are maintained of all complaints and follow-up.

Details:
Records of complaints include the following information:

- details of the complaint
- investigation
- corrective action
- non-conformity record
- follow-up verification

See also section 4.11.

All personnel are responsible for recording and reporting complaints to the Quality Manager.

4.9 Control of Nonconforming Work

4.9.1 Procedures to Control Nonconforming Work

Policy:
The SOP# QSP *4-9-1, Control of Nonconforming Work* is used to control any aspect of testing work, or the results of this work, when they do not conform to the test methods.

Details:
The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports as necessary) are defined and taken into consideration when nonconforming work is identified
- an evaluation of the significance of the nonconforming work is made
- correction is taken immediately, together with any decision about the acceptability of the nonconforming work
- where necessary, the client is notified and the work is recalled
- the responsibility for authorizing the resumption of work is defined

Identification of nonconforming work or issue with the quality management system or with testing activities can occur at various locations within the quality management system and technical operations such as:

- client complaints
- quality control
- instrument calibration
- checking of consumable materials
- staff observations or supervision
- technical/administrative review
- management reviews
- internal or external audits

4.9.2 Evaluation of Nonconforming Work

Policy:
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures,

the corrective action procedures outlined in section 4.11 are followed to identify the root cause(s) of the issue and to eliminate this (these) cause(s).

Details:
The SOP# QSP 4-9-1, Control of Nonconforming Work and QSP 4.11.1 Corrective Action guides the investigation of nonconforming work.

4.10 Improvements

4.10.1 Policies and Procedures

Policy:
The laboratory continually improves the effectiveness of its Management System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective actions, preventative actions, nonconformity documentation and management review.

Details:
The laboratory has implemented a continual improvement philosophy within the management system. Every employee in the laboratory is encouraged to suggest new ideas for improving services, processes, systems, productivity, and the working environment.

Opportunities for improvement of operations and processes are identified by managers on a continual basis from ongoing feedback on operations and through management reviews. Opportunities for improvement of services are identified by anyone within the organization.

Inputs for improvement opportunities are obtained from the following sources:

- client satisfaction surveys and any other client feedback
- employees, suppliers, and other interested parties
- internal and external audits of the management system
- records of service nonconformities
- data from process and service characteristics and their trends

Opportunities for improvement from daily feedback on operational performance (i.e., internal audits, client feedback, and test/calibration results) are evaluated by the Technical Leader or Quality Manager. Typically, they are implemented through the corrective and preventive action system.

Opportunities for improvement from analysis of longer-term data and trends are evaluated and implemented through the management review process. They are prioritized with respect to their relevance for achieving quality objectives. When opportunities for improvement are no longer supported by the current policy and objectives, management will establish new quality objectives. The process for this evaluation is described in

section 4.15. Longer-term improvement projects are initiated through the management review process, as well as the corrective and preventive action system.

Service improvement opportunities are evaluated by management. They are implemented through the Technical Leader who ensures that the improvements are validated as outlined in section 5.4 of this manual and appropriate level of quality control is performed on an ongoing basis.

4.11 Corrective Action

4.11.1 General

Policy:
The SOP# *QSP 4-11-1,Corrective Action* is utilized for implementing corrective action when nonconforming work or departures from policies and procedures in the quality management system or technical operations have been identified. The procedure requires that appropriate authority be designated for the implementation of corrective actions. The procedure includes cause analysis, selection and implementation of corrective action, and monitoring of actions.

Details:
Issue with the quality management system or technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feed-back from clients, or staff observations.

Corrective action investigations are documented and required changes to operational procedures are implemented. The corrective action request (CAR), investigation and resolution are recorded on a (CAR) form.

4.11.2 Cause Analysis

Policy:
Corrective action always begins with an investigation to determine root cause(s) of the issue (see SOP# *QSP 4-11-1,Corrective Action*)

Details:
Potential causes of the issue could include client requirements, the samples, sample specifications, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration.

4.11.3 Selection and Implementation of Corrective Actions

Policy and Details:
After determining the cause(s) of the issue, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the issue and to prevent recurrence. It should be noted that any

corrective actions taken to eliminate the cause(s) of nonconformities or other departures are to a degree appropriate to address the magnitude of the issue and commensurate with the risks encountered (Note – in plain language, this means determine whether the benefit outweighs the cost). Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Action

Policy:
After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the issue originally identified.

Details:
Monitoring is assigned to Quality Manager or Technical Leader. Changes resulting from corrective action are documented.

4.11.5 Additional Audits

Policy:
Where the identification of nonconformities or departures casts doubts on compliance of policies, procedures, regulations, international quality standards, the appropriate areas of activity are promptly audited in accordance with section 4.14.

Details:
Special audits follow the implementation of corrective actions to confirm their effectiveness. A special audit is only necessary when a serious issue or risk is identified. Special audits are carried out by trained and qualified personnel who are whenever resources permit independent of the activity to be audited. See section 4.14 for more details.

4.12 Preventive Action

4.12.1 Preventive Action Identification

Policy:
Opportunities for needed improvement and potential sources of nonconformities, either technical or with the quality management system shall be identified. If preventive action is conducted, action plans are developed, implemented and monitored to take advantage of the improvement opportunities.

Details:

Records of preventive action include the following information:

- details of potential nonconformities
- investigation
- preventive action
- follow-up verification

These records are maintained electronically in the Preventive Action Request (PAR) folder.

4.12.2 Preventive Action Plans

Policy:
The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective.

Details:
Preventive action may result from the review of operational procedures and analysis of data. Analysis of data includes trend analysis, analysis of proficiency testing results, and risk analysis.

The SOP# *QSP 4-12-1, Preventive Action* is utilized to implement opportunities for needed improvement and prevent potential sources of nonconformities.

4.13 Control of Records

4.13.1 General

4.13.1.1 Procedures

Policy:
The SOP# *QSP 4-13-1,Control of Records* is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective and preventive action records.

Details:
Records are available to demonstrate conformance to requirements and effective operation of the Quality Management System. Quality records from suppliers are also controlled.

All records, including test reports, are safely stored and held secure in locked areas, and in confidence to the client. Records are maintained in the designated archival area for 10 years.

All records are organized with the following information:

- Record Name and/or Case File number (Generated by RMS for test item records)
- Filing Method (filed as completed , printed or electronic)
- Active Files (files referred to within the work area) Forms/logs are retained during active period printed or electronic. If retained electronically it will be located on the secure server location designated and access from work area computer. If retained in printed form it shall be stored in designated location/binder.
- Inactive Files (files referred to but not often and kept in storage) shall be retained for at least 10 years by secure file cabinet in laboratory and/or secure storage on site and/or electronic.
- All personnel assigned to Laboratory have access and responsibility to safeguard all documents. These persons shall also be designated users to their level of responsibly as designated by Laboratory Director or Quality Manager.

The dating format for records shall reflect the original dating format of the particular document, form or log.

4.13.1.2 Record Integrity

Policy:
All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Details:
The retention times for records are 10 years; however, retention times may be longer if directed by management. Records may be in the form of hard copy or electronic.

4.13.1.3 Record Security

Policy:
All records are held secure and in confidence.

Details:
Access to records is secured through authorized access rooms, rights protected server locations and filing cabinets.

4.13.1.4 Record Backup

Policy:
The SOP# *QSP 4-13-1,Control of Records* is followed to protect and backup data/records held on computers at all times and to prevent unauthorized access.

Details:
Data is password/rights access protected.

Backups ensure integrity and availability of data / information in the event of a system/power failure.

4.13.2 Technical Records

4.13.2.1 Record Information

Policy:
Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records and a copy of each test report are retained for 10 years;

however, retention times may be longer if directed by management or otherwise required by other legal requirements.

The records for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the test uncertainty and to enable the test to be repeated under conditions as close as possible to the original. Test Records shall be identified by a unique case number generated by RMS Records Management System. The records include the identity of personnel responsible for sampling, performing of each test and checking of results.

Details:
Technical records are accumulations of data (see 5.4.7) and information that result from carrying out tests and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, note books, instrument printouts, magnetic media, check sheets, work notes, control graphs, test reports, and test reports to clients.

The records for each test contain sufficient information to permit its repetition. Records include:

- date analyzed (start date)
- date of report (end date)
- test item receipt
- test item handling, storage, and disposition
- identification of personnel conducting test
- equipment identification and performance
- control samples or positive control data
- calibration records
- results
- reports (mailed, faxed, posted electronically)
- review

Note – the above records may be stored in separate locations. They are cross-referenced by master case number for easy retrieval.

4.13.2.2 Recording

Policy:
Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific case file at the time they are made.

Details:
Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected and/or after calculations are made.

4.13.2.3 Corrections to Records

Policy:
Changes to test data are made so as not to obscure or delete the previous data entry.

Details:
Mistakes are crossed out with a single strike through and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records are signed or initialed by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.

4.14 Internal Audits

4.14.1 Internal Audit Program

Policy:
The internal audit program involves periodic audits conducted according to a predetermined schedule. This program is conducted as outlined in this section with further details found in SOP# QSP 4-14-1, Internal Quality Audit. This Quality Manual will be audited each year and all relevant laboratory records are available to personnel conducting the audit. These audits are performed to verify operations continue to comply with the requirements of this Quality System and are effective.

Details:
The Quality Manual, test procedures, and laboratory results are verified for compliance. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are carried out by qualified personnel who are wherever resources permit independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.11.5). Audits are performed through the aid of an audit form, Form# 4-1-5-L3, *Internal Audit Checklist* prepared in advance to minimize the possibility of overlooking any details during the audit. The internal audit will mirror the external audit program. The initial internal audit will address all line items on the external audit checklist. Internal audits shall be conducted in the month of September each calendar year. The Quality Manager will prepare an internal audit report to be included in the Management Review.

Generally, the types of audits include:

- quality management system
- processes and procedures
- products, services, and reports

4.14.2 Corrective Action

Policy:
When audit findings reveal doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken.

Details:

Nonconformities that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformities that require a more involved resolution are recorded on a (CAR) Corrective Action Request and resolved as described in section 4.11.

Corrective actions and procedural deviations must be kept on record for each audit.

4.14.3 Records and Management

Policy:
Records are made of the activity being audited, the audit findings, and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.

Details:
A report is prepared by the auditors in accordance with QSP# *QSP 4-14-1, Internal Quality Audit* and distributed to those audited and/or the discipline Technical Leader within an appropriate timeline.

4.15 Management Reviews

4.15.1 Review of Quality Management System and Testing

Policy:
Top management shall annually in January of each calendar year in accordance with SOP# *QSP 4-15-1, Management Review*, conduct a review of the laboratory's quality management system and testing activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The results of the review shall be recorded by the Quality Manager and reported to the Lab Director.

Details:
The review takes account of:

- suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal audits
- corrective and preventive actions
- assessments by external bodies
- results of inter-laboratory comparisons or proficiency tests
- changes in the volume and type of work undertaken
- feedback from clients, including complaints and Form# 4-4-1-F1, *Client Satisfaction Survey*
- recommendations for improvement
- other relevant factors, such as quality control activities, resources and personnel training

Results of the review feed into the laboratory planning system and include goals, objectives and action plans for the coming year.

4.15.2 Findings, Actions, and Records

Policy and Details:
Findings from management reviews and the actions that arise are recorded in the minutes of the meeting. Management will ensure that the actions are discharged within an appropriate and agreed upon timeline.

4.16 Revision History

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2016/07/01	Original version
2	2018/04/01	Change Issue Date to Effective Date, Change Rev# to Ver#, Changed Revision History table, and Changed issue date to effective date. Changed Rev# to Ver#. Change revision history table format. Section 4.1.3- deleted last sentence. Section 4.1.4 – changed DOC# 4-1-4-d1 to 8_ Job Description. Section 4.1.5a – Change title of who is authorized to approve departure from test method or technical procedure to match QSP. Section 4.1.5c clarified who client refers to. Section 4.1.5h revised title of technical leader. Change and clarify (spell out) which documents are controlled in this system. Section 4.3.2.1 Master list requirement changed – next review date, effective date, and version#, Add reference to QSP Control of nonconforming work Section 4.13.2.1 added Identity of personnel conduction test, Add " or other legal requirement " in retention of report. Change 4 year schedule to quarterly calendar year schedule, Change 4.14.1 internal audit time frame to each calendar year in September.
3	2018/10/17	4.2.2 defined top management.4.13.2.1 Defined test record identifier, define the start of analysis and date of report, 4.2.2 Update Quality Policy statement. Modify and update document format to single section (4) and update to one revision history table.
4	2019/01/04	Under internal audit corrected typo, corrected formatting issues, applied heading formatting, updated listing numbers, inserted table of contents, updated internal document hyperlink to cross references