8 Contents

8.1 Management System Options

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Criteria 8.4 to 8.7, the laboratory shall implement a management system in accordance with Option A or Option B.

8.1.2 Option A

As a minimum, the management system of the laboratory shall address the following:

- management system documentation (see 8.2);
- control of management system documents (see 8.3);
- control of records (see 8.4);
- actions to address risks and opportunities (see 8.5);
- improvement (see 8.6);
- corrective actions (see 8.7);
- internal audits (see 8.8);
- management reviews (see 8.9).

8.1.3 Option B (N/A)

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Criteria 8.4 to 8.7, also fulfils at least the intent of the management system requirements specified in Criteria 8.2 to 8.9.

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 issues 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), Deviation Request Form (DRF) 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

8.2 Management System Documentation

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

8.2.1.1 The following words (to include forms of the same word) used in ISO/IEC 17025:2017 or in this document require addressing the requirement in writing: **agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify**

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

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4 All documentation, processes, systems and records related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

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

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:
The Pitt County Forensic Services Unit Quality Policy Statement is located in section 1 of the Quality Manual.

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

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.

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
- copies of the Quality Policy Statement posted in the laboratory
- identification of resources and management review
- job descriptions
- statistical techniques
- test reports
- identification of the laboratory's approved signatures
- laboratory's scope of tests
- equipment inventory and records
- calibration status indicators
- reference standards inventory
- verification records
- quality control plan / criteria for workmanship
- corrective action records
- preventive action records
- client complaint records
- audit schedule and records
- procurement
- training records
- master list of documentation
- confidentiality agreements
- contract review
- validation of test methods
- facility floor plan

8.3 Control of Management System Documents

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfillment of this document.

8.3.2 NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3.3 The laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;
b) documents are periodically reviewed, and updated as necessary;
c) changes and the current revision status of documents are identified;
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
e) documents are uniquely identified;
f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

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 7.11. The control of records is covered in section 7.5.

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 version, effective date and last review date 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 4-03-1, Document Control). A revision history of documents is also maintained. Documents are formally reviewed annually in January to ensure their continuing suitability.

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.

QSP 4-03-1, 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 electronically stored to prevent unintended use.

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

Document Changes 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.

Identification of Changes

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

Details:
As outlined in SOP# QSP 4-03-1, Document Control.

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

Amendments by Hand are not permitted.

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

Computerized Documents

Policy and Details:
The SOP# QSP 4-03-1, Document Control details how changes in documents maintained in computerized systems are made and controlled.

8.4 Control of Records

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available. Contractual obligations for records retention include legal requirements and customer expectations.

Policy and Details:

QSP 4-13-1,Control of Records and section 7.5 details the control of records used in the quality management system.

8.5 Actions to Address Risks and Opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the laboratory;
c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
d) achieve improvement.

8.5.1.1 Risks and opportunities related to health and safety shall be considered.

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;
b) how to:
   - integrate and implement these actions into its management system;
   - evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

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 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. 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 7.2 of this manual and appropriate level of quality control is performed on an ongoing basis.

8.6 Improvement

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

8.6.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.

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.

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.

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.

8.7 Corrective Actions

8.7.1 When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and, as applicable:
   - take action to control and correct it;
   - address the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   - reviewing and analyzing the nonconformity;
   - determining the causes of the nonconformity;
   - determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the management system, if necessary.

g) shall establish a reasonable timeframe for completion for each corrective action

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;
b) the results of any corrective action.

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.

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.

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. Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

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.

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 8.8.

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 8.8 for more details.

8.8 Internal Audits

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:
- the laboratory's own requirements for its management system, including the laboratory activities;
- the requirements of this document;
- Internal audits shall provide information on whether the management system conforms to the requirements of AR 3125.

b) is effectively implemented and maintained.

8.8.1.1 Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment.

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
b) define the audit criteria and scope for each audit and shall include direct observation of a sample of accredited services within each discipline;
c) ensure that the results of the audits are reported to relevant management;
d) implement appropriate correction and corrective actions without undue delay;
e) retain records as evidence of the implementation of the audit program and the audit results.

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. 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

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 and resolved as described in section 8.7.

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

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.

8.9 Management Reviews

8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.1.1 Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;
b) fulfilment of objectives;
c) suitability of policies and procedures;
d) status of actions from previous management reviews;
e) outcome of recent internal audits;
f) corrective actions;

g) assessments by external bodies;
h) changes in the volume and type of the work or in the range of laboratory activities;
i) customer and personnel feedback;
j) complaints;
k) effectiveness of any implemented improvements;
l) adequacy of resources;
m) results of risk identification;
n) outcomes of the assurance of the validity of results; and
o) other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources;
d) any need for change.

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.

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.

8.10 Revision History

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2019/11/18	Original version
2	2020/01/15	Removed quality policy statement from section 8.2