
	<p align="center">Quality Manual</p> <p align="center">Pitt County Sheriff's Office Forensic Services Unit</p> <p align="center"><i>Issued by the Quality Manager</i></p>	<p>Effective Date:</p> <p align="center">2019/11/18</p>	<p>Ver.:</p> <p align="center">1</p>
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5.1 Structural Requirements

5.1.1 Legal Identification / Registration

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

5.1.2 Management and Technical Personnel

Policy:

The Laboratory Director and Quality Manager have the overall responsibility for the laboratory. 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. These duties include a) implementation, maintenance and improvement of the management system, b) identification of deviations from the management system or from the procedures for performing laboratory activities, c) initiation of actions to prevent or minimize such deviations, d) reporting to laboratory management on the performance of the management system and any needs for improvement and e) ensuring the effectiveness of laboratory activities.


Details:

Responsibilities are detailed in [section 5.1.2.2](#).

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](#).

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5.1.2.1 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*](#).

5.1.2.2 Responsibility and Authority


5.1.2.2.1 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.

5.1.2.2.2 Technical Leader[s]

- knowledgeable of the scope of all processes under their supervision

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- 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, develops, modifies, verifies, and validates SOPs and test methods

5.1.2.2.3 Quality Manager

- ensures that the Quality Management System is established, implemented and maintained in accordance with ISO 17025:2017 & AR3125 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

5.1.2.2.4 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

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5.1.2.2.5 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

5.1.2.2.6 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

5.1.2.2.7 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

5.1.2.3 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

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orientation and training program is adhered to for all new employees. Ongoing training for regular personnel is required.

5.1.2.4 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.

5.1.2.5 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.

5.1.2.6 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.

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If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

5.1.2.7 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 relates to their activities to achieve the objectives of the management system.

5.1.3 Scope of Laboratory System

The Pitt County Sheriff's Office (PCSO) Forensic 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 Forensic Services Unit management system covers activities in the laboratory's permanent facility. The fields of activities include:

Drug Chemistry-Analyze all suspected controlled substances 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.

5.1.4 Laboratory Requirements

The work areas of Pitt County Sheriff's Office Forensic Services Unit have been organized to satisfy the needs of all entities we serve. The Pitt County Forensic Services Unit will carry out all crime laboratory services in accordance with stated methods regulatory authorities and to meet the international standards ISO 17025:2017 & AR3125. Pitt County Sheriff's Office Forensic Services Unit is composed of the following work areas:

Laboratory personnel offices and workspaces

Drug Chemistry

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Blood Alcohol
General Laboratory
Records Room
Supply Room
SAFIS, Unknown and Known Impression Evidence Room

*Pitt County Forensic Services Unit shall conform to requirements in PR 1018 ANAB policy on use of ANAB Accreditation Symbols and claims of accreditation Status.

**Laboratory testing performed under the authority of statute, regulation or other legal requirement shall be made readily available.

5.1.5 Laboratory 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 validity of results generated (includes analysis and data interpretation to arrive at a result, opinion or interpretation). 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\(NCR\)](#) are utilized to address laboratory issues.
- by other methods approved by the Laboratory Director, Quality Manager, or Technical Leader(s).

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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 methods
- organizational charts
- forms
- logs
- other documents


5.1.6 Laboratory Communication and change

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.

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

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

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5.2 Revision History

REVISION HISTORY		
CURRENT VERSION	EFFECTIVE DATE	SUMMARY OF CHANGES
1	2019/11/18	Original version