# 5 Contents

## *5.1 General*

### 5.1.1 Correctness and Reliability

**Policy and Details:**
Correctness and reliability of the tests performed have many contributing factors including:

- human factors (see section 5.2)
- accommodation and environmental conditions (see section 5.3)
- test methods and method validation (see section 5.4)
- equipment (see section 5.5)
- measurement traceability (see section 5.6)
- sampling (see section 5.7)
- handling of test items (see section 5.8)

### 5.1.2 Measurement Uncertainty

**Policy:**
When developing test methods and procedures, total measurement uncertainty must be at least 95%, and be accounted for in the training and qualification of personnel, and in the selection and calibration of equipment.

**Details:**
The extent to which the factors contribute to total measurement uncertainty differs between (types of) tests.

See section 5.4.6 for more details.

### 5.1.3 Prepared Reagent Identification

See Section technical procedures.

### 5.1.4 Prepared Reagent Reliability

See Section technical procedures.

## *5.2 Personnel*

### 5.2.1 Competence and Qualification

**Policy:**
Management ensures the competency of all specific equipment operators, those performing tests, those evaluating results, and those signing Laboratory Reports. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in Laboratory Reports also have:

- relevant knowledge of the technology used for the identification of the items and materials or the way they are used or intended to be used and of the defects or degradation that may occur during use
- knowledge of the general requirements expressed in the legislation and standards
- an understanding of the significance of deviations found with regard to the normal use of the items and materials

**Details:**
Management defines the minimum levels of qualification and experience necessary for all positions within the laboratory. In some technical areas it may be required that the personnel performing certain tasks be certified. The laboratory is responsible for fulfilling specified certification requirements of personnel. The requirements for personnel certification might be regulatory and might be included in the standards for the specific technical field.

Continued competence is monitored through proficiency testing and continued training by the Quality Manager/Technical Leader.

Each discipline shall have a documented training program that is used to develop the knowledge, skills, and abilities required to perform forensic examinations. The requirements for the training program for each discipline as well as Technical Reviewers for that discipline shall be found in the Technical Training Procedures for each discipline, QSP 5.2.1a and QSP 5.9.4.

## 5.2.2 Training Policies and Procedures

**Policy:**
Management will formulate training plan with respect to the education, experience and skills of the laboratory personnel. The training program is relevant to the present laboratory disciplines. SOP# *QSP 5-2-1, Training* is utilized to identify training requirements and how to achieve competency of personnel. The effectiveness of the training actions taken is evaluated by practical exams, competency test and moot court.

**Details:**
The skills and knowledge are defined in the job description for each job function as described in section 5.2.4. Management compares the job description to the skills and knowledge of the new employee to determine the training needs.

Training in the laboratory must include all methods or parts of methods and techniques that personnel are asked to perform. Minimally, the analyst (chemists, technicians, examiners) must demonstrate competency through observation by management and verification using written and practical exams.

In some cases, it may be appropriate to define competence related to a particular technique or instrument rather than methods. If so, it will be necessary to define for each method, the necessary technique-based competence required together with any additional requirements.

## 5.2.3 Employees

**Policy:**
The Laboratory Director/Quality Manager ensures that all personnel are trained and work in accordance to the policies and procedures of the Quality Management System.

**Details:**
All employees in the laboratory shall undergo training in the quality management system at the direction of the Quality Manager. Training shall be documented according to *QSP 5-2-1, Training*.

## 5.2.4 Job Descriptions

**Policy:**
Current job descriptions for managerial, technical and key support personnel involved in tests are maintained centrally in the administration documents and human resources.

**Details:**
Minimum contents of job descriptions include:

- the duty of performing tests
- the act of planning tests and evaluation of results
- expertise and experience
- qualifications
- managerial duties

Job descriptions are dated and signed to demonstrate that each employee has read it and is in agreement. They are maintained current.

### 5.2.5 Authorized Personnel

**Policy:**
Management authorizes specific personnel to perform particular types of sampling, test, to issue Laboratory Reports, to give opinions and interpretations and to operate particular types of equipment. Records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel are maintained. This information is available in the training file and includes the date on which authorization and/or competence was confirmed.

**Details:**
The purpose of these records is to provide evidence that personnel have been adequately trained and their competence to perform particular tests has been assessed. Records are maintained in electronic form:

- academic and professional qualifications
- external and internal courses attended
- relevant on- the-job training and retraining as necessary (i.e., demonstration of competence)
- skills and experience (i.e., resume)
- relevant authorizations

## *5.3 Accommodation and Environmental Conditions*

### 5.3.1 Facility

**Policy:**
A safe, secure, and efficiently operated facility is crucial to employee performance and overall productivity. Laboratory procedures should reflect this belief and be in accordance with best known practices. Employees adherence to and understanding of facility operations and security procedures is imperative to maintaining the strictest level of security regarding the evidence, records, and examinations conducted on a daily basis by laboratory staff.

Accredited Laboratory facilities are appropriate to attain correct performance of tests. This may include, but not limited to, energy sources, lighting, heating, ventilation and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented. Laboratory will maintain facility access and security procedures in compliance with ISO 17025 standards. The laboratory's facility floorplan is diagrammed in document DOC# *5-3-1-D1, forensic services floorplan*, and management shall ensure that all personnel are familiar with layout.

**Details:**
This section deals with the test areas in the laboratory and premises for support such as item receipt and storage. Laboratory supplies and services, such as water purification systems, air supply, vacuum source, and item storage, are appropriate to facilitate proper performance of tests.

Employees shall have workspace appropriate for the job to be performed. Sufficient space shall be provided near work areas for storage of supplies, equipment, and tools. Storage areas for items shall accommodate retention of items for the time and conditions needed to protect their integrity.

Separate storage areas of sufficient size shall be present in laboratory areas to ensure that evidence, glassware, instrumentation, supplies, reagents, solvents, chemicals, hazardous or regulated wastes, and reference standards and materials are properly stored.

Chemicals and solvents shall be stored based on compatibility and in accordance with the manufacturer's guidance, Safety Data Sheets, and the fire code.

Adequate lighting shall be provided in all work areas. Adequate plumbing and wiring shall be available and accessible for all tasks.

Laboratory areas shall be maintained in a clean and orderly manner to prevent contamination and to facilitate the efficiency of operations.

### 5.3.2 Monitoring

**Policy:**
Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Due attention is paid, for example, to biological sterility, dust, air quality, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests are stopped when the environmental conditions jeopardize the results of the tests.

**Details:**
Laboratories are ventilated to reduce humidity and control temperature. Laboratory's test areas are air-conditioned. The relative humidity in test areas are monitored if deemed important and the temperature is monitored if deemed important.

Airflow is designed to minimize and prevent cross contamination. Exhaust hoods and biological safety cabinets shall be provided and shall have sufficient airflow to provide a safe environment. All hoods shall be calibrated annually. Heating, cooling, and general ventilation shall be adequate. De-ionized water systems shall be provided as needed and shall be maintained according to manufacturer's specifications.

### 5.3.3 Separation of Incompatible Activities

**Policy:**
Effective separation between neighboring areas is made when there is any potential for cross-contamination.

**Details:**
Reference material and test item material storage must be segregated and include proper sanitation to exclude the possibility of cross-contamination. Segregation of activities is

achieved through time and space allocations. If possible, separate rooms shall be used for work areas and clean areas.

Bench tops and floors are made of easily cleaned materials. Walls and ceilings are made of materials that are easily cleaned or replaced.

An example of time segregation would be the coordination of activities at different times. It may be appropriate to perform work on "cleaner" items first before starting "dirtier" type items.

### 5.3.4 Controlled Access

**Policy:**
Access to and use of areas affecting quality of the tests is defined and controlled. The Laboratory Director shall be solely responsible for the authorization of individual access to all portions of the facilities. This access is documented on a key LOG #5-3-4- L1, Key Log. The Pitt County Sheriff's Office Detention staff will maintain perimeter checks of laboratory facilities on a 24hour basis.

**Details:**
Access to the laboratory is restricted to Forensic Services personnel and others escorted by Forensic Services personnel with valid reason to access the Laboratory. Validity of access shall be determined by the Laboratory Director, Quality Manager or Technical Leader of that discipline. At no time will escorted personnel be allowed in the testing areas while active case work is in progress. This is to ensure that the case work, environment and personnel are protected from cross contamination, accidental chemical and/or biohazard exposure, etc. Drug Chemistry and Blood Alcohol testing areas are only accessed by Chemist and Supervisor/Quality manager. Escorted access shall be recorded on sign in log book located at the two entrances to the general laboratory.

**Overall Security Measures:**
The Laboratory Management retains responsibility for the Laboratory's alarm, facility keys and locksmith services. The issuance and return of all facility keys shall be documented and maintained by the Laboratory Director and/or Quality Manager. Those who have keys and access to Laboratory are Forensic Services Unit employees with only one exception. In emergency situations, a key is kept in a lock box in the detention center's shift lieutenant's office. There are a total of four (4) lieutenants and one (1) key. The lieutenants do not have the code to the security alarm.

Emergency access by Detention Supervisory staff is documented at time of entrance through alarm activation, notification to Pitt County Sheriff's Communications Center and Email notification to Laboratory Management.

**Video Surveillance**
Predetermined areas of the laboratory and this facility have been designated as necessitating constant video surveillance coverage. These areas include main hallway from entrances, drug chemistry and marijuana work area, Deputy Room temporary lockers and Evidence Control long term storage area. Requests for copies of any video surveillance shall be authorized only with prior approval from and under the direct authority of the Laboratory Director or the Quality Manager.

## 5.3.5 Good Housekeeping

**Policy:**
Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary. The Laboratory Safety Manual addresses good housekeeping and other special procedures that are monitored for effectiveness by the designated Safety Officer.

**Details:**
Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements. Further guidance and information can be obtained from the Laboratory Safety Manual.

## *5.4 Test Methods and Method Validation*

### 5.4.1 General

**Policy:**
Laboratory uses appropriate methods and procedures for all testing.

Methods and procedures used for all tests are appropriate as per:

- sampling, handling, transport, storage, and preparation of items to be tested
- an estimation of the measurement of uncertainty as well as statistical techniques for analysis of test data where appropriate

Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing are available in discipline Procedures. All instructions, standards, manuals and reference data relevant to the work of the laboratory are maintained current and readily available to personnel. Deviation from test methods must be documented on Form # 4-1-5-F1 (DRF) Deviation Request Form, technically justified and authorized.

**Details:**
There are SOPs for sampling, item handling, transport, storage, preparation of test items, QA/QC procedures (media QC, incubation times and temperatures, equipment calibration and maintenance, process control QC), and standards for approving / rejecting results. These may be combined with or separate from the method. The content of a test method includes:

- Name of Procedure
- Suggested Uses and Documentation
- Apparatus/ Materials and Equipment Required
- Reagent Preparation/if applicable
- Quality control check
- Expiration date/Not Applicable
- Procedure and Presentation
- Safety Measures
- References

International, national, or regional standards or other recognized procedures that contain sufficient and concise information on how to perform the tests utilized by this laboratory

are not necessarily supplemented or rewritten as an internal procedure when they are written in a way that can be used as published by laboratory staff and reference in the internal Technical Procedures. Upon verification of any technical procedure consideration shall be given to providing additional documentation for optional steps in the method as outlined in the operation procedure 4-1-5-F1 (DRF) Deviation Request Form.

### 5.4.2 Selection of Methods

**Policy:**
Test methods, including methods for sampling, meet the needs of the client and are appropriate for the tests it undertakes. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

**Details:**
The laboratory will provide procedure and method of testing upon request of the client.
Methods that have been published either in international, national, or regional standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer are selected by the Quality Manager/Technical Leader as the method to be used.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The laboratory confirms that it can properly operate standardized methods before introducing the tests. If the standardized method changes the confirmation is repeated.

Infrequently performed tests (less than once per year) are verified by replicate testing by analyst using appropriate reference material prior to testing actual case evidence using that method.

All standards and components used for testing are verified for suitability and lot, batch numbers (if available) are recorded prior to use. All critical reagents are tested prior to use for its intended purpose.

All purchased and prepared reagents are labelled appropriately in accordance with Chemical Safety and Hygiene Plan.

A list of all the laboratory chemicals are outlined in Log# *5-4-2-L1, Chemical inventory list*.

### 5.4.3 Laboratory-Developed Methods

**Policy:**
Introduction of test and calibration methods developed internally is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and ensure effective communication amongst all personnel involved.

**Details:**
Methods developed in-house are validated and authorized before use in accordance with *QSP 4-2-1, Validation of Technical Procedures*.

### 5.4.4 Non-Standard Methods

**Policy:**
Utilization of non-standard methods shall be determined by Quality Manager/Technical Leader and includes a clear specification of the purpose of the test. The developed method is validated appropriately before use according to QSP 4-2-1, Validation of Technical Procedures.

**Details:**
Discussion and agreement for the use of non-standard methods is recorded as part of review procedures (see section 4.4).

All non-standard and new tests are validated for their intended purpose. Qualitative and Quantitative test methods must be validated prior to use.

New test methods are documented prior to providing results to clients and contain at least the following if applicable:

- appropriate identification
- scope
- description of the type of item to be tested
- parameters or quantities to be determined(if applicable)
- apparatus and equipment, including technical performance requirements
- reference standards and reference materials required(if available)
- environmental conditions required and any stabilization period if needed

- description of the procedure,
- affixing identification marks, handling, transporting, storing and preparing of items
- ensuring checks are made before the work is started
- checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use
- listing method of recording the observations and results
- indicating any safety measures to be observed
- criteria and/or requirements for approval/rejection (quality control plan)
- data to be recorded and method of analysis and presentation
- uncertainty or procedure for estimating uncertainty

## 5.4.5 Validation of Methods

### 5.4.5.1 Performance Characteristics

**Policy:**
Validation of a method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the test results.

**Details:**
The performance characteristics of a validation plan includes, as applicable:

- selectivity and specificity
- range
- linearity
- sensitivity
- limit of detection
- limit of quantitation
- ruggedness
- accuracy
- precision
- reporting limit
- repeatability
- reproducibility
- recovery
- confirmation techniques
- criteria for the number of items tested to validate method as per defined scope of method

- action levels where defined by regulation
- quality control incorporating statistics as applicable
- interpretation of population results as applicable

Methods may be validated by one or more alternative procedures. Some of these procedures are described below. Apparent differences can be analyzed statistically to confirm their significance. In all cases, the reasons for choosing one or more alternatives must be documented.

- analysis of standard reference materials (SRM) that are identical or almost identical to the test items
- in the absence of suitable SRMs, analysis of reference materials that are similar in all respect to the test items; the use and validity of this reference material must be documented
- using an alternative method to measure the same parameter provides a very high level of confidence if results are confirmed
- recovery studies by the addition of a known concentration of the parameter of interest to some of the replicates being measured

The parameters to be determined include:

- the scope of the method and any known interference
- detection limit
- the range of concentration where the method is valid
- precision and bias

## 5.4.5.2 Fit for Use

**Policy:**
The laboratory validates non-standardized methods, laboratory-designed/developed methods, standardized methods used outside their intended range, and amplifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs in the given application or field of application (may include procedures for sampling, handling, and transportation). The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

**Details and Procedure:**
Validation records are kept as in *QSP 4-3-1, document control*. Included in these records is the validation procedure. The procedure used for the validation is likely to vary between different methods.

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

- comparison of results achieved with other methods
- systematic assessment of the factors influencing the result
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When changes are made in the validated non-standard method, the influence of such changes carried out is documented and if appropriate a new validation is performed.

### 5.4.5.3 Client's Needs

**Policy:**
The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the item/test object) are assessed for the intended use is relevant to the clients' needs.

**Details:**
Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

As method development proceeds, regular review is required to verify that the needs of the Client are still being fulfilled. Changing requirements requiring modifications to the development plan are approved and authorized by Quality Manager/Technical Leader.

## 5.4.6 Uncertainty of Measurement

### 5.4.6.1 Calibration

N/A

## 5.4.6.2 Testing

**Policy:**
The Technical Procedure for Measurement Assurance is utilized to estimate uncertainties of measurement in testing, except when the test methods preclude such rigorous calculations. In certain cases it is not possible to undertake metrological and statistical valid estimations of uncertainty of measurement. In these cases the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope and makes use of previous experience and validation data.

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

- requirement of the test method
- if there are narrow limits on which decisions on conformity to a specification are based

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the reporting instructions (see section 5.10).

## 5.4.6.3 Uncertainty Components

**Policy:**
When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

**Details:**
Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested and the operator.

The predicted long-term behavior of the tested item is normally not taken into account when estimating the measurement uncertainty.

## 5.4.7 Control of Data

### 5.4.7.1 Calculations and Data Transfers

**Policy:**
Calculations and data transfers are subject to appropriate checks in a systematic manner.

**Details:**
Test data are validated through the following arrangements by the Technical Reviewer:

- checks to determine accuracy of calculations, conversions, and data transfers
- checks for transcription errors, omissions, and mistakes
- checks to determine consistency with normal or expected values

For those analyses where manual data reduction is required, it is performed according to the instructions provided in the test method or SOP.

### 5.4.7.2 Computers and Automated Equipment

**Policy:**
When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

- computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use
- procedures are established and implemented for protecting the integrity of data; such procedures include, but are not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, data processing and records backup
- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data
- data is securely maintained by preventing unauthorized access to, and unauthorized amendment of, computer records

**Details and Procedures:**
Data generated using computer software programs that are interfaced directly to instruments incorporates all dilutions and calculations. Any additional data calculations shall be recorded in accordance with technical procedures.

Commercially developed software in general use within its designed application range may be considered sufficiently validated. Laboratory software configuration / modifications are validated as outlined in SOP# *QSP 5-5-1, Equipment*.

## *5.5 Equipment*

### 5.5.1 Required Equipment

**Policy:**
The laboratory is furnished with all items for sampling, measurement and test equipment required for the correct performance of the tests (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). When equipment is used outside the laboratory's permanent control, it ensures that the requirements of this Quality Manual are met.

**Details:**
Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method.

### 5.5.2 Required Accuracy

**Policy:**
Equipment and software used for testing, calibration and sampling are capable of achieving the accuracy required and comply with specifications relevant to the tests concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. When received, equipment, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with section 5.6 before use.

**Details:**
The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

### 5.5.3 Authorized Personnel

**Policy:**
Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel.

**Details:**
Access to laboratory equipment is controlled to ensure that only authorized personnel use equipment.

### 5.5.4 Unique Identification

**Policy:**
Each item of equipment used for testing and calibration is uniquely identified as appropriate.

**Details:**
Measuring and testing equipment is uniquely identified through an asset number or serial number. Measuring and testing equipment includes any instrument that could affect the quality of test results. Components that can be interchanged between various instruments are tracked in equipment logbooks but are not assigned individual asset number or serial number.

### 5.5.5 Inventory and Maintenance Records

**Policy:**
Records are maintained for each item of equipment significant to the tests performed. The records include the following:

- identity of the item of equipment (and its software)
- manufacturer's name, type identification, and serial number and/or other unique identification
- checks that equipment complies with the specification (see section 5.5.2)
- current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)
- damage, malfunction, modification or repair to the equipment

**Details:**
A database is used to capture the above inventory information. The above information related to service and maintenance is kept in individual equipment files and/or binders. Other information kept in these files and/or binders may include:

- date received and date placed in service

- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification
- performance history, where appropriate (e.g., response time, drift, noise level)

### 5.5.6 Equipment Procedures

**Policy:**
The SOP# *QSP 5-5-1, Equipment* is utilized as an established plan for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and in order to prevent contamination or deterioration.

**Note** – additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations, or sampling (currently not applicable at our laboratory).

**Details and Procedures:**
The technical procedures for each piece of measuring equipment are located in DM Document Management System. These procedures detail any information for safe handling, transport, storage, use, and maintenance of measuring equipment.

### 5.5.7 Out of Service Equipment

**Policy:**
Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly.

**Details:**
Routine testing work is completely discontinued on equipment that even shows minor nonconformance until repair.

Out of service equipment is clearly marked as outlined in section 5.5.8.

The laboratory examines the effect of the defect or departure from specified limits on previous test and institutes the "Control of Nonconforming Work" procedure as outlined in section 4.9.

### 5.5.8 Calibration Status

**Policy:**
Equipment requiring calibration shall have a means to indicate the calibration status including the date of the last calibration and the date or expiration criteria when recalibration is due.

**Details:**
Measuring equipment that has failed calibration or is deemed out of service shall be labeled as such.

### 5.5.9 Return to Service

**Policy:**
When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

**Details and Procedures:**
The procedures used to check and ensure that the function and calibration status of the equipment are satisfactory before the equipment is returned to service are outlined in the manufacturer's equipment manual. Any additional quality control checks are outlined in the section of the appropriate test method.

### 5.5.10 Periodic Checks

**Policy:**
When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedure.

**Details and Procedures:**
SOP# *QSP 5-5-1, Equipment* establishes a plan for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and in order to prevent contamination or deterioration.

## 5.5.11 Correction Factors

**Policy**
Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software).

**Details and Procedures:**
The updating of correction factors, including all copies, is assured by following the appropriate test method or SOP. It is the responsibility of the quality manager to ensure that all copies are updated.

## 5.5.12 Safeguards against Adjustments

**Policy:**
Test and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate test and/or calibration results/status.

**Details:**
Safeguards against adjustment for laboratory equipment include:

- detailed SOPs and manufacturer's manuals on the operation of the equipment
- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel

Safeguards against adjustment for software includes:

- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel

## *5.6 Measurement Traceability*

### 5.6.1 Measurement Traceability

**Policy:**
Test equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test or sampling are calibrated before being put into service. All measurement and test equipment having an effect on the accuracy or validity of tests is calibrated and/or verified before being put into service.

**Details:**
The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform tests and calibrations

Procedures are documented where appropriate. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained for each standard. These records include, as applicable:

- supplier, grade, batch#
- dates of preparation or verification
- measurement of weights, volumes, time intervals, temperatures, and pressures and related calculations
- relevant processes (e.g., pH adjustment, sterilization)
- verification results
- identification of personnel involved

Reagents prepared in the laboratory are labelled as needed to identify substance, strength, solvent, any special precautions or hazards, restrictions of use, and date of preparation and/or expiry. The person responsible for the preparation of the reagent is identified either from the label or from records.

## 5.6.2 Specific Requirements

### 5.6.2.1 Calibration

**Policy:**
The program for calibration of equipment is designed and operated to ensure that calibration measurements are traceable to the Systeme International (SI) units of measurement.

**Details:**
Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

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

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

When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

Maintain certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability. Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

Reference standards, such as thermometers and weights, are traceable in accordance with QSP 4-06-1 Purchasing.

## 5.6.2.2 Testing

### *5.6.2.2.1*

**Policy:**
The requirements given in section 5.6.2.1 apply to measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that equipment used can provide the accuracy of measurement needed.

**Details:**
The extent to which the requirements in section 5.6.2.1 are followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements are strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in section 5.6.2.2.2.

### *5.6.2.2.2*

**Policy:**
Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:

- the use of suitable reference materials certified to give a reliable characterization of the material
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned
- participation in a suitable program of inter-laboratory comparisons or proficiency testing

**Details:**
Reliable characterization involves an estimate of recovery.

The laboratory participates in proficiency testing and/or check item programs. The list of programs is maintained by the Quality Manager.

## 5.6.3 Reference Standards and Reference Materials

### 5.6.3.1 Reference Standards

**Policy:**
The SOP# *QSP 5-6-1, Reference Standards, Reference Materials and Prepared Reagents* outlines the program for the use of reference standards and reference materials.

**Details:**
Reference standards are obtained from the National Institute of Standards and Technology (NIST) if applicable. Reference standards are obtained or calibrated by a body that can provide traceability as described in section 5.6.2.1.

### 5.6.3.2 Reference Materials

**Policy:**
Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

**Details:**
Reference materials, including calibration standards, used in chemical measurement are prepared so that the point of measurement is similar or equivalent to that of the items. The matrix, prior to the addition of the analyte does not have a detectable concentration of the analyte. Reagents used in the preparation of reference materials, including calibration standards are of certified purity.

### 5.6.3.3 Intermediate Checks

**Policy:**
Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

**Details and Procedures:**
The control check standards used to verify the accuracy of all the other standards are prepared independently from all the other standards used to establish the original calibration. These control check standards are preferably prepared from a separate lot # or source. It is

the responsibility of the Technical Leader to establish and maintain the individual schedule for each SOP and/or test method.

### 5.6.3.4 Transport and Storage

**Policy:**
The SOP# *QSP 5-6-1, Reference Standards, Reference Materials and Prepared Reagents* outlines safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

**Details:**
Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations, or sampling.

Proper conditions are established for housing, handling, and care of reference standards/reference materials. All information needed to properly identify references appears on their housing or containers.

## *5.7 Sampling*

### 5.7.1 Sampling Plan and Procedures

**Policy:**
The Technical Procedure for Sampling outlines the sampling plan and procedures for suspected controlled substances in the Drug Chemistry discipline. The sampling plan and procedures are easily accessible electronically on DM Document Management. The sampling plan is based on appropriate statistical methods. The sampling process addresses the factors to be controlled to ensure validity of the tests.

**Details:**
Sampling is a defined procedure whereby a part of a substance or material is taken to provide for testing as a representative item of the whole. Sampling can also be required by the appropriate specification for which the substance or material is to be tested.

The sampling plan describes the allocation, withdrawal and preparation of an item or items from a substance or material to yield the required information. All items are collected and placed in sealed containers.

### 5.7.2 Deviations, Additions or Exclusions

**Policy:**
Any deviations, additions or exclusions from the sampling procedure shall be approved by technical leader in accordance with *QSP 4-1-5, Authorizing Deviations*.

**Details:**
The physical appearance of all test items is observed and recorded. Cross-contamination is the most critical issue from broken, leaking items for qualitative tests.

### 5.7.3 Records

**Policy:**
The Technical Procedure for Sampling outlines the procedures for recording relevant data and operations relating to sampling that forms part of the testing that is undertaken. These records include the sampling procedure used, case identification number and the identification of the item to include Item number.

## *5.8 Handling of Test Items*

### 5.8.1 Procedures

**Policy:**
The SOP# *QSP 5-8-1, Handling of Test Items* outlines the procedures for the receipt, handling, protection and storage of test items, including all provisions necessary to protect the integrity of the test item.

**Details:**
Test items are stored so as to ensure their integrity by preventing against deterioration, contamination, and loss of identity.

**Chain of Custody**
The Pitt County Forensics Services Unit uses Records Management System to record all internal transfers of Test Item from the time of receipt. This documentation tracks the chain of custody for each Test Item submitted for analysis. This system includes a signature or equivalent identification of the person/location receiving the Test Item, the date of receipt or transfer, and the unique identifier of the evidence.

**Subdivision of Test Items**
When test items are sub-divided in the Forensics Services Unit, sub-items will be tracked to the same extent that the original items of evidence are tracked.

### 5.8.2 Identification of Test Items

**Policy:**
Test items are systematically and uniquely identified in the Records Management System as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

**Details:**
Item labelling and chain of custody is outlined in procedure *QSP 5-8-1, Handling of Test Items*.

### 5.8.3 Receipt

**Policy:**
When there is any doubt as to the suitability of an item for testing, or when an item does not conform to the description provided, or the test required is not specified in sufficient detail, the analyst shall contact the submitter for clarification prior to testing and keeps a record of the discussion.

**Details:**
Upon receipt of evidence, any departures from normal or specified conditions will be documented according to the Procedure SOP# *QSP 5-8-1, Handling of Test Items* .

### 5.8.4 Protection

**Policy:**
The SOP# *QSP 5-8-1, Handling of Test Items* is the procedure for avoiding deterioration, loss or damage to the test item during storage, handling and preparation and testing.

**Details:**
Proper requirements for packaging, environmental conditions, and separation from incompatible materials are observed. Where items have to be stored or conditioned under specific conditions, these conditions are maintained, monitored, and recorded, where necessary. All requirements are found in *QSP 5-8-1, Handling of Test Items.*

## *5.9 Assuring the Quality of Test and Calibration Results*

### 5.9.1 Quality Control / Quality Assurance

**Policy:**
Quality control procedures are utilized to monitor the validity of test results. These procedures may include, but are not limited to, the following:

- proficiency testing programs and review of results
- replicate tests using the same or different methods
- process verification with test item like material
- regular use of certified reference materials and/or internal quality controls using secondary reference materials

**Details:**
The methods utilized from the above list will be appropriate for the type and volume of the work undertaken. Records are maintained of assurance activities and any actions taken.

### 5.9.2 Quality Control Data

Sections shall define the criteria for evaluating quality control data. When data is found to be outside the established criteria, action shall be taken in accordance with the Section technical procedures and the procedures for Control of Nonconforming Work.

As a guide, the level of internal quality control is 100% of the item throughput. For analyses performed infrequently, a quality control check is performed on each occasion. This may typically involve the use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the item and spiked item.

Internal quality control schemes using statistics may include:

- error analysis
- regression analysis
- safety evaluation/risk analysis
- tests of significance
- statistical sampling inspection

Technical personnel use certified reference materials to evaluate test performance according to the relevant technical procedure. These data are used to evaluate the validity of the test results.

Re-testing of items shall not be allowed to be performed by this Laboratory without prior authorization of the Laboratory Director. Judicial orders requiring Re-testing shall be directed to external testing source.

### 5.9.3 Proficiency Testing

**Policy:**
The Laboratory proficiency testing program shall be carried out, documented and monitored according to QSP 5-9-3, Proficiency Testing.

### 5.9.4 Administrative Reviews

**Policy:**
Administrative reviews of examination documentation and Laboratory Reports shall be conducted as provided in *QSP 5.9.4, Administrative and Technical Reviews*.

### 5.9.5 Technical Reviews

**Policy:**
Technical reviews of examination records and Reports of Examination shall be conducted as provided in the *QSP 5.9.4, Administrative and Technical Reviews*.

### 5.9.6 Monitoring of Court Testimony

**Policy:**
The testimony of Forensics Services Unit personnel shall be monitored and evaluated on an annual basis. This testimony shall be evaluated by authorized technical reviewer in that discipline. This evaluation shall be recorded on form *# 5-9-6-F1, Testimony Review* and maintained by the Quality Manager.

**Details:**
Forms *# 5-9-6-F1, Testimony Review* is available to be distributed to members of the court to evaluate the witness. Feedback shall be provided to each employee by the Quality Manager, Technical Leader or designee who shall initiate remedial action(s) as

necessary. Records of testimony monitoring shall be retained by the Pitt County Forensics Services Unit.

## *5.10 Reporting of Results*

### 5.10.1 General

**Policy:**
The results of each test are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.

**Details:**
The results of the findings are reported in a Laboratory Report and the conclusion is based on the data obtained from analysis. Reporting shall include all information necessary for the identification of the test case and test item according to *QSP 5-10-1 Reporting Results*. This QSP ensures that the case record relating to a specific investigation contains all the relevant information required by ISO/IEC 17025.

Laboratory Reports are issued as either hard copy or by electronic data transfer.

### 5.10.2 Laboratory Reports

**Policy:**
Laboratory Reports include the following information, as appropriate:

- a title (e.g., "Laboratory Report" )
- name and address of laboratory
- unique identification of the Laboratory Report (such as Pitt County Sheriff's Office Case RMS#), and on each page an identification in order to ensure that the page is recognized as a part of the Laboratory Report, and a clear identification of the end of the Laboratory Report
- name of test item submitter, agency and agency case identifier
- description, condition, and unambiguous identification of the item(s) tested
- date of receipt of test items, where this is critical to validity of the results
- test results with, where appropriate, units of measurement
- the name(s), function(s) and signature(s) or equivalent of person(s) authorizing the Laboratory Report
- where relevant, a statement to the effect that the results relate only to the items tested
- hard copies of Laboratory Reports include the page number, total number of pages and accrediting body identifier

- case record relating to a specific investigation contains all the relevant information required by ISO/IEC17025

**Details:**
Personnel initiating the results have the responsibility of signing Laboratory Reports.

A statement is included specifying that the Laboratory Report is not to be reproduced except in full, without written approval of the laboratory. Data reported to the customer contains the appropriate significant digits for each test method. Uncertified copies are not controlled.

## 5.10.3 Laboratory Reports

### 5.10.3.1 Case File Requirements for Interpretation

**Policy and Details:**
In addition to the requirements listed in section 5.10.2, the case file includes the following, where necessary for the interpretation of results:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in Laboratory Reports when it is relevant to the validity or application of the test results
- where appropriate and needed, opinions and interpretations (see section 5.10.5)
- additional information required by specific methods or end user requirements upon approval by Laboratory Director
- any numerical results shall be reported in accordance with technical procedures
- hard copies from the Master case file shall be paginated
- administrative documents may be bound and attached to the inside of the case file folder and do not require pagination as long as the Case Identifier is on the top page

### 5.10.3.2 Case File Requirements for Laboratory Reports containing Sampling

**Policy and Details:**

In addition to the requirements listed in sections 5.10.2 and 5.10.3, Laboratory Reports containing the results of sampling include the following, where necessary for the interpretation of test results:

- date of sampling
- unambiguous identification of substance, matrix, material or test item (including name of manufacturer, model or type of designation and serial numbers as appropriate)
- location of sampling, including any diagrams, sketches or photographs
- details of any environmental condition during sampling that may affect the interpretation of the test results
- Any reference to the sampling plan or the identification of the method used shall be included in the case file.

### 5.10.3.3 Additional Requirements for Issuance and Interpretation of Laboratory Reports

**Policy and Details:**
In addition to the requirements listed:

- Laboratory Reports shall be issued in accordance with the Procedure for Reporting results (QSP 5.10.1)
- Analyst/Examiner who issue findings, including writing reports and providing testimony, based on examination documentation generated by another person shall document the review of such examination documentation, as provided in QSP 5.10.1
- The significance of an association shall be communicated clearly in the Laboratory report
- All eliminations shall be communicated clearly in the Laboratory Report
- When a definitive conclusion cannot be reached, the reason shall be stated clearly in the Laboratory Report.

## 5.10.4 Calibration Certificates

N/A

## 5.10.5 Opinions and Interpretations

**Policy Details:**

All opinions and interpretations shall be clearly marked as such in the Laboratory Report. The basis for any opinions and/or interpretations shall be documented in the analysis Case Record.

### 5.10.6 Testing and Calibration Results Obtained from Subcontractors

N/A

### 5.10.7 Electronic Transmission of Results

**Policy:**
Electronic transmission of test results shall adhere to Pitt County Sheriff Forensic Services Quality System.

**Details:**
Transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, shall meet the requirements of this Quality Manual.

### 5.10.8 Format of Reports

**Policy:**
The format of reports is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

**Details:**
The layout of the Laboratory Report is such that the presentation of the test data facilitates ease of assimilation by the reader.

### 5.10.9 Amendments to Reports

**Policy:**
Material amendments to a Laboratory Report after issue are made only in the form of a further document, or data transfer, which includes the statement "Supplement to Laboratory Report, case number", or an equivalent form of wording. Such amendments meet all the requirements in *QSP 5-10-1 Reporting Results*.

**Details:**
When it is necessary to issue a complete new Laboratory Report, it is uniquely identified and contains a reference to the original.

## *5.11 Revision History*

| REVISION HISTORY | | |
|---|---|---|
| **CURRENT VERSION** | **EFFECTIVE DATE** | **SUMMARY OF CHANGES** |
| 1 | 2016/07/01 | Original version |
| 2 | 2018/04/01 | Change Header to reflect Ver# and change revision history table. Issue date to Effective Date, change Forensic Scientist to Analyst/Examiner Adequate item identification criteria changed, took out QSP procedure for sampling, substituted replacement Drug Chemistry Technical procedure, took out Calibration reference. |
| 3 | 2018/10/22 | 5.1.2 Added requirement that uncertainty of measurement be calculated to at least 95.45%.Added Sections 5.1.3 and 5.1.4 Updated 5.5.8 equipment labelling requirements and removed example labels. In 5.6.2.1 referenced QSP 4.6.1 Purchasing, 5.6.3.1 consolidated policy and details, referenced QSP 5.6.1 in several locations. Removed language from 5.9.4 and 5.9.5 and referred to QSP 5.9.4. Added statement 5.9.6 that courtroom testimony shall be monitored by authorized technical reviewer. Modify and update document format to single section (5), add table of contents, and update to one revision history table. |
| 4 | 2019/01/04 | Added two Statements to 5.10.3.1 list. Deleted text and added Proficiency Procedure reference. Changed formatting of document and added table of contents. Updated internal hyperlinks. |