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7.1 Review of Requests, Tenders and Contracts

Policy and Details:
The Pitt County Sheriff's Office shall make available to the Forensic Services Unit personnel, facilities, equipment, systems and support services necessary to manage and perform laboratory activities.

7.1.1 Procedure for Review of Request, Tenders and Contracts

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

a) the requirements are adequately defined, documented and understood;
b) the laboratory has the capability and resources to meet the requirements;
c) where external providers are used, the requirements of section 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;
d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

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

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

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

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

a) confidentiality agreements
b) new client request
c) submission requests

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

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.

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence, in accordance with section 7.1.1. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by

the customer shall not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer shall be informed of any deviation from the contract.

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

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

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

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

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

7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

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

Details and Procedures:
Service to the client includes:

Affording the client or the client's representative the right to discuss laboratory functions with Lab Director or Quality Manager; it is understood that such discussions should not conflict with rules of confidentiality of work for other clients or with safety.

Preparing, packaging, and dispatching of test items needed by the client for verification purposes.

The client may receive advice and guidance in technical matters, and opinions and interpretations based on results. The laboratory should inform the client of any delays or major deviations in the performance of the tests.

7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

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

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

7.1.9 The extent of database (e.g., DNA profiles, friction ridge, ballistics, and biometrics) searches shall be communicated to customers and updated as needed. This search shall be communicated on a case-by-case basis, in the report.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and Verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

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

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

a) sampling, handling, transport, storage, and preparation of items to be tested
b) 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 in accordance with QSP 4-1-5 Authorizing Deviations and documented on Form # 4-1-5-F1 (DRF) Deviation Request Form.

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 referenced 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.

7.2.1.1.1 The laboratory shall use appropriate methods and procedures for all associated data analysis and interpretation as detailed in each sections technical procedures. All test methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s).

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to all Pitt County Sheriff's Office Forensic Services Unit personnel.

7.2.1.3 The laboratory shall use the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable

technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

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.

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 7.1.4).

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

7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer in accordance with QSP 4-01-5 Authorizing Deviations.

7.2.2 Validation of Methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

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

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.

7.2.2.1.1 The laboratories procedure for method validation QSP 4-02-1 Validation of Technical Procedures shall:

a) include the associated data analysis and interpretation;
b) establish the data required to report a result, opinion, or interpretation; and
c) identify limitations of the method, reported results, opinions, and interpretations.

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

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

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.

7.2.2.4 The laboratory shall retain the following records of validation:

a) the validation procedure used;
b) specification of the requirements;
c) determination of the performance characteristics of the method;
d) results obtained;
e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

Policy:
Drug Chemistry 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. 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.

7.3.2 The sampling method shall describe:

a) the selection of samples or sites;
b) the sampling plan;
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing.

7.3.2.1 Statistical sampling at a stated level of confidence shall be used if an inference will be made to report on the whole population.

7.3.3 The laboratory shall retain records of sampling data that forms part of the testing that is undertaken. These records shall include, where relevant:

a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name);
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

Policy:
The Drug Chemistry 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.

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.

7.4 Handling of test or calibration items

7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item shall be followed.

7.4.1.1 For all test items received, except known origin individual characteristic database samples, the procedure shall:

a) address requirements for storage, packaging, and sealing of items to: protect the integrity of all items; and require items to be re-sealed as soon as practicable;
b) address measures to be taken to secure unattended items;
c) require chain-of-custody for: all items received; and items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, trace evidence, DNA extracts);
d) require chain-of-custody to securely and accurately identify the individual(s) or location(s) receiving or transferring the item(s); and the item(s) being transferred; and the chronological order of all transfers, minimally including the date;
e) require communication to the customer regarding the disposition of all items received; and
f) address communication to the customer regarding items collected or created and preserved for future testing.

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.

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:
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 utilizes the Records Management System, the FS1 Form, and internal Case File documentation 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.

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.

7.4.2 The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

7.4.2.1 The system used to identify items shall cover all items received.

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 labeling and chain of custody is outlined in procedure QSP 5-8-1, Handling of Test Items.

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for testing, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

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 keep 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.

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded as needed in accordance with QSP 5-8-1, Handling of Test Items.

7.5 Technical Records

7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

7.5.1.1 Define the technical record(s) to be retained if all related technical records are not maintained.

7.5.1.2 Where abbreviations or symbols specific to the forensic service provider are used, the meaning of the abbreviations or symbols shall be defined.

7.5.1.3 Technical records to support a report (including results, opinions, and interpretations) shall be such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.

7.5.1.4 Records shall be created or maintained in a permanent manner.

7.5.1.5 If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record.

7.5.1.6 If an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained.

Policy:
The SOP# QSP 4-13-1,Control of Records is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose of quality and technical records. Quality records include

reports from internal audits and management reviews as well as corrective and preventive action records.

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

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

All records are organized with the following information:

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

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

Record Integrity- All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. The retention times for records are 10 years; however, retention times may be longer if directed by management. Records may be in the form of hard copy or electronic.

Record Security- All records are held secure and in confidence. Access to records is secured through authorized access rooms, rights protected server locations and filing cabinets.

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

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

Technical Records- Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records and a copy of each test report are retained for 10 years; however, retention times may be longer if directed by management or otherwise required by other legal requirements.

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

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

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

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

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

Recording- Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific case file at the time they are made. Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected and/or after calculations are made.

Corrections to Records- Changes to test data are made so as not to obscure or delete the previous data entry. Mistakes are crossed out with a single strike through and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records are signed or initialed by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations in accordance with QSP 4-3-1 Document Control and QSP 4-13-1, Control of Records. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6 Evaluation of measurement uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.1.1 The method of analysis for evaluation of measurement uncertainty shall:

a) require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;
b) include the process of rounding the expanded uncertainty;
c) require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and
d) specify the schedule to review and/or recalculate the measurement uncertainty.

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.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations. The Pitt County Sheriff's Office Forensic Services Unit is not a Calibration Laboratory.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

7.6.3.1 Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results.

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. 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

7.6.4 As detailed in The Technical Procedure for Measurement Assurance, the following records shall be maintained for each evaluation and estimation of measurement uncertainty:

a) statement defining the measurand;
b) statement of how traceability is established for the measurement;
c) the equipment (e.g., measuring device[s] or instrument[s]) used;
d) all uncertainty components considered;
e) all uncertainty components of significance and how they were evaluated;
f) data used to estimate repeatability, intermediate precision, and/or reproducibility;
g) all calculations performed; and
h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

7.7 Ensuring the validity of results

7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests or calibrations using the same or different methods;
g) retesting or recalibration of retained items;
h) correlation of results for different characteristics of an item;
i) review of reported results;
j) intralaboratory comparisons;
k) testing of blind sample(s).

7.7.1.1 When a verification of a result is carried out:

a) it shall be conducted by an individual who is currently authorized to perform the testing;
b) a record of the verification shall be made and the record shall identify who performed the verification, when it was performed, and the result of the verification; and
c) the resolution of any discrepancy shall be recorded.

7.7.1.2 There shall be a procedure for the technical review of technical records, including reports, and testimony. The procedure shall:

1. require the individual performing the technical review to have been competency tested to perform the testing or calibration work that is being reviewed.
2. preclude an individual from technically reviewing their own work;
3. define the method to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;
4. define the method to be used to ensure testimony in each discipline is reviewed;
5. define the method to be used to conduct and record the review;
6. ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record;

7. ensure conformance with methods and applicable management system documents; and
8. describe a course of action to be taken if a discrepancy is found.

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;
b) participation in interlaboratory comparisons other than proficiency testing.

7.7.2.1 The process for monitoring performance by comparison with results of other forensic service providers shall at a minimum:

a) ensure successful completion of at least one proficiency test for each discipline prior to accreditation being granted in that discipline; and
b) ensure each location on the scope of accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB from the test provider.

7.7.3 Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.7.4 The performance of personnel shall be monitored. This monitoring shall ensure that all personnel who perform testing shall successfully complete at least one intralaboratory comparison, interlaboratory comparison or proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts work. In the event that the preceding options are not available or appropriate, observation-based performance monitoring is acceptable.

7.7.5 The process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing shall at a minimum:

a) ensure that results are not known or readily available to the participant being monitored;
b) ensure use of approved methods;
c) establish criteria for determining successful completion prior to the monitoring activity;
d) require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity; and

e) for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using an item that was calibrated by the person performing the comparison or test- N/A.

7.7.6 There shall be a plan that will:

a) demonstrate conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4; and
b) ensure inclusion of a representative sample of the components/parameters and equipment/technologies within each discipline listed on the scope of accreditation.

7.7.7 To satisfy the proficiency test requirements in clauses 7.7.2.1.a) and b), the forensic service provider shall:

a) where available and appropriate for the work conducted, use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA5 and has the applicable proficiency test(s) on its scope of accreditation, or
b) where not available or not appropriate for the work conducted, gain approval from ANAB for alternative means by which the laboratory's performance can be assessed; and
c) submit results to the proficiency test provider, if applicable, on or before the agreed upon due date.

7.7.8 The following records shall be maintained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests and observation-based monitoring:

a) discipline(s) monitored;
b) design of the monitoring activity;
c) expected results;
d) location, when more than one location is associated with a single accreditation certificate;
e) records submitted to a proficiency test provider, when applicable;
f) appropriate technical records;
g) evaluation of results and action taken for unexpected results; and
h) feedback on individual performance provided to the participant.

Quality Control / Quality Assurance

Policy:
The monitoring activities to ensure the validity of results in the Pitt Sheriff's Office Forensic Services Unit are detailed in QSP 5-09-1 Ensuring the Validity of Results.

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.

Quality Control Data
Each discipline's monitoring of quality control and quality assurance is detailed in the respective section's technical procedures.

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.

Proficiency Testing

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

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.

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.

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, and documented on Form # 5-9-6-F1, 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.

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results shall be reviewed and authorized prior to release.

7.8.1.1.1 The authorizer of results shall review the technical record and document the review.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a test report and shall include all the information agreed with the customer

and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

7.8.1.2.1 The results shall be provided in a written report or through electronic access.

7.8.1.2.2 There shall be a procedure for reporting of results that:

a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed;
b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement;
c) requires communicating the reason(s) in the report when the reported results are inconclusive; and
d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics).

7.8.1.2.3 The documented process for reporting of results of calibration shall: - N/A

a) identify what information will be reported in the calibration certificate; and
b) require the issuance of an endorsed calibration certificate if requested by the customer.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8.1.3.1 When results are reported in a simplified way, the agreement with the customer shall specify which information in 7.8.2 through 7.8.7 of ISO/IEC 17025:2017 will not be included in a written report or through electronic access. The requirements 7.8.2 through 7.8.7 in this document are applicable even if the forensic service provider reports results in a simplified way.

Policy:
The results of each test are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods. All results are reviewed and authorized prior to release. The review is documented by the authorizer on an administrative and technical review worksheet.

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 and retained as either hard copy or by electronic data transfer.

7.8.2 Common requirements for test reports

7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

a) a title (e.g. "Test Report");
b) the name and address of the laboratory;
c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
e) the name and contact information of the customer;
f) identification of the method used;
g) a description, unambiguous identification, and, when necessary, the condition of the item;
h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;
i) the date(s) of performance of the laboratory activity;
j) the date of issue of the report;
k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;
l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
m) the results with, where appropriate, the units of measurement;
n) additions to, deviations, or exclusions from the method;
o) identification of the person(s) authorizing the report;
p) clear identification when results are from external providers.

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

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
- 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.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) information on specific test conditions, such as environmental conditions;
b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
   — it is relevant to the validity or application of the test results;
   — a customer's instruction so requires, or
   — the measurement uncertainty affects conformity to a specification limit;
d) where appropriate, opinions and interpretations (see 7.8.7);

e) additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.1.1 The measurement uncertainty shall:

a) be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;
b) include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;
c) be in the format of $y \pm U$;
d) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
e) be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.

7.8.3.1.2 If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, the forensic service provider shall:

a) have objective evidence of the regulation, statute, case law or other legal requirement; and
b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

Case File Requirements for Interpretation

Policy and Details:
In addition to the requirements listed in section 7.8.2, 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

Case File Requirements for Laboratory Reports containing Sampling

Policy and Details:
In addition to the requirements listed in sections 7.8.2 and 7.8.3, 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 as needed
- 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.

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.

7.8.4 Specific requirements for calibration certificates (**N/A)**

7.8.5 Reporting sampling – specific requirements

a) the date of sampling;
b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
c) the location of sampling, including any diagrams, sketches or photographs as needed;
d) a reference to the sampling plan and sampling method;
e) details of any environmental conditions during sampling that affect the interpretation of the results;
f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.5.1 If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.

7.8.6 Reporting statements of conformity **(N/A)**

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

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.

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report,

serial number... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

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.

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.

7.9 Complaints

7.9.1 The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

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

Details:
Records of complaints include the following information:

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

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

7.10 Nonconforming work

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are defined;
b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
d) a decision is taken on the acceptability of the nonconforming work;
e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

Procedures to Control Nonconforming Work

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

Details:
The procedure ensures that:

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

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

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

Evaluation of Nonconforming Work

Policy:
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the procedure for corrective action QSP 4-11-1 is followed to identify the root cause(s) of the issue and to eliminate this (these) cause(s).

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

7.11 Control of data and information management

7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities.

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

7.11.2.1 There shall be a plan for validation of computer software developed by the user and records of the validation shall be maintained.

7.11.3 The laboratory information management system(s) shall:

a) be protected from unauthorized access;
b) be safeguarded against tampering and loss;
c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
d) be maintained in a manner that ensures the integrity of the data and information;
e) include recording system failures and the appropriate immediate and corrective actions.

7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

7.11.6.1 The technical record shall indicate the check was performed and who performed the check. When possible, this check shall not be conducted by the person who performed the calculation(s) or the data transfers.

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.

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.

7.12 Revision History

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