6 Contents

6.1 General

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.

6.2 Personnel

6.2.1 Laboratory Personnel

Policy:
The Laboratory Director/Quality Manager ensures that all laboratory personnel, either internal or external are impartial, competent and work in accordance to the policies and procedures of the Quality Management System.

Details:
The selection and supervision of all personnel shall be in accordance with the policy and procedures of the Pitt County's Sheriff's Office and Pitt County Forensic Services Unit. 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.

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

6.2.2 Competence and Qualification

Policy:
Management ensures the competency of all specific equipment operators, those performing tests, those evaluating results, and those signing Laboratory Reports. Competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skill and experience are documented in accordance with QSP 5-2-1 Training. 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 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.

6.2.2.1 Educational Requirements

Policy and Details:
Personnel who authorize results, opinions and/or interpretations shall meet the minimum educational requirements stated in Annex A of AR3125 and this shall be documented in the employees job description and training file.

6.2.2.2 Training Requirements

Policy:
Training programs based on job function with respect to the education, experience and skills of the laboratory personnel shall include knowledge, skills and abilities needed to perform work, general knowledge of forensic science, the application of ethical practices in forensic science, criminal law, civil law, and testimony, provisions for retraining, provisions for maintenance of skills and expertise, and criteria for acceptable performance. The training program is relevant to the present laboratory disciplines and outlined in *QSP 5-2-1, Training*. *QSP 5-2-1, Training* and discipline specific Training programs are 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. 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, examiners) must demonstrate competency through observation by management and verification using written and practical exams. All completed training records are maintained by the Quality Manager.

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.

6.2.2.3 Authorization

Policy:
Management authorizes specific personnel to perform particular types of sampling, tests, 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 employee training file (as well as the Work Authorization Log) 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

6.3 Facilities and Environmental Conditions

6.3.1 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.

Laboratory will maintain facility access and security procedures in compliance with ISO 17025:2017 & AR3125 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 its layout.

This Laboratory shall not perform laboratory activities at sites or facilities outside its permanent control.

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.

6.3.2 Documentation

Policy and Details:
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 in accordance with the appropriate procedure.

6.3.3 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.

6.3.4 Control Measures

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.

Controlled Access
Policy:
Access to and use of areas affecting quality of the tests is defined and controlled. The Quality Manager 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 shall unescorted personnel be allowed in the testing areas. 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.

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.

6.4 Equipment

6.4.1 Required Equipment

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 processing and analysis of tests. Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method.

6.4.2 Outside Equipment

When equipment is used outside the laboratory's permanent control, it ensures that the requirements of this Quality Manual, ISO 17025:2017 and AR 3125 are met.

6.4.3 Handling, Transport, Use and Maintenance

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).

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

6.4.3.1

In addition to all procedural requirements, prepared reagents shall be labeled with at a minimum, the identity of the reagent and date of preparation or lot number. Records shall be maintained identifying who made the reagent and the components used in preparation.

6.4.3.2

Reference collections shall have each entry documented, uniquely identified and handle in accordance with procedures to protect the characteristic(s) of interest.

6.4.4 New Equipment or Equipment being returned to service

New equipment or equipment being returned to service, 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 QSP 5-5-1 before use. The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

6.4.5 Equipment used for measurement

Equipment and software used for measurement, 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. 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.

6.4.6 Measuring Equipment is calibrated when:

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

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.

6.4.6.1 Specific Requirements Calibration

Policy:
The program for calibration of equipment is designed and operated to ensure that calibration measurements are traceable to the System 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.

6.4.6.2 Specific Requirements Testing

Policy:
The requirements given in section 6.4.6.1 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 6.4.6.1 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 6.4.6.2.1

6.4.6.2.1 Means of Providing Confidence

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.

6.4.6.3 Reference Standards and Reference Materials

6.4.6.3.1 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 6.4.6.1.

6.4.6.3.2 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.

6.4.6.3.3 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.

6.4.6.3.4 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.

6.4.7 Calibration of Equipment Shall Include:

- A list of equipment requiring calibration
- Specifications for the Calibration Laboratory
- Specified requirements for the calibration
- Interval of calibration

The calibration procedure is outlined in QSP 5-5-1 Equipment. The calibration process is vital to all measurement programs and is outlined in the appropriate technical procedure.

6.4.8 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.

6.4.9 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 6.4.8.

The laboratory examines the effect of the defect or departure from specified limits on previous tests and institutes the "Control of Nonconforming Work" procedure as outlined in QSP 4.9.1.

6.4.10 Intermediate 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. The use of the equipment, the stability of the equipment, the method specification and risk associated with a failed check shall be considered when evaluating the need for periodic checks.

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:
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.

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.

6.4.11 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.

6.4.12 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

6.4.13 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 6.4.2)
- 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)

6.5 Metrological Traceability

Policy/Details:
The Metrological Traceability program is delineated in section 6.4, QSP 5-5-1 Equipment, Drug Chemistry Technical Procedure for Quality Assurance, Drug Chemistry Technical Procedure for Balances and Drug Chemistry Technical Procedure for Measurement Assurance. This program shall address the following criteria.

6.5.1 Metrological Traceability of measurement results

The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

NOTE 2 See Annex A of ISO 17025:2017 for additional information on metrological traceability.

6.5.1.1

The laboratory shall establish and maintain metrological traceability of its measurement results by utilizing products and services from suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials that are:

a) a National Metrology Institute that is a signatory to the BIPM1 - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB)2; or
b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation; or
c) an accredited reference material producer that is accredited to ISO 17034, by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material to be purchased.

6.5.1.2

In situations where a supplier that meets section 6.5.1.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased shall be confirmed. Objective evidence of the confirmation shall be available for review.

6.5.1.3

For the purpose of establishing traceability of a measurement, an accredited laboratory may calibrate its own equipment that supports an accredited parameter on the scope if the related requirements in ISO/IEC 17025 and this document are met:

a) the calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel;
b) the calibration method shall be validated or verified prior to use;
c) certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties;
d) the calibration shall be carried out in an appropriate environment;
e) technical records of the calibration shall be established and maintained;
f) the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts; and
g) a technical review of the technical records including any data transfers and calculations shall be completed by an individual other than the person(s) who performed the work.

6.5.1.4

If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for applicability of measurement traceability accreditation requirements.

6.5.2 Traceable to International System of Units

The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 Traceability to Appropriate Reference

When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer; or
b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as

6.6 Externally Provided Products and Services

6.6.1 Purchasing Services and Supplies

The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory's own activities;
b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
c) are used to support the operation of the laboratory.

NOTE: Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

Policy:

The SOP#, QSP 4-6-1 Purchasing is used to select and purchase services and supplies and is used for procurement, reception, and storage of supplies. Only services and supplies of the required quality are used. These quality requirements are detailed in laboratory SOPs under the "Materials Required" section and will identify the appropriate minimum specifications when necessary.

Details:

Consumable materials are stored according to the appropriate test method, SOP, or work instruction. Packing slips are checked against package content labels and matched with the Purchase Order if accepted. Certificates of analysis (COA) for those materials that require it are maintained on file after the COA (if provided) is checked to ensure the received item meets minimum specifications.

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

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

6.6.2 Purchasing Documents

The laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

Policy:
The procedure for purchasing is described in QSP 4-6-1 Purchasing. Purchasing requests are recorded on the Purchase Order form and contain data describing the product ordered.

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

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

6.6.3 Approved Suppliers

The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided;
b) the acceptance criteria;
c) competence, including any required qualification of personnel;
d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

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

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

The records are maintained by the Quality Manager.

6.7 Revision History

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2019/11/18	Original version
2	2020/01/15	6.2.2.1 changed personnel file to job description and training file.