Purpose

This document establishes guidelines for the development of new technical procedures and for the validation of standard and non-standard methods.

Scope

This procedure applies to all technical procedures introduced into the Pitt County Forensics Services Unit.

Definitions

- **Validation –** The performance of a set of experiments to establish the efficacy and reliability of a technique or procedure or modification thereof.
- **Standard method –** A method that is traceable to a recognized, validated method within the scientific community. Laboratory methods are the validated and documented technical procedures of each Section.
- **Non-Standard Method –** A scientifically sound method that is not frequently used and is not covered by an established Section technical procedure.
- **Performance Verification –** The initial confirmation of the reliability of a previously or externally validated method, instrument or reagent.
- **Quality Control Checks –** Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents.

Procedure

Overview

Each Section shall be responsible for determining whether a new method or instrument requires formal validation study or performance verification.

A formal validation study shall be performed prior to the use or implementation of:

- Technical procedures/methods largely developed at the Laboratory.

- Non-standard methods.
- Standard methods used outside the intended scope.
- Amplifications and modifications of standard methods not covered by temporary authorized deviations as provided in the Procedure for Authorizing Deviations.

Performance verification shall be performed prior to the use or implementation of a standard method or instrument new to the Laboratory.

All new or modified technical procedures shall be validated or verified before the first use and shall be approved by the Quality Manager and/or Technical Leader.

Technical Procedure Validation and Validation Records

The development and implementation of in-house procedures and methods shall be planned and performed by qualified personnel. Validation studies shall follow a plan of action that was previously prepared and documented.

The validation study shall address the following criteria:

- Accuracy and precision of the procedure over the range of parameters expected in casework as determined by examining accuracy, detection limits, 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 sample.
- Apparatus and equipment.
- Reference standards and reference materials.
- Environmental conditions.
- Data.

If a criterion does not apply to the method or procedure in question, the validation study may simply state N/A (for not applicable).

The Section shall document and reference any technical work to support the use of the new technology.

Prior to applying a new or existing procedure to the examination of evidence in the Laboratory, documentation shall demonstrate that the technical procedure performs as expected.

Acceptable results (acceptance criteria) shall be clearly defined and maintained in the validation study records.

A summary page shall be included in the validation study documentation noting that the technical procedure is suitable for use within the Section.

When validating a standard or non-standard method, known samples shall be used.

If a new procedure shall replace or be used as an alternative to an existing method, the new procedure shall generate comparable results as demonstrated by analyzing split samples using both procedures in parallel.

Minor modifications of methods already in use shall be evaluated to determine the effect(s) of the modification.

All validation records shall be maintained by the Quality Manager or designee (i.e., Technical Leader, etc.).

The technical procedure shall be written accordingly.

Performance Verification and Verification Records

Prior to implementation of a standard method or instrument new to the Laboratory, the reliability shall be demonstrated in-house against performance characteristics of that procedure or instrument.

The performance verification shall utilize one or more of the following:

- Documentation of previous or external validation studies.
- Calibration or analysis using reference standards or reference materials.

- Comparison of results achieved with other methods or instruments.
- Inter-laboratory comparisons.
- 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 or instrument and practical experience.

At a minimum, any procedure taken directly from reference sources shall be demonstrated and documented to be effective when performed by Laboratory personnel.

Performance verification records shall be maintained by the Quality Manager or designee. Records of studies that demonstrate that a procedure is not suitable for use shall be maintained.

Approval and Implementation of Procedures

The technical procedure shall be approved as provided in the Laboratory Procedure for Document Control and Management.

Procedures shall be available on the Laboratory shared drive only after formal approval.

After the validation process for a technical procedure is complete, each analyst shall successfully complete a practical examination and sign necessary acknowledgement of training prior to using the new technical procedure to analyze evidence.

Newly validated technical procedures shall be incorporated into the Section Proficiency Testing program.

Where a change in method involves only minor adjustments, such as item size, or different reagents, the amended method is validated and the changes brought to the attention of the accreditation body at the next accreditation audit.

Technical Procedure Maintenance

Each Section Technical Leader is responsible for the generation, maintenance, and revision of the Section's technical procedures as provided in the QSP# 4-3-1 Procedure for Document Control.

Protocol Deviations and or Modifications

Some examinations cannot be performed exactly as written in the Section's technical procedures because of the variable nature of evidence. Changes to or deviations from a technical procedure shall be within the bounds of good laboratory practice, documented, justified, and authorized as provided in the Laboratory Procedure for Authorizing Deviations.

Records

All records and documentation related to any validation study (including the study plan, results, technical review, and competency test documentation) shall be retained permanently.

REVISION HISTORY		
CURRENT VERSION	**EFFECTIVE DATE**	**SUMMARY OF CHANGES**
1	2016/07/01	Original version
2	2018/04/01	Change issue date to effective date, Change Rev. to Ver. ,Change version history table , Deleted technical leader and training officer from pg. 4