Procedure for Validation of Technical Procedures

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

2.0 Scope – This procedure applies to all technical procedures introduced into the State Crime Laboratory (Laboratory).

3.0 Definitions

- **Validation** – The confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled.
- **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 or instrument.
- **Quality Control Checks** – Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents.

4.0 Procedure

4.1 Overview

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

4.1.2 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.

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

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

4.1.5 Employees who are authorized to perform testing may perform method development, modification, verification, and validation in that discipline.

4.2 Technical Procedure Validation and Validation Records

4.2.1 Validation includes specification of the requirements; a determination of the performance characteristics of the procedures; a check that the requirements can be fulfilled by using the procedure; and a statement on the validity.

4.2.2 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. Periodic reviews of the progress and results shall be conducted throughout the validation study. If it is determined that the validation plan needs to be modified, the modifications shall be approved prior to implementation by the Forensic Scientist Manager and/or Technical Leader.

4.2.3 The validation study shall address the following criteria:

- Performance characteristics: Accuracy and precision of the procedure over the range of parameters expected in casework as determined by examining accuracy, measurement range, detection limits, quantification limits, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences, cross sensitivity against interference from the matrix of the sample, and/or bias.
- Apparatus and equipment.
- Reference standards and reference materials.
- Environmental conditions.
- Data interpretation.
- The data required to report a result, opinion, or interpretation.
- Limitations of the method, reported results, opinions, and interpretations.
- Uncertainty or the procedure for estimating uncertainty.

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

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

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

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

4.2.5 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.

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

4.2.7 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.

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

4.2.9 All validation records shall be maintained by the Forensic Scientist Manager or designee (i.e., Technical Leader, Training Officer, etc.) and shall include, at a minimum, the validation procedure used, specification of the requirements, determination of the performance characteristics of the method, the results, and a statement as to whether the procedure is suitable for its intended use.

4.2.10 The technical procedure shall be written as provided in the Laboratory Procedure for Writing Technical Procedures.

4.3 Performance Verification and Verification Records

4.3.1 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.

4.3.2 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.

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

4.3.3 Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method or instrument and practical experience.

4.3.4 Performance verification records shall be maintained by the Forensic Scientist Manager or designee (i.e., Technical Leader, Training Officer). Records of studies that demonstrate that a procedure is not suitable for use shall also be maintained.

4.4 Estimation of Uncertainty of Measurement

4.4.1 Technical procedures shall include considerations for estimating the uncertainty of measurement for quantitative test results. If the nature of the examination procedure precludes a metrologically and statistically valid calculation of uncertainty of measurement, the case-working Sections shall attempt to identify all the components of uncertainty and produce a reasonable estimate. The degree of rigor in an estimation of uncertainty of measurement depends on factors such as:

- The requirements of the test procedure.
- The existence of limits on which decisions on conformity to a specification are based.

4.4.2 Estimation of uncertainty of measurement shall be based on knowledge of the performance of the method, previous experience, and validation data, as well as any significant parameters that

affect the measurement result. The uncertainty of measurement portion of technical procedures shall:

- Require the specific measuring device or instrument used for a reported test result to have been included in, or evaluated against, the estimation of uncertainty for the technical procedure,
- Include the process of rounding the expanded uncertainty,
- Require the coverage probability of the expanded uncertainty to be a minimum of 95.45%, and
- Specify the schedule to review and/or recalculate the measurement uncertainty.

4.4.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account. Contributors to uncertainty include, but are not limited to, reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested, and the employee performing the test and estimate.

4.4.4 Records shall be maintained by the Sections for each estimation of uncertainty including:

- Statement defining the measurand,
- Statement of how traceability is established for the measurement,
- The equipment (e.g., measuring device(s) or instrument(s)) used,
- All uncertainty components considered,
- All uncertainty components of significance and how they were evaluated,
- Data used to estimate repeatability, intermediate precision, and/or reproducibility,
- All calculations performed, and
- The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

4.5 Approval and Implementation of Procedures

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

4.5.2 Procedures shall be available on the Laboratory shared drive only after formal approval and transmittal to members of the Section.

4.5.3 After the validation process for a technical procedure is complete, each Forensic Scientist that was not intimately involved in the validation shall successfully complete a competency test prior to using the new technical procedure. Forensic Scientists intimately involved in the validation may have the competency test requirement waived by the Technical Leader. Release for casework shall be documented according to the Procedure for Personnel Training.

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

4.6 Technical Procedure Maintenance

4.6.1 Each Forensic Scientist Manager is responsible for the generation, maintenance, and revision of the Section's technical procedures as provided in the Laboratory Procedure for Document Control and Maintenance.

4.7 Protocol Deviations and or Modifications

4.7.1 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.

5.0 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.

6.0 Attachments - N/A

Revision History		
Effective Date	Version Number	Reason
06/01/2021	9	4.2.2 – added plan approval 4.2.3, 4.2.9 – updated requirements