Maine State Police Crime Laboratory

Methods and Validations

1. Scope

This document will outline the laboratory's policies on method development, validation and quality control measures. The laboratory will validate all non-standard methods, laboratory-developed methods, standard methods used outside their intended scope, and modifications of standard methods prior to being used in forensic casework or database samples. Standard methods are methods developed by overarching regional, national or international organizations such as ASTM.

2. Methods

2.1 The laboratory shall use appropriate methods for all types of analyses performed at the laboratory and in facilities outside of the laboratory such as crime scenes.

2.2 Each section is responsible for method development and validation.

2.3 Where specific instructions or methods are required for sampling, evidence handling, transport, storage, and preparation of evidence items, the method will be documented in the section methods.

2.4 Estimation of uncertainty or other statistical analysis methods will be the responsibility of the appropriate section.

2.5 Each Section Supervisor is responsible for maintaining methods for the use and operation of all relevant equipment and evidence examinations where the absence of such methods would jeopardize the integrity of the work.

2.5.1 The Section Supervisor may choose to reference a commercially provided instruction manual or product insert in lieu of repeating the information in a method. In that instance, the manual or product insert will be maintained as an externally generated controlled document.

2.6 Deviations from approved methods will be documented, technically justified, and approved by the Section Supervisor. Approval should be granted prior to the deviation. However, at times circumstances will require supervisor notification after the deviation has occurred. In those instances, the supervisor will be notified as soon as practicable. The supervisor will initial and date the case notes to indicate the approval of the deviation.

2.7 The laboratory reserves the right to deviate from approved methods without prior notification of the customer.

2.8 The laboratory will utilize the most appropriate available methods for evidence examinations.

2.9 Any laboratory-developed methods will be validated prior to use in forensic casework.

2.9.1 Occasionally the laboratory must rely on methods that have not been validated in-house. In these circumstances, the methods must either have been published in a relevant peer-reviewed journal, validated in another accredited laboratory, or be standard methods. Standard methods will be used if available. In the instance an outside method is used, the laboratory will use only the latest edition of the method, unless it is not appropriate to do so.

2.10 Prior to implementing any new method in forensic casework, the laboratory will perform some confirmation testing to ensure the method is working properly. Confirmation testing will include a minimum of performance verification. Additionally, should changes occur to the standard method, confirmation testing and performance verification will be conducted.

2.11 Opinions or interpretations in reports are based on those test results for which the laboratory is accredited. There may be instances when an examiner is requested to perform analyses in a discipline that is not under the laboratory's scope of accreditation (ie, fiber analysis). The examiner may perform and report the appropriate analyses, providing that the examiner has proper training documentation and has the Director's approval prior to testing. However, the report will include a disclaimer that the findings are outside the laboratory's scope of accreditation and will not be reported using the laboratory letterhead.

3. Validations

3.1 Laboratory-developed software, laboratory-developed methods, new chemicals and new instrumentation will be validated prior to being used in casework or database samples.

3.2 Validations will take into account factors relevant to the samples being tested. Examples of relevant factors include sensitivity, specificity, substrate effects, data interpretation, limitations, etc.

3.3 Validations will be conducted to ensure that the chemical, method, or instrument will be reliable, accurate, and appropriate to forensic casework and database samples.

3.3.1 Validations will include samples indicative of those encountered during normal casework.

3.3.2 Validations may include the use of evidence from adjudicated cases.

3.3.3 Validations will establish the data needed to report a test result, opinion or interpretation.

3.3.4 Validations will specify when a currently validated method, including associated data interpretation, needs additional validation.

3.3.5 Comparative studies may be conducted where the proposed method or instrument is utilized at the same time as the current method or instrument. The laboratory will only report results from the validated instrument or method.

3.3.5.1 Comparative studies will only be conducted in instances where the evidence being examined will not be permanently changed, consumed, or lost.

3.4 Validations will be conducted or supervised by personnel proficiency tested in the discipline.

3.5 Proposed validations will be documented in Paradigm.

3.6 Validation proposals and schemes will be approved by the Technical Manager of the discipline. Changes in the validations and schemes will be communicated to the Technical Manager and other relevant personnel.

3.7 At the completion of the validation, a summary will be documented and reviewed by the Technical Manager. The summary should outline the purpose of the validation, the procedures used, the results, and the recommendations for using the new piece of equipment, chemical or method.

3.8 The Technical Manager and the Laboratory Director will approve the implementation of any new procedure or method.

3.9 Prior to implementation, new policies and / or methods, where applicable, must be approved and in place.

4. Control of Testing

4.1 Each section is responsible for developing quality control procedures to ensure the accuracy and validity of the laboratory testing. These procedures will be defined in the laboratory policies and methods.

4.2 Section specific quality control policies will define what is considered acceptable and unacceptable (passing or failing, etc.) data for quality control processes and will identify measures to be taken in the event the quality control does not meet the minimum criteria.

4.3 The quality control procedures may include but are not limited to the regular use of certified reference materials, control samples, replicate testing using the same or different methods, or correlation of results of different tests leading to the same conclusion (dual confirmation).

4.3.1 The laboratory typically does not retest retained items.