



Wilmington Police Department Crime Laboratory  
Quality Management System Procedure  
Method Validation

## 1.0 Purpose

This procedure describes the method validation and verification procedures.

## 2.0 Discussion

Methods used in the laboratory are validated to confirm their reliability and suitability for use prior to use on casework samples. Validation of methods are collected and/or generated by the laboratory and maintained. Methods are validated by external validation, internal validation or a combination of the two.

## 3.0 Definitions

- 3.1 External validations: Consist of studies conducted by the general scientific community or other forensic science laboratories.
- 3.2 Internal validations: Consist of studies conducted by and within the laboratory.

## 4.0 Procedure

- 4.1 Method validation includes an assessment of the range and accuracy of the values obtained from the method considered to meet the needs of the method application. The validation includes, as necessary, the measurement uncertainty of the results, detection limit, and selectivity of the method, linearity, repeatability and/or reproducibility and robustness.
- 4.2 Method validation is performed by authorized personnel with the proper equipment and resources to complete the validation.
- 4.3 Authorized personnel, with the guidance of the Quality Manager, develop a plan for the method validation. During validation the original plans may be updated and changed as the validation proceeds. Validation documentation and communication between the validation personnel is updated, as required, to ensure that the change in validation plans are effectively applied and recorded.
- 4.4 The final evaluation of a method to show reliability is established through use of at least one of the following:
  - Split samples
  - Blind trials
  - NIST traceable standard analysis
  - Analysis of PT samples
  - Collaborative testing

The evaluation is supplemented by referencing the method to the scientific literature on an as needed basis.



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- 4.5 The completed validation plan, analytical data and supporting documentation are reviewed by the Quality Manager. The Forensic Lab Manager authorizes the implementation of the method as recommended by the Quality Manager.
- 4.6 The laboratory maintains records of the analytical data and supporting records leading to the validation of the methods used for case materials.

**5.0 Health and Safety**

Personnel follow the health and safety precautions found in MSDS for reagents and chemical used during method validation. Refer to the Chemical Hygiene Plan, QD002 for guidance on the use of PPE.

**6.0 Records Management**

- 6.1 Validation plan, analytical data and supporting records

**7.0 References**

- 7.1 ISO/IEC 17025:2005, Section 5.4.5
- 7.2 ASCLD/LAB-International: Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, Section 5.4.5.4
- 7.3 Quality Manual, Section 2.4, Test Methods and Method Validation
- 7.4 Chemical Hygiene Plan, QD002

**8.0 Appendices**

None

**9.0 Revision Table**

Revision #	Effective date	Revised by	Description of Revisions
Original Issue	10/01/2012	B. Pridgen	



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**Authorization**

This Standard Operating Procedure, Original Issue, has been approved and authorized by:

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Bethany P. Pridgen, MFS  
Forensic Lab Manager

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Date

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Ralph M. Evangelous  
Chief of Police

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Date