

	LOM 2.9 Validation and Verification	
	<i>Document #: 1341</i>	<i>Page 1 of 3</i>
	<i>Revision #: 4</i>	<i>Issued Date: 09/18/2020</i>
	<i>Document Manager: John Bowen</i>	<i>Approved By: Ryan Larrison</i>

2.9 Validation and Verification

2.9.1 Overview

To ensure that analyses are carried-out in a planned, systematic, and controlled manner, analysts and examiners shall be provided with approved technical procedures and equipment. Technical procedures and equipment and software must undergo validation and review prior to approval for official use.

It is recognized that many acceptable procedures exist to accomplish a particular evidence examination. The considerable variations that exist in actual casework demand that forensic scientists be free to exercise professional discretion in choosing the method most appropriate to the problem at hand. It is important to give the analyst reasonable flexibility in the selection and application of analytical methods to suit the needs of a particular case situation. If a method varies significantly from the published procedures or if the issuing body revises the methods, validation must occur as outlined as detailed in this procedure manual.

It is equally important that the Technical Leader ensures that those procedures that are followed meet acceptable scientific standards and they are applied appropriately.

New methods, significant modifications of old methods, or significant deviation from accepted procedures must be appropriately validated before being adopted for routine analysis. Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic science laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

An understanding of the theoretical basis for the method is essential to the proper design of a validation study. Such understanding provides a means of assessing the specificity and limitations of the method and predicting possible sources of error in the procedure. When applicable, the method should be tested using known samples. If the new method is to parallel or supersede an existing method, both methods should be compared on split samples. The known samples should be designed to resemble actual evidence materials as closely as possible, so that the effects of such factors as matrix, sample age, degradative environment, and sample inhomogeneity are taken into account. This is especially important in attempting to apply methodology originally developed for routine chemical or clinical samples to evidence type materials. If the test provides quantitative data, the validation study should include an estimation of its accuracy and precision at concentrations which are representative of casework samples.

The extent to which a method needs to be evaluated is a matter of professional judgment. For example, a limited series of proficiency samples may be adequate when implementing a method that has been accepted and widely used in the field.

External exchange of blind and reference samples with another competent laboratory is particularly important if the method has been developed in-house, as it serves to guard against internal systematic error.

Individuals deemed competent and authorized to conduct testing activities in a discipline are considered competent and authorized to conduct equipment and method validations and verifications, as are IT specialists within FSD for certain software validations (LIMS, other applications).

	LOM 2.9 Validation and Verification	
	<i>Document #: 1341</i>	<i>Page 2 of 3</i>
	<i>Revision #: 4</i>	<i>Issued Date: 09/18/2020</i>
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2.9.2 New Methods

Laboratory personnel desiring to submit a new method, software type/version, or procedure shall forward a written description of the method detailing advantages over existing methods (if applicable), a description of supplies and materials required and a literary source(s), if available, of the proposed method (e.g. Journal of Forensic Science) to the Unit Supervisor for consideration. The method validation plan and subsequent reviews shall include consideration for the associated data interpretation.

After review, the Unit Supervisor shall forward the proposed method or procedure and a recommendation to the appropriate Technical Leader.

Upon approval from the appropriate Technical Leader, the originating laboratory may begin validation of the method. Individuals deemed competent and authorized to conduct testing activities in a discipline are considered competent and authorized to conduct validations. Methods and technology using new equipment also require validation and verification.

Periodic updates during the validation at intervals agreed upon between validation team and the Technical Leader shall be provided to the corresponding Technical Leader for their review. These updates and reviews are intended to ensure the validation is proceeding at an acceptable pace and that the needs of the customer are being fulfilled. Any changes to the validation plan shall be approved by the corresponding Technical Leader prior to making the changes. Once the validation has been completed, a copy of the proposed method or procedure, along with the pertinent validation data and summary should be forwarded to the appropriate Technical Leader for final review and approval.

After reviewing all validation documentation, the Technical Leader shall prepare a memorandum with recommendations and forward it to the QAM for final publishing. Once approved, the Technical Leader shall incorporate the new method or procedure into the appropriate procedures manual making reference within as to the date of the validation and the laboratory where the validation took place. The discipline specific procedure manuals shall include data interpretation, data required to report a result/opinion/interpretation and detail limitations of the method/reported results/opinions/interpretations based upon the outcomes of the validation. When changes are made to the interpretation of data, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

The procedure change(s) and notification process shall be in accordance with [LOM 2.12 Document Revision and Control](#).

All original records, data, procedures used, specifications of the requirements, determinations of the performance characteristics and correspondences generated as a result of the validation study shall be kept by the laboratory conducting the validation. Also, at a minimum, a summary report of each validation including a statement of the validity of the method that details its fitness for the intended use shall be maintained on the FSD Document Management System.

2.9.2.1 Exceptions

Modifications to existing procedures and methods which do not materially affect the performance of the test do not require additional validation studies. These modifications should affect the efficiency and/or effectiveness of the test without affecting the results. Such a modification shall be approved by the Technical Leader prior to their use and recorded in the case notes.

	LOM 2.9 Validation and Verification	
	<i>Document #: 1341</i>	<i>Page 3 of 3</i>
	<i>Revision #: 4</i>	<i>Issued Date: 09/18/2020</i>
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2.9.3 Verification

2.9.3.1 Requirements

Equipment received as a replacement for or supplemental to existing instrumentation and used to conduct casework analysis/examination requires verification. Additionally, verification of standard methods new to the Forensic Science Division and those published in the community require verification.

2.9.3.2 Process

Data generated during the verification of new or supplemental equipment shall be reviewed by the appropriate Technical Leader and/or Unit Supervisor.

Upon review and acceptance of the verification data by the Technical Leader, documentation shall be issued to the laboratory that indicates the instrumentation/equipment is functioning on-site as designed. All original records, data and correspondences generated as a result of the verification shall be kept by the laboratory conducting the verification. Also, at a minimum, a summary report of each verification shall be maintained on the FSD Document Management System.

The Technical Leader shall ensure that all appropriate personnel (i.e. Unit Supervisor, Laboratory Director, Analysts, and QAM) are notified that the new equipment/instrumentation has been approved for use in casework.

2.9.4 Non-Standard Method Validation

Method validation is a critical part of the quality assurance system. It ensures consistent and reliable results reported to the customer. Minor deviations to existing validated methods may be necessary to accommodate the varied nature of forensic evidence. Occasionally, evidence items may present unique circumstances that require a case-specific validation that may not be utilized beyond the particular case. When these instances are presented, the appropriate Technical Leader shall be contacted for an analysis plan that includes necessary validation studies prior to commencing analysis of the case evidence item(s). The Technical Leader shall approve all case-specific validation studies, with documentation of the approval and data from relevant studies stored within the case record. If it is anticipated the case-specific validation study may be utilized on future case analyses, a complete validation summary shall be prepared, approved by the Technical Leader and archived for future reference.