District of Columbia Department of Forensic Sciences

DOM04 – Procedures for Validating Technical Procedures

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1.   Background

1.1.   These procedures provide direction for validating new technical procedures prior to those procedures being introduced into casework in the Department of Forensic Sciences (DFS). Validation is the process by which the scientific community and the laboratory acquire information to assess a procedure's capability for obtaining reliable and reproducible results. These procedures conform to the requirements of the Agency, government regulations, accreditation standards, and the applicable supplemental standards.

2.   Definitions

2.1.   For the purposes of this document, the following terms shall have the designated meanings:

DFS: Department of Forensic Sciences

DOM: Departmental Operations Manual

SOP: Standard Operating Procedure

3.   Scope

3.1.   These procedures apply to new technical procedures or methods, whether developed internally or externally, that pertain to casework or laboratory work.

4.   Responsibilities

4.1.   The **Individual/Group** performing the validation will:

4.1.1.   Plan the validation study.

4.1.2.   Ensure qualified personnel are performing the validation.

4.1.3.   Ensure there are adequate resources for the validation.

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4.1.4. Appropriately document and retain results of validation and modification studies.

4.1.5. Retain the documentation of the review process.

4.1.6. Prepare the SOP(s) for casework.

4.2. The **Manager/Supervisor**, **Technical Leader**, and/or **Division Director** will:

4.2.1. Review and approve the validation plan.

4.2.2. Review the validation process and results before the procedure is used in the DFS.

4.2.3. Document this review after all concerns/issues have been raised and addressed between the individual/group preparing the validation documentation and the technical reviewer(s).

4.2.4. Approve all validations deeming a method ready and appropriate for casework.

5. Procedures

5.1. Prior to beginning a validation study, a plan of action will be prepared and documented by the person/group tasked with the validation. The Manager/Supervisor, Technical Leader and/or Division Director will review and approve the plan of action for the proposed validation study.

5.2. Each unit will define and/or reference the requirements for a discipline-specific validation study, if applicable and where appropriate. The validation study will determine:

5.2.1. The limitations of the procedure.

5.2.2. Conditions under which reliable results can be obtained.

5.2.3. Critical aspects of the procedure that must be controlled and monitored.

5.2.4. The scope and accuracy of the procedure necessary to meet the needs of the given application.

5.3. When validating a novel or existing procedure, known samples must be used. Prior to applying a novel or existing procedure to the examination of evidence, documentation must demonstrate the procedure performs as expected, or with modification performs as expected, in the DFS.

5.4. A validation report will be compiled once the validation is complete. The report will contain, at a minimum, procedure used, results, other relevant validation

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notes, and a statement as to whether the technical procedure is suitable for use in casework.

5.5.   Validation Review and Documentation

  5.5.1.   The review of the validation must be commensurate with the complexity of the validation project.

  5.5.2.   A technical reviewer will evaluate the validation study before use of the procedure in the DFS. A technical reviewer is an individual who possesses the knowledge and/or experience on the corresponding scientific application. The technical reviewer(s) will document agreement with the validation results with a signature and date of review on the validation report.

  5.5.3.   Upon completion of the technical review, a SOP will be written for the validated technical method for use in forensic examinations. The SOP must be approved prior to use for forensic examinations. The SOP will be prepared and approved according to the requirements set forth in *DOM03 – Procedures for Writing Standard Operating Procedures.*

5.6.   Competency Tests

  5.6.1.   Each analyst who will apply the validated technical method to casework must successfully complete a competency test prior to use on casework. This test will demonstrate the analyst can accurately perform the technical method using the approved SOP. The competency test file and its associated results will be maintained with the Deputy Director or designee.

6.   Documentation

6.1.   The following records will be generated and permanently retained by the applicable unit in the laboratory:

  6.1.1.   Validation Notes and Results

  6.1.2.   Validation Report

7.   References

7.1.   ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, (current revision).

7.2.   ANAB Supplemental Requirements for Forensic Testing, ANSI-ASQ National Accreditation Board, Milwaukee, WI, (current revision).

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7.3.   Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

7.4.   Division-specific Quality Assurance Manuals, (current revisions).