Purpose: Procedure for the Validation of a New Method or Technology

Validations will be conducted when the Unit receives a new piece of equipment or new software for use in casework. This SOP is to act as guidance for the validation plan; if modifications are required for the plan, these will be approved by the Deputy Director and Director. The validation plan may also be used for software upgrades that reflect a major change.

In the case of minor updates to software, a performance check is sufficient to determine if the new upgrade is acceptable for use in casework. A performance check will also be conducted if a piece of equipment is sent out for repairs and is now ready to be placed back into service. Performance checks may also be conducted when casework software is loaded for the first time onto a computer. Refer to GL-22 for guidance.

Responsibility:

Forensic Science Examiners assigned to the Questioned Documents Unit or performing casework in the Unit.

PROCEDURE:

1. Before a new method, software or technology is introduced, a validation of the method will be performed. A plan will be written detailing the steps of the validation procedure.

2. The plan will be reviewed by the Lead and/or Supervisor Assistant Director and Deputy Director and Director prior to commencement of the validation. The Deputy Director or their designee will complete the Laboratory Method Validation Form. After the validation plan is reviewed, the Deputy Director or their designee and the Director will approve the plan by completing the plan approval portion of the form. Approval may also have the initials of the plan approver on the printed pages of the validation plan.

3. This plan may be updated during the process as new information or results of the validation require changes to the original plan. Any changes to the plan will need to be re-approved Deputy Director and or their designee and the Director.

4. After completion of the validation, the results will be clearly communicated in the validation and the results will be submitted for review by the Lead and/or Supervisor, Assistant Director and Deputy Director.

5. These validation results will be evaluated to determine if SOPs changes are needed prior to casework use. The approved software/equipment list will be updated with the validated software/equipment.

6. A final memo will be issued by the Deputy Director or their designee of the review of the validation and its results. The memo will have a statement indicating if the equipment or software has successfully passed its validation and is acceptable to be placed into service or use for casework. This memo will be approved by the Quality Manager and the Director.

Performance Check Procedure:

1. Using a known file or control example, or a completed case file, the updates to software will be evaluated to determine if the same results are obtained after the upgrade or if the software will still work correctly.

2. A memo indicating that the performance check was completed and if it passed successfully will be issued and kept on file in the Deputy Director's office.

3. Software updates will be documented in the Units Software list of the current approved version in use.

Sources of Error: Not applicable

References:
GL-1, GL-22
SWGDOC
Laboratory Method Validation Summary Form