LP SOP-33 Software Validation	Document ID: 6448
	Revision: 2
	Effective Date: 10/07/2020
Approved by Director: Dr. Guy Vallaro	Status: Published
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Purpose:

To establish a validation procedure or performance check procedure for the use of new equipment or software being introduced to the Latent Print Unit.

Validations will be conducted when the Unit receives a new piece of equipment or new software for use in casework. GL 22 (Policy on Validation and Performance Checks) and this SOP are to act as guidance for the validation plan; if modifications are required for the plan, these will be approved by the Deputy 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.

Responsibility:

Forensic Science Examiner assigned to the Latent Print Unit or conducting casework in the Unit.

Validation Procedure:

- 1. A plan will be written detailing the steps of the validation procedure. This plan will be reviewed by the Deputy Director and Quality Manager and approved by the Director.
- 2. This plan may be updated during the process as new information or results of the validation require changes to the original plan. Any changes in the validation plan will need to be approved.
- 3. After completion of the validation, the results will be clearly communicated in the validation and submitted for review by the Deputy Director.
- 4. The Deputy Director will review the validation and will determine if more testing is necessary or work with the analysts conducting the validation to assess if there are SOP or Quality Record changed needed.
- 5. Record of all steps in the validation process will be recorded on the "Laboratory Method Validation Summary Form". Once all the sections of the form are completed, this will be reviewed and approved by the Supervisor, Deputy Director and Director.
- 6. The Deputy Director will review the validation and will issue a statement if the equipment or software has successfully passed its validation and is acceptable to be placed into service or use for casework. Software or equipment is considered acceptable for casework if it can produce reliable and repeatable results. A "fit for use" type memo will be issued and attached to the validation.

Reference:

GL1 – Quality Manual

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GL 22 – Policy on Validation and Performance Checks