A. <u>Performance Check</u>

A performance check is a quality assurance process to assess the functionality of laboratory instruments and procedures that affect the accuracy and/or validity of the analysis. Performance checks are typically required after any of the following events:

- A minor modification of a currently validated procedure
- Additional purchases of previously validated critical instruments
- Repair of a previously validated critical instrument
- For certain types of upgrades of previously validated critical instruments

Performance Checks are generally not required after routine in-house maintenance. Unit specific SOPs will address when a performance check will be done.

A Performance Check is much less than a validation. Therefore a plan for the performance check is not needed. However, the conclusion of the performance check needs to be documented. The data collected during the performance check must be reviewed to determine the effects, if any, of the modification and/or the suitability of the new or repaired analysis instrument. This information must be reviewed and approved by the technically responsible person or their designee.

Performance Check Scenarios

a. <u>Minor modification of a currently validated procedure (comparison study)</u>
    i. Perform the modified procedure in parallel with the original procedure.
    ii. Evaluate the results to show whether the change has an effect on the end results.
    iii. Example: if an incubation temperature is increased, samples can be processed using both this increased temperature and the original temperature, and then the end results compared.
b. <u>Additional Purchases of Previously Validated Critical Instruments</u>
    i. If the laboratory currently uses one instrument and adds another of the same make and model, the performance of the new instrument must be evaluated.
    ii. The components of the performance check will depend on the instrument's function and application. The performance check should demonstrate the results are reproducible on the new instrument and that values from the in-house validation can be compared.
    iii. Example: if the new instrument is used for quantitation, a dilution series can be created and analyzed on both the new and current instrument and the end results compared.

c. Repair of a Validated Critical Instrument
   i. The extent of the performance check will depend on what type of service was performed on the instrument.
   ii. Specific Unit SOPS will define the parameters of this type of performance check.

d. Certain types of upgrades of previously validated software
   i. New software or significant software changes that impact interpretation or the analytical process and significant instrument upgrades shall require a validation prior to implementation into casework.
   ii. A software upgrade that does not impact the analytical process will only require a performance check.
   iii. Example: If the new version of software only has superficial changes, e.g., the addition of more user-friendly features, but the analytical algorithms are kept the same, a performance check and not a validation would be required. This performance check may include for example, analyzing the same data with the old and new versions.

B. Validations

A validation is the process of performing a set of experiments to demonstrate the efficacy and reliability of a procedure in the laboratory. Validation studies are typically required for any of the following events:

- A major modification of a currently validation procedure
- A new method
- A new instrument

During a validation, known samples of those typically encountered in casework shall be examined to demonstrate any potential limitations of the procedure and to determine if the procedure generates acceptable results. The number and type of samples will depend of what is being validated. Documentation of a validation plan, results, and summary will be maintained.

Validation Process

a. Plan
   i. The Validation of a new procedure will generally be initiated by the technically responsible person or designee. A validation plan will be provided to the appropriate Section Deputy and/or Director. The DNA TL will approve

validations in DNA. This proposal shall include a description of what the validation is, and a summary of the experiments planned to evaluate the new method.

ii. The Section Deputy and/or Director (and TL in DNA) must approve the proposal before the validation is to be initiated. This approval can be documented through signing and dating the plan.

iii. When implementing a validation plan, if a change to the plan is required, the change plan will be updated and approved by the Deputy Director (or DNA TL if in DNA).

b. Experiments

i. The validation experiments should include:

- Certification from the manufacturer that the instrument is functioning (if applicable)
- The analysis of reference standards or reference materials
- The testing of known samples designed to resemble actual casework samples
- A complete assessment of the factors influencing the results
- Other requirements of validation experiments will be found in Unit specific SOPs. Example: The FBI DNA QAS standards for validation require other experiments to be performed.

c. Summary of Results

i. A validation summary will be completed and provided to the Section Deputy and/or Director (TL in DNA). The results will contain a table of contents and be organized/separated in a way that is easy to read and be able to follow what was completed.

ii. The validation summary will contain

- The experiments used for the validation
- The results of these experiments
- Appropriate literature references
- A statement as to whether the procedure is suitable for its intended use

iii. The validation summary should also include an assessment of the following when applicable:

- Accuracy
- Range
- Uncertainty of the results

- Limit of detection
- Selectivity/Specificity
- Linearity
- Precision (reproducibility)
- Robustness

d. New SOP

After approval of the completion of the validation, a new or modified written SOP in Qualtrax will be approved and published. This procedure will be based on the results of the validation and include interpretation guideline if applicable.

e. Training

Prior to initiating casework with any new validated method, the unit must ensure that staff have been trained and have successfully completed a competency test to their extent of their participation in casework.

For personnel intimately involved in the validation activities, the technically responsible person may document that the validation activities served as demonstration of competency.

f. CT DSS Forms

At the completion of a validation, General Laboratory Form "Laboratory Method Validation Summary Form" will be filled out to ensure all necessary information is captured. This form can be found the "General Laboratory Forms" folder in Qualtrax.