A. **PURPOSE**:

Method validations are required to assure that new methods or instruments meet the needs of the laboratory. Validations can be used when instrumentation is updated, replaced or when a new technology is acquired. The extent of the validation varies depending on the what is being validated.

B. **RESPONSIBILITY**:

1. Laboratory Director: must assure that validations plans are developed and are performed to meet the needs of the laboratory prior to case materials being reported using the method/instrumentation.
2. Quality Manager: is responsible to assure that the person(s) performing the validation completely document the validation
3. Supervisor or designee: with the Laboratory Director are responsible to directly oversee the validation.

C. **PROCEDURE**:

1. General: Validations performed will ensure that the instrument/method is appropriate for the needs of the laboratory and the laboratory's customers.

   Situations which will require validations to be performed include:

   a. Obtaining instrumentation that represents new technology for the laboratory
   b. Upgraded instrumentation in a manner that may affect results
   c. Developing new methodology such as extraction techniques

2. New Technology:

   a. The Laboratory Director with the Quality Manager or section Supervisor will develop a plan for the validation that is based on the needs of the laboratory and the laboratory's customers.
   b. A full validation will be required. Manufacturers guidelines should be followed for set up and general maintenance. A full validation will entail at minimum:
      i. Verification by the manufacturer that at instillation the instrument is working as specified by the manufacturer.

ii. Instrument checks performed by the laboratory are within parameters set by the laboratory (these may be guided by the manufacturers guidelines)

iii. Standards and/or controls run on the instrument perform as expected. This can include wither qualitative or quantitative work depending on the needs of the laboratory.

iv. Typical samples, previously run on existing instrumentation give comparable results. When possible previously run and evaluated proficiency test samples will be included with case samples for this comparison. The number and range of samples should be sufficient to cover all aspects of the requirements of the method. Note that blank samples should be included in the assessment process.

(a) The Laboratory Director with the Quality Manger will be responsible for determining the parameter based on laboratory needs. It must be recognized that new technology may give what appears to be different results.

v. The individual appointed by the Laboratory Director as leading the validation is responsible to document the process as it occurs. This individual will need to present the compiled documentation to the Quality Manager and Laboratory Director for review.

vi. When the validation is acceptable and is demonstrated to be fit for the intended purpose the Laboratory Director will document that that method is acceptable for use on case materials.

vii. A new SOP will be issued and training on the method will be conducted.

viii. The validation will be complied in a laboratory validation book for the instrument and maintained in the laboratory for a minimum of ten years.

3. Instrument Upgrades:

a. To determine if an instrument upgrade requires validation the following should be considered:

i. Is the up-grade another version of currently used instrumentation (such as a new GC/MS)? This may only require verification by the manufacturer that at set-up the instrument is operating to their specifications then verification that normal checks performed in-house are up to the laboratories standards.

(a) Example: On a GC/MS the instrument provides acceptable results for tuning, Air/water checks and the daily standard run.

ii. Does the upgrade/change include anything that can affect the quality of the analysis?

Examples:

(a) A new computer on a GC/MS would not affect the quality of the GC/MS results

(b) A new type of detector on a GC/MS could affect the quality of the results.

iii. To what extent could the update/change affect the results?

b. A validation plan will be developed by the Laboratory Director with the Quality Manger and/or the section Supervisor. In most cases a validation at this level will be minimal, it may include:

   i. Determination of proper instillation of the up-grade, this could be simply shown by normal daily instrument set-up being acceptable.

   ii. Re-analysis of previously run samples and comparing the results.

c. The individual appointed by the Laboratory Director as leading the validation is responsible to document the process as it occurs. The level of documentation will be decided at the time of developing the validation plan.

   i. If the validation plan requires a full scale validation with the determination of sensitivity or other parameters the documentation include the data produced.

   ii. If the validation plan simply requires the running of the daily standard to check the working condition it may be acceptable to simply document the change in the instrument log book.

d. This level of validation may require an update to the SOP.

4. <u>New Methodology</u>:

   a. New methodology may include:

      i. A technique that is new to the laboratory but published and used in the scientific community.

         (a) This may require simple verification of results by the use of standards and controls and verification that the method meets the needs of the laboratory and the laboratory's customers.

      ii. A method used in the laboratory but being used in a different manner for a different purpose.

         (a) This may require simple verification of results by the use of standards and controls and verification that it meets the needs of the laboratory and the laboratory's customers

      iii. A method being developed with-in the laboratory.

         (a) This may require a full validation demonstrating the appropriateness of the method for the defined task.

   In all cases the validation process must demonstrate that, prior to case results being issued based on the method, the method is fit for the intended purpose.

   b. New methodology does not include simple changes to current methods such as using a different solvent where problems would be identified during the normal use of controls and/or standards.

   c. A validation plan will be developed by the Laboratory Director with the Quality Manager and/or section Supervisor. The level of validation will depend on what is being developed. The plan must consider, what need is to be met:

i. Is the method qualitative or quantitative

(a) Qualitative: minimally qualitative standards and blanks will be used in the method to show that the method will work as expected.

(b) Quantitative: the needed level of quanatitation must first be determined. Minimally standards and controls that encompass the needed calibration range must be made or obtained and analyzed by the new method to determine if the method parameters are acceptable.

(i) Ideally controls will be run that are lower than the lowest needed quantization level the limit of detection and limit of quantitation being identified.

(ii) If available previously run samples will be used for comparison.

d. The individual appointed by the Laboratory Director as leading the validation is responsible to document the process as it occurs. This individual will present the compiled documentation to the Quality Manager and Laboratory Director for review. The Laboratory Director will annotate that the validation is acceptable on the documentation allowing the updated equipment to be placed in use.

e. The validation will be complied in a laboratory validation book and maintained in the laboratory for a minimum of ten years.

f. This level of validation may require an update to an existing SOP, or a new SOP and training on the method.