1. Purpose

This statement set out PNAC policy on method validation and applies to laboratory accreditation to ISO/IEC 17025.

2. Policy

PNAC will apply the principles that Method must be 'suitable for purpose i.e., Measures what is required, **h**as known and adequate accuracy and precision (Uncertainty) and can be shown to be stable, i.e accuracy and precision maintained in routine use (Quality Control)

3. Definitions:

- **Validation** establishes the performance characteristics of a non standard method in laboratory
- **Verification** establishes the performance of a standard method in a laboratory
- **Quality Control** checks that the performance established at validation is maintained in routine operations
- **Selectivity and Specificity**-extent to which method measures the wanted element without interference
- **Scope-**Range types of samples or objects.
- **Range**-Quantitative range over which method is valid.
- **Linearity or other Algorithm-**Linear range if any.
- **Sensitivity-**Difference in measured value corresponding to smallest difference in response of the method.
- **Limit of Detection-**minimum amount distinguishable from blank. Sample dependent.
- **Limit of Quantitation-**lowest level of target determinable with an acceptable level of uncertainty.
- **Ruggedness-**Sensitivity of the method to changes in procedure, conditions, different laboratories.
- **Accuracy-**Closeness to 'true' value
- **Precision-**Closeness of agreement between independent determinations on same or identical samples. Leads on to UNCERTAINTY.

4. PNAC Requirements

4.1 For non standard/ in-house method **validation** is needed using one or a combination of the following:

- Calibration using reference standards or reference materials
- Comparison of results achieved with other methods
- PT/ Inter-laboratory comparisons
- Full validation including Selectivity/Specificity, Scope, Sensitivity, Ruggedness, Range, Linearity, LOD/LOQ, Accuracy, Precision

4.2 For standard method outside their intended scope **validation** based on one or a combination of the following is needed:

- Calibration using reference standards or reference materials
- Comparison of results achieved with other methods
- PT/ Inter-laboratory comparisons
- Validation techniques including: Selectivity/Specificity, Scope, Sensitivity, Ruggedness, LOQ/LOD, Accuracy, precision

4.3 For standard method outside its range **validation** based on one or a combination of the following is needed:

- Calibration using reference standards or reference materials
- Comparison of results achieved with other methods
- PT/ Inter-laboratory comparisons
- Validation techniques including Range, Linearity, LOQ/LOD, Accuracy, precision

4.4 For standard method the following **verification** is needed before adoption:
- Repeatability
- Reproducibility