



PNAC POLICY ON ASSURING THE QUALITY OF TESTING PROCEDURES

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1. Purpose

To meet the requirement of ISO/IEC 17025 & ISO 15189 of quality control procedures, for monitoring the validity of tests and calibration undertaken.

2. Policy:

PNAC will apply the principles of ILAC G18:04/2010 Guideline for the Formulation of Scopes of Accreditation for Laboratories, The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing (Which can be viewed at www.ilac.org) to the assessment and accreditation of laboratories.

3. PNAC's requirements on Quality Assurance:

1. Each PNAC accredited laboratory shall adopt an appropriate set of quality control procedures suitable to the range of work done and to the number of testing staff available. The results of such procedures shall be fully recorded and be available for review during PNAC assessments. Where a standard specifies a quality control procedure, it shall be followed.
2. The laboratory shall participate in at least one proficiency testing programme annually for each discipline. The programme(s) shall cover all accredited test areas in each discipline.
3. When developing new examination procedures, the laboratory shall consider carefully their quality control requirements. This should be documented as part of the quality assurance plan for those examination procedures. Where necessary, the existing quality control procedures should be extended to cover the new work or new procedures. The adequacy of the quality control procedures will be examined critically during assessments. The quality control plan, together with the acceptable criteria and actions to be taken in out of control situations, shall be documented.
4. Quality control plans shall include, where relevant, the use of control samples (positive and/or negative), duplicates, blanks, spikes, etc. Control samples shall be of a similar matrix as the test/calibration items samples. Correlation of results in a sample shall be reviewed, where relevant.
5. Quality control samples, external proficiency testing and other alternative performance assessment samples shall be analysed using exactly the same procedures as for client samples and analysed by personnel who routinely analyzed.
6. Programmed submission of certified reference materials and other materials of known characteristics during the course of routine sets of analyses. This practice, done routinely, also allows for the use of control charts and for the monitoring of the ongoing level of precision being achieved in the laboratory, and if sufficient reference materials are available, for evaluation of the accuracy being achieved at various concentration levels.



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7. Regular testing of replicate samples by the same person. This allows for an ongoing estimate of the repeatability being achieved by an individual. It may be done either fully known to the person or by programmed resubmission of previously analysed samples suitably re-identified.
8. Regular examinations of the same sample by two or more persons. This allows for the estimation of precision between staff members being achieved in the laboratory and for identifying any significant biases evident in an individual's results.
9. Programmed examination of the same sample by different examination techniques or two different items of the same apparatus type. This allows for estimation of any technique-dependent bias or equipment bias in the laboratory's results.
10. Recording and monitoring of results obtained from the same sample by the reference laboratories. This allows, given sufficient data, for control charts to be established to monitor the between-laboratory precision achieved between the two laboratories concerned. The data obtained may also be compared with any available published data on reproducibility for the examinations concerned, if both laboratories are using the same examination method.