Guidance Document for Accreditation of Chemical Testing Laboratories

Introduction

This document provides guidance to all accredited and applicant laboratories in conforming to the requirements of PNS ISO/IEC 17025:2017. Laboratories are encouraged to take note of these interpretations. The numbering system of this Supplementary Requirements follows the numbering of ISO/IEC 17025.

Authorship

This document was prepared by the PAB Laboratory Accreditation Technical Committee for Chemical Testing through deliberation by a group of stakeholders convened by the PAB.

3 Terms and Definitions

3.1 Chemical Testing Laboratory: A facility where measurements related to chemical testing are conducted.

3.1.1 Permanent laboratory: A testing laboratory situated in a fixed location for a period expected to be greater than three years.

3.1.2 Site/Field laboratory: A testing laboratory facility set up in a dedicated area on-site for the duration of the testing activities for a period expected less than three years.

3.1.3 Mobile laboratory: A fully equipped; self-contained, transportable testing laboratory capable of performing tests under controlled environmental conditions. (Note: Mobile laboratories are subject to the same terms of accreditation as a site laboratory. Mobile laboratories left at one site for three years or more will be subject to the same terms of accreditation as a permanent laboratory).

3.2 Field testing: Testing (including sampling and sample preparation where it forms part of the subsequent chemical testing) performed by staff of a laboratory or organization outside of the premises or grounds on which the permanent laboratory facility is located.

Field testing is normally performed under two categories:

- By staff sent out on-site by an accredited permanent laboratory
- By organizations that do not have a permanent laboratory

3.3 Chemical analysis: refers to a physico-chemical or biochemical procedure which involves the following and related techniques:

a. Measurement of properties, such as power of hydrogen (pH), oxidation-reduction potential, density, atomic or molecular weight, and others;

b. Use of methods, such as titration, gravimetric analysis, electrochemical measurements, spectroscopy, chromatography, and others;

c. Determination of the atomic or molecular quantity of one or more components of a substance;

d. Determination of the atomic, molecular, surface or supramolecular nature or structure of substance;

e. Preparation of a sample for chemical analysis;

f. Separation and/or purification of a mixture into its components using techniques, such as distillation, crystallization, density, reactivity, extraction, adsorption, size exclusion, affinity, chromatography, and others;

g. Calculations of physico-chemical or biochemical properties or concentrations of chemicals or biochemicals;

h. Computational methods applied to chemically or biochemically related matters, such as molecular design, molecular modelling, chemometrics, and others; and

i. Other analytical methods which characterize matter at the atomic, molecular or supramolecular level.

3.4 Chemical synthesis refers to the preparation of a compound or chemical entity from its elements or from other compounds or chemical entities by one or more chemical reactions. Synthesis, as defined herein, refers to both chemical synthesis which may use chemical catalysts, and biochemical synthesis which uses enzymes and other biological compounds to promote a reaction

4 General requirements

4.1 Impartiality

4.1.1 For laboratory personnel who have production or marketing-related responsibilities, appropriate controls should be established to ensure that impartiality to the laboratory's testing activities is not compromised.

4.1.2 The laboratory should establish controls to ensure that there is no infraction to policies or other measures established by the laboratory to address impartiality.

4.2 Confidentiality

4.2.1 The laboratory should establish controls to maintain and manage the information obtained or created during the performance of laboratory activities.

5 Structural requirements

5.4 The laboratory management is responsible for fulfilling the specified requirements by existing regulatory and/or statutory for technical personnel and management of the laboratory.

6 Resource requirements

6.2 Personnel

6.2.1 The laboratory should ensure that the technical operation of laboratories carrying out chemical testing activities is under the direct control and supervision of competent laboratory personnel.

Any chemical testing activity conducted on site, in mobile and field laboratories should be carried-out either by having an authorized signatory at each facility or having an authorized signatory regularly visiting the facility and maintaining a record of the dates and relevant activities of each visit.

7 Process requirements

7.7 Ensuring the validity of test results

For infrequently performed techniques/ tests, the laboratory should carry out regular performance checks to demonstrate continuing competence to perform them and in

order to maintain accreditation. Performance checks should be conducted in accordance with an established quality control plan/ program. Records of these checks and their results should be kept with other quality control data and should be available for examination during assessments.

7.8 Reporting of results

7.8.1 General

The use of signature stamps, photographic, electronic and/or mechanical means of reproduction of signatures or names of signatories for endorsed test reports will be reviewed at assessments. The laboratory should establish and implement appropriate controls to demonstrate that the authorized signatory approved the test reports at the time of its issue and to protect test report integrity and confidentiality (e.g. by use of password protected templates).

8 Management system requirements

8.2 Management system documentation (Option A)

8.2.1 Measurable quality objectives should be established showing key indicators, key result areas, or other criteria defined by the laboratory. These objectives should be consistent with the laboratory's policies which address competence, impartiality and consistent operation of the laboratory

8.8 Internal Audits (Option A)

8.8.1 Internal audits should cover a twelve-month period and should address all elements of ISO/IEC 17025, PAB supplementary requirements, the laboratory's documented management system as well as compliance to regulatory authorities. The audit maybe at one time or spread out within the twelve-month period.

8.8.2 Internal audit activities should include laboratory activities performed in the laboratory's permanent facilities, at sites away from the permanent facilities, in associated temporary or mobile facilities, or at a customer's facility.

8.9 Management reviews (Option A)

8.9.1 The effectiveness of the management system should be reviewed by the laboratory's management at least once per year.

8.9.3 Decisions and actions identified during the management review should include personnel responsible for the action and timeline of completion (if applicable).

References

[1] ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories
[2] Republic Act No. 10657: Chemistry Profession Act