Supplementary Requirements for

Accreditation of Chemical Testing Laboratories

Foreword

This Philippine Accreditation Bureau (PAB) Laboratory Accreditation Supplementary Requirements for Accreditation of Chemical Testing Laboratories was developed by the Laboratory Accreditation Technical Committee (LATC) for Chemical Testing by providing specific technical criteria and guidelines for both assessors and for laboratories carrying out chemical testing.

The numbering in the texts of this document follows the ISO/IEC 17025 (current version) numbering of requirements.

1 INTRODUCTION

All accredited and applicant chemical testing laboratories are required to satisfy these Supplementary Requirements in addition to the general requirements for the competence of testing and calibration laboratories in ISO/IEC 17025.

2 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 DEFINITIONS

3.1 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 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 documented testing procedure) performed by staff of a laboratory or organization outside of the premises or grounds on which the permanent laboratory or the organization's permanent base of headquarters 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.

4 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.4 For laboratory staff that may also have production or marketing-related responsibilities, clear policies shall be available to define how impartiality is assured for their testing responsibilities.

4.1.5h. The laboratory shall ensure that the technical operations of laboratories carrying out physico-chemical tests is under the direct control and supervision of competent laboratory personnel.

Note: Existing regulatory and/or statutory requirements stipulate that the technical management of the laboratory hold applicable personnel certification/ registration. Top management is responsible for fulfilling the specified personnel certification/ registration requirements.

4.2 Management system

4.2.1 Management system documentation shall include, or make reference to approved signatories, scope of accreditation and the policy on the use of the PAB laboratory accreditation symbol.

4.2.2 Measurable quality objectives shall be established showing key indicators, key result areas, or other criteria and reviewed during the management review.

4.5 Subcontracting of tests

4.5.1 This clause applies in cases where a laboratory is required to subcontract part of its normal service e.g. due to temporary incapacity, excess workload or where a laboratory subcontracts due to need for further expertise and the result of the subcontracted service(s) are incorporated into the laboratory's test reports. Refer also 5.10.6.

A competent subcontractor is defined as an accredited PAB laboratory or a laboratory accredited by one of PAB mutual recognition partners or a laboratory which, after thorough assessment and inspection, is found to have established quality assurance similar to the technical requirements set in PNS ISO/IEC 17025.

All results from subcontractor shall be properly identified in the endorsed report (e.g. notation in the test reports). Copy of test report from subcontractors will be provided if needed by the customer.

4.13 Control of records

4.13.2 Technical records

4.13.2.3 Alterations to data shall also include the date the change was made.

4.14 Internal Audits

4.14.1 Internal audits shall cover a twelve-month period and shall address all elements of ISO/IEC 17025, and applicable PAB supplementary requirements. The audit may not be conducted simultaneously and at one time but may be spread out within the twelve-month period.

Refer to LA/GD15, PAB Guidelines on Internal Audit for Laboratories and Inspection Bodies, for additional information

4.15 Management reviews

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

Please Refer to, LA/GD16, PAB Guidelines on Management Review for Laboratories and Inspection Bodies, for additional information.

5 TECHNICAL REQUIREMENTS

5.2 Personnel

Any testing conducted on site, in mobile and field laboratories shall also be under adequate technical control. This is carried-out either by having an approved signatory at each facility or having an approved signatory regularly visiting the facility and maintaining a record of the dates and relevant activities of each visit.

Personnel and/or nominated/ approved signatories' competency shall be evaluated as defined in LA/GD07, PAB Guidelines for Laboratory Personnel and Approved Signatories.

Note 1: Existing regulatory and/or statutory requirements stipulate that personnel signing or certifying test reports hold applicable personnel certification/ registration. The laboratory is responsible for fulfilling the specified personnel certification/ registration requirements.

Note 2:After an assessment, PAB may:

a. Delete test or measurement from the Scope of Accreditation when it is no longer satisfied that the test or measurement concerned is within the laboratory's field of competence, the Scope of Accreditation shall be amended and the CAB shall be informed in writing.

b. Remove the name of a particular person from the list of Approved Signatories or amend the scope of an Approved Signatory when it is no longer satisfied that the person meets the criteria for Approved Signatory.

5.3 Accommodation and environmental conditions

5.3.1 A laboratory undertaking analyses of trace concentration shall take special precautions to prevent sample contamination. Testing environment shall be monitored in accordance with test method and/ or equipment specifications. Where dedicated clean rooms are required, airborne particles shall be controlled to specified limits.

5.4 Test methods and method validation

5.4.2 Selection of test methods

Common sources of methods covered by the accreditation include the American Society for Testing and Materials (ASTM), American Public Health Association (APHA), United States Environmental Protection Agency (USEPA), Association of Official Analytical Chemists (AOAC), British Pharmacopeia (BP), United States Pharmacopeia (USP), International Organization for Standardization (ISO), Philippine National Standard (PNS) and other recognized technical publications.

If the use of the latest valid edition of a standard is not appropriate or laboratory resources is not adequate, method validation shall be conducted according to a defined procedure. Refer to 5.4.5.2.

Published test methods shall be verified by the laboratory to demonstrate that it can achieve the expected results. Records of the verification shall be retained. For published

test method that does not include precision data, the laboratory shall determine its own precision data based on test data.

All methods shall include criteria for rejecting suspect results.

Note: Copyright laws may prohibit reproduction of standards in any form or by any means, electronic or mechanical, including photocopying and microfilm without permission from the publisher. Laboratory management shall be responsible for any related infringement thereof.

5.4.4 Non-standards methods

For new test methods, procedures should be developed prior to tests performed and should contain at least the following information as specified in the Notes under clause 5.4.4, PNS ISO/IEC 17025.

PAB will consider requests for accreditation for a test kit method provided that:

a. The laboratory has records of its own validation of the method for all applicable matrices against an appropriate standard method;

b. The laboratory is capable of using a standard confirmatory method in the event of dispute.

PAB does not provide accreditation to applicant laboratories using methods based on draft standards. Laboratories may, however, be accredited for such methods if such methods are documented and validated as laboratory-developed methods.

5.4.5 Validation of methods

5.4.5.2 Methods may be validated by comparison with other established methods using appropriate certified reference materials. In developing and validating test methods, the following parameters among others may need to be determined:

a. precision
b. accuracy
c. specificity
d. linear range
e. limit of detection
f. limit of quantification

The laboratory shall have documented procedures for method validation. The procedures need to include details of the statistical analysis to be applied when deriving precision data. Records of the application of these procedures shall be retained and will be reviewed at each assessment.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 The extent to which the estimation of uncertainty of measurement is applicable to and is required for a chemical testing laboratory performing its own calibration. . Refer to PAB Guidelines on Estimation of Uncertainty of Measurement in Testing (APLAC TC005) LA/GD05.

5.5 Equipment

5.5.5 For verifications done by the laboratory, records shall also include:

a. full details (including raw data) for each verification
b. identity of the calibrating officer

5.6 Measurement traceability

5.6.1 Test and calibration equipment that has significant effect on the reported results and associated uncertainties of measurement (including, where relevant, instrument used for monitoring critical environmental conditions) shall be calibrated by laboratories complying with the traceability requirements. Refer to LA/SR10, PAB Supplementary Requirements for Traceability of Measurements.

5.6.2.2 Testing

Reference standards (e.g. test weights) and equipment shall be calibrated over the range and to the appropriate level of accuracy specified in relevant test methods.

A laboratory performing its own calibrations shall be subjected to proficiency testing and technical competence confirmation based on ISO/IEC 17025 Clause 5, Technical Requirements.

5.6.3 Reference standards and reference materials

5.6.3.2 Reference materials

When the laboratory undertakes calibration of equipment using certified reference materials or reference materials developed through comparison with certified reference materials, it shall be able to demonstrate that it has:

a. sufficient reference materials to calibrate the relevant items of equipment over the desired measurement ranges;
b. full records of the identity and source of each reference material;
c. full documentation of the assigned values (and associated measurement uncertainty) of each reference material including details of the mode of validation;
d. taken all necessary precautions to match the matrices of the reference material to those encountered in the laboratory's test samples, or determined and accounted for the effects of any non-matching of matrices.

It is the responsibility of the laboratory to ensure that traceability of reference materials is demonstrated. It may well be necessary to verify at least the identity of the reference compound.

At the very least the following information shall be obtained for purchased reference material:

a. certified values (and associated uncertainties, if a certified reference material);
b. technique(s) by which the certified/assigned values were established;
c. date of certification;
d. period for which certification is valid;

e. storage condition

5.6.3.4 Transport and storage

Consumable materials shall be appropriately stored. Shelf-life of perishable materials shall be set, documented and applied.

The following details of standard solutions shall be recorded and retained along with other analytical data:

a. All raw data relating to preparation (weights, volumes, etc.);
b. result of standardization, if applicable (including standard curves);
c. date of preparation and an expiry date;
d. the identity of the person who prepared the solution

Likewise, each container of reagents and standard solutions shall be labelled with the date of preparation, the concentration, and the identity of the one who prepared the solution.

5.7 **Sampling**

5.7.1 **On-Site Sampling**

Sample containers shall be leak-proof and impervious to contamination during transport. Any temperature or other environmental tolerances specified in the method shall be satisfied during transport and storage. It may be necessary to test containers before use to ensure freedom from contamination.

Identification labels shall be secure and legible. Labelling on caps or lids alone is not acceptable because of the risk of wrongly replacing lids during testing like batches.

5.9 Assuring the quality of test results

5.9.1 Prior to gaining accreditation, applicant laboratories and inspection bodies (where relevant) must be able to provide evidence of satisfactory participation to PT within the last two years, for at least one testing parameter for each class of test structure, where PT is available and appropriate.

5.9.2 To maintain accreditation, laboratories and inspection bodies (where relevant) must be able to provide evidence of satisfactory participation to PT for all accredited tests/measurements per class of test structure within the validity period of accreditation.

Refer to LA/SR09, Supplementary Requirements on Participation to Proficiency Testing Programs for additional information relating to requirements on proficiency testing, where PT is available and appropriate. Tests/measurements not subjected to PT or any other quality assurance activities will be delisted during the Reassessment application (Renewal of Accreditation).

For infrequently performed techniques/tests, the laboratory shall carry out regular performance checks to demonstrate continuing competence to perform them and in order to maintain accreditation. Performance checks shall be conducted in accordance with an established quality control plan/ program. Records of these checks and their results shall

be kept with other quality control data and shall be available for examination during assessments.

5.10 Reporting the results

5.10.2 Test reports

PAB endorsement

Endorsed test reports are test reports which bear the PAB Accreditation symbol. Apart from the requirements specified in clauses 5.10.2 and 5.10.3, ISO/IEC 17025, the following information shall also be included:

1. The name of the laboratory in which accreditation is held,
2. The relevant accreditation number of the laboratory, and
3. The date of issue of the endorsed test reports.
4. A statement of the page number and the total number of pages (for multi-page test reports).

When a batch or consignment is sampled in accordance with a method included in the scope of accreditation, the PAB endorsement may be applied to test reports extending test results for samples to the batches or consignments from which they are drawn.

Additional details relating to the appropriate forms of endorsement and the reproduction of endorsed reports are provided in LA/SR11, Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol.

Approved signatories

Endorsed test report shall be signed by signatory/ies approved by PAB for the scope/ scopes indicated therein. Approved signatory/ies assumes the responsibility for PAB endorsed test reports on field tests carried out by other staff.

The use of signature stamps, photographic, electronic and/or mechanical means of reproduction of signatures or names of signatories for PAB endorsed test reports will be reviewed at assessments. Policy and procedure shall be established and implemented to demonstrate that the approved signatory authorized 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).

Additional details on personnel and approved signatories are provided in LA/GD07, PAB Guidelines for Laboratory Personnel and Approved Signatories.

6 References (for alignment to other PAb Supplementary requirements under revision)

6.1 PNS ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories

6.2 Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol, LA/SR11/Issue 01/Revision 01/01 May 2016

6.3 Supplementary Requirements on Traceability of Measurements, LA/SR10/Issue 01/Revision 01/01 May 2016

6.4 Supplementary Requirements on Participation to Proficiency Testing Programs, LA/SR09/Issue 01/Revision 02/ 07 ay 2016

6.5 Guidelines on the Estimation of Uncertainty of Measurement in Testing (APLAC TC 005), LA/GD 05/Issue 1/January 2015

6.6 Guidelines for Laboratory Personnel and Approved Signatories, LA/GD07/Issue 01/ Revision 0/ January 2015

6.7 AS 2929 Test methods – Guide to the format, style and content provides guidance on the documentation of test methods.

6.8 PNS ISO Guide 31 – Contents of certificates of reference materials

6.9 PNS ISO Guide 32 - Calibration in analytical chemistry and use of certified reference material

ISSUE AND AMENDMENT RECORD

Title	Issue	Revision	Date	Amendment
Supplementary Requirements for Accreditation of Chemical Testing Laboratories	01	00	January 2015	• Initial Issue
Supplementary Requirements for Accreditation of Chemical Testing Laboratories	01	01	01 May 2016	• Re-alignment of some changes to applicable clauses/ sub-clauses; • Changes in some terminologies; • Deletion of some items which are redundant and are already prescribed in PNS ISO/IEC 17025:2005; • Inclusion of some items on quality assurance re-PT participation, particular to chemical testing. • Inclusion of notes for regulatory/statutory requirements. • Inclusion of notes for action to be taken during surveillance visits.