Supplementary Requirements for Accreditation of Biological Testing Laboratories

Foreword

This Philippine Accreditation Bureau (PAB) Supplementary Requirements for Accreditation of Biological Testing Laboratories was developed by the Laboratory Accreditation Technical Committee (LATC) – Biological Testing to supplement ISO/IEC 17025 requirements by providing specific technical criteria and guidelines for both assessors and for laboratories carrying out biological testing.

3.8 Preventive Action: Action to eliminate the cause of a potential nonconformity or other undesirable potential situation, thus preventing occurrence of potential nonconformity.

3.9 Proficiency Test (PT) Samples: Test materials (split samples) with microorganisms that are tested periodically by a number of locations to determine that proficiency of recovery, using statistical analysis where appropriate.

3.10 Reference Cultures (RCs): A culture with characteristics sufficiently well established to be used to calibrate/verify test systems, and test media and to validate methods, e.g., cultures used for verifying test systems, and validation of methods; in addition to the use of "wild strains," quality control of test media shall also be traceable to a type culture collection.

Note: For some analyses, such as screening tests for high consequence pathogens, Reference Cultures are not available to the testing laboratory. In this case, a culture with suitable properties should be used as a reference. The required properties of this culture should be characterized by repeat testing, preferably by more than one laboratory.

3.11 Reference Stock Culture: A microorganism preparation that is derived from Certified Reference Cultures (CRCs).

3.12 Replicate Testing: Any analysis of laboratory sample performed more than once; the result of each individual analysis is a replicate test result.

3.13 Split Samples: Unknown test samples of adequate homogeneity, sub-sampled and analyzed separately within the laboratory or other different laboratories

3.14 Test Samples: Samples in the laboratory that are in the process of being tested (not to be confused with in-process product samples from a manufacturing standpoint.)

4. MANAGEMENT REQUIREMENTS

4.1 Organization

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.

4.2 Management System

4.2.1 Quality documentation shall include reference, approved signatories, scope of *accreditation and the policy on the use of the PAB endorsement.*

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

1. Introduction

All applicant Biological Testing Laboratories are required to meet this supplementary requirement in addition to the general requirements for the competence of testing and calibration laboratories ISO/IEC 17025. The numbering system of this Supplementary Requirements follows the numbering of ISO/IEC 17025.

This document describes additional, specific accreditation requirements for laboratories performing biological testing of food products (raw, in-process and processed products), ingredients in the production of food, veterinary products, human drugs, waters including effluents, cosmetics, biocidal agents, microbial cultures and environmental samples pertinent to the products/materials mentioned above.

Majority of the accredited biological testing laboratories are primarily involved in microbiological testing. However, this document can also provide guidance to laboratories using techniques in areas related to toxicology, veterinary science, biochemistry, molecular biology and cell culture, although there may be additional requirements for such laboratories.

2. Authorship

This document was prepared by the PAB LATC for Biological Testing. It is based on deliberation by the group of experts and stakeholders convened by the PAB.

3. Definitions

3.1 Certified Reference Culture (CRCs): Microbiological; a reference culture certified by technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body; e.g., cultures used for verifying test systems, validation of methods; quality control of test media must be traceable to a type culture collection.

3.2 Control Samples: A test sample with known properties of microorganisms examined on a routine basis to evaluate laboratory performance and to determine if their processes are in control.

3.3 Correction: Action to eliminate a detected nonconformity.

3.4 Corrective Action: Action to eliminate the root cause of a detected nonconformity or other undesirable situation, thus, preventing recurrence of nonconformity.

3.5 Culture: An isolated microorganism grown on laboratory medium.

3.6 Food Testing Laboratory: Laboratory that performs microbiological tests on finished food products, ingredients, in-process samples and associated environmental samples.

3.7 Inspection: Activities such as measuring, testing and examining one or more characteristics of a product or services and comparing these with specified requirements to determine conformity.

4.5 Subcontracting of Tests

4.5.1 A competent subcontractor is defined as an appropriate PAB accredited laboratory or a laboratory accredited by one of APLAC Mutual Recognition Arrangement (MRA) signatories. All results reported by the subcontractor shall be covered by an appropriate endorsed report

The accreditation status of subcontractors should be regularly reviewed to ensure its competency.

4.5.3 In case no PAB/APLAC-accredited subcontractor is available, the laboratory shall ensure that the chosen subcontractor complies with the ISO/IEC 17025 requirements, e.g. the subcontracting laboratory may conduct quality audit to check if the management and technical requirements of this international standard is being followed by the chosen subcontractor.

4.6 Purchasing Services and Supplies

Calibration Service Providers

Providers of calibration service shall be placed with a competent supplier. A competent supplier is any PAB accredited calibration laboratory, a calibration laboratory accredited by one of APLAC Mutual Recognition Arrangement (MRA) signatories or any recognized national metrology institute. In such cases wherein supplier is the sole service provider or there is no PAB/APLAC-accredited calibration service provider for particular equipment, the supplier shall demonstrate its traceability of measurement. Refer to LA/SR10 - Supplementary Requirements for Traceability of Measurements.

4.11 Corrective Action

4.11.1 The laboratory shall perform a timely investigation of nonconforming works or departures from policies and procedures. A time frame shall be defined in the laboratory's management system from detection of non-conformity to raising or generating a corrective action report (however named).

4.11.2 The cause analysis must be extensive enough so as to identify the root cause(s) and not simply the symptom(s).

4.11.4 Timely corrective action(s) shall be appropriate such that the root cause of the nonconformity is addressed and eliminated.

4.12 Preventive Action

Preventive action is a proactive process to identify opportunities for improvement, rather than a reaction to the identification of problems or complaints. Trend analysis of complaints and turn-around time of samples may assist this process. Consideration should also be given to providing staff with a formal mechanism for contributing suggestions for improvement.

4.13 Control of Records

4.13.4 General

4.13.1.4 Test records that are created and/or retained electronically (e.g. Compact Disc, DVD, Hard Disk Drive, USB Flash Drive, etc.) shall be stored in a manner that protects them from hazards that degrade such media. Provision shall be made for the printing of such records when required.

4.13.2 Technical records

4.13.2.1 All records shall include the identity of the person making the record and the date of such creation, the person(s) checking data transcriptions and calculations and the date of such checking. Appropriate checking shall be done, i.e. the person checking the records is not the same person who made/created them.

The records system shall include a copy of each report and certificate that includes work covered by the scope of accreditation, or shall allow one to be reproduced, including details such as the endorsement (if applicable) and identification of the person who authorized the report.

4.13.2.3 Alterations to data shall include the date the change was made. Corrections or amendments to test records are made in a manner that does not obliterate the original data and are signed or initialled and dated by the person responsible.

4.14 Internal Audits

The laboratory shall conduct an internal audit within a twelve-month period that covers both the management and technical requirements of ISO/IEC 17025.

For the minimum requirements, refer to LA/GD 15 – Guidance Document for Internal Audits for Laboratories and Inspection Bodies (APLAC TC 002).

4.15 Management Review

The laboratory's management shall review the effectiveness of the management system and testing activities at least once per year.

For the minimum requirements, refer to LA/GD 16 – Management Review for Laboratories and Inspection Bodies (APLAC TC 003).

5. TECHNICAL REQUIREMENTS

5.2 Personnel

5.2.1 Staff competence and technical control

5.2.1.1 The minimum qualification for the technical staff in a biological testing laboratory shall be a graduate in Biology /Microbiology/ Food Science/ Pharmacology/ Biotechnology/

Biochemistry/ Toxicology/Veterinary Science/Medical Technology. Alternative qualifications in biological sciences may meet requirements where staff has relevant training and experience relating to the laboratory's scope of accreditation.

5.2.1.2 The laboratory shall be under the supervision of a trained, competent supervisor having at least two years relevant laboratory experience for graduates of microbiology/biology major in microbiology and three years relevant laboratory experience in microbiological work for graduates of biomedical sciences and/or food sciences.

5.2.1.3 Any testing away from the base laboratory (such as in field laboratories, mobile testing laboratories or in the field) shall be under adequate technical control. This would normally require either the location of an approved signatory at each facility or having an approved signatory visit each facility at least once each week and maintain a diary record of the dates and relevant activities of each visit.

5.2.1.4 In case testing requires visual observation (e.g. color retention), laboratory management shall consider color vision as one of its qualification when determining the suitability of staff to perform such tests.

5.2.1.5 PAB Approved signatory shall meet the following requirements:

- Shall have relevant laboratory experience and have conducted at least 30 completed tests that are positive for the target organism in at least five samples (5) per matrix (based on class of test structure LA/GD10) being tested by the laboratory, and have participated in proficiency testing with satisfactory rating in at least one parameter applied.

  Note: For parameters with no existing PT provider, other suitable means in assuring the quality of tests may apply.

- The competence of approved signatory will be assessed and approved by the PAB once he/she meets the requirements. Consideration in minimum qualification, training and experience requirements for approved signatory on competence with objective evidences for proven competency may be considered by PAB upon recommendation by the assessment team.

5.2.2 The laboratory shall have a selection procedure and training system to ensure technical competence of all staff members.

5.2.2.1 Training shall include all methods or portions of methods and techniques that each person is responsible for performing. At a minimum, each analyst shall demonstrate competency for each parameter being applied for through observation by management and verification using replicate and/or check samples. For technicians performing only portions of a specific method, competency may be confirmed/ verified by observation only.

5.2.2.2 Competence shall be monitored at least annually with provision for re-training where necessary. For infrequently performed techniques/tests, the lab shall carry out regular performance check to demonstrate continuing competence. Performance checks shall be conducted in accordance with an established program.