LA/SR01 – Supplementary Requirements on Participation to Proficiency Testing Programs

Foreword

This Philippine Accreditation Bureau (PAB) Supplementary Requirements on Participation to Proficiency Testing (PT) Programs was developed to provide specific criteria as supplement on the use of PT activities in achieving and maintaining accreditation of laboratories and, where relevant, inspection bodies.

1. Terminology

1.1 Proficiency Testing (PT): Evaluation of participant's performance against pre-established criteria by means of interlaboratory comparison.

1.2 Interlaboratory Comparison (ILC): Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions.

1.3 Internal Quality Control (IQC): In-house procedures for continuous monitoring of operations and systematic day-to-day checking of the generated data to decide whether these are reliable enough to be released.

1.4 Major Areas: Area of technical competence defined by a minimum of one measurement technique, property and product, which are related.

1.5 Measurement technique: The process of testing/calibrating/identifying the property, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device.

1.6 Property: The quantity being measured.

1.7 Product: The item that the measurement technique is being applied.

2. General

ISO/IEC 17011 forms the basis of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) between accreditation bodies; it shall be adopted by accreditation bodies as part of their general rules of operation. Hence, PAB, as a signatory to the ILAC MRA, is required to have a policy regarding the participation of its accredited laboratories in PT activities [(6)].

ISO/IEC 17025[(1)] requires laboratories to have quality control procedures for monitoring the validity of tests and calibrations undertaken. Monitoring shall be planned and reviewed and may include participation to interlaboratory comparisons or proficiency testing programs. ISO 15189[(2)] also requires participation in suitable interlaboratory comparison such as those organized by external quality assessment schemes. Where applicable, ISO/IEC 17020[(3)] provides requirements for the operation of various types of bodies performing inspection.

It is recognized that PAB may take into account the suitability of test data produced from other activities apart from participating to PT programs due to technical characteristics of the measurement, the lack of PT schemes, the low number of existing laboratories on the particular field, etc. In these cases, laboratories are required to provide objective evidence of other suitable means to demonstrate technical competence. This may include but are not limited to the following:

- Regular use of Certified Reference Materials (CRMs)
- Comparison of analysis by independent techniques
- Use of internal quality control measures
- Participation in method development/validation and/or reference material characterization studies
- Other Inter/Intra-laboratory comparisons

It is important for both the assessors and laboratories carrying tests or measurements to have a clear understanding of PAB policies and procedures for PT participations and results from proficiency tests.

3. Establishing the Validity of Proficiency Testing

3.1 The laboratory shall participate in at least one (1) PT for each major area which accreditation is being sought. The validity of PT participation shall be maximum of two (2) years prior to application for accreditation.

3.2 Applicant laboratories and inspection bodies (where relevant) seeking PAB accreditation shall be able to provide evidence of satisfactory participation to PT where PT is available and appropriate, prior to gaining accreditation. Applicants should enrol in suitable PT programs as early as possible to ensure that the completion of accreditation process is not delayed.

Note: On a case to case basis, evidence of satisfactory PT participations may not be required for the purpose of achieving initial accreditation as determined by the assessors and provided that other suitable means to demonstrate technical competence is in place.

3.3 Proficiency testing programs shall be appropriate for the type and volume of work undertaken.

Laboratories and inspection bodies (where relevant) shall conduct proficiency tests in accordance with their normal tests or measurements and reporting procedures, unless otherwise specified in the instructions from the proficiency testing provider.

3.4 PT may be used in some types of inspection where available and justified by the inclusion of testing activities that directly affect and determine the inspection result or when required by law or regulators. It is recognized that proficiency testing is not a usual and expected element in the accreditation of most types of inspection.

3.5 Accredited laboratories and inspection bodies (where relevant) shall identify and participate in major area of tests, measurements or related activity for which accreditation is being maintained within the validity of accreditation, where such programs are available.

3.6 Accredited laboratories shall formulate a PT participation plan for each major area of tests or measurements covered by the scope of accreditation. The plan shall be regularly reviewed and updated by the laboratory in response to any changes in staffing, methodology, instrumentation, etc. The plan shall be in the form of matrix (see Annex 1 for the sample PT plan) which indicate the following:

a. How the plan covers the scope classification based on the approved scope of accreditation;

b. The type of PT activities planned for each identified major area of tests or measurements within the validity of accreditation. The details shall include the following, as appropriate:

- The name of the PT programs or any other inter-laboratory comparison activities the laboratory plans to undertake,
- The date and frequency of participations,

- Where no PT activities are available or appropriate, other suitable activities the laboratory plans to undertake to demonstrate technical competence, including the dates and frequency.

3.7 During PAB on-site assessment, the assessors shall review the plan and check the implementation with evidence of satisfactory participation in each major area of tests or measurements covered by the scope of accreditation. The laboratory shall provide evidence to the assessment team that it has successfully participated in PT programs according to the plan.

4.0 Selection of Proficiency Testing Programs

4.1 Proficiency testing should be provided by PT providers, which are accredited to ISO/IEC 17043 whenever possible. It is the responsibility of the laboratory to check the availability of appropriate PT program which corresponds to their day to day activities and select the programs in which to participate. The laboratory shall check the accreditation status of its PT providers. Where none is available, ISO/IEC 17043 should be used as criteria for evaluation of competence.

The laboratory or inspection body may select any one program from APAC PT 03- APAC Proficiency Testing Directory. This list is not exhaustive and is constantly revised to include new programs. ILAC has endorsed the use of European Information System on Proficiency Testing Schemes (EPTIS) database for use by laboratories. This database may be accessed by http://www.eptis.bam.de.

4.2 Where accredited or other PT providers are not available for relevant tests or measurements, acceptable options could include the following:

Interlaboratory Comparison

a. This program is done among similar laboratories or any interested laboratories using artefacts or samples commonly tested/ calibrated at comparable level of competence.

b. This program shall be organized by an independent party to ensure objectivity.

Intralaboratory Comparison

a. This program involves a comparison study of one or more methods by multiple analysts/technicians in the laboratory system. The degree of satisfactory agreement among participants shall be recorded and reviewed properly.

b. This program shall include a comparative study of one or more tests or calibrations in comparison with a competent or high-end laboratory or institute. Baseline for satisfactory agreement shall be included.

The framework of ISO/IEC 17043 should be used for both variations to the extent possible. Proper design for PT program is required to ensure its success and smooth operation. The staff involved in providing the possible program shall have adequate qualifications and experience to design the implementation and reporting of results.

Acceptability of such programs will be based on the design of the program, its frequency, the suitability of the samples, and defined written criteria for data analysis and corrective action. The program design must be submitted and approved by PAB

prior to its execution.

Measurement Audit

a. Measurement audit refers to a practical test whereby a well-characterized and calibrated test item (artefact) is sent to a laboratory and the results are compared with a reference value (usually supplied by NML).

b. Where suitable artefacts exist, measurement audits shall be conducted to a laboratory applying for accreditation or significantly extending its scope of accreditation. Measurement audits may also be implemented for the evaluation of applicant PAB signatories or where laboratories due for reassessment have not recently participated in a proficiency testing activity in a particular field. Measurement audit may also be conducted for a calibration laboratory which exhibited an outlying result in an inter-laboratory comparison.

c. Procedures are the same as for a normal inter-laboratory comparison except that usually, only a simple report is generated (see Annex 2 for the Measurement Audit Procedure).

5.0 Performance Evaluation

5.1 The selection of PT programs, results of participation and any corrective action taken in response to unsatisfactory results shall be reviewed by PAB during on-site assessments. The laboratory shall keep all the records of all the PT programs it has participated.

The laboratory shall ensure that appropriate acceptance criteria are defined in case it utilizes other suitable means of quality assurance activities.

5.2 The laboratory shall review their performance for every PT participation or other quality assurance activities. Its performance provides information on the laboratory's overall capability to generate valid test/calibration/inspection data. If performance has unsatisfactory results, the laboratory shall promptly conduct an investigation to review its technical competence and shall prepare a corrective action. This will be reviewed during on-site assessment.

Any unresolved issues during the assessments shall be elevated to appropriate Technical Committees.

5.3 If the investigation results to cast doubt on the technical competence and quality management system, the laboratory shall inform PAB within a month and submit the result of the investigation and the corrective action taken. This includes all other proficiency evaluations (including internal performance-based checks, etc.) successive failures, failure to participate or patterns of erratic results. PAB shall review the submission and decide either the corrective action taken is acceptable as it resolves the finding or takes further action such as:

a. Participation to another interlaboratory comparison or proficiency testing program;
b. Undertaking a partial or full reassessment of the laboratory; or
c. Suspension of all or part of laboratory's scope of accreditation.

6.0 Confidentiality

All information supplied by the laboratory/inspection body as part of a proficiency-testing program is treated with confidentiality. This information will however be made available to the assessor(s) of the laboratory/inspection body, and if needed, to technical experts and/or members of the Technical Committees.

7.0 References

1. ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories

2. ISO 15189:2012 – Medical Laboratories – Particular Requirements of Quality and Competence

3. ISO/IEC 17020:2012 – General Criteria for the Operation of Various Types of Bodies Performing Inspection

4. ISO/IEC 17011:2017 – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

5. ISO/IEC 17043:2010 – Conformity Assessment: General Requirements for Proficiency Testing

6. ILAC P9:06/2014 – ILAC Policy for Participation in Proficiency Testing Activity

Annex 1: Sample Proficiency Testing Plan

Laboratory / Inspection Body Name: ABC						
Accreditation Number: LA-XXYY-AAAL						
Field:						
Major Areas	**Specific Test or Measurement**	**Covered Scope of Accreditation** *(refer to class test structure per field)*	**Details of Proficiency Testing Provider/ Other Programs**	**Proposed Date of Participation**	**Status**	**Remarks**
Environmental	Determination of Arsenic in Soil using ICP-MS	2.36 Constituents of the environment (.04 Soils)	Determination of As in environmental sample (Provider: DEF Company)	June 2016	Participated: June 2016 (Satisfactory)	
Length	Gauge block	5.07 Length and angle standards (.04 Gauge block and accessories)	Interlaboratory Comparison on Gauge Block (NML)	July 2016	Participated: August 2016 (Satisfactory)	

Annex 2: Measurement Audit Procedure

1. The laboratory shall officially inform PAB through writing a letter of request indicating the instrument, range to be calibrated, declared Calibration Measurement Capability (CMC) value, and the reference laboratory prior commencing the process.

2. The participating laboratory should ensure that the reference laboratory has accreditation to ISO/IEC 17025 and can achieve a CMC value that is better than its declared value.

3. A reference laboratory can also be outside from its own economy. A normal calibration request to a calibration service provider may be required. Further instruction will be given if the artefact will be provided by the reference laboratory.

4. An endorsement letter from PAB will be given if the reference laboratory meets the set requirements and confirm the measurement audit process. Participating laboratory should wait for PAB approval.

5. Participating laboratory are required first to send a copy of their calibration result to PAB before they send the artefact to the reference laboratory. Then, the reference laboratory should send the calibration certificates and measurement audit report to PAB. All results of evaluation and other related documents shall be given to PAB.

6. In cases where the reference laboratory does not evaluate the results, all the calibration data both from the participating and reference laboratory (i.e. calibration certificate, the data worksheets and reports of uncertainty) shall submit to PAB and shall evaluate by a technical assessor/expert.

7. If results show not a 100% satisfactory or have outliers and other anomalies identified in the measurement audit report, the laboratory shall conduct an investigation and corrective action. Effectiveness of actions taken will be reviewed during assessment. Suspension or withdrawal of affected scope of accreditation for the measurement involves may consider for the unsatisfactory results.