Supplementary Requirements for Accreditation of Mechanical Testing Laboratories

Foreword

This Philippine Accreditation Bureau Laboratory Accreditation Supplementary Requirements for Accreditation in the Field of Mechanical Testing was developed by the Laboratory Accreditation Technical Committee (LATC) for Mechanical Testing to provide clear technical criteria and guidelines for mechanical testing laboratories covered by the PAB.

In the preparation of this document, substantive reference was made to the Supplementary Requirements for Accreditation in the Field of Mechanical Testing 2002 Version 1 of the National Association of Testing Authorities, Australia and other relevant documents.

The numbering in the texts of this document follows the PNS ISO/IEC 17025:2005 numbering of requirements.

1 INTRODUCTION

All laboratories conducting mechanical testing are required to meet the supplementary requirements in addition to the general requirements for the competence of testing and calibration laboratories, PNS ISO/IEC 17025:2005.

2 AUTHORSHIP

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

3 DEFINITIONS

3.1 Permanent Laboratory: A testing laboratory situated on a fixed location for a period expected to be greater than three years.

3.2 Site Laboratory: A testing laboratory facility set up in a dedicated area on-site for the duration of the testing activities but not for periods expected to exceed three years.

3.3 Field Laboratory: A testing laboratory facility set up in a dedicated area on-site for the duration of the testing activities but not for periods expected to exceed three years.

3.4 Mobile Laboratory: Fully equipped, self-contained, transportable testing laboratory capable of performing testing 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.

4 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.1 Particular care shall be taken to ensure adequate supervision of personnel undertaking tests at its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities. A program of on-site audits must be developed and implemented. Refer to clause 4.13 for details of audits.

4.1.2 To assure impartiality and that its personnel are free from any undue commercial, financial or other pressures which might influence their technical judgement, clear policies on the responsibilities of all laboratory personnel and its key staff shall be defined to avoid potential conflict of interests. If the laboratory wishes to be recognized as a third-party laboratory, it should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities

4.2 Management System

Management system documentation must include or make reference to approved signatories, terms of accreditation and the policy on the use of the PAB endorsement.

4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall have documented procedures and records regarding alterations on request or tender and contract. There should be a proof that the customer conforms to the alterations made in the contract.

4.5 Subcontracting of Tests and Calibrations

This clause applies in those 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 the need for further expertise and the results of the subcontracted service(s) are incorporated into the laboratory's test reports (refer also to 5.10.6)

4.5.1 A competent subcontractor is defined as a testing or calibration laboratory that complies with the requirements of the current PNS ISO/IEC 17025 and its supplementary requirements appropriately accredited by PAB or by PAB MRA partners.

4.5.4 The accreditation status of subcontractors should be regularly reviewed by the laboratory to ensure currency.

4.9 Control of nonconforming testing and / or calibration work

When recall of test certificate is required, intermediate checks of measuring equipment shall be verified during the assessment.

4.12 Preventive Action

Preventive action is a proactive process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints. Total quality management tools such as brainstorming, flowcharting, Pareto charts etc. 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

4.13.1 General

4.13.1.1 All records must include the identity of the person making the record.

4.13.1.2 Unless otherwise prescribed by legislation or contractual obligation, retention times will not be less than one year.

4.13.2 Technical records

4.13.2.1 The records system must include a copy of each original worksheet, report, and certificate that includes work covered by the scope of accreditation, or must 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 must also include the date the change was made.

4.14 Internal Audit

The internal audits schedule shall cover all elements of the management system over a twelve-month period. It is recommended that the internal audits should be conducted before any PAB assessment is made. Refer to PAB LA/GD15 Internal Audits for Laboratories and Inspection Bodies (APLAC TC 002).

4.15 Management Reviews

Management shall review at least once per year the effectiveness of the management system. Refer to PAB LA/GD16 Management Review for Laboratories and Inspection Bodies (APLAC TC 003).

5 TECHNICAL REQUIREMENTS

5.2 Personnel

The technical management group shall compose of the following:

a) Technical Manager – shall have completed a Bachelor's degree and must have a minimum of three years experience related to the laboratory's field of testing.

b) Technical staffs / Test engineers / Analysts - shall have completed a Bachelor's degree or a graduate of technology course with minimum of one year experience related to the laboratory's area of activity.

5.3 Accommodation and Environmental Conditions

Many test methods require samples to be exposed to periods of standard conditions. In general laboratories shall comply with these in all aspects. Records on monitoring environmental conditions shall be available in the laboratory, either in its permanent or associated temporary or mobile facilities, during assessment.

If conditioning requirements are not met due to unforeseen circumstances, records and reports must identity the conditions, and also state that the conditioning requirements of the test method were not met. Merely reporting the actual conditions is not sufficient, as this can imply that the conditioning requirements were met.

5.4 Test and Calibration Methods and Method Validation

5.4.2 Selection of methods

Where a test can be performed by more than one method there must be documented criteria for method selection. Where relevant, the degree of correlation between the methods must be established and documented.

Laboratories accredited for testing to standard test methods must maintain records of all interpretive decisions which they may make a response to ambiguities in the test methods or specification contained in Standards.

Laboratories must make all reasonable efforts to ensure that interpretations made are consistent with those of other laboratories and regulatory authorities. Other laboratories accredited for the same test should also be consulted. Attendance at relevant forum where such interpretations are discussed is strongly encouraged.

In some circumstances PAB may impose additional requirements on standard test methods. This action is only taken where testing in accordance with the stated requirements of a standard is likely to cause an inappropriate interpretation of the results appearing in a PAB endorsed test report and thereby bring the PAB in disrepute. Such a requirement would only remain in place until the standard was appropriately amended.

5.4.3 Laboratory-developed methods

Accreditation for draft laboratory-developed method is not available. Laboratories may however be accredited for such methods if they are documented and validated as laboratory-developed methods.

In some instances the unique nature and configuration of the item under test precludes the use of standard testing methods except in the most general terms (e.g. proof tests upon lifting equipment). It is possible to hold accreditation for a generic test method provided that the method can demonstrate the following:

a) the relevant criteria listed in the current ISO/IEC 17025 clause 5.4.4 are met for each job;
b) an appropriately qualified officer (e.g. an engineer) has undertaken a technical review of the job plan; and
c) the job plan is accepted by the customer, if applicable.

5.4.5 Validation of methods

In some areas of mechanical testing it is difficult to validate a test method. At the very least, details of the action taken to ensure the test results are repeatable and reproducible must be kept.

When the laboratory is performing “type” test that demonstrate the typical performance of a design, model or version, the following conditions apply, where possible:

a) manufacturer’s drawings must be supplied with the item;
b) the item under test must be described in sufficient detail to distinguish it from possible variants. The use of photographs, blueprints or drawings is recommended;
c) compliance of the item with the manufacturer’s drawings must be established;
d) the origin of the item (e.g. “Supplied by importer”) must be reported.

Validation data must be retained and available for review at assessment.

5.4.6 Estimation of uncertainty of measurement

5.4.6.2 Where results of tests are not numerical (e.g. pass/fail, positive/negative, detected/not detected or other qualitative data) estimates of uncertainty or other variability estimates will not be required at this stage. However, laboratories are encouraged to have an understanding of the variability of all their results where this is possible.

Laboratory staff, however, should consider the requirement in any review or new validation/verification carried out in relation to the testing methods. Consideration should at least be given to the key components that will contribute to the estimation of the uncertainty of test results. Progress in relation to this activity will be discussed during the assessment.

5.6 Measurement Traceability

5.6.1 General

Test and calibration equipment that has a significant effect on the reported results and associated uncertainties of measurements (including, where relevant, instruments used for monitoring critical environmental conditions) shall be calibrated by PAB recognized calibration laboratories. Refer to LA/SR10, Supplementary Requirements for Traceability of Measurement.

5.6.2 Specific requirements

5.6.2.2 Testing

Reference standards 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 may also be subjected to proficiency testing and technical assessment to ensure that all the relevant requirements of the current ISO/IEC 17025 are met (e.g. adequately documented procedures, procedures to estimate the uncertainty of measurement, complete records of calibration data) in relation to the calibration.

5.6.3 Reference Standards and Reference materials

5.6.3.3 Intermediate Checks

Equipment that does not use standard reference materials before conducting the test shall be verified at least twice prior to the next calibration schedule.

5.7 Sampling

Laboratories responsible for sampling are encouraged to gain accreditation for sampling. The following conditions must be met to gain accreditation for sampling.

a) documented sampling procedures must be held. These may be national or international standards. If in-house methods are used, their validity for the intended purpose must be demonstrated by appropriate data;

b) the sampling procedure must be cited on the test report whenever the laboratory wishes to extend the test results from a sample to an entire batch.

5.9 Assuring the Quality of Test and Calibration Results

See also PAB Supplementary Requirements on Participation to Proficiency Testing Programs, LA/SR09 for additional information relating to the requirement on proficiency testing.

The program for monitoring the reliability of test results must include criteria for rejecting suspect results. Factors that influence the design of the program include the availability of reference materials, the nature and range of the test, and the number of testing itself.

Quality control data must be fully documented in such a way that they are readily accessible for evaluation of trends in analysis, and these trends must be monitored with appropriate action being taken when necessary.

In general, the laboratory must carry out regular (e.g. every 1 to 3 months depending on the technique/test) performance checks on techniques/tests seldom conducted to demonstrate continuing competence to perform them in order to maintain accreditation. Records of these checks and their results must be kept with other quality control data and must be available for examination during assessments. Each accredited laboratory should include a list of techniques/tests that are subject to performance checks in their documentation. This must be approved by PAB upon assessment and will serve as basis for checks on succeeding PAB audits. This will prevent witch hunt later.

5.10 Reporting the Results

5.10.2 Test reports and calibration certificates

Laboratories are required to meet PAB LA/SR11 on endorsement of tests or calibrations.

In general, approved signatories are expected to apply their signatures in manuscript. The use of photographic, electronic and mechanical means of reproduction of signatures or names of signatures may be approved in writing by the PAB following receipt of a written submission. This approval may also be granted following review of the procedures in place at an assessment.

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

PAB endorsement

Accredited laboratories are encouraged to apply the PAB LA endorsement for tests covered by their accreditation.

Endorsed test documents must include the information (a) – (k) detailed in this clause of ISO/IEC 17025. Additional details relating to the appropriate forms of endorsement and

the reproduction of endorsed test reports are provided in LA/SR11: Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol.

Approved Signatories

The test document must be signed by a PAB approved signatory. Please refer to LA/GD 07: Guidelines for Laboratory Personnel and Approved Signatories and LA/SR11: Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol.

Unendorsed reports and Partial reports

An accredited laboratory may issue unendorsed documents reporting results within and outside its scope of accreditation or may issue partial test reports prior to final endorsed test reports. The final test report shall contain a reference to the partial test report. For information related to this cases, please refer to LA/SR11: Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol.

Electronic Signatures

The electronic report should show the identity of all the signatories in the original test report. This may involve an electronic signature. The security of these signatures should be such as to prevent inadvertent use or misuse.

5.10.3 Test reports

5.10.3.1b) Statements of Compliance

If the results of a test or calibration fall into the range where neither compliance nor non-compliance can be proved, taking into account the estimated uncertainty of the measurements, then the result and its associated measurement uncertainty shall be reported. A compliance statement may be made if the test specification:

- Limits the major uncertainty components by prescribing specific types and classes or accuracies of measuring equipment and the test method and prescribes acceptance limits for test/measurement results, provided that the results meet the acceptance limits; or
- Specifies numerical limits on the uncertainty of measurement and prescribes acceptance limits for test/measurement results, provided that the results meet the acceptance limits and the specified uncertainty limits have not been exceeded; or
- Specifies numerical limits on actual values, provided that the results fall within the specified limits by an amount at least equivalent to the uncertainty of measurement.

Compliance statements shall indicate those sections or clauses of the test specification to which the compliance statement relates.

The uncertainty of measurements shall be reported whenever there is an acceptance criteria for the specific test performed.

5.10.5 Opinions and interpretations

In accordance with PAB policy, endorsed test documents must avoid the inclusion of interpretations and expressions of opinion.

5.10.7 Electronic transmission and remote issue of results

Test reports may be electronically issued (including from a site other than the accredited laboratory) provided that the reports have been appropriately authorized for release. The adequacy of such arrangements will be reviewed at assessment.

Endorsed documents may be issued from a site other than the accredited laboratory provided they bear:

a) the signature, facsimile signature or typescript name of an approved signatory;
b) the signature of a checking officer at the issuing location, approved for this purpose.

Copies of the documents shall be retained at the issuing site and at the laboratory.

The laboratory must be able to demonstrate appropriate controls over the electronic generation, access, storage and back-up of results and reports and program controls such as password protection. If the report is to be accessed from a website by the client there must be an appropriate control in place to ensure the report can only be downloaded in a protected format.

Printing issues may also need to be considered. Any information normally included in a hardcopy report must be included on the electronically transmitted version and appear in any hard copy printed by the recipient. Flexible pagination to accommodate formatting changes when printed by the recipient may also be required.

6 References

6.1 Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol, LA/SR11/Issue 1/January 2015

6.2 Supplementary Requirements on Traceability of Measurements, LA/SR10/Issue 1/January 2015

6.3 Supplementary Requirements on Participation to Proficiency Testing Programs, LA/SR09/Issue 1/January 2015

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

6.5 Guidelines for Laboratory Personnel and Approved Signatories, LA/GD07/Issue 1/January 2015

ISSUE AND AMENDMENT RECORD

Title	Issue	Date	Amendments
Supplementary Requirements for Accreditation of Mechanical Testing Laboratories	01	January 2015	Initial Issue