LAS-Q008

Proficiency Testing Requirements for Testing and Calibration Laboratories

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PROFICIENCY TESTING REQUIREMENTS

FOR

TESTING AND CALIBRATION

LABORATORIES

1.0 INTRODUCTION

1.1 The assurance of the quality of test and/or calibration results, including medical examination results, is a requirement for accreditation as stated in ISO/IEC 17025 and ISO 15189. The monitoring of the technical performance of tests and calibrations, including medical examinations, can be done using interlaboratory comparisons (ILCs) or proficiency testing programmes (PTs). The regular use of reference materials (RMs), replicate testing or calibrations, also provide other means for a laboratory to demonstrate its competence. TTLABS considers participation in ILCs and PTs an important tool for demonstrating laboratory technical competence.

2.0 SCOPE

2.1 This policy is applicable to all applicant and accredited laboratories.

3.0 DEFINITIONS

3.1 Proficiency Testing (PT) – evaluation of participant performance against pre-established criteria by means of externally-managed interlaboratory comparisons.

3.2 External Quality Assurance (EQA) – a system for objectively checking the laboratory's performance using an external agency or facility.

3.3 Interlaboratory Comparison (ILC) – organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.4 Reference Material (RM) – material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

4.0 POLICY

4.1 PT PROGRAMMES OR EQUIVALENT

4.1.1 All laboratories that seek to become accredited and to maintain their accreditation status shall participate in PT programmes or ILC schemes.

4.1.2 Technical competence can also be demonstrated by successful participation in interlaboratory comparisons that have been organised for purposes other than PT in its strictest sense, for example:

- to evaluate the performance characteristics of a method;

- to characterise a reference material;
- to compare results of two or more laboratories on their own initiative; and,
- to support statements of the equivalence of measurement of NMIs.

4.2 LISTING OF PT PROVIDERS

4.2.1 TTLABS advocates the use of the EPTIS database for sourcing authorized PT programmes.

4.2.2 The Ministry of Health of Trinidad and Tobago, has endorsed the OneWorld Accuracy PT programme and has partnered with TTLABS to ensure PT programmes are available for local medical laboratories. Further information can be accessed on the TTLABS page at www.ttbs.org.tt.

4.2.3 ISO/IEC 17025 and ISO 15189 require laboratories to evaluate suppliers, which includes PT providers. ISO/IEC 17043 contains criteria for the competence of PT scheme providers. This International Standard is recognised as the acceptable basis for such an evaluation. Accredited PT scheme providers have demonstrated satisfaction of this International Standard based on their specific scopes of accreditation.

4.3 DOCUMENTED LABORATORY PT PLAN

4.3.1 Laboratories shall formulate and document a plan for the level and frequency of participation in PT, the plan shall be regularly reviewed in response to changes in staffing, methodology, instrumentation and scope. Laboratories should refer to the EA Publication EA 4/18 TA Guidance on the level and frequency of proficiency testing participation for further guidance on how to establish a plan.

4.3.2 Laboratories must be prepared to justify their plan and approach to both frequency of participation and any non-participation in readily available PTs that are appropriate.

4.3.3 The laboratory should define its level and frequency of participation after careful analysis of its other QA measures (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The participation should be made dependent on the extent to which other measures have been taken. Other types of QA include, but are not limited to:

- regular use of reference materials;
- comparison of analysis by independent techniques;
- participation in method development/validation and/or reference material characterisation studies;
- use of internal quality control measures; and
- other inter/intra – laboratory comparisons e.g. analysis of blind samples within the laboratory.

4.3.4 Applicant laboratories or those wishing to extend their scope of accreditation must have performed satisfactorily in the PT and/or ILC Schemes covering their proposed scope of accreditation before accreditation can be granted.

4.3.5 Where no appropriate PT or ILC is available, laboratories are required to demonstrate the on-going validity of their tests by other means such as but not limited to the use of reference materials, and replicate testing.

4.3.6 Laboratories are required to have appropriate acceptance criteria (normally those used by the scheme provider) and a procedure for investigating flagged (or anomalous) results and carrying out appropriate corrective/preventive actions. Laboratories are also required to monitor and review their on-going participation and performance and to monitor trends in results as appropriate

NOTE PT shall be performed by the applicant or accredited laboratory and shall not be subcontracted to other laboratories.

5.0 REFERENCES

5.1.1 JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

5.1.2 ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing

5.1.3 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

5.1.4 ISO 15189 Medical laboratories – Requirements for quality and competence

5.1.5 World Health Organisation International Health Regulation Laboratory Quality Management System training toolkit Chapter 10 – Assessment – External Quality Assessment (EQA) http://www.who.int/ihr/training/laboratory_quality/10_b_eqa_contents.pdf

5.1.6 ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities

5.1.7 EA-4/18 INF: 2010 Guidance on the level and frequency of proficiency testing participation http://www.european-accreditation.org/publication/ea-4-18-inf-rev00-june-2010-rev