Guidance on Proficiency Testing / Inter-laboratory Comparisons

May 12, 2012

Table of Contents

Purpose

The purpose of this guidance document is to further convey the ACLASS proficiency testing/inter-laboratory comparison requirements. This document is intended to give ACLASS customers, assessors, and experts the necessary understanding of proficiency testing/inter-laboratory comparisons in order to achieve and/or maintain accreditation to ISO/IEC 17025.

This guidance document applies to all applicant and accredited ACLASS customers.

Definitions

Proficiency testing (PT): The determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body against pre-established criteria by means of inter-laboratory comparison.

Inter-Laboratory Comparisons: The organization, performance, and evaluation of calibration/test results for the same or similar item by two or more laboratories in accordance with predetermined conditions.

Major Discipline: Defined as Calibration and Testing

Major Sub-Discipline: Parameters falling within the two major disciplines of Calibration and Testing as shown in listings in the *ACLASS Guidance for Scopes of Accreditation*. Some examples of calibration major sub-disciplines include: Dimensional, Electromagnetic-DC/Low Frequency, Mechanical, and Thermodynamic. Some examples of testing major sub-disciplines include: Environmental-Soil, Environmental-Air, Chemical-Organic (or Inorganic), etc.

ACLASS PT/ILC Requirements

ISO/IEC 17025 requires that laboratories have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in inter-laboratory comparisons or proficiency testing programs. Other means may include the regular use of reference materials, or replicate tests or calibrations using the same or different methods. By these mechanisms a laboratory can provide evidence of its competence to its clients, interested parties, and the accreditation body.

ACLASS requires that any laboratory applying for accreditation show evidence of successful participation in relevant proficiency testing where available prior to granting of initial accreditation. If proficiency testing is not available for a particular measurement discipline or parameter through existing proficiency testing programs, alternatives may be considered including internal performance-based data demonstrating laboratory competence and measurement performance, if possible, in comparison with another laboratory entity. These alternatives may be substituted for the traditional proficiency testing programs, which could allow a laboratory to achieve initial

accreditation and still meet the ACLASS requirement. These alternate plans must be approved by an ACLASS Accreditation Manager.

Laboratories accredited by ACLASS are encouraged whenever possible to select proficiency testing providers that can demonstrate their programs are accredited to ISO/IEC 17043, *General requirements for proficiency testing*. Where appropriate accredited proficiency testing providers are not available or do not provide a meaningful offering, laboratories should use programs that operate in accordance with ISO/IEC 17043 as fully as possible.

As defined in ACLASS Document #3 for ISO/IEC 17025, each accredited laboratory will be expected to participate in a minimum of one proficiency test/inter-laboratory comparison where available for each major sub-discipline of major disciplines of the laboratory's scope of accreditation at least every four years. Participation in at least one proficiency test/inter-laboratory comparison is required prior to the granting of accreditation.[1] Regardless of the number of sub-disciplines on a laboratory's scope, the minimum participation required is once per calendar year.

Any laboratory that is unable to locate a suitable proficiency test provider or requires assistance in the selection thereof, should contact one of the ACLASS Accreditation Managers for assistance. ACLASS maintains a link on its website (www.aclasscorp.com) listing several commercial proficiency test providers; however, no warranty or approval is designated for any specific provider. Each accredited lab is responsible to adhere as best as possible to the requirements of ISO/IEC 17025 and the guidance of ISO/IEC 17043 in this matter.

ACLASS assessors review and tentatively approve proficiency testing/inter-laboratory comparison programs individually with laboratories before and during each visit. ACLASS Accreditation Managers have oversight authority to review and finally approve each proficiency testing/inter-laboratory comparison program and will discuss with laboratories alternative methods of verifying competence in the absence of available PT/ILC programs where warranted. The four year plan will also be reviewed to ensure that laboratories with high-accuracy scopes participate in high level PTs and that all major sub-areas will be covered in that period.

Why the need for PT/ILC?

ACLASS, in following ISO/IEC 17025 and ILAC guidance[2] for proficiency testing and inter-laboratory comparisons, believes the use of proficiency testing/inter-laboratory comparisons is to assure that every accredited laboratory is:

[1] Laboratories that have applied to or have recently completed PT/ILC but are awaiting the results may be granted accreditation prior to receipt of the results. The granting of accreditation is done on a case by case basis and is the sole discretion of ACLASS. Failure to submit at least one set of PT summary results within 6 months of accreditation, however, will cause suspension of a laboratory's accreditation.

[2] Suggested ILAC guidance includes: ILAC G22:2004, *Use of Proficiency Testing as a Tool for Accreditation in Testing.*

- Receiving a regular comparison with other laboratories relative to their technical proficiencies and accuracies. Demonstration of competence through PT/ILC is of primary importance to the list of measures that gives the international community confidence in both a laboratory and its accreditation body's operations.

- Striving to adhere as closely as possible and practical to ISO/IEC 17043 in the conduct of this proficiency testing/inter-laboratory comparison

- Participating in commercially-provided proficiency testing/inter-laboratory comparison schemes, when feasible; or designing their own to meet the intent of ISO/IEC 17043

- When not feasible, unreasonably cumbersome or expensive, designing their own proficiency testing/inter-laboratory comparison program and ensuring the program complies, in good faith, with the ACLASS requirements (See Internal or Non-Commercial PT/ILC section of this document)

- Demonstrating some activity related to proficiency testing/inter-laboratory comparisons each calendar year. A laboratory with a minimal scope and/or prohibitively expensive, cumbersome, or non-existent proficiency testing/inter-laboratory comparison options may arrange an alternative to actual proficiency testing/inter-laboratory comparison on alternate years. In such a case, written permission must be sought from ACLASS (See Internal or Non-Commercial PT/ILC section of this document)

- Participating in proficiency testing/inter-laboratory comparison activities over each four year period which cover all accredited scope areas (e.g. major sub-disciplines).

- Showing evidence of satisfactory proficiency testing/inter-laboratory participation prior to initial accreditation. If no proficiency testing/inter-laboratory participation plan or initial activity is in place at the time of accreditation, a major non-conformance will be written. If the plan is in place and the laboratory has participated but no report is yet in hand to verify satisfactory participation, a minor non-conformance will be written. While accreditation can be secured as a result of the minor non-conformance, it may be suspended and/or withdrawn if no verification is in place within 6 months of accreditation.

- Obtaining regular feedback, which includes analyses of the quality control data, from their proficiency testing/inter-laboratory comparison provider(s) regarding relative competence and accuracy. Laboratories are expected to initiate warranted corrective actions in their quality system to correct any problems and to prevent incorrect results from being reported. The use of normalized results via E_n or Z-scores allows easy and internationally recognized feedback, and is therefore generally preferred. It is precisely this type of feedback that is critical to alert a

laboratory that it may have either a measurement bias or an uncertainty issue that warrants corrective action within their system.

Internal or Non-Commercial PT/ILC Programs

Laboratories that have access to commercial PT programs but choose to organize their own inter-laboratory comparisons or PTs (whether internal or external to their organization) must provide ACLASS with the reason for not using commercial PT providers and must submit a plan to ACLASS. The plan must be documented and include the following:

- Designated coordinator with name and contact information
- The objective, nature, and purpose of the plan
- A procedure for selection of PT/ILC participants or criteria to be met before participation is allowed
- Anticipated number of participants
- A description of the manner in which PT items are to be obtained, processed, checked, and distributed, which takes account in its design of the major sources of analytical errors involved in the area of PT offered
- Designation of the reference lab with proof of successful completion of commercial PT for the affected parameter(s),where available
- A description of the information which is to be supplied to participants (pre-notification) and the time schedule for the various phases of the plan
- Information on methods or procedures which participants may need to use to perform the tests or measurements (commonly their routine procedures)
- The basis of performance evaluation techniques, where appropriate
- A description of the extent to which test results, and the conclusions that will be based on the outcome of the plan, are to be made
- The origin and traceability of any reference values
- The traceability of the key reference standards of each participant lab, as warranted
- (For calibration laboratories) the plan to include Calibration and Measurement Capability (CMC) and Measurement Uncertainty (MU) for each participant in the reports
- Additional details as warranted, such as assuring artifact stability

The PT reports which result from the related PT programs should contain the following:

- Name and contact details of the provider
- Date of participation and date of report
- Number of pages and clear identification of the end of the report
- Report number and clear identification of the plan
- Clear description of the PT items used
- Laboratory participation codes and test results

- Statistical data and summary, including assigned values and range of acceptable results
- Procedures used to establish any assigned value or reference values
- Details of traceability and uncertainty, as warranted, of the reference value(s)
- Assigned value and summary statistics for test methods used by each participant Comments on participants' performance by the technical advisors as warranted
- Procedures used to statistically analyze the data

Laboratories only need apply and be approved once to be approved to conduct tests unless their procedures change. ACLASS Accreditation Managers are responsible for the approval of the submitted internal PT plan.

PT/ILC Planning - Sample Scenarios

An example scenario of an acceptable proficiency testing/inter-laboratory comparison program entails a laboratory that performs 90 percent of its accredited calibrations doing dimensional work and 5 percent each doing mechanical and thermodynamic work, respectively. The laboratory may participate in a dimensional proficiency testing/inter-laboratory comparison program every year and add a mechanical and/or thermodynamic scheme every other year as long as all three areas are covered within a four-year period. Additionally, participation must occur annually.[3]

Submission of PT/ILC Results

ACLASS has drafted a suggested summary planning record form (Form 15 – PT/ILC Four-Year Plan) for use by its customers regarding proficiency testing/inter-laboratory comparison activity.[4] The entire proficiency testing/inter-laboratory comparison report may be submitted in lieu of the summary report form.

The customer is encouraged to submit their proficiency testing/inter-laboratory comparison results to ACLASS prior to each assessment. Once fully functional, customers may be able to accomplish this through the company EQM database. Currently assessors and accreditation managers can input this summary information. Once received, the ACLASS assessor(s) will review the laboratory proficiency testing/inter-laboratory comparison program and results both prior to and on-site during each visit. If proficiency test/inter-laboratory results have not been made available ahead of the assessment, and are still not available while the assessor(s) is on site, a non-conformance will be issued.

ACLASS requires all customers to promptly review and analyze proficiency test/inter-laboratory comparison results, and if the results are found to be outside pre-defined criteria (i.e. unsatisfactory results or outliers), corrective actions shall be promptly taken

[3] Annually is defined as participation during each calendar year.
[4] The PT/ILC Summary Report Form 15 will be available online as part of ACLASS' online database management system available to all customers. It is expected that completion of this online form will replace completing hard copies of the form.

and submitted to ACLASS. PT/ILC is so critical to satisfactory ISO/IEC 17025 accreditation that ACLASS requires all customers to provide ACLASS any corrective actions taken relative to PT/ILC activities as soon as corrective actions have been accomplished. Customers are not to wait for the next ACLASS visit to communicate corrective actions.

ACLASS PT records in the EQM database are normally a sufficient record summary to satisfy PT/ILC reporting requirements. We also need to maintain current Form 15 records related to the PT/ILC plan for the coming years. This allows ACLASS the ability to review customers' performance and diligence in coving all sub-disciplines on the scope of accreditation within a four year period. This summary (or if made available, the complete PT/ILC report) is not only part of the assessment report from each visit but is also retained separately in a client proficiency testing/inter-laboratory comparison file. Submission of the entire proficiency testing/inter-laboratory comparison report is always acceptable in lieu of the summary report form.

Non-Conformances against PT/ILC - Scenarios

ACLASS assessors will issue non-conformances against the PT/ILC requirements when deficiencies are noted. The classification of the non-conformance as a minor or major will depend upon the severity of the situation. The following are some examples of minor and major non-conformances that could be issued against the PT/ILC requirements.[5]

Minor Non-Conformances

Scenario 1: During a surveillance assessment, the laboratory has completed PT/ILC and can demonstrate their data and uncertainties, but the results were not yet available.

Scenario 2: The laboratory received their PT/ILC results one week prior to the assessment. The results show three unsatisfactory results out of twenty, yet the laboratory has not yet taken corrective actions, stating they were aware but only had a few days since receiving the results before the assessment was to begin.

Scenario 3: The laboratory shows a report demonstrating participation in a commercial PT/ILC, and two of the resultant En values were between 1.00 and 1.05. The lab decided that the values were sufficiently close to 1.0 to be ignored.

Scenario 4: A testing lab participates in over 150 PT/ILC tests over a year's time. They review their results each month and note that 2 of 150 results were outliers in the z-scores. They decide that the % of outliers is so small that no real corrective action is needed.

Scenario 5: A testing lab participates in dozens of PT/ILC tests over a year's time. They occasionally have outliers and review the results, fixing their instrument maintenance and

[5] ILAC-G20:2002, *Guidelines on Grading Non-conformities*, is used as guidance.

assuring satisfactory performance in subsequent PT tests, but they have no record of the fixes.

Major Non-Conformances

Scenario 6: The laboratory received results from an inter-laboratory comparison, which showed E_n values greater than one. The laboratory staff and management were unaware of the outliers. There are no records or explanation of corrective actions taken or if any follow-up action was taken on the potential problem.

Scenario 7: No evidence exists to show that PT/ILC was designed or initiated prior to initial accreditation (or within a calendar year)

Scenario 8: The laboratory has not participated in a PT/ILC in one of the major sub-areas on its scope of accreditation in the last four years. (Since this requirement is based on calendar years, the four year period encompasses the four years prior to the current year.)

Participation in Regional Cooperation PT/ILC Programs

At times, ACLASS is invited to participate in proficiency testing programs operated through regional co-operations such as ILAC, APLAC, or IAAC, of which ACLASS is a signatory. Participation by ACLASS is a mandatory requirement in order to maintain signatory status to each cooperation's respective MRA/MLA.

Typically, ACLASS is allowed to nominate a limited number of customers to participate. Participation is typically at no cost to the customer other than the time it takes to perform the tests and the expense of shipping the artifact to the next participant or back to ACLASS. This participation may meet yearly proficiency testing requirement if within the ACLASS scope of accreditation.

Results of participation may take an extended time to become available as a result of worldwide participation and the length of time it takes to ensure the necessary artifacts reach each participating economy. Because of the potential delay, participation in the international PT/ILC programs should be supplemental to the laboratory's normally scheduled PT/ILC program.

ACLASS asks for volunteers to participate where available. ACLASS also reserves the right to require mandatory participation of any laboratory it accredits in any future proficiency program that may be mandated or administered by APLAC, ILAC, or IAAC. ACLASS highly encourages its customers to participate in these programs because it gives both ACLASS and its customers a benchmark against international peers.

PT/ILC FOUR-YEAR PLAN -- Form 15

Company Name:
Date Submitted:

Estimated Number of Participants	Estimated Month / Yr of Participation	In Progress or Planned	PT/ ILC Provider / Coordinator	If Internal, has plan been submitted to ACLASS?	Scope of Accreditation Major Sub-Discipline	Planned Artifact or Test Scheme

Future scope coverage was verified with the laboratory using this plan: (Assessor initials): _____

For labs with ACLASS for 4+ years, past scope coverage was verified with EQM data: (Assessor initials): _____

CARs were available and reviewed for all outliers in the last calendar year: (Assessor initials): _____

Assessor comments or recommendations:

Revision History

Date	Description
June 15, 2005	Initial Draft – B. Hirt
July 1, 2005	Final review – K. Greenaway
October 11, 2005	Revisions to update in response to MRA obligations and to give further clarification to customer(s) and assessor(s) – K. Greenaway
October 31,2005	Final Review – Keith Greenaway and Bill Hirt
June 15, 2006	Minor edits and review – B. Hirt; L. Yates; K. Greenaway
December 27, 2006	Revised to update sample scenarios, defined annual basis, minor improvements to language – B. Hirt
January 1, 2007	Final Review – K. Greenaway; L. Yates; B. Hirt
March 12, 2009	Minor revisions. Add section for internal PT/ILC – M. Weisrock
April 13, 2009	Final Review – K. Greenaway
September 29, 2009	Changed BMC to CMC – minor edits – T. Burgess
November 1, 2009	Final Review – K. Greenaway
April 16, 2010	Updated for new ISO 17043 issuance and non-commercial PT program details– M. Weisrock
May 11, 2010	Final Review – K. Greenaway
March 9, 2011	Removed reference to ILAC G 13. Replaced Form 15 Added Copyright
April 7, 2011	Final Review – B. Hirt
May 10, 2012	Revised internal PT/ILC requirements and added discussion of other types of competency verification. Updating and editing throughout.-T.Burgess