Developing a Proficiency Testing Plan for your Laboratory

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Abstract

Whether responding to new requirements from accreditation bodies, or ensuring that your laboratory quality system meets the requirements of ISO 17025, developing a documented plan for Proficiency Testing benefits the laboratory. Formal development of a Proficiency Testing Plan provides a long term "roadmap" for laboratories to ensure validation of all calibration services that they provide, and conveniently summarizes corrective and preventive actions that result from participation in proficiency testing. When developing a Proficiency Test Plan, it is important to optimize the costs to the laboratory by ensuring that the minimum requirements are met and the entire technical scope of the laboratory is covered in the required timeframe.

This presentation will discuss the proficiency testing requirements from the International Laboratory Accreditation Cooperation, through the regional accreditation organizations, to the accreditation bodies, and the laboratory itself. Information will be shared on the development of the NIST Weights and Measures Division Proficiency Test Policy and Plan that was jointly developed by NIST and Quametec Proficiency Testing Services. Examples of Proficiency Testing Plans for laboratories will be provided.

What is a Proficiency Test?

A proficiency test (PT) is simply, a method that you may use to validate a particular measurement process. The artifact's reference value is not known by the participating laboratory at the time of its measurement (test). In a well designed proficiency test, the reference value for the artifact should be principally determined by a competent laboratory with appropriate traceability to the International System of Units (SI). The reference laboratory should also have demonstrated its competency though key comparisons, interlaboratory comparisons, or proficiency tests appropriate to validate their measurement capability. It is also preferable that the laboratory has had its competency independently assessed through the process of laboratory accreditation. Lastly, in order to appropriately validate the measurement capability of the participating laboratory, the uncertainty assigned to the artifact by the reference laboratory should be sufficiently smaller than the expanded uncertainty reported by the participating laboratory.

Why does my laboratory need a Proficiency Testing Plan?

Regardless of the standard that your calibration laboratory's quality system is based upon, proficiency testing is an excellent way to validate one's measurement processes. Proficiency tests can validate the participating laboratory's measurement method, technical training, traceability of standards, and uncertainty budgets. Even though the laboratory has been most rigorous in developing the aforementioned laboratory processes, it is important to use proficiency testing as an additional way to verify that all aspects of the laboratory measurement system are sound.

For laboratories that must either comply to or be accredited to ISO 17025, this document provides specific guidance why proficiency testing is important, and why it is preferable to develop a Proficiency Testing Plan. Section 5.9 of ISO 17025, Assuring the quality of test and calibration results, states that the laboratory is required to have procedures to monitor the validity of calibrations. The laboratory is required to plan and review the monitoring process. This section goes on to suggest several ways to accomplish the monitoring, one of which is participation in proficiency tests.

Proficiency Testing and the Accreditation Process

In order for a calibration laboratory to be accredited to ISO 17025, the accreditation body often has specific requirements for participation in proficiency tests. Before discussing specific accreditation body proficiency testing requirements, it is helpful to understand why proficiency testing is required to be accredited.

In order for an accreditation body to be eligible to enter into a Mutual Recognition Arrangement (MRA) with the International Laboratory Accreditation Cooperation (ILAC) or a regional accreditation cooperation such as the Asia Pacific Laboratory Co-operation (APLAC), the accreditation body must develop a quality system which meets the criteria for recognition. ILAC provides the procedure ILAC P1:2003 “ILAC Mutual Recognition Arrangement Requirements for Evaluation of Accreditation Bodies by ILAC Recognized Regional Co-operations” which sets forth the requirements for entry into a MRA.

ILAC P1:2003 specifies in section 5, Criteria for Evaluation, requirements of proficiency testing activities that the accreditation body must require of laboratories that they accredit. Section 5.3 recommends that at a minimum, laboratories successfully participate in at least one proficiency test prior to gaining accreditation and one proficiency test relating to each major sub-area of major disciplines of a laboratory’s scope of accreditation during a four-year period.

Regional organizations such as the National Cooperation for Laboratory Accreditation (NACLA) and the Asia Pacific Laboratory Accreditation Cooperation (APLAC) further clarified the requirements of ILAC P1:2003 within their quality system documents. For example, APLAC MR0001 “Procedures for Establishing and Maintaining Mutual Recognition Agreements Between Accreditation Bodies” Section 3.3 requires accreditation bodies to specify that accredited laboratories participate in a minimum of one proficiency test prior to accreditation and one proficiency test for each major sub-area of major disciplines of a laboratory’s scope of accreditation at least every four years.

The following paragraphs summarize the proficiency testing requirements of some of the major accreditation bodies in the United States. This is not a complete listing of all accreditation bodies, so if your accreditation body is not included in this list, please contact your accreditation body for proficiency testing requirements.

PT Requirements – A2LA

Some accreditation bodies such as the American Association for Laboratory Accreditation (A2LA) have supplemented the ILAC recommendation by requiring laboratories participate in a minimum of two proficiency tests per year and cover all major sub-disciplines of the laboratory technical scope every four years (Document - A2LA Proficiency Testing Requirements January 1, 2004) in addition to the requirement of successfully completing at least one proficiency test prior to obtaining accreditation. A2LA also requires that accredited laboratories have a documented plan of how they intend to cover their technical scope during the four year period. Details of the documented plan requirements will be discussed later. At the time of writing this paper, A2LA has not defined “major sub-disciplines” as it relates to calibration laboratories.

PT Requirements – NVLAP
The National Voluntary Laboratory Accreditation Program (NVLAP) most recent version of Handbook 150 has no specific minimum proficiency testing requirements, but NVLAP has published two documents in the 150-2 series (150-2C technical guide for time and frequency measurements and 150-2E technical guide for optical radiation measurements) do specify that 1 proficiency test is to be completed per year per field, where a field is represented within the specific document such as 150-2C or 150-2E. At the time of writing this paper, there are no formally released publications to cover any fields of calibration other than those mentioned in this paragraph.

PT Requirements – LAB
Laboratory Accreditation Bureau's Policy 002 on proficiency testing requires laboratories to have satisfactorily completed at least one proficiency test before accreditation will be granted. The policy goes on further to state that accredited laboratories must complete a minimum of one proficiency test per major field each year for 25% of the major fields of their technical scope, so that all major fields of the technical scope is covered in a four year period. The LAB policy goes on to further state that laboratories participate in at least two proficiency tests per year. LAB also requires the laboratory to submit a proficiency testing schedule to the accreditation body so that LAB may monitor compliance to the schedule. LAB defines major fields of calibration in Policy 002 as Electrical, Mechanical, Dimensional, Pressure, Thermodynamics, Force, and Torque.

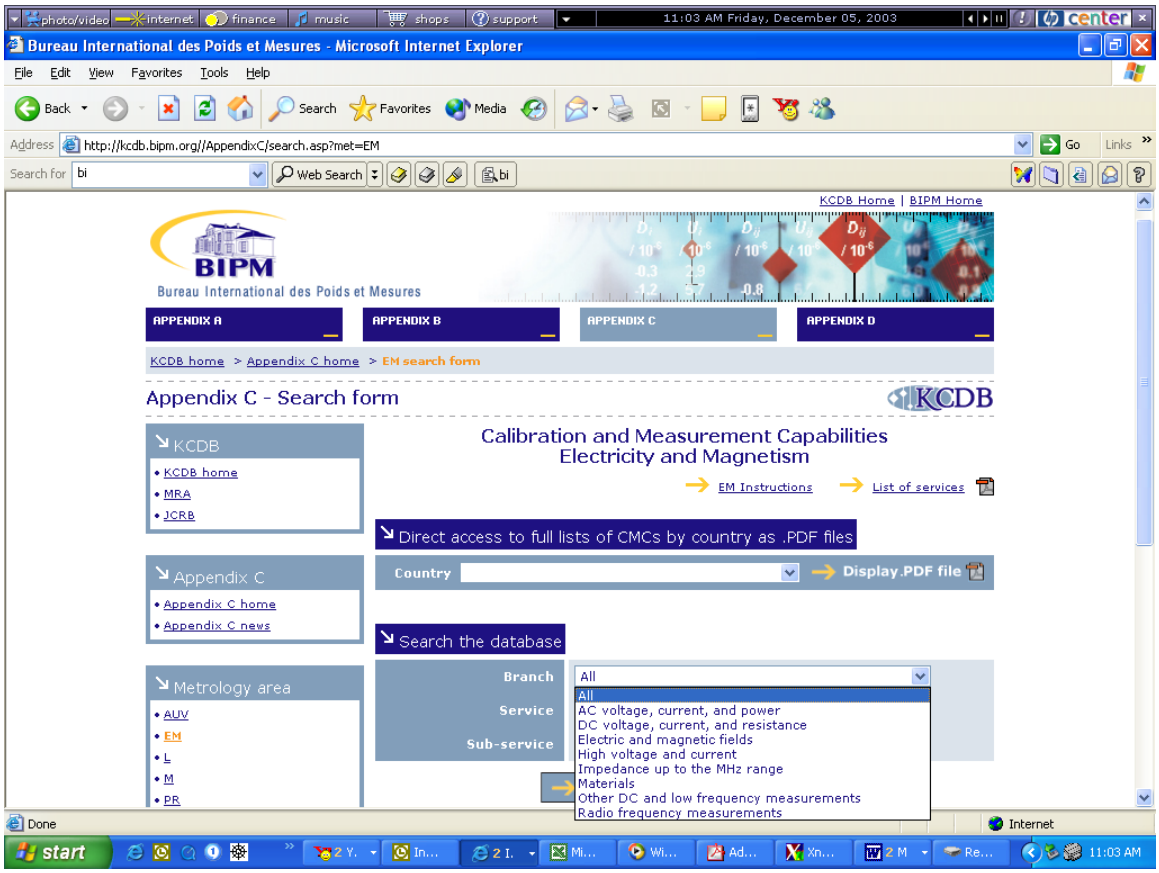
PT Requirements – NIST Weights and Measures Division (WMD)
The NIST WMD is not a formal accreditation body following ISO Guide 58 and does not enter into national or international agreements for acceptance and reciprocity. However, the WMD manages the State laboratory program, which is a program that provides training, guidance, and technical assistance to State legal metrology laboratories to ensure that measurements made by these laboratories are traceable to NIST. In addition, NIST Handbook 143, Program Handbook contains the requirements for participation in the measurement assurance program, which are based on ISO/IEC 17025.

NIST WMD and Quametec Proficiency Testing Services has recently developed and published (Document number not available at this time) Proficiency Test Policy and Plan to aid State weights and measures laboratories in meeting the requirements of NIST Handbook 143. This document also requires applicant laboratories to successfully complete at least one proficiency test prior to obtaining recognition by WMD. Laboratories that are recognized to NIST Handbook 143 must complete one proficiency test per year at a minimum and participate in at least one proficiency test for each major sub-discipline during a four year period. The NIST WMD Proficiency Test Policy and Plan defines Major Disciplines and Major Sub-Areas for NIST WMD. Lastly, this document requires proficiency tests to be planned to meet the participation requirements.

Key Elements in Developing a Proficiency Testing Plan

When developing a Proficiency Testing Plan for your laboratory, the first element to consider is the length of the proficiency testing cycle for your laboratory. The laboratory should plan to participate in enough proficiency testing activities to cover the technical scope of the laboratory. If your laboratory is not accredited, you can select any length of time for the cycle that suits you, but if you are applying for accreditation, it is advisable to align your proficiency test plan to the requirements of the accreditation body to which you are applying. If you are an accredited laboratory, the maximum cycle time that you can select is four years. It is important to note that the laboratory may select a smaller period of time for the proficiency testing cycle. A shorter cycle may be necessary for laboratories with a small technical scope of accreditation to meet additional accreditation body requirements, or may be desirable if the laboratory is interested in a more comprehensive quality program. For accredited laboratories, beginning with selecting the maximum cycle time of four years minimizes cost to the laboratory while still ensuring compliance to applicable requirements.

The next element to consider is the definition of “Major Discipline” and “Major Sub-Area” as it applies to your technical scope of accreditation. Again, if you are not an accredited laboratory, you can define these terms yourself. One possible source of guidance for defining these terms (which can be used for both laboratories and accreditation bodies) can be found at the Bureau International des Pois et Mesures (BIPM) Key Comparison Database (KCDB). This information can be located at http://kcdb.bipm.org//. This database (in appendix C, Calibration and Measurement Capabilities) defines Major Disciplines and Major-Sub Areas used in the support of the Mutual Recognition Arrangement (MRA). If your accreditation body has defined major disciplines and major sub-areas, you must align your Proficiency Testing Plan to these definitions. If you accreditation body has not defined major disciplines and major sub-areas, please consult with your accreditation body for further guidance, preferably in writing.



Example of Key Comparison Database for Electricity and Magnetism

For some accreditation bodies, it may not be enough to cover the laboratory technical scope in the four year period; the accreditation body may require a minimum number of tests per year be completed. For example, A2LA and LAB requires that the laboratories participate in two tests per year at a minimum, regardless of the number of major sub-areas contained on a scope of accreditation.

Lastly, some accreditation bodies require that the proficiency test plan must:

- include information such as an explanation of why proficiency testing may not be possible for certain major sub-areas
- address the laboratory’s process for timely submission of proficiency testing results to the accreditation body in the required timeframe

- complete and implement corrective actions for measurement areas that have received unsatisfactory proficiency testing results and submit the information to the accreditation body in a timely manner.

Documenting the Proficiency Test Plan

Once the laboratory technical scope has been divided into major disciplines and major sub-areas and minimum annual proficiency testing requirements are understood, the laboratory may begin to schedule proficiency testing activities. The proficiency test may be either from a commercial provider, developed internally, or completed through a cooperative effort such as those provided by NCSL International, but the proficiency test must meet the applicable requirements of the accreditation body, such as the requirement that the proficiency test be designed in accordance with ISO Guide 43-1 (1997), Proficiency Testing by Interlaboratory Comparisons – Part 1: Development and operation of proficiency testing schemes.

The scheduling of proficiency tests to be accomplished during the proficiency testing cycle, proficiency tests already accomplished, and other previously mentioned elements should be contained in a single, easy to use document. There are no formatting requirements for the document, so the laboratory may develop a document that meets the requirements of the accreditation body (or their own requirements if the laboratory is not accredited). It is also permissible for the laboratory to work with consultants or proficiency test providers (some of which will develop a Proficiency Testing Plan at no charge and include price discounts to the laboratory) in the development of their Proficiency Test Plan. It is important to understand that despite whoever develops the Proficiency Testing Plan, it is the ultimate responsibility of the laboratory to ensure that the data is correct and the plan is carried out.

In order to aid the reader, an example of a Proficiency Testing Plan is included in the appendix of this document.

Conclusion

In order to develop a successful PT plan for your laboratory, it is important to understand the documented PT requirements from your accreditation body. It is also helpful to review the quality system requirements that your accreditation bodies must comply to in order to have a better understanding of what drives the PT policies of your accreditation provider.

A well developed and documented PT schedule will allow better oversight and management of PT requirements, spreading tests out over the entire technical scope of the laboratory instead of over-concentrating in one particular area. The time and resources associated with proficiency testing is generally associated with overhead costs of operating a laboratory, so it is usually desirable to minimize these costs. A well constructed PT plan will allow the laboratory to meet quality and accreditation requirements and verify the measurement processes associated with the laboratory technical scope at a minimum of expense.

References

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. International Organization of Standardization, 12/15/1999.

ILAC P1:2003, *ILAC Mutual Recognition Arrangement: Requirements for Evaluation of Accreditation Bodies*. International Laboratory Accreditation Cooperation 2003.

APLAC MR-001, *Procedures for Establishing and Maintaining Mutual Recognition Arrangements Amongst Accreditation Bodies*. Asia Pacific Laboratory Accreditation Cooperation 12/02.

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White, V.R., Alderman D.F., Faison C.D. NIST Handbook 150 (2001 Edition), *National Voluntary Accreditation Program Procedures and General Requirements*. National Institute of Standards and Technology 7/01.

Faison, Douglas C, BrickenKamp, Carroll S. editors. NIST Handbook 150-2C *National Voluntary Accreditation Program Calibration Laboratories Technical Guide for Time and Frequency Measurements.* National Institute of Standards and Technology 9/01.

Faison, Douglas C, BrickenKamp, Carroll S. editors. NIST Handbook 150-2E *National Voluntary Accreditation Program Calibration Laboratories Technical Guide for Optical Radiation Measurements.* National Institute of Standards and Technology 8/01

LAB Policy 002, *Proficiency Testing*. Laboratory Accreditation Bureau, 01/07/03.

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Appendix A
Example Proficiency Test Plan for LAB Accredited Laboratory

Proficiency Testing Plan
XXX Calibration, Inc.
LAB Certificate ZZZ

Date Generated: 10/02/2003
Plan Developed by: Quametec Proficiency Testing Services

Summary Schedule for Coverage of Scope

Field	Proficiency Test	Scheduled Date
Dimensional	QPTS Micrometer #1	03/2003
Electrical	QPTS DC Volt #1	09/2003
Force	QPTS Force #1	03/2006
Torque	QPTS Torque #1	09/2004
Pressure	QPTS Pressure #1	03/2005
Thermodynamic	QPTS Temperature #1	09/2006

[1]Accredited Proficiency Test Planned, but not yet available
[2]No Commercial Tests are available at this time, if no commercial tests are available by the date shown, the laboratory will develop a test to satisfy this parameter.

Summary Schedule for Annual Proficiency Test Participation

Date	Proficiency Test	Status	Any Unsatisfactory Results? (Y/N)	Date Submitted to Accreditation Body
03/15/03	QPTS Micrometer #1	Complete	No	04/10/03
09/06/03	QPTS DC Volt #1	Complete	No	09/26/03
03/2004	QPTS Caliper #1	Scheduled		
09/2004	QPTS Torque #1	Scheduled		
03/2005	QPTS Pressure #1	Scheduled		
09/2005	QPTS Resistance #1	Scheduled		
03/2006	QPTS Force #1	Scheduled		
09/2006	QPTS Humidity #1	Scheduled		

Technical Manager:_____

Date:_____

Appendix A
Example Proficiency Test Plan for LAB Accredited Laboratory

Detailed Proficiency Test Schedule

Field	Parameter	Proficiency Test	Scheduled Date
Dimensional	Gage Blocks		
	Height Gages		
	Indicators		
	Calipers	QPTS Caliper #1	03/2004
	End Standards		
	OD Micrometers	QPTS Micrometer #1	03/2003
	Rules and Scales		
	Cylindrical Gages – Major Diameter		
	Cylindrical Gages – Minor Diameter		
	External Thread Gages		
Electrical	DC Current - Measure		
	DC Voltage –Measure	QPTS DC Volt #1	09/2003
	Resistance – Measure	QPTS Resistance #1	09/2005
	Electrical RTD Simulation – Generate		
	Electrical TC Simulation – Generate		
	AC Voltage – Measure		
	AC Current – Measure		
Force	Force - Generate	QPTS Force #1	03/2006
Torque	Torque – Generate	QPTS Torque #1	09/2004
Pressure	Pressure – Generate Hydraulic		
	Pressure – Generate Pneumatic	QPTS Pressure #1	03/2005
Thermodynamic	Relative Humidity	QPTS Humidity #1	09/2006
	Temperature – Generate		
	Pyrometric Indicators		
	TC Probes		
	Temperature Uniformity Survey		