

	<b>DEPARTMENT OF COMMERCE</b> National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	<b>ISSUE DATE:</b> December 5, 2011
	<b>LAB BULLETIN</b>	<b>NUMBER:</b> LB-63-2011
		<b>LAP:</b> Calibration
<b>SUBJECT:</b> Proficiency Testing Requirements for Calibration Laboratories		

**Please read this entire bulletin, which includes an action item for NVLAP-enrolled calibration laboratories (see page 2).**

### **Background and scope**

This bulletin applies to calibration laboratories accredited or seeking accreditation by NVLAP. It provides information about requirements regarding proficiency testing (PT).

According to ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, and NIST Handbook 150, *NVLAP Procedures and General Requirements*, 5.9.1 [1, 2], a laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. This monitoring may include the participation in interlaboratory 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 customers, interested parties, and the accreditation body.

In 2010, ISO/IEC 17043, *Conformity assessment – General requirements for proficiency testing* [3], was published to specify general requirements for the competence of providers of proficiency testing, as well as the development and operation of proficiency testing programs. This standard replaced ISO/IEC Guide 43 (1997), *Proficiency testing by interlaboratory comparisons*, Part 1 and Part 2, which was a guidance document.

NIST Handbook 150 was recently amended to reflect the transition from ISO/IEC Guide 43 to ISO/IEC 17043 [4]. NIST Handbook 150, 3.4.1, which describes NVLAP’s general requirements for proficiency testing, was revised as follows:

#### **3.4.1 General**

**3.4.1.1** Proficiency testing, along with document review and on-site assessment, is an integral part of the NVLAP accreditation process. The performance of tests or calibrations and the reporting of results from proficiency testing assist NVLAP with determining a laboratory’s competence and the effectiveness of its management system. Information obtained from proficiency testing helps to identify technical problems in a laboratory and assists in maintaining the quality of laboratory performance.

**3.4.1.2** NVLAP’s proficiency testing is consistent with the requirements contained in ISO/IEC 17043, *Conformity assessment – General requirements for proficiency testing*, where applicable. Proficiency testing may be organized by NVLAP itself or by an external provider of proficiency testing services.

**3.4.1.3** Where applicable, requirements regarding the minimum level and frequency of participation in proficiency testing by accredited laboratories and other information about proficiency testing programs are provided in NVLAP’s program-specific documentation.

## Implementation of ILAC-P9:11/2010

ILAC-P9:11/2010, *ILAC policy for participation in proficiency testing activities* [5], is a policy document that was released in November 2010. This policy identifies satisfactory participation in PT activities, where such activities are available and appropriate, as one of the elements by which accredited laboratories can demonstrate technical competence. ILAC-P9 also sets out the requirements for accreditation bodies on the use of proficiency testing activities in the accreditation process.

A new requirement in ILAC-P9 is for accredited labs to have a PT plan. An accreditation body, like NVLAP, must be able to evaluate, through the accreditation process, that the participation of their accredited laboratories in PT activities is effective, and that corrective actions are carried out when necessary.

Accreditation bodies must also review the PT plans prepared by laboratories with regard to their suitability in relation to the scope of accreditation. Where these plans are not considered to be suitable, it may be necessary for the accreditation body to provide guidance in identifying the required PT coverage.

NVLAP-accredited calibration laboratories are required to develop suitable plans to participate in relevant proficiency testing schemes that demonstrate the technical competence of their scopes of accreditation. NVLAP requires its laboratories to satisfactorily participate in proficiency testing activities where they are available and appropriate prior to gaining accreditation in that field of calibration. Where possible and appropriate, NVLAP will coordinate specific proficiency testing activities, notifying laboratories of their required participation. Laboratories, however, are responsible for developing their own plans, actively seeking proficiency testing, interlaboratory comparisons, and other appropriate measurement assurance activities. Laboratories shall maintain adequate records of performance in proficiency testing activities, including actions taken to improve technical competence (corrective/preventive action and analysis of nonconforming work) when unsatisfactory results occur. The process for analyzing proficiency testing results and follow-up activities shall be included in the plan.

Laboratories may seek proficiency tests provided by proficiency test providers accredited to ISO/IEC 17043 as long as these tests provide adequate coverage of the scope of accreditation at the appropriate uncertainty levels. Plans shall include any specific requirements from regulatory bodies (such as the Nuclear Regulatory Commission).

It is recognized that there are areas of testing and calibration for which suitable PT does not exist or is not practical. In such cases, the accreditation body and the laboratory shall discuss and agree on suitable alternative means by which performance can be assessed and monitored. This alternative means shall be considered as part of the laboratory's planned PT and/or related activities.

### Action Item for Labs

**To comply with ILAC-P9, NVLAP is requesting that calibration laboratories submit their PT plans with their renewal applications and other supporting documents beginning with applications for the April 1, 2012 renewal cycle. (Failure to submit the required PT plan in time to proceed with the accreditation renewal may result in a nonconformity being cited against the requirements of NIST Handbook 150, 5.9.1, for which corrective action must follow.)**

If you have any questions regarding this bulletin, please contact your NVLAP Program Manager at (301) 975-4016.

### References

- [1] ISO/IEC 17025:2005
- [2] NIST Handbook 150:2006
- [3] ISO/IEC 17043:2010
- [4] NVLAP Policy Guide PG-8-2011
- [5] ILAC-P9:11/2010