



Perry Johnson Laboratory Accreditation, Inc.

**Proficiency Testing Requirements
for Applicant and Accredited Laboratories**

2007



Introduction

A laboratory's participation in proficiency testing activities is a requirement of the ISO/IEC 17025:2005 standard. The purpose of this requirement is to provide interested parties with objective evidence of a laboratory's capability to produce data that is both accurate and repeatable for the activities listed in its scope of accreditation. Favorable proficiency testing data can be used to demonstrate a laboratory's competence to clients, potential customers, accreditation bodies and other external entities. Participation in proficiency testing activities also provides invaluable feedback in the internal monitoring of a laboratory's quality system. Through these activities, a laboratory can verify its competence to perform specific calibrations or tests.

Proficiency Testing Requirements: Applicant Laboratories

Prior to accreditation by PJLA, an applicant laboratory must provide objective evidence of proficiency testing activity for each item included in its desired scope of accreditation. The results of this proficiency testing must be meaningful, in that the laboratory not only needs to perform the proficiency testing, the resulting data must demonstrate the laboratory's competence in performing the specified test or calibration. PJLA will not include any item in a laboratory's scope of accreditation for which appropriate proficiency testing activities have not been performed or for which unfavorable results have been obtained.

Proficiency Testing Requirements: Accredited Laboratories

PJLA makes no attempt to confirm compliance with ISO/IEC Guide 43

Upon achieving accreditation by PJLA, laboratories are required to perform proficiency testing annually. Even if a laboratory finishes its proficiency testing in a single year, proficiency testing activities must occur every year. Results of this testing shall be monitored during the laboratory's annual surveillance. Although it is *preferred* that accredited laboratories complete proficiency testing activity for each sub-area of its scope within a two-year timeframe, PJLA requires objective evidence of favorable proficiency testing results for each sub-area in a laboratory's scope of accreditation within a four year cycle. **Failure to complete proficiency testing resulting in data demonstrating competency will necessitate the removal of the specified sub-area from the laboratory's scope of accreditation.**

All accredited laboratories shall monitor their proficiency testing activity and performance through the use of documented proficiency testing plans or schedules, which shall be made available to PJLA during regular surveillance assessments or upon request.

Additionally, PJLA is required to participate in proficiency testing programs sponsored by recognition bodies including (but not limited to) APLAC (Asia Pacific Laboratory Accreditation Cooperation) and NACLA (National Cooperation for Laboratory Accreditation). PJLA will inform all laboratories with appropriate scopes of accreditation of these mandatory proficiency tests when they become available. These tests will be of no cost to the laboratory except for the time to perform the test. Laboratories will be selected first on a voluntary basis, however PJLA reserves the right to require participation by any laboratory.



Approved Means of Proficiency Testing

The following activities have been approved by PJLA for the purpose of demonstrating proficiency:

- a) participation proficiency testing programs sponsored by a third party
- b) interlaboratory comparisons
- c) Intralaboratory comparisons
- d) repeatability studies

Based on the requirements of the ILAC –P9: 2005, ILAC Policy for Participation in National and International Proficiency Test Activities, Section 4.1, Note 1 & 2. PJLA requires that its accredited laboratories participate in proficiency testing programs sponsored by a third party whenever such programs exist. If a third party sponsored program does not exist for a particular scope, the proficiency testing requirement may be satisfied through the employment of interlaboratory / intralaboratory comparisons, repeatability studies or a combination thereof, provided that the program is documented and approved by PJLA.

Third Party Programs

Where such programs exist for a particular scope, PJLA mandates that its accredited laboratories participate in proficiency testing programs sponsored by third party providers, operated in accordance with ISO Guide 43. A listing of proficiency testing providers can be found on our website. Some of the advantages to participating in this type of program are: assurance that the proficiency testing takes place at appropriate and regular intervals; complete objectivity on the part of the proficiency testing sponsor; statistical analysis and reporting of the resultant data by the provider; and direct reporting of the results to PJLA by the provider on behalf of the laboratory upon availability. It is the responsibility of the laboratory to confirm the proficiency testing provider's compliance to Guide 43.

Interlaboratory Comparisons

An acceptable interlaboratory comparison is one in which two or more accredited laboratories perform testing or calibration on the same or similar artifact, using compatible methods, under specified conditions. The resulting data from each laboratory should be in agreement with that of the other participants.

Agreement in results is generally determined through the use of the following equation:



$$E_n = \frac{| Lab - Ref |}{\sqrt{(U_{95}Lab)^2 + (U_{95}Ref)^2}}$$

Where *Lab* is the result obtained, *Ref* is the value obtained by the outside laboratory, to be used as reference, $U_{95}Lab$ is the expanded uncertainty of the laboratory at the 95% confidence level and $U_{95}Ref$ is the expanded uncertainty of the reference laboratory at the 95% confidence level. E_n values that are greater than 1 are unacceptable and indicate that the results of the respective laboratories are not in agreement.

For certain laboratories with proprietary concerns or highly specialized scopes, an interlaboratory comparison is not feasible. In this case, the proficiency testing requirement may be satisfied through the use of intralaboratory comparisons.

Intralaboratory Comparisons

An intralaboratory comparison is conducted when several analysts or technicians within a laboratory perform testing or calibrations on the same or similar artifact, using the same method, under specified, controlled conditions. The data resulting from this activity shall be analyzed for statistical validity. The standard deviation of the data points shall be less than or equal to 1.0, indicating excellent agreement between analysts' results in this type of proficiency study.

Repeatability Studies

If none the aforementioned proficiency testing activities are feasible, as in the case of a specialized laboratory employing a single technician, proficiency may be demonstrated through repeatability studies with the prior approval of PJLA.

Repeatability studies consist of a number of tests or measurements (generally at least 8) performed on the same or similar artifact, using the same method, under specified, controlled conditions. The results of these studies shall be statistically analyzed using the same method that is used for intralaboratory comparisons.

Regardless of the method used to demonstrate proficiency, failure to produce meaningful, acceptable results shall necessitate an investigation and, if required, corrective action by the accredited laboratory. The proficiency testing activity shall be repeated upon implementation of corrective action to demonstrate the laboratory's competency and the effectiveness of the corrective action taken. Records of such activity shall be provided to PJLA during subsequent surveillances or upon request.