Perry Johnson Laboratory Accreditation, Inc.
Proficiency Testing Requirements

1.0 Introduction

1.0 An organization'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 an organization'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 an organization'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 an organization's quality system. Through these activities, an organization can verify its competence to perform specific calibrations or tests. This document outlines PJLA's general requirements in regards to proficiency testing including: required frequencies, acceptable means of comparing and analyzing data, competency requirements and international program requirements. This document is designed based upon requirements of ISO/IEC 17025:2005, ISO/IEC 17011:2004 and ILAC P9. Some accreditation programs have more specific requirements regarding proficiency testing, established by legislation, regulation, or specification. These may involve increased frequency, sources for PT, acceptability criteria and the like. PJLA will enforce these requirements as part of its recognition as an accrediting body for these programs.

2.0 Proficiency Testing Requirements: Applicant Organizations

2.1 Prior to accreditation by PJLA, an applicant organization must provide objective evidence of proficiency testing activity for at least one item included in its desired scope of accreditation. The item that the organization chooses for proficiency testing must be one that is suitable to demonstrate the competence of the organization for the main field of activities. The results of this proficiency testing must be meaningful, in that the organization not only needs to perform the proficiency testing, the resulting data must demonstrate the organization's competence in performing the specified test or calibration.

3.0 Proficiency Testing Requirements: Accredited Organizations

3.1 Upon achieving accreditation by PJLA, organizations are required to perform proficiency testing annually. Even if an organization finishes its proficiency testing in a single year, proficiency testing activities must occur every year. Results of this testing shall be monitored during the organization's subsequent surveillance or reaccreditation assessment. Although it is preferred that accredited organizations 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 organization's scope of accreditation within a four year cycle. PJLA may choose to shorten the interval for proficiency testing should there be any significant changes to the organization's staff or scope of accreditation. This decision will be made on a case-by-case basis.

3.2 The organization shall provide to PJLA at a time not later than the initial accreditation assessment a plan of PT activity for the next four years. This plan must address all sub areas of the scope at least once during the time interval covered by the four year plan. The organization shall submit a new four year plan to PJLA prior to the expiration of any current plan. All plans submitted will be reviewed by PJLA headquarters staff and if found to be acceptable they will be marked as approved by the reviewer who will initial and date the plan and return it to the client for their records. All accredited organizations shall monitor their proficiency testing activity and performance through the use of documented plans or schedules. The documentation which defines the manner in which an organizations proficiency testing program is managed and any information regarding results or evaluation of performance shall be made available to PJLA or its assessors during subsequent assessments or upon request. Failure to produce meaningful, acceptable results shall necessitate an investigation and, if required, corrective action by the accredited organization. An approved means of proficiency testing activity (see below) shall be conducted upon implementation of corrective action to demonstrate the organization's competence and the effectiveness of the corrective action taken. Records of such activity shall be provided to PJLA during subsequent surveillance or reaccreditation assessments or upon request. In the case that an organization fails to investigate or take appropriate corrective action for proficiency testing that produces unacceptable results, PJLA will initiate its policy for removal of the affected calibration or test activity from the scope of accreditation of the organization involved.

3.3 All accredited organizations 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 surveillance and reaccreditation assessments or upon request. These plans or schedules, however specified or written, should address the requirement for testing of each sub-area over a four year period. Accredited organizations wishing to expand their scope shall apply the requirements of section 2.0 and 3.0 of this policy.

4.0 International Scheme Proficiency Testing

4.1 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 ILAC (International Laboratory Accreditation Cooperation). PJLA will select potential participants from its listing of accredited

organizations and select nominees from those who qualify on the basis of CMC or Detection Limit appropriate for the calibration or test available. There will be no cost to the organization except for the time to perform the test. Organizations will be selected first on a voluntary basis, however PJLA reserves the right to require participation by any organization.

5.0 PJLA Coordinated Proficiency Testing

5.1 PJLA may choose to organize an inter-laboratory comparison scheme itself or through arrangements with a third party. Such schemes would be announced and available to PJLA accredited organizations through direct communication or our website. Participation in these programs would be strongly encouraged, but would not be mandatory. Organizations would be expected to pick up direct costs associated with such schemes for participation. Participation in these schemes would meet the requirements of this policy for proficiency testing in the appropriate sub-area.

6.0 Approved Means of Proficiency Testing

6.1 The following activities (listed in their order of preference and acceptability) have been approved by PJLA for the purpose of demonstrating proficiency:

a) participation in proficiency testing programs sponsored by a third party provider
b) inter laboratory comparisons
c) intra laboratory comparisons
d) repeatability studies

6.2 Third Party Programs

6.2.1 PJLA promotes third party proficiency testing and strongly encourages its accredited organizations to participate in proficiency testing programs sponsored by third party providers whenever such programs exist. Some of the advantages to participating in this type of program are:

a) assurance that the proficiency testing takes place at appropriate and regular intervals
b) complete objectivity on the part of the proficiency testing sponsor
c) statistical analysis and reporting of the resultant data by the provider
d) direct reporting of the results to PJLA by the provider on behalf of the organization upon availability

6.2.2 A listing of some of these proficiency testing providers can be found on the PJLA website. It is the responsibility of the organization to confirm the proficiency

testing provider's competence. Competence can be demonstrated in several ways one of which is through ISO/IEC 17043:2010 compliance or accreditation. However, there are other bases for determining competency such as well recognized national or international programs or organizations mandated by regulatory authority. If the organization has questions or concerns regarding potential third-party proficiency test providers, contact PJLA headquarters. 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, or the analysis of particular program specific reference materials or standards, provided that the program is documented and approved by PJLA.

6.3 Interlaboratory Comparisons

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

6.3.2 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 organization, to be used as reference, U_{95}Lab is the expanded uncertainty of the organization at the 95% confidence level and U_{95}Ref is the expanded uncertainty of the reference organization at the 95% confidence level. If the resulting E_n value is between 1 and -1 the organization is considered to have an acceptable measurement and a "meaningful" result. Values beyond the range of 1 to -1 (higher or lower) are unacceptable and indicate that the results of the respective organizations are not in agreement.

Note: Unusual circumstances can produce an E_n that is beyond the range of 1 to -1 for results that upon closer evaluation are found to be acceptable (as an example the case where a device is very repeatable and has a comparatively course resolution). If you get such a result and feel that it is valid then submit a copy along with all pertinent documentation to PJLA headquarters for review on a case-by-case basis.

6.3.3 Other sound, statistical or graphical analyses may be appropriate. Typically these involve other statistics (for example, "Z" scores), correlative analysis of "repeat" measurements, or other graphical techniques that can compare a laboratory's relative performance in relationship to others, in the study in terms of measured values and variation or uncertainty.

6.3.4 For certain organizations 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.

6.3.5 Other interlaboratory studies that meet the intent of the requirement would be participation as a collaborator in the characterization of a reference material by a competent reference material provider (ISO Guide 34) or the development or refinement of a standard to determine bias, precision, repeatability, reproducibility, and/or uncertainty in a test or calibration method by a competent or recognized standards development body.

6.4 Intralaboratory Comparisons

6.4.1 An intralaboratory comparison is conducted when several analysts or technicians within an organization 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.

6.5 Repeatability Studies

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

6.5.2 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.