Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

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Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;

Requirements Specified in PJLA Policy on Proficiency Testing Requirements "PL-1"

https://www.pjlabs.com/downloads/Update_55.pdf

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PJLA Assessors | 2. Assessment Folder Tem... | LF-Forms - All Documents | Henrico County Active Po... | A New & Improved Testin...

PJLA Update Notification

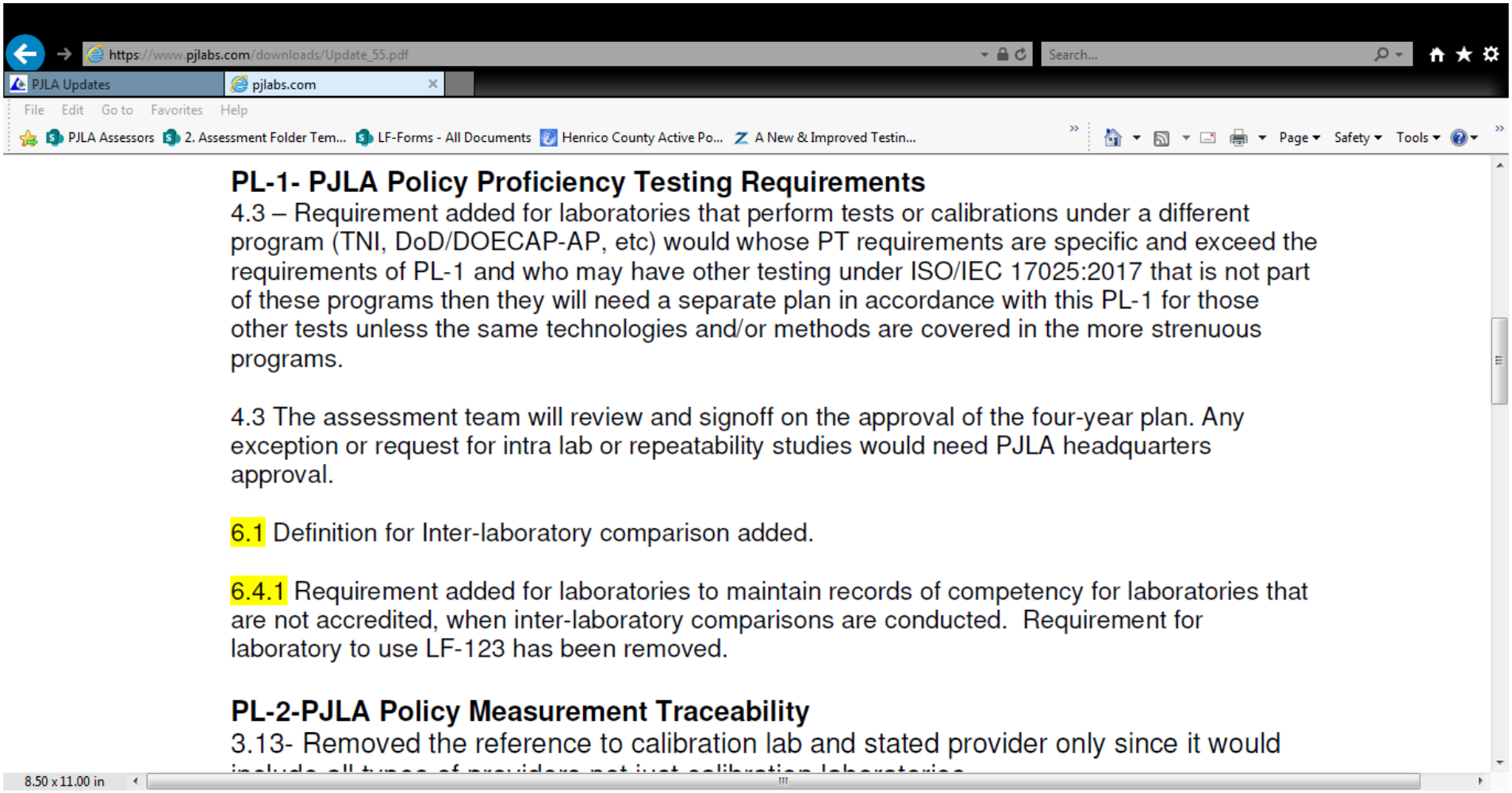
Update Notification # 55
Update Notification Release Date: April 2, 2021 revised 4/8/21 for corrections as highlighted
Form/Procedure/Policy:
PL-1-PJLA Policy Proficiency Testing Requirements 1.16
PL-2-PJLA Policy Measurement Traceability Rev 1.11
PL-3-PJLA Policy Measurement Uncertainty Rev 1.11
PL-4-PJLA Policy Calibration Scopes of Accreditation Rev 1.7

Attention All Applicant and Accredited Organizations:

Below is a summary of new documents available and a modification to our current Accreditation Procedures. Implementation for the procedures is immediate.

Summary of Changes:

Requirements Specified in PJLA Policy on Proficiency Testing R "PL-1"



Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

ILAC (P9) Policy for Participation in Proficiency Testing Activities

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

Perry Johnson Laboratory Accreditation, Inc. (PL-1) Policy on Proficiency Testing Requirements

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

PJLA's PL-1 general requirements in regardsincludes required frequencies, acceptable means of comparing and analyzing data, competency requirements and international program requirements

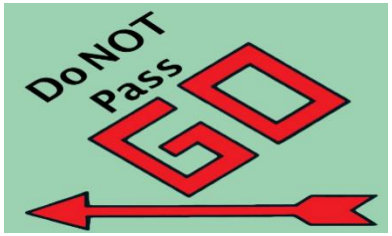
Proficiency Testing can provide objective evidence of:

- 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.

Requirements Specified in PJLA Policy on Proficiency Testing "PL-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. This needs to be done within the requirements set down in PL-1.

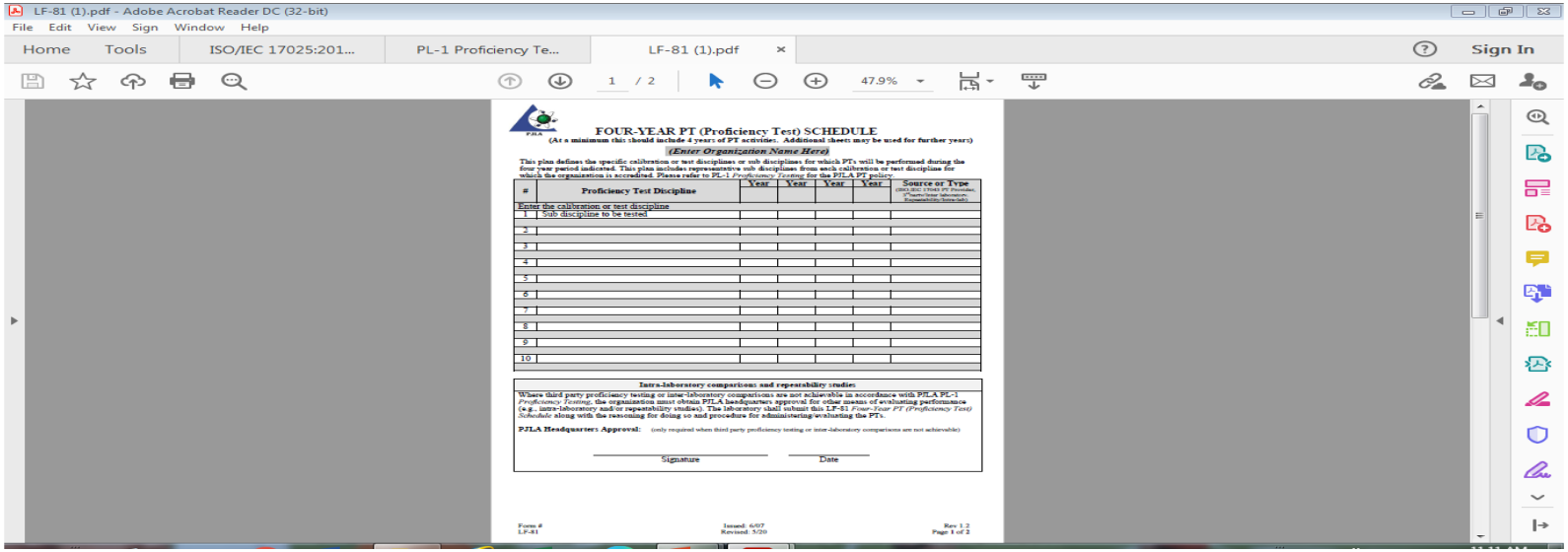
An applicant lab should plan ahead and assure that the initial proficiency test is successfully completed prior to the initial assessment.



Upon achieving accreditation by PJLA, organizations are required to perform proficiency testing annually

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

Organizations seeking accreditation shall develop a 4 year PT plan using the PJLA template PT Plan Form (LF-81) or other equivalent document prior to initial assessments. Organizations are responsible for updating 4 year PT plans prior to expiration of any current plan; available at www.pjlabs.com; resource tab under forms;



Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

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Those laboratories performing testing or calibration under programs (TNI, DoD/DoE, EPA NLLAP, etc) whose PT requirements are specific and exceed the requirements in this document for other programs such a plan is met by maintaining participation in the program. If laboratory in these programs also has other testing under ISO/IEC 17025:2017 that is not part of these programs then they will need a separate plan in accordance with this document for those other tests unless the same technologies and/or methods are covered in the more strenuous programs.

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

Calibration or Testing "Discipline": A category of calibrations or set of test intended to quantify or evaluate common or related parameters of a unit, device or substance submitted for calibration or test.

PJLA currently accredits organizations in the following disciplines

Calibration: Acoustic, Chemical, Dimensional, Electrical, Mass, Force, and Weighing Devices, Mechanical, Optical ,Thermodynamic &Time and Frequency

Testing: Acoustical, Biological, Chemical, Dimensional Inspection, Electrical, Environmental, Optical, Mechanical, Microbiological

Non-Destructive, Thermodynamic

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

Calibration or Testing "Sub-discipline": At a minimum a sub discipline is an element of an associated calibration or test discipline for which the magnitude of a stated parameter has been defined as a measurement objective and will be determined by a specified method using appropriate skills and equipment.

If you can do one, you can do the other

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

A sub-discipline may be composed of one or more such elements where the organization has determined that the measurement objective, the specified method and the appropriate equipment are either identical or similar to such a degree that they can be considered as mutually representative. In addition the organization shall have determined that the successful performance of either would be satisfactory objective evidence of the technical competence necessary to successfully perform the other.

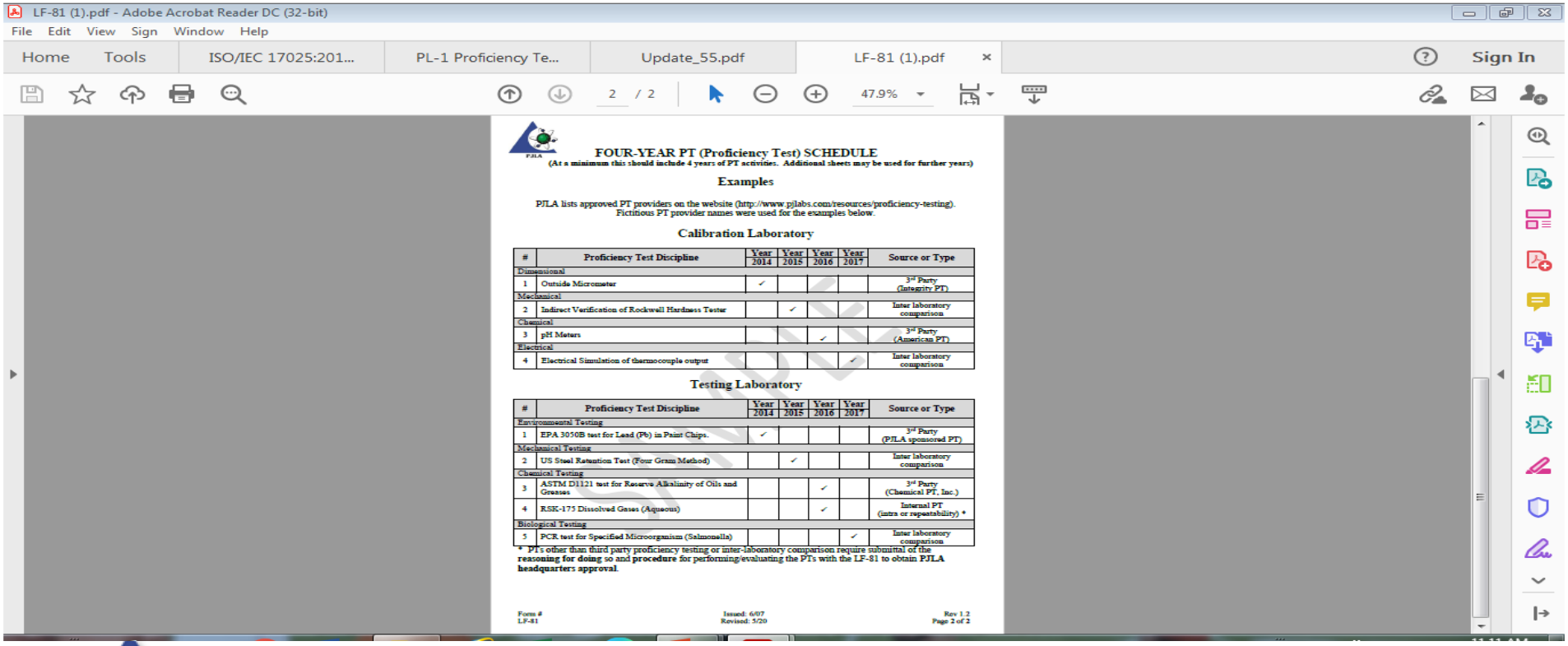
A record is required for the organizations reasoning for a sub-discipline group.

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

In putting together a four year proficiency testing plan assure the plan addresses all disciplines of the scope at least once during the time interval covered by the four year plan. Where a discipline is composed of several sub disciplines the sub discipline chosen shall be from among the more challenging and comprehensive within the specific discipline. Each successive sub-discipline chosen in subsequent proficiency tests shall be from the more challenging of the sub disciplines remaining.

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

This process shall continue until all disciplines and sub disciplines have been included at least once. Within the period of time when any four-year plan is active not all sub disciplines may be selected for proficiency testing, however all disciplines shall be represented at least once during each successive four-year period.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FOUR-YEAR PT (Proficiency Test) SCHEDULE

(At a minimum this should include 4 years of PT activities. Additional sheets may be used for further years)

Examples

PJLA lists approved PT providers on the website (http://www.pjlabs.com/resources/proficiency-testing). Fictitious PT provider names were used for the examples below.

Calibration Laboratory

#	Proficiency Test Discipline	Year 2014	Year 2015	Year 2016	Year 2017	Source or Type
Dimensional						
1	Outside Micrometer	✓				3rd Party (Integrity PT)
Mechanical						
2	Indirect Verification of Rockwell Hardness Tester		✓			Inter laboratory comparison
Chemical						
3	pH Meters			✓		3rd Party (American PT)
Electrical						
4	Electrical Simulation of thermocouple output				✓	Inter laboratory comparison

Testing Laboratory

#	Proficiency Test Discipline	Year 2014	Year 2015	Year 2016	Year 2017	Source or Type
Environmental Testing						
1	EPA 3050B test for Lead (Pb) in Paint Chips.	✓				3rd Party (PJLA sponsored PT)
Mechanical Testing						
2	US Steel Retention Test (Four Gram Method)		✓			Inter laboratory comparison
Chemical Testing						
3	ASTM D1121 test for Reserve Alkalinity of Oils and Greases			✓		3rd Party (Chemical PT, Inc.)
4	RSK-175 Dissolved Gases (Aqueous)			✓		Internal PT (intra or repeatability) *
Biological Testing						
5	PCR test for Specified Microorganism (Salmonella)				✓	Inter laboratory comparison

* PTs other than third party proficiency testing or inter-laboratory comparison require submittal of the **reasoning for doing** so and **procedure** for performing/evaluating the PTs with the LF-81 to obtain **PJLA headquarters approval**.

Form # LF-81 Issued: 6/07 Revised: 5/20 Rev 1.2 Page 2 of 2

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"

Calibration: Discipline: Dimensional

Discipline: "Dimensional"; MEASURED INSTRUMENT, QUANTITY OR GAUG includes the following

Micrometer, Dial Indicator, Caliper

For the dimensional discipline the organization has determined that the measurement objective, the specified method and the appropriate skills and equipment used to calibrate micrometers and to calibrate calipers are either identical or similar to such a degree that they can be considered as mutually representative.

Testing: Discipline: Mechanical Testing

Discipline: Mechanical: ITEMS, MATERIALS OR PRODUCTS TESTED

"Threaded fasteners, Knoop hardness"; "Machined components Vickers hardness"; "Leaf springs Rockwell hardness";

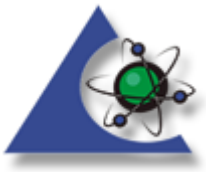
For the mechanical testing discipline the organization has determined that the measurement objective, the specified method and the appropriate skills and equipment used to test hardness by the Knoop and Vickers method are either identical or similar to such a degree that they can be considered as mutually representative

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1

At minimum organizations are required to have objective evidence of favorable proficiency testing results for each discipline in their scope of accreditation within a four year cycle.

Example:

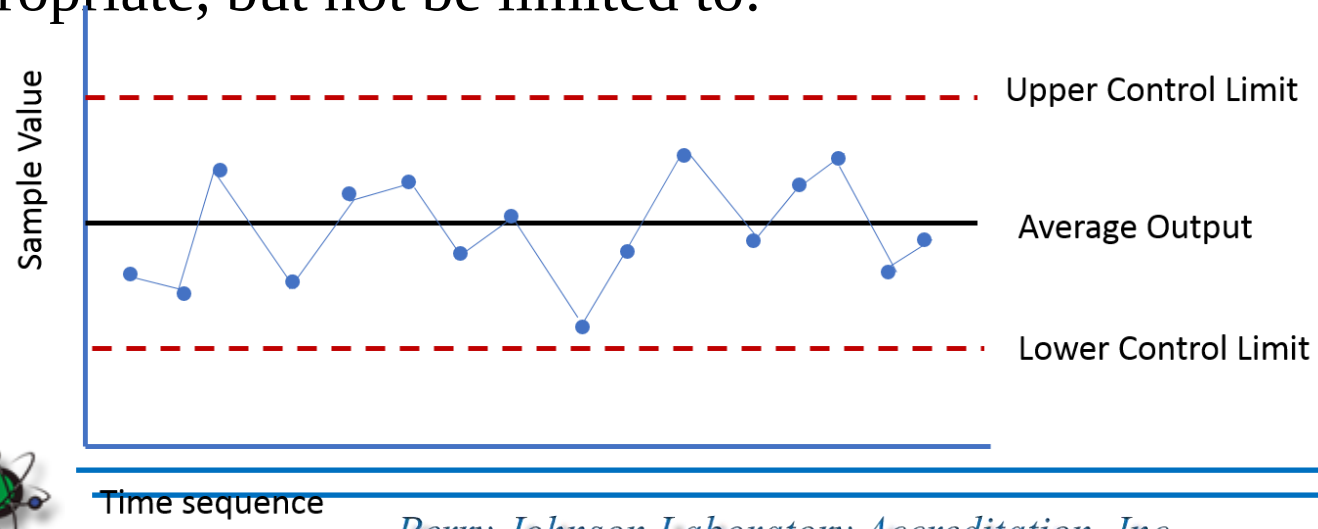
If an organization is accredited for only four disciplines and two have no sub disciplines while the other two disciplines have multiple sub disciplines, all four disciplines must be represented on the four year plan at least once during the four years in which the plan is active. Two disciplines have no sub disciplines to choose from and will be present on the plan in years chosen by the organization. The other two disciplines will be represented by selections from their sub disciplines The sub disciplines chosen are to be from the more challenging of those available. During the next four year plan those disciplines represented by selected sub disciplines will be represented by different sub disciplines selected again from the more challenging of those remaining



Requirements Specified in PJLA Policy on Proficiency Testing "PL-1

From ISO/IEC 17025:2017

7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:



Requirements Specified in PJLA Policy on Proficiency Testing "PL-1

Accredited organizations wishing to expand their scope shall apply the requirements of this policy- modifying the 4-year plan as necessary in order to include the capabilities being added as a result of the scope expansion.

From ISO/IEC 17025:2017

7.2.1.5 *The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.*

Proficiency Testing can be used as a means of meeting this requirements.

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1

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

- participation in proficiency testing programs sponsored by a third party accredited provider; (ISO/IEC 17043);
- participation in proficiency testing programs sponsored by a third party provider, and;
- inter-laboratory comparisons organized by industry groups (round robins, method validation studies, small group (including two party)comparisons etc;

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1

When use of third party or inter laboratory is considered by the organization as being impractical as a means of demonstrating proficiency the following activities, listed in their order of preference, may be used pending prior approval by PJLA:

-intra-laboratory comparisons, and;

-repeatability studies.

Note: If an organization wishes to proceed with one of the above-mentioned means, **they must state in writing** why third party or inter laboratory comparisons are not feasible and how they plan to conduct the test and analyze the data. This document **shall be submitted to PJLA headquarters f**or review and approval

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1

If an organization provides a 4-year plan with intra lab or repeatability studies without prior authorization from PJLA headquarters, a nonconformance can be written against this policy.

PJLA does maintain a list of all organizations who has been approved for intra lab testing and repeatability studies which are available to assessors. This is subjected to reapproval with each four year plan. The lab should maintain a copy of this approval for their records

Third Party Programs

A third party proficiency test is organized and managed by an independent third party. Additionally, a proficiency test includes the participation of a reference laboratory and uses their results to determine participant performance.

PJLA promotes third party proficiency testing and strongly encourages its accredited or applicant 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

Third Party Programs

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;

Inter-laboratory Comparisons

An acceptable inter laboratory comparison is one in which two or more 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. Organizations should be accredited whenever practicable. However, in cases where the participating laboratories are not accredited, it is up to the laboratories to confirm their competency. Records of this competency shall be maintained

PJLA has updated and removed the requirement for the LF 123 to be completed for traceability if lab is not accredited. That still can be used if applicable however not mandatory and more flexibility has been given.

Inter-laboratory Comparisons

From ISO/IEC 17025:2017

7.7.3 Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

Analyzing PT Data

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

$$E_n = \frac{Lab - Ref}{\sqrt{Unc_{95Lab}^2 + Unc_{95Ref}^2}}$$

Where Lab is the result obtained, Ref is the value obtained by the outside organization, to be used as reference, U95Lab is the expanded uncertainty of the organization at the 95% confidence level and U95Ref is the expanded uncertainty of the reference organization at the 95% confidence level. If the resulting En

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

En calculator available on PJLA website

Alternate methods of PT analysis

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. This is not an all-inclusive list of statistical methods. (See ISO 13528 for further guidance)

Z-Score = (Participant's Reported Value – Mean Reference Value) / Standard Deviation

Intra-laboratory Comparisons

For certain organizations, in extraordinary circumstances with proprietary activities or highly specialized scopes, an inter laboratory comparison may not be feasible. In such cases, the proficiency testing requirement may be satisfied through the use of intra laboratory comparisons

From ISO/IEC 17025:2017

7.7.2 The laboratory **shall** monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following

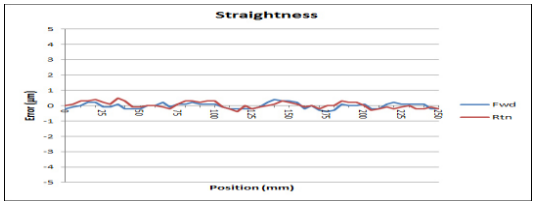
Intra-laboratory Comparisons

An intra-laboratory 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.

Repeatability Studies

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.

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 analyzed for statistical validity by appropriate means



International Scheme Proficiency Testing:

PJLA is required to participate in proficiency testing programs sponsored by recognition bodies including (but not limited to) APAC and ILAC . PJLA will select potential participants from its listing of accredited or applicant 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.

PROFICIENCY TESTING REQUIREMENTS: DOD/DOE APPLICANT OR ACCREDITED ORGANIZATIONS

Highlights specified under Section 7.0 of PL-1

- Applicant and/accredited organizations under the DoD ELAP, DOECAP program shall meet the requirements for proficiency testing as specified in the DOD/DOE QSM.
- Organizations shall supply PJLA, prior to accreditation, proficiency testing results for at least 18-months of data (no data older than 18 months, with the last data no older than 6 months).
- Organizations that fail to meet the requirements throughout their accreditation cycle (i.e. 2 out of the 3 acceptable rounds in the time intervals specified, with consideration and time intervals for corrective action PT samples) will result in the scope of accreditation being modified

Annex A: Proficiency Testing Requirements for Medical Laboratories (ISO 15189:2012)

Highlights

- The Laboratory shall designate appropriate authorities for ensuring that the laboratory carries out all aspects of proficiency testing
- PT (s) for all sub-disciplines shall be conducted twice per year not to exceed a 6-month interval
- Prior to accreditation all sub-disciplines shall undergo a PT
- Sub-dicipline table example given
- Laboratories shall use ISO/IEC 17043:2010 accredited providers when available.

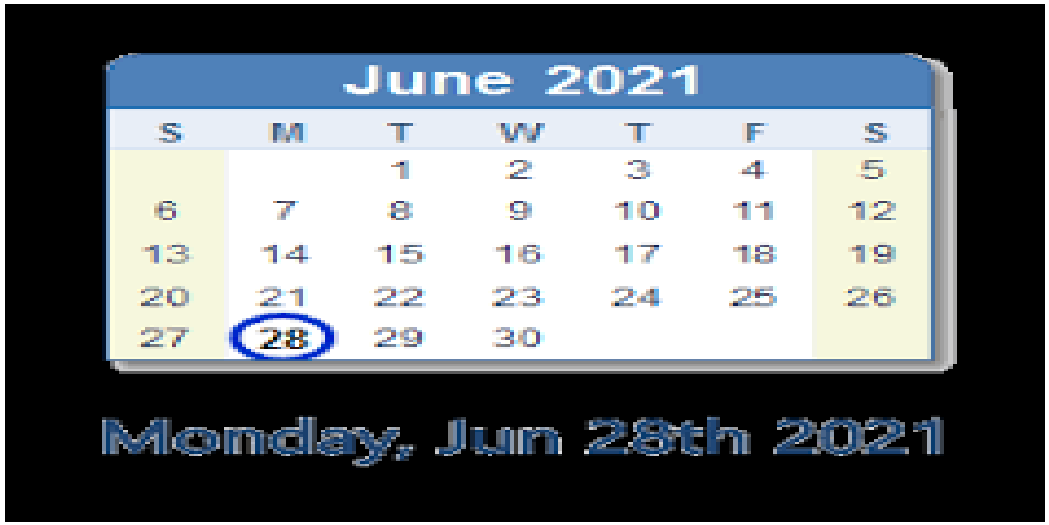
Requirements Specified in PJLA Policy on Proficiency Testing Requirements "PL-1"

This time is allocated for answering questions. You should have a space provided for submitting questions.

Please keep questions related to the topic covered in this webinar;

Save the Date

Next PJLA Webinar



Requirements Specified in PJLA Policy on Traceability PL-2