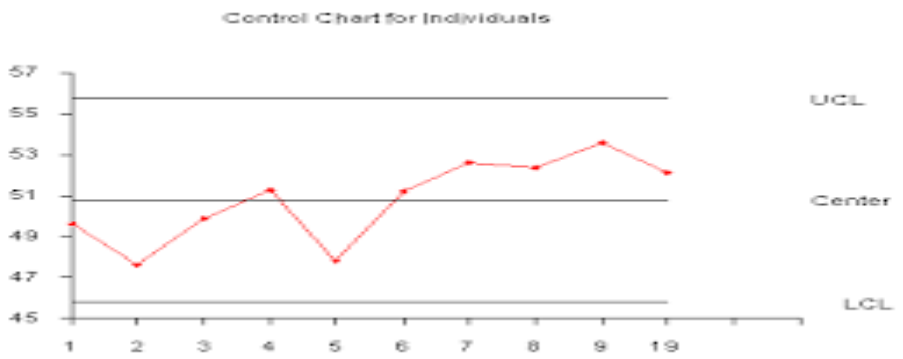
ISO/IEC 17025: 2017 Section 7.7 “Assuring the Validity of Results” and Associated PL-1 Requirements



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PJLA Calibration/Inspection Program Manager
31-May-2022

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ISO/IEC 17025: 2017 Section 7.7 “Assuring the Validity of Results” and Associated PL-1 Requirements

- This webinar is being recorded
- All PJLA webinar recordings and slides are available for download from the Past Webinars section of our website
  - https://www.pjlabs.com/training/pjla-webinars
- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

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7.7 Ensuring the Validity of Results

ISO/IEC 17025:2017 places emphasis on interlaboratory comparison and proficiency testing. Other than the fact that ISO/IEC 17025:2017 and PJLA PL-1 requires it proficiency testing can be a beneficial tool for the laboratory to check the reliability of their results by comparison within their peer group and to demonstrate their performance to clients and accreditation bodies. With the increasing availability of PT schemes in many technical fields, the criteria for the selection of an appropriate scheme are becoming more important.

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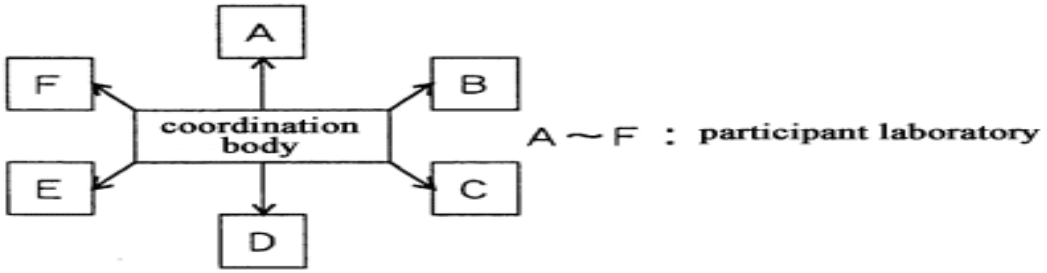

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7.7 Ensuring the Validity of Results

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:

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7.7 Ensuring the Validity of Results

a) use of reference materials or quality control materials; (ISO Guide 34)

ISO Guide 34

b) use of alternative instrumentation that has been calibrated to provide traceable results;

c) functional check(s) of measuring and testing equipment;

This can be the verification that the equipment responds properly to process inputs.

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7.7 Ensuring the Validity of Results

d) use of check or working standards with control charts, where applicable;

e) intermediate checks on measuring equipment;

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results;

j) intralaboratory comparisons;

k) testing of blind sample(s);

Records should be made to support that these activities are being performed.

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7.7 Ensuring the Validity of Results

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:

a) participation in proficiency testing;

NOTE: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing

interlaboratory comparison - organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions;

proficiency testing - evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons -*3rd party as specified in PL-1*

Requirements specified in PL-1 are in harmony with ISO/IEC 17025:2017

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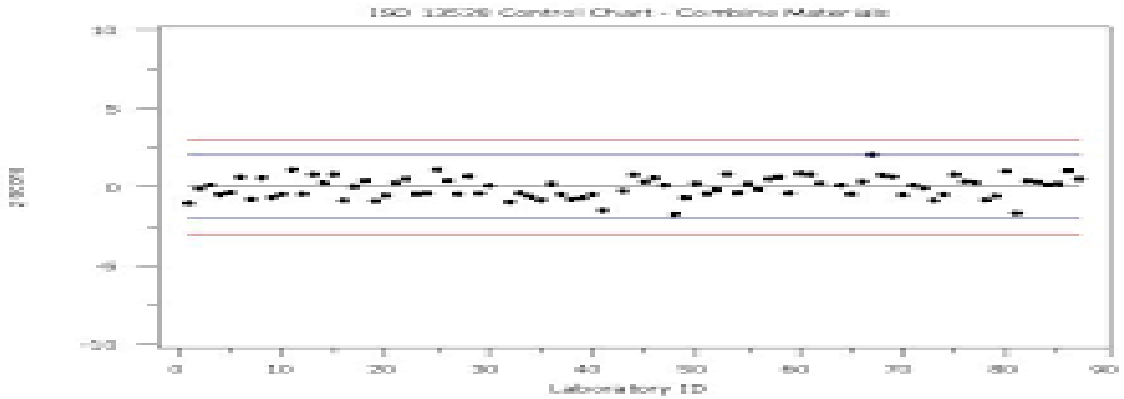
7.7 Ensuring the Validity of Results

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.



Predefined limits need to be specified and supporting data should clearly indicate whether the system is in control, and/or results are in agreement.

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7.7 Ensuring the Validity of Results

Relevance of interlaboratory comparisons

Interlaboratory comparisons (ILCs) are performed for various reasons other than to fulfill the requirements of your accreditation body

- to validate/verify procedures,

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.

- to certify reference materials,
- to assess the competence of laboratories or
- more general, to investigate the degree of comparability among laboratories.

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7.7 Ensuring the Validity of Results

Irrespective of the specific aim(s) of an ILC, the results can be used by a participating laboratory

- to check the performance of its test procedures and / or its staff,
- to demonstrate its competence towards clients and accreditation bodies,
- to gain useful information for the evaluation of its measurement uncertainty

For additional information regarding proficiency testing please visit the PJLA website:

- http://www.pjlabs.com/resources/proficiency-testing

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Proficiency Testing

- **ILAC Policy for Participation in Proficiency Testing Activities P-9**

International Laboratory Accreditation Cooperation

PJLA is a MRA Signatory of the International Laboratory Accreditation Cooperation and of the Asia Pacific Laboratory Accreditation Cooperation for both testing and calibration;

As and ILAC signatory, PJLA is expected to enforce P “Policy” documents of ILAC.

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Proficiency Testing

Hence, Perry Johnson Laboratory Accreditation has PL-1

“Perry Johnson Laboratory Accreditation, Inc. Proficiency Testing Requirements”

Available at www.pjlabs.com under the resource tab;

Proficiency Testing PL-1

3.1 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 either calibration or testing. 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.

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Proficiency Testing PL-1

4.1 Upon achieving accreditation by PJLA, organizations are required to perform proficiency testing **annually**. Results of this testing shall be monitored during the organization's subsequent surveillance or reaccreditation assessment. 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**.

4

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;

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Proficiency Testing Plan

PJLA currently accredits organizations in the following disciplines

Calibration: 1) Acoustic 2) Chemical 3) Dimensional 4) Electrical

5) Mass, Force, and Weighing Devices 6) Mechanical 7) Optical

8) Thermodynamic 9) Time and Frequency

Testing: 1) Acoustical 2) Biological 3) Chemical 4) Dimensional Inspection 5) Electrical 6) Environmental 7) Mechanical

8) Microbiological 9) Non-Destructive 10) Thermodynamic

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Proficiency Testing Plan

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. 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

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Proficiency Testing Plan

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

Proficiency Testing Plan

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.

Proficiency Testing Plan

4.3 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. Plans will be reviewed by the assessment teams during the on-site visit for compliance to this policy. Any deviations from the mandatory requirements as outlined in this policy shall be submitted to headquarters for approval. Headquarters will notify the assessment team and the client of any such approvals for deviations to this policy. The assessment team will review and signoff on the approval of the four year plan. Any exception or request for intra lab or repeatability studies would need PJLA headquarters approval.

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Proficiency Testing Plan

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;

(Enter Organization Name Here)

#	Proficiency Test Discipline	Year	Year	Year	Year	Source or Type (3rd party/Inter laboratory)
Enter the calibration or test discipline						
1	Sub discipline to be tested					
2						
3						

This plan defines the specific calibration or test disciplines or sub disciplines for which PT will be performed during the four year period indicated. This plan includes representative sub disciplines from each calibration or test discipline for which the organization is accredited. Please refer to PL-1 regarding PJLA policy on PT. ***Where third party proficiency testing or Inter laboratory comparisons are not feasible, then the organization must include other means of evaluating such as intra laboratory or repeatability studies. When these are indicated, the organization must submit their reasoning for doing so and their procedure.***

PJLA Approval: _____

Signature/Date

PJLA

Proficiency Testing Plan

4.4 Accredited organizations wishing to expand their scope shall apply the requirements of section 3.0 and 4.0 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.

4.5 Accredited organizations shall be able to provide objective evidence that their policies and procedures related to proficiency testing are reviewed for suitability The review as well as any conclusions or actions resulting from it shall be

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

c) suitability of policies and procedures;

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Types of Proficiency Testing

International Scheme Proficiency Testing

5.1 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 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;

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Types 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:

- participation in proficiency testing programs sponsored by a third party accredited provider;
- 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.

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Approved Means of Proficiency Testing

When use of the above approved methods 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:

- a) intra laboratory comparisons
- b) 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 for review and approval.

Third Party Programs

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;

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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 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;

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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

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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

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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

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Proficiency Testing Requiring PJLA Advanced Approval

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;

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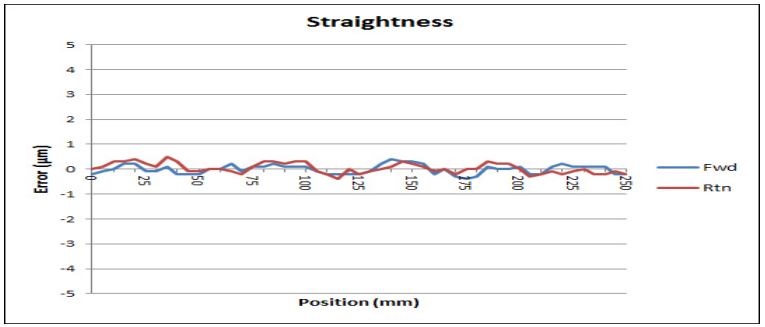
Proficiency Testing Requiring PJLA Advanced Approval

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;



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Intra-Laboratory and Repeatability Studies

For intra-laboratory comparison and repeatability studies recall requirement stated in 7.2 of PL-1

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 for review and approval;

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DOD ELAP and EPA NLLAP Programs

Applicant and/accredited organizations under the DoD ELAP program shall meet the requirements for proficiency testing as specified in the DoD ELAP QSM. Refer to Section 7.0 of PL-1 for additional details and requirements;

Applicant and/accredited organizations under the EPA NLLAP program shall meet the requirements for proficiency testing as specified in the EPA LQSR Version 3.0. All laboratories applying or maintaining accreditation under the EPA NLLAP program shall participate in the American Industrial Hygiene Association (AIHA) Environmental Lead Proficiency Testing Program. Refer to Section 8.0 of PL-1 for additional details and requirements;

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

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If a question is not answered, please submit directly to webinar@pjlabs.com

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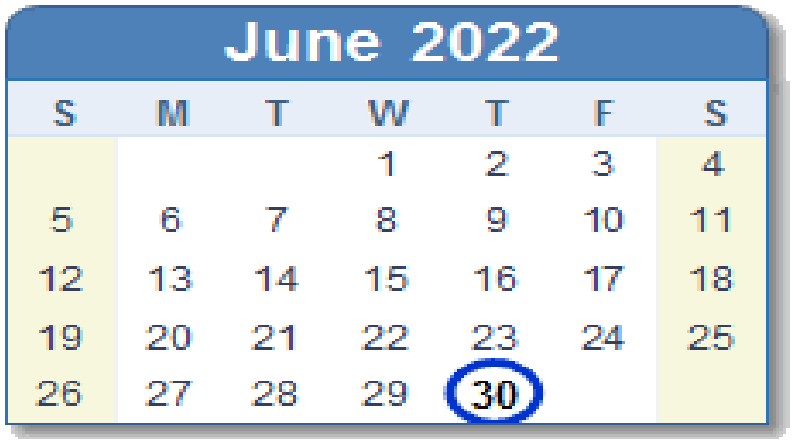
Save the Date

ISO/IEC 17025:2017 Section 6.5 Evaluation of Measurement Uncertainty “Requirements and Fundamentals”



Thursday, Jun 30th 2022

PJLA