Perry Johnson Laboratory Accreditation, Inc.

Policy on Proficiency Testing Requirements

1.0 INTRODUCTION

1.1 Organizations seeking or maintaining accreditation shall participate in proficiency testing. 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.

1.2 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 17025:2017, ISO 15189:2012, ISO 17034:2016, ISO/IEC 17011:2017, ISO/IEC 17043:2010 and ILAC P9:6/2014. Some accreditation programs have more specific requirements regarding proficiency testing, established by legislation, regulation, or specification. These may involve increased frequency, specified sources for PT, acceptability criteria, and the like. In some instances, these requirements are more stringent and comprehensive than those mandated as referenced above and PJLA's own requirements as detailed in this document. In such cases PJLA will enforce such requirements by exercising its responsibility as a recognized accrediting body for these programs (i.e. DoD ELAP, EPA NLLAP, TNI EL Program).

1.2.1 *Note:* Specific PT criteria for PJLA's Medical Laboratory Program (ISO 15189:2012) are detailed in Appendix A of this policy. Appendix A and the body of the main policy shall be adhered to for medical laboratories.

2.0 PROFICIENCY TESTING SPECIFIC REQUIREMENTS TESTING AND/OR CALIBRATION LABORATORIES (INCLUDES PROGRAMS UTILIZING ISO/IEC 17025:2017 AS A BASELINE DOCUMENT.

2.1 Two terms which appear frequently in the discussion of proficiency testing and for which internationally recognized definitions do not currently exist are **Discipline** and **Sub-discipline**. The following definitions for these terms have been established by PJLA to apply to all procedures and documents, both internal and external, wherein an organization's calibration or testing capabilities are stated or referenced. This applies as well to all procedures and documents, both internal and external, from organizations accredited by PJLA. In order to maintain consistency of interpretation of procedures, documents, and requirements to which these terms relate, any questions regarding their use will be decided at the discretion of PJLA's technical staff having given due consideration to any opposing points of view from all interested parties.

2.1.1 Definitions:

2.1.1.1 **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.

2.1.1.2 **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 necessary to successfully perform the other. The organization must document the basis for its decision to group multiple elements of a discipline into a single composite sub-discipline. Such documentation shall be available for review by an assessor at the time of assessment or at other times as requested by PJLA.

2.2 PJLA currently accredits organizations in the following disciplines:

2.2.1 **Calibration:**

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

2.2.2 **Testing:**

Acoustical
Biological
Chemical
Dimensional Inspection
Electrical
Environmental
Optical
Mechanical
Microbiological
Non-Destructive
Thermodynamic

2.3 Calibration discipline and sub-discipline examples:

FIG. 2.3.1 DIMENSIONAL

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Micrometer	0.05 in to 12 in	(56 +2.3L) µin	Gage Blocks
Dial Indicator	0 in to 4 in	(610 + 27L) µin	Gage Blocks and Surface Plate
Caliper	0.05 in to 12 in	(112 + 7.8L) µin	Gage Blocks

FIG. 2.3.2 ELECTRICAL

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Equipment to Measure AC Voltage at the listed frequencies			Fluke 5500A-SC300 Calibrator
10 Hz to 45 Hz	1 mV to 33 mV	10 Hz to 45 Hz	
45 Hz to 10 kHz	1 mV to 33 mV	45 Hz to 10 kHz	
10 kHz to 20 kHz	1 mV to 33 mV	10 kHz to 20 kHz	
Equipment to Measure DC Voltage	9 µV to 330 mV	60 µV/V + 3 µV	Fluke 5500A-SC300 Calibrator
	330 mV to 3.3 V	50 µV/V + 5 µV	
	3.3 V to 33 V	50 µV/V + 50 µV	
	33 V to 330 V	55 µV/V + 500 µV	
	330 V to 1 000 V	55 µV/V + 1500 µV	
Equipment to Measure Resistance	0.024 Ω to 10.99 Ω	0.12 m Ω/Ω + 0.008 Ω	Fluke 5500A-SC300 Calibrator
	11 Ω to 33 Ω	0.12 mΩ/Ω + 0.015 Ω	
	33 Ω to 110 Ω	90 µΩ/Ω + 0.015 Ω	
	110 Ω to 330 Ω	90 µΩ/Ω + 0.015 Ω	
	330 Ω to 1.1 kΩ	90 µΩ/Ω + 0.06 Ω	
	1.1 kΩ to 3.3 kΩ	90 µΩ/Ω + 0.06 Ω	

2.3.3 The calibration scope example above has two disciplines, **Dimensional** and **Electrical.** 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. In addition the organization has determined that the

successful performance of either would be satisfactory objective evidence of the technical competence necessary to successfully perform the other.

2.3.4 The organization determines therefore that the dimensional discipline consists of two sub disciplines. The first of these two being dial indicators and the second being the composite sub discipline of micrometers and calipers.

2.3.5 For the electrical discipline the organization has determined that the measurement objective, the specified method and the appropriate skills and equipment used to calibrate equipment to measure AC voltage at the listed frequencies, DC voltage and resistance differ from each other in fundamental ways to an extent that they cannot be considered as either identical or similar to such a degree that they are mutually representative. In addition the organization has determined that the successful performance of either would not be satisfactory objective evidence of the technical competence necessary to successfully perform the others. The organization determines therefore that the electrical discipline consists of three sub disciplines. The first of these three being AC voltage, the second being DC voltage and the third being resistance.

2.3.6 This scope has a total of 2 disciplines (Dimensional and Electrical) and 5 sub disciplines as follows:

Dial indicators
Micrometers and Calipers (as a composite sub discipline)
Equipment to measure AC voltage (at the listed frequencies)
Equipment to measure DC Voltage
Equipment to measure Resistance

2.4 Testing Discipline and Sub Discipline Example:

FIG 2.4.1 MECHANICAL TESTING

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Mechanical	Threaded fasteners,	Knoop hardness	ASTM E384	120 to 920 HK Detection limit 1 HK
	Machined components	Vickers hardness	ASTM E384	107 to 940 HV Detection limit 1 HV
	Leaf springs	Rockwell hardness	ASTM E18	HRC 46 to HRC 50 Detection limit 0.1 HRC

FIG 2.4.2 CHEMICAL

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Chemical	High pressure and cryogenic gases	Trace moisture concentration	Electrolytic Hygrometer	0.6 µmol/mol to 1 000 µmol/mol Detection limit 0.2 µmol/mol
		Trace hydrocarbon concentration	Flame Ionization Detector	0.2 µmol/mol to 100 000 µmol/mol Detection limit 0.06 µmol/mol
		Gas mixture concentration	Gas Chromatograph with Thermal Conductivity Detector	400 µmol/mol to 1 000 000 mol/mol Detection limit 130 µmol/mol

FIG 2.4.3 DIMENSIONAL INSPECTION

FIELD OF TEST	ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Dimensional Inspection	2 Dimensional and3 Dimensional Manufactured Products and Components	2 Dimensional and 3 Dimensional Features for Size, Location, and Orientation using a CMM	Customer Supplied Dimensional Information ANSI Y14.5-M	CMM 36 in x 42 in x 80 in Detection limit 0.000 1 in
		2 Dimensional Features for Size using a Micrometer		Micrometers 0 in to 6 in Detection limit 0.0001 in
		2 Dimensional Features for Size using Gage Pins		Gage Pins 0.25 in to 1 in Detection limit 0.001 in

2.4.4 The testing scope example above has three disciplines, Mechanical Testing, Chemical Testing and Dimensional Inspection.

2.4.5 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. In addition the organization has determined that the successful performance of either would be satisfactory objective evidence of the technical competence necessary to successfully perform the other. They have also determined that Rockwell hardness testing differs from Knoop and Vickers hardness testing in fundamental ways to an extent that it cannot be considered as either identical or similar to such a degree that they are mutually representative. In addition the organization has determined that the successful performance of a Knoop or Vickers hardness test would not be satisfactory objective evidence of the technical competence necessary to successfully perform Rockwell hardness test.

2.4.6 The organization determines therefore that the mechanical testing discipline consists of two sub disciplines. The first of these two being Knoop and Vickers hardness testing as a composite sub discipline and Rockwell hardness testing as a second sub discipline.

2.4.7 For the chemical testing discipline the organization has determined that the measurement objective, the specified method and the appropriate skills and equipment used to test high pressure and cryogenic gases differ from each other in fundamental ways to an extent that they cannot be considered as either identical or similar to such a degree that they are mutually representative. In addition the organization has determined that the successful performance of either would not be satisfactory objective evidence of the technical competence necessary to successfully perform the others. All three test high pressure and cryogenic gases using entirely different types of equipment. The organization determines therefore that the chemical testing discipline consists of three sub disciplines. The first of these three being Trace moisture concentration, the second being Trace hydrocarbon concentration and the third being Gas mixture concentration.

2.4.8 For the dimensional inspection discipline the organization has determined that the measurement objective, the specified method and the appropriate skills and equipment used to perform dimensional inspection of 2 Dimensional and 3 Dimensional Features for Size, Location, and Orientation using a CMM, 2 Dimensional Features for Size using a Micrometer and 2 Dimensional Features for Size using Gage Pins differ from each other in fundamental ways to an extent that they cannot be considered as either identical or similar to such a degree that they are mutually representative. In addition the organization has determined that the successful performance of either would not be satisfactory objective evidence of the technical competence necessary to successfully perform the others. All three inspect different aspects of the features or inspect them using different equipment. The organization determines therefore that the

dimensional inspection discipline consists of three sub disciplines. The first of these three being inspection of 2 Dimensional and 3 Dimensional Features for Size, Location, and Orientation using a CMM, the second being 2 Dimensional Features for Size using a Micrometer and the third being 2 Dimensional Features for Size using Gage Pins.

2.4.9 This scope has a total of 3 disciplines (Mechanical Testing, Chemical Testing and Dimensional Inspection) and 8 sub disciplines as follows:

- Knoop and Vickers hardness testing (as a composite sub discipline)
- Rockwell hardness
- Trace moisture concentration
- Trace hydrocarbon concentration
- Gas mixture concentration
- 2 Dimensional and 3 Dimensional Features for Size, Location, and Orientation using a CMM
- 2 Dimensional Features for Size using a Micrometer
- 2 Dimensional Features for Size using Gage Pins

3.0 PROFICIENCY TESTING REQUIREMENTS: APPLICANT ORGANIZATIONS

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. In cases where organizations need to support claims of stated CMCs and/or uncertainties, additional proficiency tests may be required. Proficiency Testing data utilized for the adherence of this section shall be dated no more than 12 months from the initial assessment date.

4.0 PROFICIENCY TESTING REQUIREMENTS: ACCREDITED ORGANIZATIONS

4.1 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. 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. 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. In cases where an organization

needs to support claims of stated CMCs and/or uncertainties, additional proficiency tests may be required.

4.2 In summary:

4.2.1 If an organization is accredited for only one discipline and that discipline has no sub disciplines then the lone discipline would be the subject of proficiency testing on an annual basis at a minimum.

4.2.2 If an organization is accredited for only one discipline and that discipline has two sub disciplines then the more comprehensive of the two should be selected for proficiency testing the first year and the remaining sub discipline will be scheduled for the following year. After two years the plan repeats these two sub disciplines in years three and four.

4.2.3 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. Barring changes to the scope or the proficiency testing requirements, this process of selection would continue until all sub disciplines have been the subject of proficiency testing at least once and all disciplines of the scope have been addressed at least once in each successive four year period.

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. 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. 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.

4.3.1 PT plans must address 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. 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.

4.3.2 Organizations are responsible for updating 4-year PT plans prior to expiration of any current plan. A copy of current plans will be kept in client assessment files. All 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 assessments or upon request. Failure to produce meaningful, acceptable results shall necessitate an investigation and, if required, corrective action by the 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 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.

4.4 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 reassessments or upon request. These plans or schedules, however specified or written, should address the requirement for testing of each discipline over a four-year period. 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 Changes in an organizations staffing, the methods by which calibrations and test are performed, equipment available to the laboratory etc. may render current PT policies and procedures inadequate. ISO/IEC 17025:2017 requires review of policies and procedures as a mandatory activity during management review. 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

recorded in the minutes of the management review. The record shall indicate the conclusion of any such review and the action taken if the policies and procedures related to proficiency testing are found to no longer be adequate. Additional reviews may occur at other times as deemed necessary by the organizations management or at the request of PJLA. Any such reviews and conclusions or actions resulting from them shall be recorded.

5.0 GENERAL PROFICIENCY TESTING REQUIREMENTS

5.1 International Scheme Proficiency Testing:

5.1.1 PJLA is required to participate in proficiency testing programs sponsored by recognition bodies including (but not limited to) APAC (Asia Pacific 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.

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:

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.

6.2 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:

-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 for review and approval.

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.

6.3 Third Party Programs

6.3.1 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:

- 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 organization upon availability.

6.3.2 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 inter-laboratory / intra-laboratory 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.

6.4 Inter-laboratory Comparisons

6.4.1 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.

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

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

6.4.2.1 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.

6.4.3 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. This is not an all-inclusive list of statistical methods. (See ISO 13528:2015 for further guidance)

6.4.4 Other inter laboratory 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 17034:2016) 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.

6.4.5 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.

6.5 Intra-laboratory Comparisons

6.5.1 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.

6.6 Repeatability Studies

6.6.1 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.

6.6.2 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 analyzed for statistical validity by appropriate means.

7.0 PROFICIENCY TESTING REQUIREMENTS: DOD/DOE APPLICANT OR ACCREDITED ORGANIZATIONS

7.1 Applicant and/accredited organizations under the DoD ELAP, DOECAP program shall meet the requirements for proficiency testing as specified in the DOD/DOE QSM.

7.2 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). Upon completion of routine PT studies, organizations shall provide PJLA updated results within 15 days of receipt, from the PT provider. It is the responsibility of the organization to inform its PT providers of the required format for PT data and to whom it is to be distributed when submitted to PJLA headquarters. PT data shall be submitted in .csv (comma separated values) format. The file must be compatible with MS Excel©.

7.3 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. Organizations shall take corrective

action for failed PT results. The scope can also be modified if the organization does not provide PJLA with a corrective action report with 30 days of a request for such a report.

7.3.1 *Note*: Additional information in regard to PT submission, evaluation and assessment are noted in PJLA's Accreditation Procedure SOP-1.

8.0 PROFICIENCY TESTING REQUIREMENTS: EPA NLLAP APPLICANT AND ACCREDITED ORGANIZATIONS

8.1 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 (ELPAT) on a quarterly basis. All laboratories applying for accreditation and maintaining accreditation shall perform such proficiency testing successfully and be rated "proficient" or "P". Proficient is defined as the following per each matrix: 1) the last two rounds, all samples are analyzed, and the results are 100% acceptable; or 2) Three fourths (75%) or more of the accumulated results over four rounds are acceptable.

8.2 Applicant laboratories shall demonstrate that this PT requirement has been met prior to accreditation being granted. Applicant and Accredited laboratories shall submit quarterly PT studies to PJLA within 14-days of receipt. Failure to do so will result in a nonconformance or disqualification of the EPA NLLAP Program.

9.0 PROFICIENCY TESTING REQUIREMENTS: TNI EL APPLICANT AND ACCREDITED ORGANIZATIONS

9.1 Applicant and/accredited organizations under the TNI (EL) program shall meet the requirements for proficiency testing as specified in the TNI (EL) Volume 1 Module 1 Proficiency Testing or and The TNI (EL) Volume 2 General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, Module 2: Proficiency Testing. Note: per TNI (EL) Volume 1 Module 1 Section 4.1.1 Note 1: The requirements for successful PT performance are described in Volume 2, Module 2 and in Volume 3. Organizations should obtain and reference copies of these documents in order to ensure that they meet these requirements.

9.2 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). Upon completion of routine PT studies, organizations shall provide PJLA updated results within 15 days of receipt, from the PT provider. It is the responsibility of the organization to inform its PT providers of the required format for PT data and to whom it is to be distributed when submitted to PJLA headquarters. PT data shall be submitted in .csv (comma separated values) format. The file must be compatible with MS Excel©.

9.3 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. Organizations shall take corrective action for failed PT results. The scope can also be modified if the organization does not provide PJLA with a corrective action report with 30 days of a request for such a report.

9.3.1 *Note*: Additional information in regard to PT submission, evaluation and assessment are noted in PJLA's Accreditation Procedure SOP-1.

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

Note: Medical Laboratories (ISO 15189:2012) shall follow the requirements as outlined in the body of this policy, sections 1, 5, 6 and 7 and this particular annex.

1.0 TERMS

1.1 **Discipline:** The area of examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention, and treatment of disease (i.e., Immunological, microbiological)

1.2 **Sub-Discipline:** A combination of a measurement technique with the related property (quantity being measured) & product (item being measured)

1.3 **Analyte:** Any material or chemical substance under analysis.

1.4 **Statistical Techniques:** Methods of collecting data & analyzing it for identifying needs such as the sample mean, standard deviations, hypothesis testing, or creating a linear regression. Some examples are:

- Correlation
- Descriptive
- Exploratory
- Inferential
- Predictive
- Causal
- Mechanistic

2.0 PROFICIENCY TESTING (PT) REQUIREMENTS FOR INITIAL & CONTINUOUS ACCREDITATION

2.1 This policy defines PJLA's criteria in support of ISO 15189:2012. However, laboratories are encouraged to conduct additional proficiency tests as required per country regulations where ISO 15189:2012 is utilized as a selection process. PT programs shall ensure that the requirements of the ISO 15189:2012 standard are met including the requirements of this policy. Additionally, laboratory's PT program shall define a process for determining the amount of PT(s) per sub-discipline and its suitability as well as a process for handling failed results including the use of corrective action and root cause analysis in order to prevent reoccurrence. Depending on the severity and/or risk of the failed PT additional studies may be required. The Laboratory shall designate appropriate authorities for ensuring that the laboratory carries out all aspects of proficiency testing such as enrolling in a qualified PT program, assurance that the samples are being handled and analyzed appropriately and that controls are in place to monitor the

laboratory's PT performance for all disciplines or sub disciplines listed on the scope of accreditation.

2.2 Laboratories shall conduct proficiency testing for all disciplines including its sub-disciplines. It is the responsibility of the laboratory to identify the number of sub-disciplines to undergo proficiency testing. PT (s) for all sub-disciplines shall be conducted twice per year not to exceed a 6-month interval. Laboratories shall use ISO/IEC 17043:2010 accredited providers when available. When ISO/IEC 17043:2010 accredited programs are not available then laboratories shall conduct internal performance verification as documented in ISO 15189:2012, section 5.6.3. PT(s) regardless of the type shall utilize appropriate statistical techniques.

2.2.1 If laboratories utilize other means of PT, (i.e., not an accredited provider), then an approval for these activities must be submitted along with objective evidence for acceptability to PJLA for review and approval.

2.3 Prior to accreditation all sub-disciplines shall undergo a PT. The results submitted for these studies shall be no more than 6 months from the initial assessment date. Additionally, a PT plan shall be developed including all sub-disciplines, dates of expected participation and type of PT (i.e. third party, inter lab, inter-laboratory comparison, repeatability). Prior to receiving accreditation PT results shall have a passing score. PJLA will evaluate the PT plan during the initial assessment and determine whether the plan is suitable. PJLA has the authority to require more (PTs) for each sub-discipline based on factors such as the risk, sector of operation, and methodology used, history of former results or staff turnover.

2.4 Failure to meet PJLA's PT policy requirements will result in nonconformity, possibly resulting in the reduction or suspension of the scope of accreditation.

3.0 DETERMINATION OF SUB-DISCIPLINES FOR PROFICIENCY TESTING:

3.1 Sub-disciplines are groups of sets of measurement techniques, properties, and products. A sub-discipline, as defined above, may contain more than one measurement technique, property, or product as long as equivalence and comparability can be demonstrated. When determining a sub-discipline, it should not contain different technical competences (Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge, or experience). The laboratory should use a stepwise method working up from measurement technique through properties to products since there will be several products and/or properties associated with one measurement technique within a given sub-discipline. Sub-disciplines that requiring proficiency tests the laboratory should list all the measurement techniques it uses within its scope, all the properties, which can be individual parameters or groups of equivalent parameters, and all the products.

3.1.1 see example below; EA-4/18: 2010 *Guidance on the Level and Frequency of Proficiency Testing Participation*

1.0 TESTS PERFORMED BY THE LABORATORY

- FSH by Chemiluminescence in blood
- LH by Chemiluminescence in blood
- Folic acid by Chemiluminescence in blood Calcium by Electrochemistry in blood and urine
- Potassium by Electrochemistry in blood and urine
- Cryoglobulins by Electrophoresis in blood
- Carbamazepine by Immunoassay in blood
- Ciclosporin by Immunoassay in blood
- Transferrin by Nephelometry in blood and urine
- α2 Macroglobulin by Nephelometry in blood and urine
- ALAT by UV-Visible spectroscopy in blood
- ASAT by UV-Visible spectroscopy in blood
- Magnesium by UV-Visible spectroscopy in blood and urine

2.0 MEASUREMENT TECHNIQUES USED FOR TESTING

- Chemiluminescence
- Electrochemistry
- Electrophoresis
- Immunoassay
- Nephelometry
- UV-Visible spectroscopy

3.0 PROPERTIES

Drugs (Carbamazepine, Ciclosporin)
Electrolytes (Calcium, Potassium, Magnesium)
Enzymes (ALAT, ASAT)
Hormones (FSH, LH)
Specific proteins (Cryoglobulin, Transferrin, α2Macroglobulin)
Vitamins (Folic acid)

4.0 PRODUCTS/SPECIMEN

- Blood
- Urine

5.0 SUB DISCIPLINE TABLE

PARAMETER	MEASUREMENT TECHNIQUE	PROPERTY	PRODUCT
FSH	Chemiluminescence	Hormones	Blood
LH	Chemiluminescence	Hormones	Blood
Folic Acid	Chemiluminescence	Vitamins	Blood
Calcium	Electrochemistry	Electrolytes	Blood
Calcium	Electrochemistry	Electrolytes	Urine
Potassium	Electrochemistry	Electrolytes	Blood
Potassium	Electrochemistry	Electrolytes	Urine
Cryoglobulins	Electrophoresis	Specific Proteins	Blood
Carbamazepine	Immunoassay	Drugs	Blood
Ciclosporin	Immunoassay	Drugs	Blood
Transferrin	Nephelometry	Specific Proteins	Blood
Transferrin	Nephelometry	Specific Proteins	Urine
α2 Macroglobulin	Nephelometry	Specific Proteins	Blood
α2 Macroglobulin	Nephelometry	Specific Proteins	Urine
ALAT	UV-Visible spectroscopy	Enzymes	Blood
ASAT	UV-Visible spectroscopy	Enzymes	Blood
Magnesium	UV-Visible spectroscopy	Electrolytes	Blood
Magnesium	UV-Visible spectroscopy	Electrolytes	Urine

6.0 RESULTING MATRIX:

6.1 From the list of analyses, the laboratory can then establish a matrix, which will highlight the sub-disciplines, as shown below. If the number of products is limited, they can be included in the matrix. If not, the evaluation of the products can be treated separately.

	DRUGS		ELECTROLYTES		ENZYMES		HORMONES		SPECIFIC PROTEINS		VITAMINS	
	BLOOD	URINE	BLOOD	URINE	BLOOD	URINE	BLOOD	URINE	BLOOD	URINE	BLOOD	URINE
Chemiluminescence							X				X	
Electrochemistry			X	X								
Electrophosesis								X				
Immunoassay	X											
Nephelometry									X	X		
UV-Visible			X	X	X							

7.0 RESULTING SUB-DISCIPLINES REQUIRING PROFICIENCY TESTING:

Hormones by Chemiluminescence in blood
Vitamins by Chemiluminescence in blood
Electrolytes by Electrochemistry in blood and urine
Specific proteins by Electrophoresis in blood
Drugs by Immunoassay in blood
Specific proteins by Nephelometry in blood and urine
Electrolytes by UV-Visible spectroscopy in blood and urine
Enzymes by UV-Visible spectroscopy in blood

NOTE: ALTHOUGH THE DIFFERENT PRODUCTS HAVE BEEN COMBINED INTO ONE SUB-DISCIPLINE FOR EACH DETECTION SYSTEM IN TERMS OF BEING EQUIVALENT FROM A COMPETENCY POINT OF VIEW, THIS DOES NOT SUGGEST THAT THEY ARE EQUIVALENT IN TERMS OF METHOD AND LABORATORY PERFORMANCE. THEREFORE, THE LABORATORY WOULD BE EXPECTED TO UNDERTAKE SUCH PTS SPECIFICALLY COVERING ALL THE PRODUCTS IN THEIR SCOPE ON A PERIODIC BASIS. THIS WOULD BE EXPECTED TO BE CLEARLY DETAILED IN THEIR PROFICIENCY TESTING STRATEGY.

B 1.0 REFERENCES

B1.1 ILAC-P9:06/ 2014 ILAC Policy for Participation in Proficiency Testing Activities

B1.2 International Vocabulary of Basic and General Terms in Metrology (VIM), 3rd edition, JCGM 200:2012 (JCGM 100:2008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.

B1.3 ISO/IEC 17011:2017 Conformity assessment – General requirements for accrediting conformity assessment bodies

B1.4 Department of Defense (DoD) Department of Energy (DOE) Consolidated Quality Systems Manual (QSM) For Environmental Laboratories- Latest Version

B1.5 E/A-4/18 – guidance on the level and frequency of proficiency testing participation, Advisory document EA-4/18:2010

B1.6 Authenticated U.S. Government Information, GPO, 42 CFR Ch. IV (10-1-10 Edition) Subpart H – Participation in Proficiency Testing for Laboratories Performing Non-Waived Testing.

B1.7 ISO/IEC 17011:2017 Conformity assessment – General requirements for accrediting conformity assessment bodies

B1.8 Environmental Protection Agency (EPA) National Lead Laboratory Accreditation Program (EPA NLLAP)-Laboratory Quality System Requirements (LQSR) Revision 3.0 (July 05, 2007).

B1.9 TNI Standard Environmental Laboratory Sector Volume 1 Module I (2016) and Volume II Module II (2016)

B1.10 ISO 15189: 2012 Medical Laboratories Requirements for quality and competence

B1.11 ILAC-G26:11/2018 Guidance for the Implementation of a Medical Laboratory Accreditation System