

Perry Johnson Laboratory Accreditation, Inc.

Policy on Proficiency Testing Requirements

1.0 INTRODUCTION

1.1 A Conformity Assessment Body (CAB) seeking or maintaining accreditation shall participate in Proficiency Testing (PT) or Inter-laboratory Comparison (ILC) activities related to their scope of applied or accredited activities.

1.2 This policy outlines the requirements for the use of PT, ILC, or approved alternative activities in the accreditation process for all CABs including testing, sampling, calibration and medical laboratories; inspection bodies; PT providers (using an in-house or non-accredited subcontracted laboratory for value assignment); and reference material producers (using an in-house or non-accredited subcontracted laboratory for value assignment).

1.3 This policy was developed to meet the requirements of Global ACI-TECH-1-008 (M).

2.0 APPROVED APPROACHES

2.1 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 schemes in a scope field offered by third-party accredited provider;
- Participation in proficiency testing schemes in a scope field offered by other third-party providers;
- Inter-laboratory comparisons in a scope field organized in conformance to ISO/IEC 17043;
- Inter-laboratory comparisons in a scope field organized by industry groups, and;
- Inter-laboratory comparisons in a scope field organized by laboratories themselves.

2.1.1 When performing one of the above activities, the CAB shall make the records of PT activity, PT performance, and corrective action when required, available to PJLA upon request. Additional program requirements may apply.

2.2 When use of the above approved methods for a field is considered by the organization not available or appropriate, the following approaches listed in their order of preference, may be used pending prior approval by PJLA:

- Intra-laboratory comparisons, and;
- Repeatability studies.

2.2.1 If CAB proceeds with one of the above-mentioned means, they shall complete and submit the following to PJLA for review and approval:

- PT plan (PJLA LF-81 or equivalent)
- PJLA Proficiency Testing Alternative Approval Request Form (LF-81a)
- Alternative Approach Procedure(s) that include the acceptance criteria for the study type

2.2.2 The above information shall be submitted for approval per the instructions as outlined in the LF-81a.

2.2.3 Alternative PT justification shall be monitored to verify its continued validity.

2.2.4 An updated LF-81a shall be submitted to PJLA (including all PT alternative approaches on the scope of accreditation)

- When additional alternative PT requests are required (e.g. scope expansion, a previous PT approach is no longer available or achievable)
- When approval expires after 4 years

2.2.5 New LF-81a approvals supersede all previous versions.

2.2.6 The CAB shall maintain a copy of the approved LF-81a.

3.0 PLANNING, PARTICIPATION, RECORD REQUIREMENTS

3.1 PT Plan

3.1.1 The CAB shall maintain and follow a documented Proficiency Testing Plan (PJLA LF-81 Form or equivalent) that meets the following requirements:

- Includes at least four years
- Includes the current year with at least one subsequent year at the time of each assessment
- Covers a representative sampling of activities as defined below

3.1.2 A representative sampling shall be determined by the CAB from the following:

- The technologies or techniques, as identified on the scope of accreditation for testing laboratories for each field accreditation is held;
- The calibration equipment or reference standards used, as identified on the scope of accreditation for calibration laboratories for each field accreditation is held;
- The specification, standard method or technique used as identified on the scope of accreditation for inspection bodies for each field accreditation is held;
- The technologies or techniques used for PT providers using an in-house or non-accredited subcontractor laboratory for value assignment, and;
- The technologies or techniques used for reference material producers using an in-house or non-accredited subcontractor laboratory for value assignment.

3.1.3 PJLA reserves the right to require additional activities, if the plan submitted by the CAB is not suitable for the scope of accreditation.

3.1.4 The CAB shall evaluate the risk of the activities associated with the scope of accreditation and incorporate that risk analysis as part of the PT plan. Risk evaluation may include:

- Complexity of test or calibration
- Number of customer tests or calibrations performed

- Staff experience
- Significance of customer end use
- Source of metrological traceability
- Extent of validation or verification

3.1.5 Additional programs may require additional PT activity. Review SOP 001 related to the program applied or accredited to.

3.2 Frequency

3.2.1 Frequency Requirements for CABs Other Than Medical Testing (ISO 15189)

3.2.1.1 Initial Accreditation for the Following Standards: ISO/IEC 17025; ISO/IEC 17020 (for related testing or calibration activities); ISO 17034 CAB using an in-house or non-accredited subcontracted laboratory for value assignment; ISO/IEC 17043 CAB using an in-house or non-accredited subcontracted laboratory for value assignment).

3.2.1.1.1 Before accreditation can be granted, the applicant CAB shall have performed satisfactorily in at least one PT/ILC or approved alternative activity within the previous 12 months.

3.2.1.1.2 The applicant CAB shall provide reported results as evidenced by either a preliminary or final report issued by an approved provider. Evidence of PT/ILC or approved alternative activity participation and submission of data may be sufficient for initial accreditation. Results must be sent to PJLA upon receipt by the CAB.

3.2.1.2 Frequency of Participation After Accreditation for the Following Standards: ISO/IEC 17025; ISO/IEC 17020 (for related testing or calibration activities); ISO 17034 CAB using an in-house or non-accredited subcontracted laboratory for value assignment; ISO/IEC 17043 CAB using an in-house or non-accredited subcontracted laboratory for value assignment).

3.2.1.2.1 The CAB shall participate in at least one approved PT/ILC or approved alternative activity each calendar year. Fields for scopes of accreditation can be found in PJLA PL-4.

3.2.1.2.2 For a CAB with four or fewer fields, the CAB shall perform PT/ILC or approved alternative activity covering a representative sampling of activities within each field in the scope of accreditation for a four-year period. For example, a CAB with three fields on its scope of accreditation would perform the three activities in the first three years of the plan and repeat at least one activity for the fourth year.

3.2.1.2.3 For a CAB with more than four fields, the CAB shall perform a PT/ILC or approved alternative activity covering a representative sampling of activities within each field in the scope of accreditation for a four-year period. For example, a CAB with five fields on its scope of accreditation may perform one activity the first three years of the plan and perform two remaining fields for the fourth year.

3.2.1.3 Scope Expansions involving a new field on the scope of accreditation (except ISO 15189)

3.2.1.3.1 At the time of the assessment for a scope expansion involving a new field or sub-field, the CAB shall update plan shall be available.

3.2.1.3.2 If applicable, PJLA approval identified in 2.2.6 must be available.

3.2.2 Frequency Requirements for Medical CABs (ISO 15189)

3.2.2.1 Initial Accreditation Requirements (ISO 15189)

3.2.2.1.1 Before accreditation can be granted, CABs shall have participated in PT/ILC or approved alternative activity for all fields and sub-fields within the previous 6 months. Fields and sub-fields for scopes of accreditation can be found in PL-4.

3.2.2.1.2 The applicant CAB shall provide reported results as evidenced by either a preliminary or final report issued by an approved provider. Evidence of PT/ILC or approved alternative activity participation and submission of data may be sufficient for initial accreditation. Results must be sent to PJLA upon receipt by the CAB.

3.2.2.2 Frequency of Participation After Accreditation of Medical CABs (ISO 15189)

3.2.2.2.1 The CAB shall participate in PT/ILC or approved alternative activity for all fields and sub-fields twice per year, with a frequency not to exceed six months.

3.2.2.2.2 Scope Expansions involving a new disciple or sub-field on the scope of accreditation (ISO 15189).

3.2.2.2.3 At the time of the assessment for a scope expansion involving a new field or sub-field, the CAB shall update PT plan shall be available.

3.2.2.2.4 If applicable, PJLA approval identified in 2.2.6 must be available.

3.3 Actions when results are outside of predefined performance criteria

3.3.1 The CAB shall investigate any results found outside of predefined performance criteria, such as unsatisfactory results. When appropriate, corrective action shall be performed. A record of the investigation summary and conclusion shall be retained.

3.3.2 PJLA reserves the right to take further action in the event of consistent poor performance. These actions may include but are not limited to the requirement of additional PT activity or the performance of an extraordinary assessment.

3.4 Records

3.4.1 The CAB shall retain records of their participation for a minimum of four years.

3.4.2 The CAB shall ensure that PT activities are not always performed by the same person if other qualified personnel in the system perform accredited work.

3.4.3 The CAB shall make available the PT plan and the records related to the activity identified within, prior to or during the assessment.

3.4.4 PJLA will assess the application of the PT plan, and the records related to the activity identified within, during the assessment.

3.4.5 Records for proficiency testing shall include, at a minimum:

- Instructions to participants
- Raw data for reported values
- Preliminary and/or final reports
- Evaluation criteria
- Corrective action, when applicable

3.4.6 Records for inter-laboratory shall include, at a minimum:

- Instructions to participants
- Raw data for reported values
- Number of participants
- Evaluation criteria
- Laboratory Score (e.g., Z-score, z'-score En score, range of results)
- Corrective action, when applicable

3.4.7 Records for intra-laboratory or repeatability studies shall include, at a minimum:

- Standard Operating Procedure or work Instructions for intra-laboratory or repeatability studies
- Raw data for reported values
- Number of participants
- Evaluation criteria
- Laboratory Score (e.g., Z-score, z'-score En score, range of results)
- Corrective action, when applicable

4.0 INTERNATIONAL SCHEME PROFICIENCY TESTING

4.1 PJLA CABs may be required to participate in proficiency testing programs sponsored by PJLA's recognition body Asia Pacific Accreditation Cooperation (APAC). 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.