Accreditation Procedure

PJLA offers third-party accreditation services to Conformity Assessment Bodies (CABs) . This procedure outlines PJLA's general accreditation process and criteria administered to conformity assessments bodies. **Additional SOP-1(s) may be available for specific programs which shall be followed along with this procedure.**

1. INTRODUCTION

1.1. Perry Johnson Laboratory Accreditation, Inc. (PJLA) is recognized under ISO/IEC 17011 and is a full member of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). PJLA follows all applicable documents of ILAC and IAF.

1.2. PJLA is also a signatory of the Asia Pacific Accreditation Cooperation (APAC) MRA and is recognized by both Federal and State regulators in the United States, as well as industry specifiers, to assess other standards.

1.3. PJLA provides third-party assessment and accreditation services to Conformity Assessment Bodies (CABs), including Testing Laboratories, Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations, Inspection Bodies, and Proficiency Testing Providers, in accordance with international and domestic standards and other programs.

1.4. CABs delivering covered services may participate in one or more of PJLA's accreditation programs to demonstrate that their technical operations and management systems meet PJLA's accreditation requirements for each program.

1.5. This document outlines the operational activities and responsibilities that both PJLA and CABs shall fulfill to seek or maintain accreditation.

1.6. PJLA reserves the right to determine the suitability of the conformity assessment schemes and standard for which it accredits to.

2. ACCREDITATION REQUIREMENTS

2.1. In addition to the relevant standard, Appendix A of this document outlines PJLA's policies and procedures that apply to each accreditation program.

2.2. Specific program requirements may also apply to conformity assessment activities that support the needs of regulators and industry specifiers. (Refer to SOP 01 Program Addendums for additional requirements.)

2.3. PJLA's policies and other relevant documents are publicly accessible on the PJLA website at www.pjlabs.com.

3. CHANGES OF ACCREDITATION STANDARDS AND PROGRAM REQUIREMENTS

3.1. When there are changes to standards, programs, or PJLA accreditation requirements, PJLA will notify CABs and applicant CABs. If applicable, PJLA will establish a timeframe for transitioning to the new or revised requirements, allowing CABs a reasonable period to implement the necessary changes.

3.2. It is the responsibility of the CAB to regularly review the accreditation documents available on www.pjlabs.com to ensure they are using the most current versions.

4. PURPOSE

4.1. To evaluate a CAB's competence in performing the technical activities outlined in its scope of accreditation and ensure conformance with accreditation standards, PJLA conducts assessments at all locations where the CAB performs key activities.

4.2. The goal of these assessments is to verify that the CAB's processes and systems are effectively implemented and meet the relevant requirements. PJLA accomplishes this by conducting interviews, reviewing documents and records, and assessing the technical activities included in the scope of accreditation.

4.3. After the initial accreditation, PJLA establishes surveillance and reassessment cycles for each accredited CAB to ensure ongoing compliance.

4.4. PJLA regularly assesses representative samples from the scope of accreditation and the CAB's management system.

5. IMPARTIALITY

5.1. PJLA is structured, organized, and operated to maintain the objectivity and impartiality of its activities in accordance with ISO/IEC 17011.

5.2. As an accreditation body, PJLA ensures that its activities do not compromise the objectivity or impartiality of its accreditations. All staff, assessors, technical experts, and members of the technical and executive committees uphold impartiality by declaring any potential conflicts of interest related to the CAB or the accreditation process.

6. CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

6.1. All information obtained by PJLA during accreditation activities is treated as confidential by PJLA staff, assessors, executive committee members, and technical committee members.

6.2. Such information will not be disclosed to any unauthorized party without the written consent of the CAB, unless required by law or program mandates. If PJLA is legally obligated to release information, the CAB will be notified of the details disclosed.

6.3. PJLA may grant access to confidential information to peer evaluators from ILAC-recognized accreditation bodies, regional cooperations (e.g., APAC), or other oversight bodies, provided they have signed agreements to maintain confidentiality as required by specific schemes.

6.4. PJLA will make the CAB's certificate, scope of accreditation, and information regarding suspensions or withdrawals of accreditation publicly available on the PJLA website, www.pjlabs.com.

7. PREPARING FOR ACCREDITATION

7.1. To prepare for an assessment by PJLA, it is essential to confirm and document that the CAB meets all relevant accreditation requirements. Several actions shall be taken before applying for accreditation.

7.2. A key requirement is to ensure that the most up-to-date versions of specific documents are available and applied, including:

a) A licensed copy of the relevant international or other standard that applies to the accreditation program.

b) PJLA accreditation documents.

c) PJLA's application form and related documents.

d) Additional documents may be required for assessment planning, depending on the program.

Note 1: Some programs may also require a licensed copy of the applicable program standard.

Note 2: ISO standards can be purchased from national standards bodies or authorized distributors, which can be found through an online search.

7.3 The CAB shall conduct an internal audit to evaluate its compliance with all accreditation requirements and its own management system requirements before accreditation is granted.

7.3.1 After completing the internal audit, and prior to the initial accreditation assessment, the CAB should implement appropriate corrections and corrective actions to address any nonconformities identified.

7.4 The CAB is also required to perform a management review, during which top management evaluates the management system to ensure its ongoing suitability, adequacy, and effectiveness.

7.5 Additionally, the CAB shall participate in proficiency testing and/or interlaboratory comparisons (PT/ILC) before accreditation is granted, as outlined in the applicable accreditation requirements per PJLA PL-1.

8 ACCREDITATION CONSIDERATIONS

8.1 **Assessment Location**: PJLA may assess a Conformity Assessment Body (CAB) either at the physical location of the activity or remotely.

8.1.1 **On-Site Assessment**---physical presence: PJLA sends assessors to the actual location where the conformity assessment activities are conducted.

This allows for:

a) Direct observation of processes, personnel, and equipment.
b) Review of physical records
c) Interviews with staff and management in person.
d) Verification of Procedures: The assessors can witness tasks being performed and evaluate the CAB's adherence to relevant standards in real time.
e) Facility and Equipment Review: They can inspect the equipment and infrastructure to ensure they meet the required specifications and operational conditions.

8.1.2 **Virtual Assessment**—virtual presence: PJLA may use technology to perform assessments using virtual assessment techniques when an assessment does not require the assessor to be at the CABs location.

These techniques may include:

a) teleconferencing,
b) videoconferencing,
c) screen sharing or other platforms.

8.1.2.1 This approach will be utilized at the discretion of PJLA based on circumstances, CAB needs and infrastructure, and an evaluation of risk.

8.1.2.2 The use of technology for assessment purposes shall be mutually agreed upon by the body being assessed and PJLA considering information security and regulations before technology is used for assessment purposes.

8.1.2.3 In the case of non-fulfilment of these measures or non-agreement of information security and data protection measures, PJLA shall use other methods to conduct the assessment.

8.1.2.4 When no agreement is reached for the use of technology for assessment, other methods shall be used to fulfil audit/assessment objectives.

8.1.3 **Hybrid Approach:** This approach can combine both on-site and remote technologies. For instance, the assessment might begin remotely with document and record review of the management system, followed by a focused on-site visit to verify conformity assessment activities

8.2 **Considerations for PJLA Risk related to location of Assessment---**the following items will be considered to determine the appropriate location of assessment activities:

a) Health and Safety Concerns

b) Geographical Barriers:
- Remote or Inaccessible Locations: If the site is in a remote or difficult-to-access area, such as a war zone, an onsite visit may not be practical.
- Travel Restrictions: Legal or logistical travel restrictions, such as government-imposed lockdowns, visa issues, or political instability, may prevent assessors from traveling to the location.

c) Technological Capabilities

d) Nature of the Conformity Assessment Activities

e) Past Assessment Results

f) Confidentiality or Security Concerns

g) Operational Disruptions

h) CAB's History

i) Legal or Regulatory Constraints

j) Type of Assessment

8.3 PJLA may collaborate with other ILAC MRA or IAF MLA Signatory Accreditation Bodies. This can involve accepting assessment results from other accreditation bodies or participating in joint assessments.

8.4 Multisite Accreditation Considerations

8.4.1 If a CAB operates across multiple locations or facilities, they may seek accreditations for all locations under a single accreditation, provided the following conditions are met:

a) The CAB has a consistent quality management system implemented across all locations.

b) The CAB has a defined management structure with clear ultimate authority over the entire accreditation.

c) The CAB confirms that routine internal audits and management reviews cover each location and are reviewed by the designated management with ultimate authority. Records of these audits and reviews shall be made available to PJLA upon request.

d) For each site of a multisite, the headquarters site shall demonstrate oversight of:

1. Policy development.
2. Process and procedure creation.
3. Contract reviews.
4. Approval and decision-making for results of conformity assessment activities.
5. Management reviews.
6. Internal audit planning and follow-up activities.
7. Evaluation of corrective actions.
8. Competence and authorizations.
9. Proficiency Testing and follow-up activities.

8.4.2 During the initial accreditation, assessments are conducted at all locations where key activities take place.

8.4.3 After accreditation, all sites will be assessed regularly during the accreditation cycle.

8.4.3.1 The headquarters site will be assessed annually, while other remote locations will be sampled throughout the cycle.

8.4.3.2 Typically, all facilities listed in the scope of accreditation will undergo a full system assessment over a two-year period. However, depending on the activities at each location, the assessment schedule may be extended to four years.

8.4.4 A sampling schedule will be developed during the initial contract stage and adjusted as needed throughout the accreditation cycle.

8.5 Mobile Facilities Considerations

8.5.1 If a CAB operates with mobile facilities, they may seek accreditations for all mobile facilities under a single accreditation, provided the following conditions are met:

a) The CAB has a consistent quality management system implemented across all mobile facilities.
b) The CAB has a defined management structure with clear ultimate authority over the entire accreditation.
c) The CAB confirms that routine internal audits and management reviews cover each mobile facility and are reviewed by the designated management with ultimate authority. Records of these audits and reviews shall be made available to PJLA upon request.
d) For each mobile facility, the headquarters site shall demonstrate oversight of:

1. Policy development.
2. Process and procedure creation.
3. Contract reviews.
4. Approval and decision-making for results of conformity assessment activities.
5. Management reviews.
6. Internal audit planning and follow-up activities.
7. Evaluation of corrective actions.
8. Competence and authorizations.
9. Proficiency Testing and follow-up activities.

8.5.2 During the initial accreditation, assessments are conducted for all mobile facilities where key activities take place.

8.5.3 After accreditation, mobile facilities will be assessed regularly during the accreditation cycle.

8.5.3.1 The headquarters site will be assessed annually, while other mobile facilities will be sampled throughout the cycle.

8.5.3.2 Typically, all facilities listed in the scope of accreditation will undergo a full system assessment over a two-year period. However, depending on the activities at each location, the assessment schedule may be extended to four years.

8.5.4 A sampling schedule will be developed during the initial contract stage and adjusted as needed throughout the accreditation cycle.

8.6 Assessment Delay Considerations

8.6.1 If a CAB causes a delay in the accreditation process, PJLA will follow the terms stated in the CAB agreement.

8.7 International Assessments Considerations

8.7.1 PJLA may require the CAB to provide any copies of applicable local accreditation regulations. This ensures that assessors, particularly those traveling from another economy, can become familiar with the relevant requirements prior to the assessment.

8.7.2 PJLA may require management system and technical documents to be submitted in English before scheduling an assessment. The assessment may be delayed until PJLA receives all the necessary translated documents.

8.7.3 If the required documents cannot be provided in English, the CAB shall notify PJLA in writing as soon as the assessment is scheduled. Any additional translation costs will be charged, and the assessment may be delayed until PJLA receives the translated documents.

8.7.4 If objective evidence is needed to close nonconformities, PJLA may request the records to be submitted in English. In that event, PJLA will postpone the review of corrective actions until all translated documents and records are received.

8.7.5 When necessary, PJLA may require an English translator during the assessment, and the translator may be a member of the CAB's staff.

9 ACCREDITATION PROCESS

9.1 Accreditation Program

9.1.1 In general, PJLA Conformity Assessment Bodies (CABs) operate on a two-year certificate cycle. The assessment program is designed to ensure appropriate coverage of the accredited scope.

9.1.2 For both initial accreditations and reassessments, a comprehensive sampling of the scope is required. This includes all disciplines as well as all techniques and technologies (for ISO/IEC 17025), or comparable attributes applicable to other accreditation standards, as identified on the scope of accreditation.

9.1.3 Surveillance assessments are guided by assessor recommendations, which are based on risk factors and performance indicators. Reassessments may include focused areas identified during prior surveillance assessments or scope expansion activities.

9.1.4 Scope expansions that were not contracted at the time of assessment scheduling shall not be conducted during the assessment. Time allocation for the assessment

is determined based on the current accredited scope and the accreditation program. No additional time is reserved for unplanned scope expansions.

9.1.4.1 Under certain circumstances, limited modifications such as the addition of analytes to an already accredited method may be considered. Such modifications shall only proceed when:

a) The assessor confirms that sufficient time, objective evidence, and technical competence are available to properly evaluate the addition; and

b) PJLA Headquarters provides prior approval, and the activity is contracted for the inclusion of the analytes during the assessment.

9.1.4.2 All other scope expansions beyond these limited cases shall follow the formal scope expansion request process outside of the scheduled assessment.

9.2 Accreditation Application

9.2.1 When a CAB expresses interest in PJLA's accreditation services, PJLA provides an application form (LF-1) and additional documentation to initiate the process.

9.2.2 The CAB shall complete the form with detailed information, including their legal company name, address, contact details, a description of their conformity assessment activities, equipment and methods used, facility location, number of employees, and the status of their current system.

9.2.3 It is crucial for the CAB to complete the application accurately. Incomplete applications will require follow-up for additional information, which can delay the quoting process.

9.2.4 Only activities conducted under the direct control and responsibility of the CAB, and for which the CAB has demonstrated technical competence, may be included on a proposed scope of accreditation. Activities performed solely by external service providers on behalf of the CAB shall not be identified on the proposed scope. Furthermore, all activities shall be directly related to the conformity assessment activity applied for. For example, a testing laboratory may not include instrument qualification procedures on its scope of accreditation; only the actual testing methods themselves may be listed.

9.2.5 Accreditation is granted on a site-specific basis. Only those sites that have been formally applied for, contracted with PJLA, and assessed during the accreditation process, shall be identified on a scope of accreditation. Sites that are not included in the contracted assessment are not eligible to appear on the accredited scope of accreditation or certificate.

9.2.6 The CAB shall provide sufficient information for PJLA to assess the time required for the accreditation process, including a clear understanding of the CAB's organizational structure and scope.

9.2.7 PJLA's services are available to all CABs, regardless of their size, structure, or location. However, in some exceptional cases, certain requests may be unfeasible for PJLA to accommodate. These cases may include situations where PJLA does not accredit certain activities, lacks resources in a specific economy, government sanctions are in place against the CAB's location, or travel to the area is advised against by the US State Department of State or other government entities where PJLA locations are present.

9.2.8 PJLA provides a quotation for the accreditation and surveillance costs based on the information provided by the applicant. Factors include the type and number of activities at both fixed and field locations, the number of sites and technicians involved, and other relevant considerations.

9.2.9 The quotation may also include additional services such as preliminary assessments.

9.2.10 As applicable, CABs are provided with assessment fees for the following:

9.2.10.1 Assessor on site time and off-site preparation time per day
9.2.10.2 Accreditation fee- Applied for initial, reassessment, site additions or scope expansion assessments. Depending upon the number of standard CABs, accreditation fees may fluctuate.
9.2.10.3 Annual File Maintenance Fee- Applied to initial, surveillance and reassessments.
9.2.10.4 Travel time may be applied for assessments occurring outside of the assessor's home country.
9.2.10.5 Travel-related expenses are not included in the cost for services initially and billed separately after the assessment is completed. Estimated travel expenses may be provided, per request.
9.2.10.6 Other fees may be applied for translation or technical expertise associated with the assessment.

9.2.11 If the CAB agrees to proceed, they shall sign and return the Agreement for Services. Afterward, PJLA will contact the CAB to confirm the preferred assessment dates and arrange the payment of the first installment.

9.2.12 PJLA will notify the CAB of any changes to accreditation requirements. If changes require CAB implementation, PJLA ensures the CAB is informed within a reasonable timeframe to complete the necessary adjustments.

9.2.13 PJLA may request on-site assessments for handling complaints or to follow up on corrective actions when warranted.

9.2.14 The CAB, however, shall notify PJLA immediately of any significant changes that could impact their accreditation. PJLA reserves the right to amend the Agreement for Services if such changes occur or unexpected circumstances arise. Significant changes may include, but are not limited to, relocation or modification of premises, changes in ownership or mergers, personnel changes, equipment changes, or changes in the CAB's ability to perform the accredited scope.

9.2.15 If fraudulent behavior or the intentional provision of false or concealed information is discovered during the accreditation process, PJLA reserves the right to refuse service.

9.3 Assessment Confirmation

9.3.1 After the Agreement for Services is finalized, PJLA will contact the applicant CAB to confirm the proposed scope of accreditation, and the organizational details provided in the application.

9.3.2 Based on this confirmation, PJLA will develop the assessment scope. Any questions or comments about the scope will be discussed with the CAB for clarification.

9.3.3 PJLA and the CAB will then coordinate the assessment process, including selecting assessors, scheduling assessment dates, and confirming any off-site locations, if applicable.

9.3.4 The assessment will cover the standard(s) and/or programs for which the applicant CAB has applied.

9.4 Assignment of Assessment Team

9.4.1 PJLA assigns an assessment team with the appropriate expertise for the CAB's specific scope of accreditation.

9.4.2 No Assessor nor Technical Expert that have worked for or consulted at the applicant CAB within the twenty-four (24) months before the last day of the assignment will be assigned or permitted to conduct any assessments or in any way has given PJLA the impression that a conflict of interest could occur between the assessor and the CAB.

9.4.3 The CAB has the right to raise objections to any member of the assigned assessment team.

9.4.4 PJLA reserves the right to rotate assessors at any time during the accreditation cycle to ensure objectivity and impartiality in the assessment process.

9.4.5 CABs shall sign the assessment confirmation forms before each assessment begins.

9.4.6 If an assessment is postponed or canceled, the CAB is responsible for paying any applicable cancellation fees as specified in the Agreement for Services.

9.5 Additional Assessment Considerations

9.5.1 All assessors shall be provided access to the necessary documents and records to review for conformance. The CAB shall provide access to the necessary documents, records, and locations to review for assessment.

9.5.2 The CAB shall provide a conference room or suitable private meeting space for the assessment team members when assessments are conducted in person at the locations being assessed.

9.5.3 If a virtual assessment is conducted, the CAB shall have videoconferencing capabilities at the sites where conformity assessment activities take place, along with screensharing capabilities to ensure a thorough and effective assessment.

9.5.4 The CAB shall ensure that PJLA has access to assess any off-site conformity assessment activities conducted at the CAB's customer locations. It is the CAB's responsibility to obtain permission through legally enforceable arrangements as applicable from its customers for this access.

9.6 Documentation Review

9.6.1 Accreditation Assessment

9.6.1.1 CABs receive a checklist form that outlines the required documentation and records to be submitted before the on-site assessment, along with a standard-related checklist.

9.6.1.2 The CAB shall complete the standard-related checklist to provide a "roadmap" of its management system for the assessment team

9.6.1.3 All required documents and records shall be submitted to PJLA at least thirty (30) days prior to the assessment.

9.6.1.4 Failure to submit the necessary documents on time may result in the postponement of the assessment.

9.6.1.5 The lead assessor will review the CAB's documentation and records to evaluate the CAB’s compliance with accreditation requirements and to help the assessor prepare for the on-site assessment.

9.6.1.6 The lead assessor will inform the CAB of any questions or comments identified during the document review.

9.6.1.7 These questions or comments may indicate unclear conformance with a specific accreditation requirement, or the absence of required documents needed for compliance.

9.6.1.8 If significant issues or concerns are found during the review prior to the initial accreditation assessment, the assessment may be postponed. PJLA will notify the CAB in writing if this happens.

9.6.2 Ongoing Assessments

9.6.2.1 CABs receive a checklist form that outlines the required documentation and records to be submitted before the on-site assessment.

9.6.2.2 All required documents and records shall be submitted to PJLA at least thirty (30) days prior to the assessment.

9.6.2.3 Failure to submit the necessary documents on time may result in the postponement of the assessment.

9.6.2.4 The lead assessor will review the CAB's documentation and records to evaluate the CAB’s compliance with accreditation requirements and to help the assessor prepare for the on-site assessment.

9.7 Assessment Plan

9.7.1 The lead assessor will develop an assessment plan (LF-146 or LF-147) that outlines the details of the assessment, including the standard(s) being evaluated, the assessment location, dates, times, and the tasks assigned to the assessors.

9.7.2 The plan typically will be provided to the CAB at least 14 days before the assessment, allowing the CAB to propose any adjustments based on workflow, staffing, or other relevant factors.

9.8 Assessment

9.8.1 Opening Meeting

9.8.1.1 The lead assessor and assessment team members will meet with the CAB point of contact, and any personnel the point of contact wishes to be present, to review the assessment plan and confirm the intended scope of the assessment and if changes need to occur in the implementation of the assessment plan.

9.8.1.2 As applicable, the CAB should inform the team of any facility rules (e.g., safety and security protocols) that shall be followed.

9.8.1.3 The lead assessor and assessment team members may request a tour of the CAB to become familiar with the location of conformity assessment activities of the CAB.

9.8.2 Evaluating Objective Evidence

9.8.2.1 Following the opening meeting, the assessment team will independently conduct the assessment activity.

9.8.2.2 To complete an assessment in the time provided, the lead assessor and assessment team will review a representative sample of the work done by the CAB.

The lead assessor and assessment team are responsible for thoroughly examining and documenting evidence to determine if the CAB is compliant and competent in meeting the requirements for accreditation.

9.8.2.2.1 The size of the sample being reviewed varies depending on factors such as the type and location of the assessment activities, the number of personnel in the CAB, and the availability of relevant records.

9.8.2.3 The evaluation of conformance, competence, and effectiveness of the management system will be carried out using various assessment techniques, depending on the type of assessment activity. These techniques may include:

9.8.2.4 Witnessing/Observation: Assessors will observe a representative sample of personnel performing authorized tasks during the assessment. These observations may involve actual conformity assessment activities or mock demonstrations designed to reflect typical work practices.

Note: Certain programs may require witnessing to take place during the first occurrence of the conformity assessment activity or as part of the next accreditation activity.

9.8.2.5 Equipment Review: Assessors will evaluate the CAB's equipment to ensure it is properly calibrated, maintained, and suitable for the intended tests or calibrations. This includes checking calibration records, maintenance logs, and ensuring the equipment meets accuracy and traceability requirements.

9.8.2.6 Interviews: Assessors will interview a sample of personnel covered by the CAB's management system. Interviews may occur before or after witnessing tasks or may involve questions related to the review of records or reports.

9.8.2.7 Document and Record Review: The assessment team will review a sample of documents and records.

- If possible, any documents and records requested in advance by the assessment team should be made available electronically or in the designated meeting space.
- Additional documents and records may be requested during the assessment.
- If applicable to the accreditation program, reports will be reviewed to ensure results are supported by adequate technical records. The sample of reports will cover each component or parameter on the requested scope of accreditation.

9.8.2.8 PT Review: The assessment team will review Proficiency Testing (PT) plans and evidence of PT participation (or approved PJLA alternatives).

- If satisfactory performance is not achieved, the assessment team will also review evidence of corrective actions taken.

9.8.2.9 A combination of assessment techniques will be applied, tailored to the specific type of assessment being conducted.

9.8.3 Nonconformities and Observations

9.8.3.1 The lead assessor will determine assessment findings based on objective evidence gathered by the assessment team. For each accreditation requirement reviewed, the lead assessor will decide if the CAB is conforming, nonconforming, or if the requirement is not applicable.

9.8.3.2 Both the lead assessor and assessment team members will record objective evidence in sufficient detail to support their findings (conformance, nonconformance, or not applicable) and to support the team's accreditation recommendation.

9.8.3.2.1 For nonconforming requirements, the lead assessor will document the nonconformances on the nonconformance and observation form for the CAB to address.

9.8.3.2.2 The lead assessor may also note observations that identify opportunities for improvement in a practice that is currently conforming but could lead to a future nonconformance if not addressed.

9.8.4 Closing Meeting

9.8.4.1 At the end of the assessment, the lead assessor and CAB representatives will hold a meeting to review the results. The following will take place during the closing meeting:

9.8.4.1.1 Attendance will be recorded on the form LF-6.

9.8.4.1.2 The assessment team and the CAB will work together to review and finalize a draft scope of accreditation.

- This draft specifies the conformity assessment activities which the CAB is seeking accreditation.
- Throughout this process, both the assessment team and the CAB will ensure that all relevant conformity assessment activities are clearly described and complies with PJLA PL-4 Scopes of Accreditation.
- Any adjustments or clarifications needed will be discussed, and once both parties reach an agreement, the draft scope will form the foundation for the formal accreditation process.

9.8.4.1.3 The assessment team will provide a summary of the assessment report (LF-9) to the CAB representatives and discuss it. A copy of the report will be given to the CAB, or in rare cases, it may be provided within 24 hours of the closing meeting.

9.8.4.1.4 The assessment team will present any nonconformances to the CAB (LF-8), explaining them in detail and allowing the CAB to ask questions or clarify any misunderstandings. A copy of the nonconformance form will be left with the CAB, or in rare cases, provided within 24 hours.

9.8.4.1.5 The assessment team will present and discuss their recommendation regarding accreditation.

9.8.4.1.6 Based on the number and severity of the nonconformities, the lead assessor may recommend a follow-up assessment to PJLA.

9.9 Post Assessment

9.9.1 Resolution of Nonconformances

9.9.1.1 Within sixty (60) calendar days of the closing meeting, the CAB shall submit a corrective action report along with evidence for each nonconformance

identified during the assessment. Note: reduced program specific corrective action timeframes may apply.

The response shall include:

a) A detailed corrective action report from the CAB, outlining the evaluation of the issue, its cause, a proposed action plan, and the timeline for implementation and completion.

b) Objective evidence showing that the action plan has been implemented to a degree which provides assurance that the nonconformance no longer negatively affects operations.

9.9.1.2 The lead assessor will review the submitted information to determine whether the CAB's evaluation and proposed actions adequately address the nonconformance and its impact and will communicate this determination to the CAB.

9.9.1.3 If the evaluation or proposed actions are insufficient, the CAB will need to conduct further evaluation and/or propose additional actions.

9.9.1.4 PJLA may require a follow-up assessment to verify that the nonconformance has been properly resolved.

9.9.1.5 If the nonconformance is not resolved within sixty (60) calendar days, the issue will be escalated to the President or their designee for further action.

9.9.1.6 Failure to resolve a nonconformance within the sixty (60) day period may result in the termination of the accreditation process or affect the CAB's current accreditation status.

9.9.2 Accreditation Decision

9.9.2.1 Once all nonconformities are resolved, the assessment results, supporting records, and any other relevant information will be reviewed by a member of PJLA's Executive Committee, who will then make the accreditation decision. This decision may either grant or deny accreditation.

9.9.2.2 The accreditation decision is based on the records provided by the assessment team, which include the standard(s) and/or program(s) fields, as well as the scope of the CAB's conformity assessment activities where the CAB demonstrated competence.

This information includes but is not limited to the details of the conformity assessment activities reviewed, the assessment report, the resolution of any nonconformities, and the scope agreed upon by the CAB and the assessment team during the closing meeting.

9.9.2.3 The Executive Committee may request PJLA to gather additional information from the assessment team or the CAB to address any issues and ensure a well-informed accreditation decision.

9.9.3 Accreditation Certificate, Scope and Symbol

9.9.3.1 Once the decision to grant accreditation is confirmed, PJLA will prepare a draft scope based on what was agreed upon by the CAB and the assessment team during the closing meeting.

9.9.3.2 PJLA will send a copy of the draft scope of accreditation to the CAB for review before it is officially issued. If any issues are identified by the CAB, they may require additional feedback from the assessment team and further review by the Executive Committee.

9.9.3.3 PJLA will provide the CAB with an official copy of the certificate and scope in both a non-editable digital format via email and a hard copy via mail. Additionally, the CAB will receive the Use of Accreditation Claims and Symbols Procedure (SOP-3) and the necessary symbol for promoting their accreditation.

9.9.3.4 All CABs shall follow the instructions in SOP-3, as specified in their service agreement. This includes the proper use of accreditation symbols, language, and any applicable bodies' recognition marks (e.g., ILAC).

9.9.3.5 The certificate will include the initial accreditation date, the issue date (based on the Executive Committee's decision), the expiration date, a unique accreditation number, and a certificate number.

The accreditation number remains the same for the CAB's entire accreditation period, while the certificate number is updated as needed.

The scope document will detail the field and conformity assessment activities for which accreditation has been granted and will be specific to each location where accredited work is performed.

9.9.3.6 The accreditation expiration date is set to allow PJLA to establish a consistent schedule for surveillance and reassessment, while ensuring enough time for the CAB to resolve any nonconformities identified during reassessment.

9.9.3.7 The use of accreditation claims and the PJLA symbol is covered in SOP-03.

9.9.4 Accreditation Extension

9.9.4.1 PJLA may occasionally grant an extension of accreditation to currently accredited CABs. Extensions are considered and approved on a case-by-case basis.

9.9.5 Post-Assessment Survey

9.9.5.1 The CAB point of contact will have the chance to complete a survey about the assessment process after the assessment.

9.9.5.2 Constructive feedback is crucial for helping PJLA identify areas for improvement.

9.9.5.3 Positive feedback is also valuable for recognizing areas where PJLA meets or exceeds expectations.

10 MAINTAINING ACCREDITATION

10.1 PJLA generally operates on a two-year accreditation cycle, starting with an initial assessment followed by a surveillance assessment. Cycles continue with regular re-assessments and surveillance assessments.

10.2 To avoid the risk of accreditation expiring, assessments are scheduled at least three months before the certificate's expiration. This allows sufficient time for CAB corrective actions (60 days), assessor review of those actions, Executive Committee review, and the issuance of a new certificate.

10.3 PJLA may modify the accreditation cycle to fit a program-specific schedule under agreements with scheme owners, regulators, and/or accredited CABs.

10.4 To maintain accredited status until the expiration date on the Certificate of Accreditation, the CAB shall continue to meet the requirements under which it was accredited.

10.5 PJLA conducts various types of assessments annually to ensure ongoing compliance with accreditation requirements, following the process described above. Details on assessment types can be found in Work Instruction WI-28.

10.6 The accreditation cycle and related activities are designed to help PJLA monitor CAB activities and ensure continued compliance with accreditation requirements.

10.7 PJLA may contact a CAB at any time to request documentation or records related to any aspect of the scope of accreditation. PJLA also reserves the right to monitor the CAB's ongoing performance through all reasonable means.

10.8 PJLA may conduct extraordinary assessments outside the typical cycle due to issues such as complaints, proficiency testing performance, location changes, organizational changes, or other situations that require verifying the integrity of the accreditation. When necessary, PJLA will inform the CAB if an extraordinary assessment is required.

11 SCOPE CHANGES

11.1 The CAB can request an additional assessment to expand their scope at any point during the accreditation cycle.

11.2 If a scope expansion request is made while the assessor is onsite, it may be deferred to a separate assessment, as it could impact the cost and time involved.

11.3 The CAB should submit requests for scope additions and have all necessary documents and records ready at least sixty to ninety days before the assessment is needed.

11.4 Scope additions involving technical changes will be reviewed by PJLA technical staff to ensure the new items meet all required standards.

11.5 The CAB's technical competence to perform new activities shall be verified before the scope of accreditation can be updated.

11.5.1 This verification may involve a remote or onsite visit or a technical review of documents and records. PJLA will assess the request, the current scope, and other factors to determine the appropriate assessment approach.

11.6 Voluntary removal of scope items or minor editorial changes typically require only administrative action by PJLA.

12 UPDATES AND TECHNICAL RESOURCES

12.1 PJLA provides updates and technical resources to help with the understanding and application of accreditation requirements.

12.2 These updates and resources are publicly accessible on the PJLA website, www.pjlabs.com.

13 CAB CHANGES

13.1 A CAB shall notify PJLA within five business days of discovering any issues that could impact its conformity assessment activities or its compliance with accreditation requirements.

13.2 The CAB shall provide evidence of compliance with any accreditation requirements that may be impacted. PJLA will assess the situation and decide whether a virtual or onsite assessment is needed.

13.3 The CAB shall notify PJLA about the following:

13.3.1 Changes of name or ownership.

13.3.2 Changes in legal, commercial, or organizational status.

13.3.3 Changes in organization and management (e.g., key managerial staff or accounting contact).

13.3.4 Major changes of or affecting policies, processes, or procedures related to conformity assessment activities.

13.3.5 Changes in physical location or premises.

13.3.6 Repeated failures in proficiency testing (or its alternatives) for the same method, approach, or technology.

13.3.7 Changes in key personnel, equipment, facilities, working environment, or other resources that affect data validity or the CAB's ability to perform accredited conformity assessments.

13.3.7.1 Key personnel include the technical and quality management, and accounting contact.

13.3.8 Changes to the CAB's payment processes.

13.3.9 Any other significant changes that impact the CAB's management system, technical operations, capability, scope, compliance, or competence as defined by PJLA.

13.4 After receiving notification from the CAB, PJLA will evaluate the impact on accreditation and may take the following actions:

13.4.1 Make a note in the PJLA database for the next assessment.

13.4.2 Schedule an assessment to evaluate the impact of the changes.

13.4.3 Request additional proof of compliance.

13.4.4 Revise the CAB's scope of accreditation.

14 CHANGE OF LOCATIONS

14.1 A CAB can request accreditation for additional locations at any time. Accreditation applies specifically to the physical locations listed on the Scope of Accreditation. If a location listed on the scope changes its address, the CAB shall notify PJLA when the move is planned.

14.2 The CAB shall provide evidence showing continued compliance with accreditation requirements that could be affected by the move.

14.3 PJLA will review the situation and decide whether a virtual or onsite assessment is needed.

15 TRANSFER OF ACCREDITATION

15.1 Organizations accredited by other accreditation bodies may apply to transfer their accreditation to PJLA under SOP 13. To be eligible for the transfer, the CAB shall be currently accredited and in good standing with an accreditation body that is a signatory of the ILAC MRA.

15.2 PJLA will assess eligibility and aim to ensure a smooth transfer of accreditation whenever warranted and possible.

16 SUSPENSION, WITHDRAWAL AND REDUCTION OF ACCREDITATION

16.1 According to PJLA's Suspension, Withdrawal, or Reduction of Scope Procedure (SOP-11), PJLA has the right to suspend, withdraw, or reduce a CAB's accreditation at any time

16.2 These actions are typically considered in the following situations:

16.2.1 The CAB fails to complete corrective actions within the agreed timeframe.

16.2.2 The CAB repeatedly fails to meet the Standard or PJLA policies.

16.2.3 The CAB misuses PJLA's Accreditation Symbol, Certificate of Accreditation, or Accreditation Language, as outlined in SOP-3.

16.2.4 The CAB is late in paying its financial obligations to PJLA.

16.2.5 The CAB is subject to bankruptcy or makes arrangements with creditors, enters liquidation, or has a receiver appointed.

16.2.6 The CAB is adjudged for loan offense that harms the facility's reputation and goodwill.

16.2.7 The CAB commits acts that, in PJLA's view, damage PJLA's goodwill, name, and reputation.

16.2.8 The CAB engages in fraudulent behavior.

16.2.9 The CAB knowingly provides false information.

16.2.10 The CAB hides information.

16.2.11 PJLA reserves the right to make public any actions related to withdrawal, cancellation, reduction, or suspension of a CAB’s accreditation.

16.3 PJLA will also cancel accreditation if the CAB makes a formal written request.

16.4 PJLA may take legal action for wrongful acts specified in section 16.2.

17 NOTIFICATION OF CHANGES TO ACCREDITATION REQUIREMENTS

17.1 PJLA will notify CABs of any changes to accreditation requirements or procedures, including the date the changes will take effect.

17.2 PJLA aims to give CABs enough time to make the necessary adjustments.

17.3 PJLA will review how the CAB has implemented the changes during the next scheduled assessment, or earlier if the changes require it.

17.4 Accreditation requirements are posted on PJLA's website.

18 DISPUTES AND APPEALS

18.1 A CAB or any interested party has the right to dispute or appeal PJLA's decisions regarding:

18.1.1 Denial of accreditation to an applicant CAB.

18.1.2 Selection of the assessment team.

18.1.3 Nonconformities identified by the assessment team.

18.1.4 Suspension, withdrawal, reduction, or cancellation of accreditation.

18.1.5 Refusal to grant or extend accreditation.

18.1.6 A third-party appeal against PJLA's decision to grant accreditation.

18.1.7 Any other matter related to the accreditation process.

18.2 For more details, refer to SOP 10 Dispute and Appeal Procedure, available at www.pjlabs.com .

19 COMPLAINTS

19.1 PJLA has a formal process for reviewing, processing, and making decisions on complaints. Complaints can be received from any source, including a CAB, another accreditation body, or a stakeholder, through verbal communication, email, or other methods.

19.2 PJLA will take steps to ensure a clear understanding of the complaint and take appropriate actions to resolve it.

19.3 For more details, refer to SOP 09 Complaint Procedure, available at www.pjlabs.com.

Appendix A

A.1 ISO/IEC 17025 PJLA Accreditation Requirements

1. For ISO/IEC 17025, the following documents are to be used:

    a. ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

    b. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

    c. PJLA Policy PL-1 on Proficiency Testing (PJLA application of ILAC P9)

    d. PJLA Policy PL-2 on Measurement Traceability (PJLA application of ILAC P10)

    e. PJLA Policy PL-3 on Measurement Uncertainty for Calibration and Testing Laboratories (Includes PJLA application of ILAC P14)

    f. PJLA Policy PL-4 on Scopes of Accreditation

    a. PJLA SOP 003 Use of Accreditation Claims and Symbols (PJLA application of ILAC P8)

2. Additionally, specific program requirements may apply to conformity assessment activities supporting the requirements of regulators and industry specifiers.

3. The following guidance documents may be used:

    a. ILAC G8 Guidelines on Decision Rules and Statements of Conformity

    b. ILAC G17 ILAC Guidelines for Measurement Uncertainty in Testing

A.2 ISO/IEC 17020 PJLA Accreditation Requirements

1. For ISO/IEC 17020, the following documents are to be used:

    a. ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

    b. ISO/IEC 17020 Conformity assessment — Requirements for the operation of various types of bodies performing inspection

    c. PJLA Policy PL-1 on Proficiency Testing (PJLA application of ILAC P9)

    d. PJLA Policy on PL-2 Measurement Traceability (PJLA application of ILAC P10)

    e. PJLA Policy on PL-4 Scopes of Accreditation

    f. PJLA SOP 003 Use of Accreditation Claims and Symbols (PJLA application of ILAC P8)

    g. ILAC P15 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

2. Additionally, specific program requirements may apply to conformity assessment activities supporting the requirements of regulators and industry specifiers.

3. The following guidance document may be used:

    a. ILAC G27 Guidance on measurements performed as part of an inspection process

A.3 ISO 17034 PJLA Accreditation Requirements

1. For ISO/IEC 17034, the following documents are to be used:

    a. ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

    b. ISO 17034 General requirements for the competence of reference material producers

    c. PJLA Policy PL-1 on Proficiency Testing (PJLA application of ILAC P9)

        i. This document applies to cases where ISO 17034 CAB in-house laboratories or subcontractor laboratories are involved in value assignment but are not accredited to ISO/IEC 17025.

    d. PJLA Policy on PL-2 Measurement Traceability (PJLA application of ILAC P10)

        ii. This document applies to cases where ISO 17034 CAB in-house laboratories or subcontractor laboratories are involved in value assignment but are not accredited to ISO/IEC 17025.

    c. PJLA Policy PL-3 on Measurement Uncertainty for Calibration and Testing Laboratories (Includes PJLA application of ILAC P14)

        iii. This document applies to cases where ISO 17034 CAB in-house laboratories or subcontractor laboratories are involved in value assignment but are not accredited to ISO/IEC 17025.

    d. PJLA Policy PL-4 on Scopes of Accreditation

    b. PJLA SOP 003 Use of Accreditation Claims and Symbols (PJLA application of ILAC P8)

4. Additionally, specific program requirements may apply to conformity assessment activities supporting the requirements of regulators and industry specifiers.

5. The following guidance documents may be used:

    a. ILAC G17 ILAC Guidelines for Measurement Uncertainty in Testing

    b. ISO 33401 Reference materials — Contents of certificates, labels and accompanying documentation

    c. ISO 33405 Reference materials — Approaches for characterization and assessment of homogeneity and stability

d. ISO 33406 Approaches for the production of reference materials with qualitative properties

e. ISO 33407 Guidance for the production of pure organic substance certified reference materials

A.4 ISO/IEC 17043 PJLA Accreditation Requirements

1. For ISO/IEC 17043, the following documents are to be used:

    a. ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

    b. ISO/IEC 17043 Conformity assessment — General requirements for the competence of proficiency testing providers

    c. PJLA Policy PL-1 on Proficiency Testing (PJLA application of ILAC P9)

        i. This document applies to cases where ISO/IEC 17043 CAB in-house laboratories and subcontractor laboratories provide results used to establish the assigned value, when those laboratories are not accredited to ISO/IEC 17025.

    d. PJLA Policy on PL-2 Measurement Traceability (PJLA application of ILAC P10)

        i. This document applies to cases where ISO/IEC 17043 CAB in-house laboratories and subcontractor laboratories provide results used to establish the assigned value, when those laboratories are not accredited to ISO/IEC 17025.

    e. PJLA Policy PL-3 on Measurement Uncertainty for Calibration and Testing Laboratories (Includes PJLA application of ILAC P14)

        i. This document applies to cases where ISO/IEC 17043 CAB in-house laboratories and subcontractor laboratories provide results used to establish the assigned value, when those laboratories are not accredited to ISO/IEC 17025.

    f. PJLA Policy PL-4 on Scopes of Accreditation

    g. PJLA SOP 003 Use of Accreditation Claims and Symbols (PJLA application of ILAC P8)

2. Additionally, specific program requirements may apply to conformity assessment activities supporting the requirements of regulators and industry specifiers.

3. The following guidance documents may be used:

    a. ILAC G17 ILAC Guidelines for Measurement Uncertainty in Testing
    b. ISO 13528 Statistical methods for use in proficiency testing by interlaboratory comparison

A.5 ISO 15189 PJLA Accreditation Requirements

1. For ISO/IEC 15189, the following documents are to be used:

    a. ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

    b. ISO 15189 Medical laboratories — Requirements for quality and competence

    c. PJLA Policy PL-1 on Proficiency Testing (PJLA application of ILAC P9)

    d. PJLA Policy PL-2 on Measurement Traceability (PJLA application of ILAC P10)

    e. PJLA Policy PL-3 on Measurement Uncertainty for Calibration and Testing Laboratories (Includes PJLA application of ILAC P14)

    f. PJLA Policy PL-4 on Scopes of Accreditation

    c. PJLA SOP 003 Use of Accreditation Claims and Symbols (PJLA application of ILAC P8)

2. Additionally, specific program requirements may apply to conformity assessment activities supporting the requirements of regulators and industry specifiers.

3. The following guidance documents may be used:

    a. ILAC G17 ILAC Guidelines for Measurement Uncertainty in Testing

    b. ILAC G26 Guidance for the Implementation of a Medical Accreditation Scheme

    c. ISO/TS 20914 Medical laboratories — Practical guidance for the estimation of measurement uncertainty