



Accreditation Procedure

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations, Inspection Bodies and Proficiency Testing Providers). 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.**



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1.0 INTRODUCTION

- 1.1 Perry Johnson Laboratory Accreditation, Inc. (PJLA) is a Michigan corporation wholly owned by Perry Lawrence Johnson ("Stockholder"). Mr. Johnson has no active management role in the operation of PJLA, and PJLA has no corporate relationship to Mr. Johnson's other business enterprises.
- 1.2 PJLA services include assessment and accreditation of conformity assessment body (CAB) systems to international, national, regulatory or governmental standards or program requirements.

2.0 SCOPE

- 2.1 This procedure covers the scope of the PJLA's accreditation process. It conforms to ISO/IEC 17011:2017 and other national and/or international standards as applicable. Accreditation criteria not covered in this procedure may be found in specific accreditation procedural documents.

3.0 DEFINITIONS

- 3.1 **Accreditation Body (PJLA):** Authoritative Body that performs accreditation.
- 3.2 **Accredited/Applicant Conformity Assessment Body (CAB):** A body that performs conformity assessment services that can be the object of accreditation.
- 3.3 **Accreditation Certificate of Approval:** A formal document or set of documents, stating that accreditation has been granted for the defined scope
- 3.4 **Assessment:** Process undertaken by an accreditation body to assess the competence of the (CAB) based on particular standard(s) and/or normative documents and for a defined scope of accreditation.
- 3.5 **Assessor:** Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a (CAB).
- 3.6 **Preliminary Assessment (Preassessment):** An informal assessment carried out by PJLA to assess a (CAB) prior to the Initial Accreditation Assessment. The objective of the preassessment is to identify system gaps so that corrective actions can be implemented prior to the formal Accreditation Assessment.
- 3.7 **Accreditation/Reassessment:** Full System third-party attestation related to a (CAB) conveying formal demonstration of its competence to carry out specific conformity assessments tasks.



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- 3.8 **Surveillance Assessment:** Set of activities, except reassessment, to monitor the continued fulfillment by an accredited (CAB) of requirements for accreditation.
- 3.9 **Accreditation Symbol:** A symbol issued by an accreditation body to be used by accredited (CAB) to indicate their accreditation status.
- 3.10 **Registry:** Listing of accredited (CABs).

4.0 REQUEST FOR ACCREDITATION

- 4.1 CABs initiate the accreditation process through verbal or written communication of their interest in PJLA's services. An application for accreditation is supplied to the CAB (LF-1) along with additional accreditation system documentation and information as necessary.
- 4.2 The applicant completes the (LF-1), which provides PJLA with the initial information required to commence the accreditation process. This document elicits from the applicant the following details, among others:
 - 4.2.1 legal company name, address, contact information
 - 4.2.2 description of testing/calibration/RMP/FSMO/Inspection/PTP performed, including a description of activities performed at the organization's facility, customer locations, and in-house calibrations performed as applicable;
 - 4.2.3 description of equipment used;
 - 4.2.4 description of methods used;
 - 4.2.5 description of premises of facility, number of employees, traveling employees and work shifts, and;
 - 4.2.6 status of existing system.
- 4.3 If the (LF-1) is incomplete, it will be rejected and the (CAB) will be contacted for further information. No quotation will be generated without having enough information to determine the appropriate amount of time to spend at the facility, including information in regards to the (CAB's) structure and scope.
- 4.4 PJLA makes its services available to all (CABs) regardless of size, structure and location unless the request is unfeasible to perform (i.e. PJLA does not provide certain scope of activities, no resources are available within an economy, government contract restrictions, and dangerous work zones).
- 4.5 On the basis of the information furnished by the applicant, PJLA provides a quotation to cover the cost of the accreditation and subsequent surveillance visits. The required number of assessment man-days is determined by examining the number and types of activities being performed at fixed locations



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and at customer locations, number of sites and number of technicians residing within the (CAB). At no such time, will an initial accreditation assessment be quoted for less than 1.0 day on-site and .50 day off-site. The quotation may also include additional services such as preliminary assessments and on-site training activities. Applicants are informed that quotations received are based on the information as detailed in the application and is subject to change if inadequate or incomplete information was provided.

4.6 Should the applicant wish to proceed, then the applicant signs and returns a copy of the Agreement for Services bearing an original signature. The receipt by PJLA of this document is taken as an instruction to proceed in accordance with the agreement for services and associated procedures. At this stage, the applicant also provides PJLA with the following:

4.6.1 Written confirmation of preferred dates for the preassessment (if applicable) and initial accreditation assessment

4.6.2 Payment of the first installment per the Agreement for Services

4.7 If the requirements for accreditation change at any time needing retroactive implementation, PJLA will ensure that the (CAB) is notified within a reasonable timeframe in order for the (CAB) to successfully complete implementation.

4.8 PJLA reserves the right to amend said Agreement for Services at any time if significant changes have occurred or unexpected circumstances take place with the applicant/accredited (CAB). **This includes, but is not limited to: relocation or modification of premises, ownership change or merger, personnel changes, equipment changes, changes in main policies or capability to perform the scope of accreditation. PJLA has the right to request an on-site assessment resulting from complaints where evidence of conformity is required. Additionally, follow-up visits may be required in order to confirm CAB's corrective action implementation when severe nonconformities are detected during an assessment. It is the responsibility of the applicant/accredited (CAB) to inform PJLA of any significant changes that could impact their accreditation immediately.**

5.0 ASSESSMENT CONFIRMATION

5.1 Once the agreement for services is finalized PJLA will contact the applicant (CAB) to confirm the scope of accreditation and details of the organization as provided on the application. The scope of assessment will be developed upon confirmation of the assessment. Any questions or comments derived from the development of the scope will be submitted to the (CAB) for clarification. During the same time the (CAB) will discuss arrangements for the assessment (assessors, dates and off-site premises where activities of their scope are being performed as applicable), to ensure adequate time and an adequate schedule can be developed to perform the assessment. No Assessor will be assigned or permitted to conduct any assessments where they have participated in more than



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two (2) preliminary assessments of the accreditation client or in any way has given PJLA the impression that a conflict of interest could occur between the assessor and the (CAB). (CABs) will be clearly communicated to in regard to the names of the assessor(s) assigned and provided the opportunity to object any assessor or group of assessors. In cases, where an assessor arrives at the (CAB) location and detects or is informed of a conflict of interest or a potential conflict of interest between them and the CAB, then they should contact PJLA headquarters immediately to discuss the issue. If PJLA finds that the assessor is in a position that imposes a conflict of interest with the CAB, then a new assessor will be assigned or the assessment will be terminated. At no such time, will PJLA allow the integrity and impartiality of an assessment to be jeopardized due to conflict of interests. PJLA appoints a qualified assessment team that includes members competent to assess the scope of the (CAB), including in-house calibration activities, as applicable. If an assessment team cannot qualify for the scope of the (CAB), then a technical expert will be added to the team to provide the necessary technical expertise. Assessors and technical expertise will be evaluated against PJLA's Personnel Procedure (SOP-2) which includes guidelines for education, training and work experience requirements.

- 5.2 (CABs) will be provided with a readiness review checklist LF-116, which outlines documentation to be submitted 30 days prior to the on-site assessment. Additionally, CABs will be provided their proposed scope or scope of accreditation to confirm adequacy. Documents should be completed to PJLA headquarters and the assessor 30 days prior to the start of the assessment. Failure to submit the required documents may result in the cancellation of the assessment.
- 5.3 (CABs) will be required to sign all assessment confirmation forms prior to each assessment. Postponement or cancellation of assessments obligates the (CAB) to pay cancellation fees as specified in (LF-3), Agreement for Services.

6.0 DOCUMENTATION REVIEW

- 6.1 Upon receipt of the requested documentation as outlined in the LF-116 readiness review checklist, the assessor will review the content of the material to ensure the readiness of the CAB. The lead assessor or team will complete their review and notify the (CAB) if any questions arise. Nonconformities may be detected during this review process and communicated to the (CAB) prior to or during the assessment. If the nonconformities are severe, the assessor(s) will recommend that the assessment be postponed.
- 6.2 Once the documentation review is completed and a recommendation is made to proceed with the on-site assessment, the lead assessor will develop an assessment plan. This will include specifics to the assessment including but not limited to: the scope of the (CAB), appropriate standard(s) and references, location(s), dates, start/end times, names of the assigned management representatives, assessor names with specific identified tasks, confidentiality



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statements and a listing to whom their final report will be distributed to. (CABs) will have the opportunity to review the assessment plan at least 14-days prior to the assessment and may communicate with the lead assessor of any proposed changes. PJLA headquarters will also retrieve a copy of the plan to review and approve within a similar timeframe.

7.0 ON-SITE ASSESSMENT CRITERIA

7.1 Assessments are carried out in accordance to ISO 17011:2017 and consist of the following:

7.1.1 **Opening Meeting** is conducted with the (CAB's) management to confirm the scope and purpose of the assessment, review the assessment plan, reporting procedures and criteria for accreditation, introduce the assessment team and to confirm all relevant details for the assessment. The assessment team will also request that the (CAB) provides them any details in regards to proprietary information within their organization. They will explain the levels of possible nonconformities and observations that may or may not be detected during the visit. All members available at the opening meeting will also be required to sign an attendance sheet as evidence of their participation.

7.1.2 **A Detailed Examination** of the (CAB): personnel, document review, facilities and equipment. The assessment is conducted at all locations where key activities are performed. Activities performed at field sites are coordinated between PJLA and the CAB and witnessed as available. The CAB shall ensure that contracts exist with their customers to allow for PJLA to witness activities as requested. An appropriate number of staff is interviewed to ensure the competency of the (CAB) to perform activities covered by its desired scope, including staff performing in-house calibrations that affect the traceability of calibrations and/or test results. A technical assessment of the CAB includes the review of : training records, environmental conditions, equipment, traceability, reports/certification, calibration records, measurement uncertainty data, records and method validation criteria and proficiency testing results. The review of the CAB's quality management system will also be part of each assessment. The (CAB) is obligated to assist the assessment team by ensuring that all facilities related to the scope of accreditation are accessible and that an appropriate number of staff members are made available to interview. Members of the (CAB) should participate with the assessment team by clearly communicating with them on their processes and have the ability to promptly provide supporting documentation or records for areas being assessed. Any delays by the (CAB) and its staff may cause a delay in accreditation. A witness schedule of the (CAB's) scope of activities will be agreed upon



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between the lead assessor and the (CAB) to ensure all assessment activities are witnessed over a 6 year period. This will be documented on the LF-21 supplement form and included in each assessment package

7.1.2.1 During the time of the on-site examination assessors will clearly communicate any nonconformities or observations detected to the (CAB) representative. This includes the following:

7.1.2.1.1 **Major:** A total absence of a required system element, or a series of minor nonconformities which, taken together, indicate a total breakdown of a required system element.

7.1.2.1.2 **Minor:** A single lapse in discipline or control.

7.1.2.1.3 **Observation:** In addition to major and minor nonconformities, an “observation” is another class of assessment finding. While not strictly a “nonconformance”, a finding classified as an observation indicates that, in the opinion of the assessor, clarification or investigation is warranted to ensure the overall effectiveness of the system being assessed (Corrective action is not mandatory for observations).

7.1.2.2 If for any reason the assessment team is having difficulty identifying whether a certain circumstance is or is not meeting the intent of the standard or PJLA policy then they may contact PJLA headquarters for clarification.

7.1.3 **Closing Meeting** is conducted upon completion of the assessment. This includes a discussion of the (CAB’s) performance against the standard being assessed and any nonconformities or observations detected. The (CAB) will be provided a copy of all nonconformities and observations as well as a detailed assessment report. A final recommendation to accredit or/not accredit will be announced during this time. The assessment team will inform the (CAB) of the timelines required for corrective action responses as applicable. The (CAB) will be informed of PJLA’s Appeal and Dispute Procedure (SOP-10) in the case nonconformities cannot be agreed upon. A final review of the scope will be reviewed and approved between the assessor(s) and the (CAB) and an overview of the final accreditation decision and certificate submission process will be provided. All members involved with the closing meeting will be asked to sign an attendance sheet as



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evidence of their participation. Nonconformities sited during the visit will as be required to be signed by the (CAB's) management representative as indication of their acceptance of the finding(s).

8.0 POST ASSESSMENT ACTIVITIES/CORRECTIVE ACTION SUBMISSION

- 8.1 (CABs) are required to submit appropriate corrective action responses for all nonconformities with sufficient objective evidence of closure. Corrective action responses should provide the assessment team confidence that the nonconformity has been corrected and contained. Objective evidence for statements or activities completed due to corrective action taken should coincide with the nonconformity and should be clearly identifiable to the assessment team. Failure to do so will cause the assessor to reject the corrective action, resulting in a delay of accreditation. (CABs) should submit corrective action on their corrective action form in accordance with their corrective action procedure.
- 8.2 (CABs) have 60-days from the last day of the assessment to submit corrective action. Depending on the severity of the nonconformity, this timeline may be adjusted, or a follow-up visit may be required to verify the effectiveness of the corrective action. *Note some programs may require different timelines. In this case, these will be provided to the (CAB) during the closing meeting.* Failure to submit corrective action on-time or sufficiently may cause the accreditation to be voided requiring the (CAB) to re-apply or conduct a follow-up visit or suspension of a current accreditation. Multiple corrective action submission reviews are strongly discouraged and may lead to additional assessment time and cost to the CAB as necessary.

9.0 FINAL ACCREDITATION DECISION

- 9.1 Once accreditation is recommended by the lead assessor, the assessment material will be reviewed by PJLA's headquarter staff and submitted to the Executive Committee for a final decision to either grant or deny accreditation without undue delay. Members of the PJLA Executive Committee are independent parties from the assessment team that have no conflict of interest with the (CAB). Members are selected based on their fields of expertise aligning with the scope accreditation of the (CAB). More than one Executive Committee Member or Technical Reviewer may be selected to complete the final review. The final review consists of a complete assessment package review that should provide executive committee members confidence that the (CAB) is fully complying with the standard assessed, PJLA policies and that they have adequately responded to all nonconformities alleviating any doubt that the fulfillment of the requirements have been met. The Executive Committee may reject the assessment and request additional information at its discretion. In this case, the President/Operations Manager and/or Technical Program Manager(s) will instruct the lead assessor to retrieve more information from the CAB or the CAB may be communicated directly from PJLA headquarters. (CABs) have the



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opportunity to respond to any rejections or comments made by the Executive Committee. If the accreditation cannot be recommended by the lead assessor or the Executive Committee, then PJLA will communicate this to the (CAB). The (CAB) will either be required to completely reapply for accreditation or perform an extensive follow-up visit. The Executive Committee may also approve the assessment material on a contingency which may require a follow up of certain activities at the next assessment or additional documentation to be provided from the assessor(s). Contingencies made for any breach of the standard assessed, PJLA policy or any other breach of PJLA's agreement for services with the CAB will not be accepted by PJLA headquarters and will result in a rejection.

10.0 CERTIFICATE OF ACCREDITATION

10.1 Should the Executive Committee grant accreditation, PJLA issues a Certificate of Accreditation. Certificates are developed based on the final scope received from the assessment team and agreed upon with the CAB. Certificates are developed based on the policies of PJLA and reviewed by PJLA technical program management prior to release to the CAB. Certificates contain an initial accreditation date, an issue date (based on the date of the executive committee decision) and an expiration date and unique accreditation number and certificate number. The accreditation number remains the same for the life of the (CAB) as the certificate number is adjusted on an on-going basis. Revision dates are also issued as necessary. In some cases, the issue date may be later than the executive committee date, as long as the date is after the final approval date. The contents of the scope of accreditation include a scope statement from the (CAB) or a general scope field, based on the preference of the (CAB). A supplement is connected to each certificate that contains the items or activities the (CAB) is accredited for including an indication of activities being performed on-site at customer locations. The appropriate standard is indicated along with disclaimers to assist with representing the entirety of the accreditation (i.e. CMC statements, remote/corporate scheme location references (some corporate certificates may include multiple certificate numbers (i.e. L12-006-1, L12-006-2), off-site activities references, etc.). The PJLA symbol is provided on each certificate and the ILAC MRA mark for which PJLA has obtained recognition for.

10.2 A draft of the approved certificate will be provided to the CAB from PJLA headquarters prior to release. An official copy of the certificate will be provided to the (CAB) via email in a non-editable format, hardcopy via mail and also posted on the PJLA website. Additionally, each (CAB) will be provided with a copy of the Use of Accreditation Claims and Symbols Procedure (SOP-3) with the necessary artwork to promote their accreditation. Additionally, they will be informed about the use of the ILAC MRA mark that can be used along with the PJLA symbol. All (CABs) must adhere to the instructions outlined in (SOP-3) as outlined in their agreement for services. This includes requirements for the use of the accreditation symbols and language and the use of the ILAC Mark.



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11.0 MULTIPLE SITE ACCREDITATION:

- 11.1 Where a (CAB) is operating through a number of remote locations or facilities, they may choose to pursue accreditation of all locations under a single accreditation if all of the following conditions exist:
- 11.1.1 the (CAB) has a similar quality management system that is implemented across all facilities;
 - 11.1.2 the (CAB) defines a tiered management structure defining ultimate authority of the entire accreditation;
 - 11.1.3 the (CAB) can attest that routine internal audits and management reviews encompass each facility and that they are reviewed by the designated management holding the ultimate authority over the entire accreditation. Note-records shall be made available to PJLA for all site internal audit or management review activities as requested, and;
 - 11.1.4 the authoritative site of the accreditation should be able to demonstrate their oversight of the following:
 - 11.1.4.1 policy formulation;
 - 11.1.4.2 process and/or procedure development;
 - 11.1.4.3 contract review;
 - 11.1.4.5 approval and decision making on the results of conformity assessments;
 - 11.1.4.6 management review;
 - 11.1.4.7 internal audit planning and evaluation of the results, and;
 - 11.1.4.8 evaluation of corrective actions.
- 11.2 On-site visits are conducted at all premises during the initial accreditation where the above key activities are performed. Upon accreditation all sites will be assessed on a routine basis throughout the accreditation cycle. In all cases, the designated authoritative location will be assessed annually and support sites/remote facilities will be sampled throughout the accreditation cycle. Typically, a full system assessment of all facilities identified on the scope of accreditation is performed over a two-year period. However, depending on the scope of activities being conducted at each location the schedule of assessments may be extended out to a 4-year period. A sampling schedule will be developed during the initial contract stage and modified as necessary throughout the accreditation cycle.

12.0 MAINTENANCE OF ACCREDITATION

12.1 Surveillance Assessments

- 12.1.1 The continued fulfillment of accreditation requirements is maintained by conducting regular surveillance assessments. Surveillance



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assessments occur on-site within 12-months from the initial accreditation assessment.

- 12.1.2 Surveillance assessments are conducted to ensure compliance with accreditation requirements and are typically less comprehensive than accreditation assessments. At a minimum, the following aspects will be assessed:
- 12.1.2.1 inquiries from PJLA to the (CAB) on aspects concerning the accreditation;
 - 12.1.2.2 declaration by the (CAB) with respect to their operation;
 - 12.1.2.3 documents and records, including updates from the quality manual;
 - 12.1.2.4 (CAB's) performance (including through proficiency testing), and;
 - 12.1.2.5 clauses of both the quality system and the scope of accreditation activities:
 - 12.1.2.5.1 internal audit and management review;
 - 12.1.2.5.2 previous visit's findings;
 - 12.1.2.5.3 outstanding corrective action;
 - 12.1.2.5.4 performance in proficiency testing;
 - 12.1.2.5.5 personnel changes and other changes;
 - 12.1.2.5.6 changes in technical personnel or equipment;
 - 12.1.2.5.7 all PJLA policy requirements;
 - 12.1.2.5.8 Accreditation Symbol utilization, and;
 - 12.1.2.5.9 representative sampling of the accredited activities, covering all areas of competence.
- 12.1.3 Since surveillance assessments are less comprehensive than initial accreditation assessments or reassessments, a lead assessor or a team of assessors may be selected for the assignment as long as they possess the skills to assess the quality management system and a portion of or all of the scope of accreditation. Assessors will be informed of any areas of the scope they are prohibited from assessing. Previous assessment reports or feedback will be communicated to the assessor(s) to ensure any follow up activities are assessed and CAB activities are witnessed that may not have been witnessed previously.
- 12.1.4 Surveillance assessments although less comprehensive than full system assessments (i.e. AC, RA) still allow for nonconformities to be detected. (CABs) should follow the requirement as indicated in section 8.0 of this procedure.



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- 12.1.5 Surveillance assessments are reviewed by PJLA technical staff for adequacy. If major nonconformities, fundamental system changes or scope changes occur during the surveillance, then the material will be sent to the Executive Committee for a final decision.
- 12.1.6 After the initial accreditation cycle, PJLA reserves the right to amend the frequency of on-site visits. The interval between on-site assessments depends on the demonstrated competency of the (CAB) during the past accreditation cycle. This is developed from the recommendation of the lead assessor on previous visits, history of the (CAB) in regards to complaints, nonconformity trends and system and/or technology changes. PJLA along with the lead assessor will make the final decision to excuse on-site surveillance visits. When on-site surveillance visits are reduced from the (CAB's) accreditation cycle, PJLA will require the (CAB) to demonstrate its maintenance of their accreditation through an off-site documentation review. This review consists of the following:
- 12.1.6.1 proficiency testing (PT) data review;
 - 12.1.6.2 internal audit results;
 - 12.1.6.3 management review;
 - 12.1.6.4 corrective actions taken;
 - 12.1.6.5 review of changes occurred in the laboratory, and;
 - 12.1.6.6 off-site technical review of at least one item on the scope of accreditation.
- 12.1.7 Designated assessment time will be provided to an assigned assessor to complete this review. Nonconformities may be detected during these reviews requiring (CABs) to following the corrective action requirements as indicated in section 8.0 of this procedure. (CABs) will be provided with an assessment schedule from PJLA that includes the date and assessor conducting the review and the items required to be submitted. CABs will receive a final report from the assessor based on the review of the above items. PJLA staff will review the report to ensure the accreditation is sustained. In cases where the documentation review provides any doubt that the CAB is maintaining their accreditation, an on-site surveillance will be scheduled.

12.2 Proficiency Testing Maintenance

- 12.2.1 In effort to ensure all (CABs) meet PJLA's Proficiency Testing (PT) Policy (PL-1). (CABs) are required to develop a 4-year Proficiency Testing Plan in accordance with (PL-1). The implementation of the plan is evaluated during on-site assessments. Any deviations from the specified requirements for (PT) will be evaluated by PJLA



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headquarters and communicated to the assessment team (i.e. use of other means of (PT) such as intra laboratory comparisons or repeatability). Any changes to the 4 year (PT) plan should be communicated to the PJLA assessment team.

12.3 Special Circumstance Assessments

12.3.1 PJLA reserves the right to conduct assessments during the course of the accreditation period when it is determined that the (CAB's) system may be or could potentially be at harm, resulting in noncompliance with the standard. Situations such as the following may impose a special visit:

12.3.1.1 complaint from customers that are directed to the (CAB's) competency and results, and;

12.3.1.2 significant changes to the organization (i.e. ownership, management, address, technology/equipment change etc.).

12.3.2 If the changes do not directly affect the (CAB's) scope of accreditation results, then it may be determined that a special assessment is not required, and the changes will be reviewed at the next assessment.

13.0 REASSESSMENT

13.1 At the end of the CAB's accreditation cycle, PJLA conducts a complete reassessment, similar to the initial accreditation assessment and its processes. Such assessments take into account the maturity of the CAB's system and previous history between the CAB and PJLA (i.e. suspensions, complaints and adherence to PJLA's policies and accreditation criteria).

13.2 (CABs) are required to complete a reassessment 2- years from the last full system assessment. CABs should conduct their reassessment prior to expiration. PJLA may grant an extension to the certificate for unforeseen circumstances. Extensions will not be granted for any CAB that has not met their accreditation obligations (i.e. financial arrangements, scheduling, and corrective action).

13.3 Once a renewal takes place, an Accreditation Cycle review will be completed which includes an analysis of the CABs nonconformities and the nature of them (major, minor, repeat, technical concerns that may give any doubt that the CAB can perform reliable results), assessment reports, complaints, and suspensions. This review establishes criteria for future assessments including modifications to the current assessor due to overfamiliarity issues as well as the surveillance type due 12 months from the renewal (i.e. on-site or documentation review). If there is any evidence that the assessor or executive committee member is overfamiliar



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with the CAB, then a reassignment of the assessor or executive committee member should be considered for future assessments.

14.0 SCOPE EXPANSION

- 14.1 A (CAB) may request to expand their scope of accreditation at any time through PJLA's application process. Scope expansions may be conducted during any type of routine assessment or alone. For less complex scope expansions (i.e. request to add analytes, SOP/method using a current accredited technique) can typically be conducted off-site via documentation review.
- 14.2 PJLA will assign qualified technical assessors to assess scope expansion assessments. Assessors should conduct a full technical review of the requested tests and any quality management system activities impacted by the expansion. Nonconformities can be detected on scope expansion assessments and are handled as outlined in section 8.0 of this procedure. All scope expansions are evaluated by PJLA's executive committee to grant or deny the extension.

15.0 SUSPENSION, WITHDRAWAL, REDUCTION OF ACCREDITATION

- 15.1 In accordance with (SOP-11) Suspension, Withdrawal or Reduction of Scope Procedure, PJLA reserves the right to suspend, withdraw or reduce accreditation with a CAB at any time.
- 15.2 Generally, such actions are considered in the following instances:
- 15.2.1 (CAB) fails to complete corrective actions during the agreed timeframe;
 - 15.2.2 (CAB) persistently fails to conform to Standard and/or PJLA policies;
 - 15.2.3 (CAB), in PJLA's judgment, misuses PJLA's Accreditation Symbol, Certificate of Accreditation, or Accreditation Language as outlined in SOP-3;
 - 15.2.4 (CAB) becomes delinquent in its financial obligations to PJLA;
 - 15.2.5 (CAB) becomes subject to bankruptcy laws or makes any arrangements or composition with its creditors; enters into liquidation, whether compulsory or voluntary; and/or appoints, or has appointed on its behalf, a receiver;
 - 15.2.6 (CAB) is convicted of an offense tending to discredit the facility's reputation and goodwill, and;
 - 15.2.7 (CAB) commits acts that, in PJLA's sole judgment; impugn PJLA's goodwill, valuable name and reputation.



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- 15.3 PJLA reserves the right to publicize any actions it may take with respect to withdrawal, cancellation, reduction or suspension of a (CAB's) accreditation.
- 15.4 PJLA will also cancel accreditation upon the formal written request of applicant (CAB).
- 15.5 PJLA may take legal action for wrongful actions specified in 15.2.

16.0 DISPUTES AND APPEALS

- 16.1 The (CAB) or any interested party may dispute or appeal the decisions of PJLA with respect to:
 - 16.1.1 refusal to accept an applicant (CAB's) application for accreditation;
 - 16.1.2 suspension, withdrawal, reduction, or cancellation of accreditation;
 - 16.1.3 refusal to grant, extend Accreditation;
 - 16.1.4 an appeal by a third party against PJLA's decision to grant accreditation;
 - 16.1.5 assignment of assessment team;
 - 16.1.6 nonconformities written by the assessment team, and;
 - 16.1.7 any other issue relevant to the accreditation process.
- 16.2 (CABS) have access to the Dispute and Appeal Procedure (SOP-10) via PJLA website.

17.0 CONFIDENTIALITY

- 17.1 Except where required by law or statute, PJLA treats any information that comes into its possession in the course of the accreditation of the (CAB) confidential. PJLA staff, including subcontracted staff, assessors, executive committee members and technical committee members, are required to sign confidentiality agreements with PJLA to not disclose any information gained from a CAB or about a CAB through PJLA except when required by law or statute. Requests received to retrieve information from any interested party of the CAB will only be distributed upon permission of the CAB.