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# Accreditation Procedure

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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 and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies. **Note-PJLA offers several supplemental programs above ISO/IEC 17025. Additional supplemental procedures may be available for these programs and shall be applied in addition to this general accreditation 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 assessment and accreditation service. It conforms to ISO/IEC 17011: 2004 and other national and/or international standards as applicable. National, regulatory or government specific accreditation programs are outlined in appendices of this document. Accreditation criteria not covered in the appendices can be found in the body of this document. Note- In many cases, throughout this document, baseline ISO/IEC 17025:2005 program documents are referenced. Some of these documents belong to a series of documents for use in other accreditation programs (i.e. LF-1, LF-1elap, etc.).

## 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.



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- 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.
- 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 The applicant (CAB) initiates the Accreditation Process via a written or verbal request for information. In response, PJLA provides the applicant with a Client Profile/Questionnaire (LF-1). PJLA will also supply them with additional PJLA accreditation system documentation/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 contact name (address, etc.);
  - 4.2.2 description of testing/calibration/RMP/FSMO/Inspection 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 not complete, it will be rejected and the (CAB) will be contacted for more detail. 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) structure and scope.
- 4.4 PJLA makes its services available to all (CABs) whose requests are concurrent with PJLA's scope of activity. In the event the applicant requests accreditation services in unfamiliar areas, PJLA will utilize a technical expert to assist with the quoting process including the determination of: allocation of assessment days,



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assessor competency, and committee competency needs. If the technical resources cannot be formulated, then PJLA will reject the request for quotation.

- 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 and at customer locations, number of sites and number of technicians residing within the (CAB). At no such time will an 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 with accreditation, the applicant then 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 accreditation assessment
  - 4.6.2 Payment of the first installment per the Agreement for Services
- 4.7 Once the agreement is finalized a proposed scope for the assessment will be created based on the information retrieved from the application. This template will be submitted to the (CAB) prior to their assessment to confirm their scope and submitted to the lead assessor for verification and finalization during the on-site assessment.
- 4.8 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.
- 4.9 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.***



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## 5.0 ASSESSMENT CONFIRMATION

- 5.1 Once the agreement for service 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 assessments (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 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). Assessors or any members of the team will have signed agreements with PJLA to avoid such conflict of interests with (CABs). The (CAB) will be clearly communicated in regards to the names of the assessor(s) by PJLA. The (CAB) has the right to object to any members of the assessment team assigned. In cases where an assessor arrives on-site at the (CAB) and detects or is informed of a conflict of interest or a potential conflict of interest by them or by 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) that includes guidelines for education, training and work experience requirements.
- 5.2 (CABs) will be provided with a readiness review checklist to ensure they are well prepared for their assessment. This includes them to provide any updates to their original application such as their scope, organizational changes, and their fulfillment of internal audits, management review and proficiency testing performance. Additionally, documents to start the initial documentation review are also requested to be submitted within a timeline of at least 30 days prior to the on-site assessment. During this stage if any feedback is provided to PJLA indicating that they are not prepared for their assessment then the (CAB) will be notified that their assessment is recommended to be postponed.
- 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.



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## 6.0 DOCUMENTATION REVIEW

- 6.1 At minimum, PJLA will request baseline documents for the (CAB) to submit to initiate the documentation review. This includes documents such as: Quality Manual, performed and completed proficiency tests/inter lab comparisons as required per PJLA Policy PL-1, and measurement uncertainty budgets. \* Note- Additional baseline documents may be requested depending on the accreditation program the (CAB) is applying for.\* This will be communicated as necessary on specific Readiness Review Checklists. Once the documentation is received from the (CAB) the assessor will be notified and will begin the documentation review. Additional documents may be requested to be provided directly to the assessor(s) as necessary (i.e. SOPs, Work Instructions, Management Reviews, and Internal Audits). The lead assessor or team will complete their review and notify the (CAB) if any questions arise. The review will be documented on the LF-5a and placed in (CAB's) file. Assessors may identify nonconformities at this time that will be 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 until the (CAB) is ready to proceed with accreditation. In such cases, the (CAB) will be communicated to in regards to the assessor(s) feedback and will be provided the opportunity to decide to 1) postpone the accreditation or 2) reduce their accreditation assessment to a preassessment. However, PJLA holds all rights to cancel assessments based on the (CAB's) undeveloped system. In any of the aforementioned situations, PJLA will place the (CAB's) application on "hold" status until receiving instructions from the applicant.
- 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 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 communicated with the lead assessor of any recommended 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 17011:2004 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



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(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 **Detailed Examination** of the (CAB) itself, via personnel assessment, document review, and interviews of personnel. The assessment is conducted at all locations where key activities are performed. Activities performed at field sites controlled by the (CAB) are witnessed when as available and as scheduled between PJLA and the (CAB). \* 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. The (CAB's) methods for performing their scope are assessed that includes: technical competency, environmental conditions, equipment, traceability, reporting of the results, measurement uncertainty, records and method validation. 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 the entire accreditation or specific applied areas of the scope.

7.1.2.1 During the time of the on-site examination assessors will clearly communicate any nonconformities or observation 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





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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 identify 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 observation detected. The (CAB) will be provided a copy of all nonconformities and observations as well as a detailed report to follow along with the discussion. A final recommendation to proceed or/not 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 assessors and the (CAB) prior to the end of the meeting. Additionally, a witness schedule of the (CABs) scope of activities will be agreed upon 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. A discussion will take place in regards to the final steps of the accreditation process including: details for corrective action submission, final accreditation decision process by the executive committee and final certificate submission. All members involved with the closing meeting will be asked to sign an attendance sheet as 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 could cause a delay in the corrective action review process or a possible rejection for unacceptable corrective action. (CABs) should submit





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corrective action on their own corrective action forms and per the (CABs) own procedure for corrective action.

- 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 to completely verify the effectiveness of the corrective action may be recommended. \*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 reviews of corrective action submissions are strongly discouraged and may cause PJLA to amend (CABs) agreements to include additional off-site time for the assessment team to complete the review.
- 8.3 In addition to corrective actions to nonconformities, the applicant (CAB) is also obligated to take corrective actions in response to complaints received, and to record the actions taken and their effectiveness.

## 9.0 FINAL ACCREDITATION DECISION

- 9.1 Upon completion and resolution of the assessment material including acceptable corrective action, the lead assessor makes a final recommendation to grant or deny the accreditation. Once the accreditation is recommended by the lead assessor the assessment material will be reviewed by PJLA headquarter staff for completion and submitted to the final decision making committee the Executive Committee. The Executive Committee is the final decision maker for the accreditation that grant or denies 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 and PJLA policies and have adequately responded to all non-conformities 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 laboratory or the laboratory may be communicated directly from PJLA headquarters. (CABs) have the 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.



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## 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. Once developed a draft is reviewed by a designated technical reviewer for adequacy against PJLA policies for certificates of accreditation. Any questions or comments derived from this review will be provided to the (CAB) or assessor for clarification. All certificates will be provided to the (CAB) for a final approval prior to release.
- 10.2 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 ongoing basis. Revision dates are also issued as necessary. In some cases, based on (CAB) preference the issue date may be later than the executive committee date. This is acceptable as long as the date is not before the 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 represent 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.) (CABs) are required to approve their certificate draft. The PJLA symbol is provided on each certificate and the ILAC MRA mark for which PJLA has obtained recognition for. \*Note some certificates are issued based on a separate accreditation cycle. The amount of these types of certificates is very minimal, but still remains valid until expiration. Effective April 1, 2011 this criteria has been relinquished and all (CABs) will be placed on a 2-year accreditation cycle.\*
- 10.3 Once accreditation certificates are accepted by the (CAB) then a final 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 PJLA Accreditation Symbol 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, the ILAC Mark and accreditation language. Assessors will review (CAB's) utilization of the accreditation symbol during on-site assessments and have full authority to document non-conformities for improper utilization. PJLA headquarters also has full authority to initiate a nonconformance against (SOP-3) if any misuse is found.



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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 activities are covered on the scope of accreditation and where the above key activities are performed. Upon accreditation all sites supporting the scope of accreditation or ones that meet the above key activities 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. It is a practice that we complete a full system assessment of all facilities identified in the scope of accreditation 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 initial contract stage and modified as appropriate based on feedback from the assessment team, or when an increase or decrease of sites or structural change occur.



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## 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 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 included during surveillance:

- 12.1.2.1 enquiries 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 accreditation or reaccreditation assessments, a lead assessor or a team of assessors may be selected for the assignment as long as they possess the skills to assess quality system areas and at least one of the technical areas. In this case, PJLA will inform the assessment team of which areas of the scope of accreditation is allowable for them to assess. PJLA along with the recommendation of the assessor(s) on the initial accreditation assessment will specify items that should be witnessed to ensure that over a full accreditation cycle a sufficient number of items on the scope of accreditation are witnessed.



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- 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.
- 12.1.5 Surveillance assessments are reviewed by PJLA technical staff to decide based on the assessor's recommendation to allow or deny the accreditation to be maintained. If major nonconformities, fundamental system changes or scope changes occur then the material will be passed onto the Executive Committee for a final recommendation.
- 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, systems 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. Non-conformities 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 can be sustained. In the case severe issues arise during these reviews; PJLA has the right to request on-site visits to occur.

### 12.2 Proficiency Testing Maintenance



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- 12.2.1 In effort to ensure all (CABs) meet the PJLA Proficiency Testing Requirements (PL-1), (CABs) are required to develop a 4- year Proficiency Testing Plan. This plan will be evaluated during on-site assessments. Any deviations from the specified requirements for (PT) will be evaluated PJLA 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 complaints 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 necessary and the changes will be reviewed during the regular assessment period.

12.3.3 If the (CAB) contemplates major changes it must notify PJLA.

## 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 PJLA's relationship with accredited (CAB) during the accreditation period as well as customer complaints and experience gained during previous assessments.
- 13.2 (CABs) are required to complete a reassessment assessment within 2 years from their last full system assessment. Some (CABs) requiring an expiration date will be scheduled at least 60-90 days prior to this date to avoid a lapse in accreditation. In the case the (CAB) runs over its expiration the President/Operations Manager will grant an extension. An extension of the certificate will granted depending on the circumstance.



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- 13.3 Once the reassessment is submitted to headquarters for review, the Accreditation Manager will conduct an entire Accreditation Cycle review of the accredited laboratory. This will consist of a full analysis of: the number of findings written throughout the cycle (2-3 years of assessment data), the nature of the findings and comments notated on the assessment report. If the Accreditation Manager finds that there is evidence that the assessor is over familiar with the laboratory's system, then the Accreditation Manager may discuss this issue with the President/Operations Manager. A decision will be made to change the assessor on the next accreditation cycle of the laboratory. However, during anytime in the accreditation cycle, PJLA may change assessors to ensure that assessments continue to be value-added, regardless of the results of the accreditation cycle review.

## 14.0 SCOPE EXPANSION

- 14.1 If a (CAB) requests to expand their scope of accreditation then they must complete an application for accreditation. PJLA will review the application and provide a quotation for the assessment time required to extend the scope of accreditation. Scope expansion may be conducted during any type of routine assessment or alone. Some scope expansions depending on the nature may be conducted off-site (i.e. expansions that include items that have already been witnessed and utilize the same equipment/technology).
- 14.2 Assessors will be selected as appropriate for all scope expansions. Special instructions will be given to the assessment team in regards to the areas to be assessed. At minimum the assessor will review the desired scope of accreditation to be extended against the applicable technical areas of the standard accredited to and any applicable quality management area that was impacted by the scope expansion. Non-conformities may be documented during scope extension assessments requiring (CABS) to comply with section 8.0 of this procedure in regards to corrective action response requirements. All scope expansions will be reviewed by the PJLA Executive Committee for a decision to grant/deny the additional scope items.

## 15.0 SUSPENSION, WITHDRAWAL, REDUCTION OR CANCELLATION OF ACCREDITATION

- 15.1 PJLA reserves the right to suspend, withdraw, reduce or cancel accreditation at any time during a (CAB's) accreditation period, in accordance with PJLA procedure SOP-11.
- 15.2 Generally, such actions are considered in the following instances:





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- 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.
- 15.3 PJLA reserves the right to publicize any actions it may take with respect to withdrawal, cancellation, reduction or suspension of an applicant (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 failure to confer accreditation;
  - 16.1.3 suspension, withdrawal, reduction, or cancellation of accreditation;
  - 16.1.4 refusal to extend an applicant (CAB's) Scope of Accreditation;
  - 16.1.5 an appeal by a third party against PJLA's decision to grant accreditation;
  - 16.1.6 assignment of assessment team;
  - 16.1.7 nonconformities written by the assessment team, and;
  - 16.1.8 any other issue relevant to the accreditation process.
- 16.2 (CABS) have access to the Dispute and Appeal Procedure (SOP-10) via PJLA website.



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## 17.0 CONFIDENTIALITY

- 17.1 Except where required by law or statute, PJLA treats as confidential any information that comes into its possession in the course of the accreditation of the (CAB). PJLA, including all assessors, administrative staff, Executive Committee, Technical Committee and any other employee or contractor, promises not to disclose such information to any third party without prior written consent of the (CAB), except when required by law or statute. In the event that disclosure of such information is required by law or statute, PJLA will disclose the information as required and inform the (CAB) of such disclosure in writing in a timely fashion. Confidentiality Agreements will be signed and retained as evidence of agreement to the requirement of nondisclosure of confidential information.