



# Accreditation Procedure

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PJLA offers third-party accreditation services to testing and calibration laboratories. This procedure outlines PJLA's accreditation process and references other beneficial PJLA procedures and policies.



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# 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 clients' Laboratory Management Systems to ISO/IEC 17025:2005 including national, regulatory or government programs.

## 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, basic ISO/IEC 17025:2005 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, LF-1med).

## 3.0 DEFINITIONS

- 3.1 **Accreditation Body (PJLA):** Authoritative Body that performs accreditation
- 3.2 **Accredited Laboratory/Applicant Laboratory:** 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 laboratory, based on particular standard(s) and/or normative documents and for defined scope of accreditation



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- 3.5 **Assessor:** Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a laboratory
  
- 3.6 **Preliminary Assessment (Preassessment):** An informal assessment carried out by PJLA to assess a laboratory prior to the Accreditation Assessment. The objective of the preassessment is to identify laboratory system gaps so that corrective actions can be implemented prior to the formal Accreditation Assessment
  
- 3.7 **Accreditation/Reaccreditation:** Full System third-party attestation related to a laboratory conveying formal demonstration of its competence to carryout specific conformity assessments tasks
  
- 3.8 **Surveillance Assessment:** Set of activities, except reaccreditation, to monitor the continued fulfillment by accredited laboratories of requirements for accreditation
  
- 3.9 **Accreditation Symbol:** A symbol issued by an accreditation body to be used by accredited laboratories to indicate their accreditation status
  
- 3.10 **Registry:** Listing of accredited laboratories

### 4.0 REQUEST FOR ACCREDITATION

- 4.1 The applicant laboratory initiates the Accreditation Process via a written or verbal request for information. In response, PJLA provides the applicant laboratory with a Client Profile/Questionnaire (LF-1). PJLA will also supply the customer with additional PJLA accreditation system documentation/information as necessary.
  
- 4.2 The applicant laboratory completes the LF-1, which provides PJLA with the initial information required to commence the accreditation process. This document elicits from the applicant laboratory the following details, among others:
  - a) Contact name (address, etc.)
  - b) Description of testing/calibration performed
  - c) Description of Equipment used
  - d) Description of Methods used



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- e) Description of premises of facility, number of lab employees, traveling employees and work shifts
  - f) Status of existing laboratory system
- 4.3 If the (LF-1) is not complete, it will be rejected and the laboratory 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 laboratory structure and scope.
- 4.4 PJLA makes its services available to all laboratories whose requests are concurrent with PJLA's scope of activity. In the event the applicant laboratory 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, 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 laboratory, 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 test and/or calibration activities being performed and the location thereof. At no such time will an accreditation assessment be quoted for less than 1.0 on-site and .50 off-site. The quotation includes the cost of any preassessment, but excludes any follow-up visit(s) that may be recommended or required for the successful completion of the accreditation process. It also assumes the accuracy of the information provided by applicant laboratory, and is subject to change to cover additional work by PJLA caused by inaccurate or incomplete information.
- 4.6 Should the applicant laboratory wish to proceed with accreditation, PJLA provides a copy of the Agreement for Services (LF-3). The applicant laboratory then completes, 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. After the contract is signed, amendments agreed on by both parties. The sales representative for PJLA will initiate a Sales Order (LF-24), which will include the lead source of the sale. At this stage, the applicant laboratory also provides PJLA with the following:
- a) Written confirmation of preferred dates for the preassessment (if applicable) and accreditation assessment;



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- b) Payment of the first installment per the Agreement for Services
- 4.7 Once the laboratory returns a signed agreement, PJLA will develop a scope template based on the information provided on the (LF-1). This template will be submitted to the applicant laboratory prior to their assessment. The laboratory will be required to review the scope template and verify that their scope of accreditation is accurate. This scope template will be given to the lead assessor to verify on-site during the accreditation.
- 4.8 If the requirements for accreditation change at any time needing retroactive implementation, PJLA will ensure that the applicant laboratory is notified and the new requirements are followed/implemented at the applicant laboratory's next assessment.
- 4.9 PJLA reserves the right to amend said Agreement for Services at any time if significant changes have occurred within the applicant/accredited laboratory. These changes include, but are not limited to: relocation of laboratory, laboratory personnel changes, laboratory equipment changes and scope changes. *It is the responsibility of the applicant/accredited laboratory to inform PJLA of any significant changes immediately.*

### **5.0 DOCUMENTATION REVIEW**

- 5.1 Upon scheduling the date of any assessment (Preassessment, Accreditation, Surveillance or Reaccreditation), the laboratory is required to submit a CONTROLLED COPY of its quality manual, proficiency testing results and uncertainty budgets/data to the assigned assessor at least 2-weeks prior to the assessment. Additionally, a copy of a 4-year proficiency test (PT) plan must be submitted to PJLA at least 2-weeks prior to the assessment. To avoid a premature accreditation the laboratory will be asked by PJLA headquarters to complete a readiness review checklist. This includes, but is not limited to: questions in regards to the laboratory's progress in completing a full-system internal audit, management review, proficiency testing and measurement uncertainty data. If PJLA feels that the laboratory will be unsuccessful in completing the criteria as listed above, then the assessment will be postponed.
- 5.2 The lead assessor will conduct a documentation review and report their results to the laboratory. This documentation review will consist of the following:
  - 5.2.1 Overall manual review to ensure that all areas of the standard have been addressed.



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- 5.2.2 That the manual is a top tier document and makes references to other document procedures, work instructions etc.
  - 5.2.3 That the Proficiency Test results reflect all areas of the laboratory's sub-scopes (note-accreditation only)
  - 5.2.4 That the Proficiency Test results reflect satisfactory results. If unsatisfactory results are displayed the assessor may ask the laboratory to provide additional information on the type of corrective action that was taken for these results.
  - 5.2.5 That the laboratory has an Uncertainty Budget that reflects all items on the scope of accreditation.
- 5.3 The lead assessor will complete a Quality Manual review (LF-5a) and submit it to the laboratory prior to the assessment. All other documentation reviewed such as PT and BMC can be reported back to the laboratory via verbal communication or via email. If the assessor's results are negative then the assessor will report back to PJLA to postpone the assessment.
- 5.4 The 4-year PT plan will be reviewed by PJLA headquarters and submitted to the lead assessor prior to the assessment. PJLA headquarters staff will review the plan to ensure that all areas of the laboratories scope are covered over a 4-year period and that the type of PT program selected by the laboratory is appropriate. Once the plan is deemed satisfactory, it will be approved and submitted to the laboratory for their record. The assessor will be expected to follow-up with the laboratory to ensure that they are following their plan.
- 5.5 Should PJLA determine that an Accreditation assessment is unlikely to be successful, PJLA will inform applicant laboratory of certain options, including:
- 1) The applicant laboratory may request PJLA to carry out an on-site preassessment to develop a clearer picture of laboratory system nonconformities (PJLA will conduct no greater than two (2) preassessments of any individual client facility).
  - 2) The applicant laboratory may ask that its accreditation assessment be postponed while it develops and implements corrective actions.
- 5.6 PJLA reserves the right not to proceed with an on-site assessment based on findings identified during the documentation review.



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- 5.7 In any of the aforementioned situations, PJLA will place the applicant laboratory's application on "hold" status until receiving instructions from the applicant laboratory.
- 5.8 Postponement or cancellation of assessments by applicant laboratories obligates applicant or accredited laboratory to pay cancellation fees as specified in (LF-3), Agreement for Services.

### 6.0 ACCREDITATION ASSESSMENTS

**NOTE:** No Assessor will be assigned or permitted to be a member or Lead Assessor on any accreditation activity (assessment) where they have participated in more than two (2) preliminary assessments of the accreditation client. No Assessor will be assigned or permitted to be a member or Lead Assessor on any assessment that they have given a Lead Source to PJLA as indicated on the sales order (LF-24).

- 6.1 In accordance with (SOP-2) Personnel Procedure, PJLA appoints a qualified Assessment Team. Qualification includes assurance that at least one team member have the same technical expertise as the scope of the applicant laboratory. Depending on the size of the scope of the laboratory there may be more than one assessor with the necessary expertise. If a qualified assessor (s) cannot be located in the appropriate scope of the assessment, then a Technical Expert will be selected to give technical expertise to the assessor(s).
- 6.2 The laboratory is informed by PJLA verbally and in writing of the names of the team members at the time of scheduling the assessment. The laboratory is allowed sufficient time to object to the appointment of any team member. The President/Operations Manager will determine the validity of the objection and reassign team members as necessary.
- 6.3 The Lead Assessor prepares a specific assessment plan based on the scope and structure of the laboratory prior to the assessment. This plan must be provided to the President/Operations Manager or Technical Program Manager(s) for review and approval prior to the commencement of any assessment. The plan may also include additional requirements deemed necessary to achieve the required accreditation. The Lead Assessor will submit a copy of the approved plan and communicate on any preliminary documentation findings to the assessment team (if applicable).



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- 6.4 The assessment is carried out in accordance to ISO 17011:2004 and consists of the following:
- a) Opening Meeting with applicant laboratory'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, including the scope to be assessed. The team conducts the opening meeting according to the guidelines provided on the Opening Meeting Agenda (LF-18).
  - b) Detailed examination of the laboratory itself, via personnel assessment, document review, and interviews of personnel. The accreditation assessment is conducted at all locations where activities covered in the desired scope of accreditation are performed. Testing/calibration performed at field sites controlled by the laboratory are witnessed when applicable. An appropriate number of staff is interviewed to ensure the competency of the laboratory to perform activities covered by its desired scope. The laboratory's methods for performing the test/calibration are reviewed along with the BMC results and PT results. All relevant work instructions and procedures will be reviewed during this process. During this examination, the assessor will complete a Field, Method, Specification-Technical Review Matrix (LF-56-2K5-Supplement) for the entire scope of the laboratory and will document any observed nonconformities using PJLA Form LF-8, Nonconformance Report. Assessors may use single supplement sheets to cover sub-scopes of the laboratory, as appropriate.

The applicant laboratory is obligated to assist the Assessment Team in the following ways:

1. Provide the Assessment Team with sufficient documentation in order for them to conduct a full system assessment to ensure compliance of the Standard
2. Provide documentation regarding its level of independence and impartiality of the laboratory from any related bodies during the course of the on-site assessment
3. Provide the Assessment Team with access to facilities, personnel, and records, so the team is able to verify that the applicant laboratory's system has in fact been established, is being operated and maintained, and is in conformance to the applicant laboratory's documentation as well as to the applicable standard being assessed to



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4. Arrange witness activities, whether in the field or at the laboratory, as requested by the assessment team
  5. Cooperate in all ways requested by the Team
- c) Closing meeting, during which the Assessment Team's findings are reported to applicant laboratory's system. Specifically, the Assessment Team:
- 1) Presents to applicant laboratory copies of outstanding Nonconformance Reports (LF-8)
  - 2) Reports to the applicant laboratory opportunities for improvements without recommending specific solutions and affords the laboratory an opportunity to ask questions
  - 3) Provides the laboratory the timeframe in which all nonconformities should be closed
  - 4) Provides a written report to the laboratory at the close of the on-site assessment. The report (LF-9) contains comments on competence, conformity to accreditation requirements, including PT results and scope activities witnessed during the assessment and identifies nonconformities.

### 7.0 RESOLUTION OF CORRECTIVE ACTION

#### 7.1 Types of ISO/IEC 17025: 2005 Nonconformities:

- a) **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.
- b) **Minor:** A single lapse in discipline or control.
- c) **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).

#### 7.2 The three types of corrective actions are:

- a) Those implemented during the course of the assessment. In these cases, the Nonconformance Reports are completed and signed off during the Closing Meeting.



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- b) Those involving document or minor changes. These may be implemented without requiring a subsequent Follow-Up Assessment. However, the laboratory must supply the assessor with sufficient objective evidence in order for the assessor to accept and verify the closure of the nonconformity. The assessor may request additional objective evidence as necessary. The completed master Nonconformance Report (LF-8) forms must be submitted to PJLA, and where applicable, re-evaluation will occur during the first surveillance assessment.
- c) Those requiring "significant changes" that can be resolved and verified only by means of a subsequent Follow-Up Assessment. The Follow-Up Assessment will be limited to the area found to be nonconforming.

7.3 Corrective Actions must be implemented within 90 days or any other reasonable and mutually agreed time period after the Closing Meeting. Thereafter, PJLA may, at its discretion, repeat the Accreditation Assessment, chargeable at the prevailing PJLA Daily Rate (per Agreement for Services, LF-3). Note: All nonconformities, whether major or minor, must be reconciled prior to recommending accreditation.

7.4 In addition to corrective actions to nonconformities, the applicant laboratory is also obligated to take corrective actions in response to complaints received, and to record the actions taken and their effectiveness.

7.5 In the event that the team cannot reach a consensus in the classification of a particular finding, the Lead Assessor contacts the PJLA President/Operations Manager or Technical Program Manager for guidance. The President/Operations Manager may contact the Executive Committee or Technical Committee, as necessary.

### 8.0 ACCREDITATION

8.1 Upon completion of the Accreditation Assessment, and resolution of any nonconformity as set forth in Section 7, the PJLA Assessment Team returns all documentation concerning the assessment to the PJLA headquarters office. The President/Operations Manager and the Technical Program Manager (s) review the packet for completeness. The President/Operation Manager and/or Technical Program Manager(s) will evaluate the Assessor/EC/TE Competency Matrix (LF-72) to select a qualified Executive Committee Member. In the case that no members of the Executive Committee are qualified in the scope of the assessment, a



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Technical Reviewer (TR) will be selected to coincide the review process with a member of the Executive Committee.

- 8.2 When selecting reviewers (EC or TR), PJLA ensures that neither party were involved in the assessment or have any other relationship with the laboratory that could impose a conflict of interest or confidentiality issue.
- 8.3 Prior to making an accreditation decision, the Executive Committee ensures that it has received sufficient information to determine conformity and competence. 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. PJLA's Executive Committee makes all accreditation decisions in a timely manner on the basis of the material and any additional information requested.
- 8.4 Should the Executive Committee members concur with the Lead Assessor and PJLA Headquarters for a recommendation to grant accreditation, PJLA issues a Certificate of Accreditation specifying the Scope of Accreditation.
- 8.5 The Accreditation Certificate is valid for a period of two years from the date of issue. On reaccreditations the issue date on the certificates may be carried over from the initial accreditation expiration date as long as the executive committee approval date is before that date and the new issue date does not extend 90-days from the actual reaccreditation assessment date. In this case certificates will expire 2-years from this date. (i.e. original certificate issue date 10/1/00 expiration date 9/30/02, reaccreditation package approved on 8/1/02, assessment conducted 7/15/02, renewed certificate issue date 10/1/02 and expiration date 9/30/05). \* This process does not allow laboratories to extend their subsequent visits; laboratories should still maintain their yearly contracted visits accordingly to their contract (LF-3). This process will only be utilized upon request from the laboratory. \* PJLA is the sole authority by which PJLA Accreditation Certificates are granted. Certificates remain the property of PJLA.
- 8.6 PJLA may issue a longer certificate expiration date based on the accreditation cycle granted by PJLA of the particular laboratory (i.e. 2-5 years).
- 8.7 The Certificate of Accreditation bears the PJLA name and logo and specifies the scope of the testing/calibration covered by the Accreditation.



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- 8.7.1 Each accreditation certificate bears a unique certificate number and accreditation number. The certificate number will be assigned using a format in which the first two digits reflect the year of original issue, e.g., 98 and will change every 2-5 years, depending on the accreditation cycle of the laboratory. The accreditation number will be assigned to the laboratory once they are initially accredited and will remain the same for the entire life of the accreditation.
- 8.7.2 Because the completion of an assessment sometimes involves assessing more than one location (“multi-site” scheme), such accreditations will be recorded on separate certificates, each including the relevant address and a description of the activities assessed at each location.
- 8.7.3 In the event that a certificate is re-issued for any reason, the original certificate number will be retained (if practicable), along with the re-issue date. The expiration date will not be calculated using the most recent re-issue date. These certificates are designated as re-issued (-R1).
- 8.7.4 The Lead Assessor will verify the scope supplement prepared by PJLA, which includes, but is not limited to: calibration/testing field; items tested/calibrated; reference standards and methods; applicable range of testing/measurement; detection limits, and measurement uncertainties.
- 8.7.5 Once verified and approved by the Lead Assessor, the information is sent to PJLA headquarters with the assessment package for the approval of the President/Operations Manager, Technical Program Manager (s) and the Executive Committee. At which time the supplement information is approved, PJLA prepares the supplement using templates created from examples furnished in PL-4 & WI 8. These provide consistency and uniformity for all PJLA certificates and supplements. The final certificate will then be reviewed and signed by the President/Operations Manager.
- 8.8 Once accreditation certificates are finalized each laboratory will receive camera-ready artwork of the PJLA Accreditation Symbol. Laboratories will receive either a symbol for calibration or testing depending on their scope of accreditation. The accredited laboratory will also receive a copy of (SOP-3) Accreditation Symbol Procedure. This procedure includes, but is not limited to, the following points:
- a) Lay-out of the Accreditation Symbol



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- b) Documents that the accreditation symbol may or may not be displayed on
- c) Appropriate language to claim accreditation
- d) Utilization of the accreditation symbol for scopes outside of the laboratory's accreditation
- e) Utilization of the accreditation symbol for scopes that are subcontracted
- f) Utilization of the accreditation symbol on calibration labels
- g) Rules and Regulations for the utilization of oversight body's symbols, logos etc.
- h) PJLA's process for taking action for improper utilization of accreditation language or symbol

8.8.1 Accredited laboratories will be expected to adhere to the Accreditation Symbol Procedure (SOP-3) as stated in their PJLA Agreement for Services (LF-3). Assessors will review laboratory's utilization of the accreditation symbol during on-site assessments and have full authority to document non-conformities for improper utilization. In the case that assessor (s) do not document a nonconformance while on-site, PJLA headquarters has full authority to initiate a nonconformance against (SOP-3).

### **9.0 MULTIPLE SITE ACCREDITATION:**

9.1 Where an applicant laboratory is operating through a number of outstations or separate facilities, they may choose to pursue accreditation of all locations under a single accreditation if all of the following conditions exist:

#### 9.1.1 Conditions

- a) The applicant laboratory produces similar services at all sites where activities are undertaken;
- b) The applicant laboratory's policy must reflect the single purpose stated above as its objective;



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- c) The system must be centrally structured and managed;
- d) Each site must be subject to regular internal audits, and objective evidence of the completion of it must be available prior to the actual on-site Assessment by PJLA
- e) The central office must demonstrate the full authority of the following activities:
  - i) Contract review (local acceptance of orders is permitted);
  - ii) Approval of applicant suppliers;
  - iii) Evaluation of training needs;
  - iv) System documentation and system changes;
  - v) Management review;
  - vi) Evaluation of corrective actions;
  - vii) Internal audit planning and evaluation of the results;

**NOTE:** Limited variations in local work instructions caused by differences in available equipment or facility size are permitted.

- 9.1.2 As certificates are site specific, each location will be numbered and issued a certificate bearing the number of the main location with the suffix '-X'.
- 9.1.3 The assessment of the applicant laboratory should establish that:
  - a) The laboratory's system relates to the sites involved and is the same for all
  - b) Evaluation of the documentation is effected from the central location
  - c) All sites have been assessed within the assessment procedure
- 9.1.4 PJLA alone will establish the sites to be selected for the external assessment for surveillances and reaccreditations, taking into account the results of prior internal audits, variations in the size of the sites, and variations in work instructions. A schedule/plan will be developed by PJLA, to ensure that the appropriate amount of sites are visited within the laboratory's accreditation cycle. All sites must be visited during the initial accreditation.
- 9.1.5 When nonconformities are detected within any of the sites visited during the assessment, submission of corrective action should be completed within a 90-day timeline. Failure to complete appropriate correction action within this timeline will cause the entire certificate to be withdrawn per PJLA procedure SOP-11: Suspension, Withdrawal and Reduction of Accreditation.



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### 10.0 MAINTENANCE OF ACCREDITATION AND SURVEILLANCE ASSESSMENTS

- 10.1 The continued fulfillment of accreditation requirements is maintained by conducting regular surveillance visits once per accreditation cycle.
- 10.2 Surveillance assessments are on-site visits to ensure compliance with accreditation requirement and are typically less comprehensive than accreditation assessments. At a minimum, the following aspects will be included during a surveillance:
- a) Enquiries from PJLA to the laboratory on aspects concerning the accreditation
  - b) Declaration by the laboratory with respect to their operation
  - c) Documents and records, including updates from quality manual
  - d) Laboratory's performance (including through proficiency testing)
  - e) Other means of monitoring the laboratory's testing & calibration equipment
  - f) Clauses of both the quality system and the testing and/or calibration activities should be assessed.
    - a. Internal audit and management review
    - b. Previous visit's findings
    - c. Outstanding corrective action
    - d. Performance in proficiency testing
    - e. Personnel changes and other changes
    - f. Changes in technical personnel or equipment
    - g. All PJLA policy requirements
    - h. Accreditation Symbol Utilization
    - i. Representative sampling of the accredited activities, covering all areas of competence
- 10.4 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. Once the team is appointed an assignment sheet will be provided to the team reflecting special instructions including an assigned scope to assess while on-site. If the assessor is fully competent in the entire scope then the assessor may determine which part of the scope to assess. Typically, this should be based on the previous year's assessment activities.



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- 10.5 The surveillance assessment follows, in broad form, the same cycle as the accreditation assessment although is less comprehensive. Laboratories are allowed 90 days to complete corrective actions from surveillance assessments. Surveillance assessment packages with no major nonconformities are reviewed by the President/Operations Manager and Technical Program Manager(s). During this review a recommendations for continuous accreditation will be made. If major nonconformities are issued during the surveillance or significant changes were made to the laboratories scope, personnel or any other area affecting the scope of accreditation then the package will be sent to the executive committee to grant a recommendation for continuous accreditation.
- 10.6 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 laboratory during the initial accreditation cycle. When on-site surveillance visits are reduced from the laboratory's accreditation cycle, PJLA may require the laboratory to demonstrate its maintenance of their accreditation through an off-site review. This review consists of the following:
- 1) PT Data Review
  - 2) Internal Audit Results
  - 3) Management Review
  - 4) Corrective Actions Taken
  - 5) Review of changes occurred in the laboratory
  - 6) Off-site Technical Review of at least one item on the scope of accreditation
- 10.7 PJLA reserves the right to conduct Special Assessments during the course of the accreditation period. Circumstances that can initiate Special Assessments include, but are not limited to:
- a) The applicant laboratory requesting an expansion of the Scope of Accreditation
  - b) Complaints from customers that are directed to the laboratory's competency and results
  - c) Laboratory implements or wishes to implement a significant change to the organization (i.e. ownership change, address change etc.)
- 10.8 If the laboratory's changes do not directly affect their test/and or calibration results then it may be determined that a special assessment may not be necessary and the changes will be review during their regular assessment period.



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- 10.9 If the accredited laboratory contemplates major changes it must notify PJLA, which may initiate a Special Assessment to ensure that such changes do not conflict with the requirements of the Standard.

### 11.0 REACCREDITATION

- 11.1 At the end of the laboratory's accreditation cycle, PJLA conducts a complete reaccreditation of the laboratory, similar to the initial Accreditation Assessment and its processes. Such assessments take into account PJLA's relationship with accredited laboratory during the accreditation period as well as customer complaints and experience gained during previous assessments.
- 11.2 To ensure that laboratory's avoid a lapse in accreditation, PJLA makes every attempt to schedule assessments at least 90-60 days prior to expiration. The monitoring of expired or soon to be expired certificates is conducted by reviewing the PJLA website of accredited laboratories. This is monitored no less than twice per month to ensure that certificates remain active. In the case a certificate has expired, PJLA will take appropriate measures to expedite the certificate and to publish the most current version on the registry. If a certificate is in the process of expiring (within 2-weeks) PJLA will take appropriate measures such as: contacting the lead assessor and/or laboratory for open nonconformity responses or if the assessment is with the executive committee they will be contacted for a status update. In very rare cases, the President/Operations Manager will approve the laboratory to have an extension on their certificate. This extension will be in a letter format and will also be updated on the PJLA website.
- 11.3 Once the reaccreditation is submitted to headquarters for review the Technical Program Manager(s) 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 Technical Program Manager(s) finds that there is evidence that the assessor is over familiar with the laboratory's system, then the Technical Program Manager(s) will discuss this issue with the President/Operations Manager. A decision will be made by the President/Operations Manager 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.

### 12.0 SCOPE EXTENSIONS

- 12.1 If a laboratory wishes to extend their scope of accreditation the laboratory



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must notify PJLA in writing of the nature of the extension. A Special Assessment will be required to assess such modifications. The extent of the Special Assessment is dependent on the degree of the scope extension proposed.

12.1.1 Once the PJLA receives the scope extension request, the following will occur:

- a) The laboratory will be requested to complete the (LF-1) Client Questionnaire Section B-C to ensure detail of the extended scope is fully available.
- b) Once returned, PJLA will review the scope extension to determine the following needs:
  - 1) Assessor competency
  - 2) Executive committee competency
  - 3) Technical committee competency
  - 4) Allocation of time needed on-site

12.1.2 If at anytime PJLA has difficulties in determining the items listed in 1-4 above a member of the Technical Committee, Executive Committee or a Lead Assessor may be utilized to assist in the decision making process.

12.1.3 If it is determined that PJLA cannot fulfill the needs of section 1-3 above then PJLA will recruit appropriate resources. No scope extension assessment will be conducted until all resources are available.

12.1.4 Once PJLA is fully capable of conducting the scope extension the laboratory will be sent a contract amendment to reflect the special assessment including the appropriate time allocation.

12.1.5 Once the contract amendment is signed and returned an assessment team will be assigned. Special instructions will be given to the assessment team in regards to the areas to be assessed. At minimum the assessor will review: the entirety of section 5.0 of ISO/IEC 17025:2005, Internal Audits and Management Review in relation to the scope being extended.

12.1.6 Upon completion of the assessment including corrective action submission the package will be submitted to a competent executive committee reviewer to grant a decision on the scope extension.

### **13.0 SUSPENSION, WITHDRAWAL, REDUCTION OR CANCELLATION OF ACCREDITATION**

- 13.1 PJLA reserves the right to suspend, withdraw, reduce or cancel accreditation at any time during the two-year accreditation period, in accordance with PJLA procedure SOP-11.



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- 13.2 Generally, such actions are considered in the following instances:
- a) Laboratory fails to complete corrective actions during the agreed timeframe
  - b) Laboratory persistently fails to conform to Standard
  - c) Laboratory does not participate in satisfactory PT activity
  - d) Laboratory, in PJLA's judgment, misuses PJLA's Accreditation Symbol, Certificate of Accreditation, etc.
  - e) Laboratory becomes delinquent in its financial obligations to PJLA
  - f) Laboratory 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;
  - g) Laboratory is convicted of an offense tending to discredit the facility's reputation and goodwill
  - h) Laboratory commits acts that, in PJLA's sole judgment, impugn PJLA's goodwill, valuable name and reputation
  - i) Laboratory improperly quotes the accreditation in its literature, including advertisements, catalogs and brochures.
- 13.3 PJLA reserves the right to publicize any actions it may take with respect to withdrawal, cancellation, reduction or suspension of an applicant laboratory's accreditation.
- 13.4 PJLA will also cancel accreditation upon the formal written request of applicant laboratory.
- 13.5 PJLA may take legal action for wrongful actions specified in 13.2.

### **14.0 DISPUTES AND APPEALS**

- 14.1 The applicant laboratory or any interested party may dispute or appeal the decisions of PJLA with respect to:
- a) Refusal to accept an applicant laboratory's application for accreditation
  - b) Failure to confer accreditation
  - c) Suspension, withdrawal, reduction or cancellation of accreditation
  - d) Refusal to extend an applicant laboratory's Scope of Accreditation
  - e) An appeal by a third party against PJLA's decision to grant accreditation
  - f) Assignment of assessment team
  - g) Nonconformities written by the assessment team
  - h) or any other issue relevant to the accreditation process



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- 14.2 Laboratories have access to the Dispute and Appeal Procedure (SOP-10) via PJLA website.

### 15.0 CONFIDENTIALITY

- 15.1 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 laboratory. 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 accredited laboratory, 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 accredited laboratory 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.



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## **APPENDIX A: THE NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM**

### **1.0 SCOPE/PURPOSE**

The National Lead Laboratory Accreditation Program (NLLAP) is an accreditation program designed to assess the competency and capability of laboratories to analyze lead in matrices of paint chips, dust and or/soil according to the NLLAP and PJLA criteria.

This appendix includes the process for which PJLA carries out its accreditations in accordance with the NLLAP. This also includes specific requirements of applicant and accredited laboratories wishing to obtain and maintain an accreditation to the NLLAP. This appendix only includes NLLAP program specific requirements, which are not found in the body of this document. Criteria outlined in the body of this document will be carried out by PJLA and enforced by PJLA to its laboratories above these requirements as necessary.

### **2.0 REFERENCES**

- 2.1 National Lead Laboratory Accreditation Program (NLLAP) Memorandum of Understanding
- 2.2 Laboratory Quality Systems Requirements (LQSR) Version 3.0, July 05, 2007.

### **3.0 DEFINITIONS**

Accreditation-A formal recognition that laboratory is competent to perform analyses of lead in paint chips, dust and or soil samples associated with the evaluation and control of lead-based hazards. Competence will be based on successful performance in both proficiency testing program and systems audit (inclusive of an on-site assessment) by programs/organizations recognized by NLLAP.

Assessor- One who performs systematic evaluation of a laboratory on behalf of a laboratory accreditation organization.

Environmental Lead Proficiency Analytical Testing Program (ELPAT Program)-The proficiency testing program recognized by the NLLAP. \* Participation on a quarterly basis in this program is mandatory for all laboratories seeking accreditation by an NLLAP recognized laboratory accrediting organization.

EPA National Lead Laboratory Accreditation Program (NLAAP)- A voluntary laboratory accreditation program with EPA OPPT oversight, which recognizes private sector and public laboratory accreditation organizations capable of performing adequate laboratory assessments as part of their accreditation program of laboratories requesting accreditation for their analysis of lead in paint chips, dust and/or soil samples associated with the



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evaluation and control of lead-based paint hazards. Laboratories accredited by an NLLAP recognized accrediting organization will be recognized by EPA under NLLAP.

Laboratory-A facility that is requesting accreditation for the analyses of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards.

Laboratory Accreditation Organization (accreditation organization)-An organization which seeks recognition from the EPA NLLAP as being capable of performing adequate laboratory assessments for laboratories requesting accreditation for the analysis of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards. (i.e. PJLA)

### 4.0 SUBSTANCE OF THE AGREEMENT

PJLA is recognized by the ILAC and APLAC MRAs as operating to ISO/IEC 17011 the successor document to ISO Guide 58. This guide is now obsolete and not used by the regional or international recognition bodies.

### 4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for laboratories seeking accreditation under the NLLAP program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of a laboratory's accreditation status based on the laboratory's failure to meet requirements of the program on an ongoing basis or at the laboratory's request. PJLA will notify the EPA NLLAP in writing within five (5) working days of such actions.

PJLA will also notify the EPA/OPPT within 30 days after deciding on implementing major, substantive changes in its policies or management which could affect the EPA NLLAP program.

### 4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors based on the EPA curriculum guidance document "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs- Revision 1.0" (EPA document No. 747-R-92-005). New and experienced assessors are required to meet the requirements contained in this document. Should the need arise to use training based on its own or other curricula, then these curricula will be submitted in advance to the EPA for review and approval. PJLA may, at its option, utilize the training of another



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accrediting organization, however, that accrediting organization must also be recognized under the EPA NLLAP.

### 4.3 ASSESSMENTS AND DOCUMENTATION

PJLA will perform on-site assessments of laboratories' quality systems to include their general ISO/IEC 17025 requirements, the LQSR, and the specifics of the EPA NLLAP program. These will, at minimum, meet the requirements of the then current EPA NLLAP LQSR. Each assessment will include the completion of a checklist that follows the example of that in the "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs- Revision 1.0" or one that gives equivalent coverage of the example current to the requirements of the EPA NLLAP program. The checklist and other pertinent documentation will be kept for 10 years or otherwise instructed by the EPA NLLAP program (see 4.7 below).

### 4.4 PROFICIENCY TESTING (ACCREDITATION PROCESS)

PJLA requires all laboratories applying or maintaining accreditation under the NLLAP to participate in the American Industrial Hygiene Association (AIHA) Environmental Lead Proficiency Testing Program (ELPAT) program on a quarterly basis. All laboratories applying for accreditation and maintaining accreditation must perform such proficiency testing successfully and be rated "proficient" or "P" by the National Institute for Occupational Safety and Health (NIOSH) in their participation in the ELPAT program. PJLA will work with NIOSH and the laboratory to secure the ELPAT data on an ongoing basis for the ELPAT program.

### 4.5 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

PJLA currently accredits laboratories for a two-year accreditation cycle, supplemented with yearly on-site surveillance assessments. While no change in this interval is anticipated, for the EPA NLLAP program, it will not exceed three years. Accreditation and re-accreditation assessments involve the off-site review of documentation and performance information and an on-site assessment that addressed all elements of ISO/IEC 17025 and the EPA NLLAP program.

### 4.6 NOTIFICATION (CERTIFICATE PROCESS)

PJLA will notify designated contacts at the EPA NLLAP of all accreditation approvals to include the effective date of accreditation, the expiration date and the specific matrices for which the laboratory holds accreditation as expressed in its scope statement or scope supplement. This notification will be made within forty-five (45) days of the date the accreditation is effective. PJLA will send EPA NLLAP a current list of all laboratories accredited under the program at least one every three months at minimum.



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### **4.7 RECORD RETENTION (RECORDS/COMPLAINTS)**

PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum. However, records for the EPA NLLAP program will be retained for at least ten (10) years minimum. These records will include all complaints received from customers and others about laboratories accredited by PJLA in the EPA NLLAP program.

### **4.8 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)**

PJLA will not delegate (whole or in part) the responsibility of laboratory assessment to another organization, which is not itself recognized under the EPA NLLAP. This will not extend to the assessors themselves, many/most of whom are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.

### **4.9 SUBCONTRACTING OF LABORATORY ACTIVITIES**

Laboratories accredited by PJLA under the EPA NLLAP program will not subcontract routine sample analyses as described under the scopes of their accreditation and for which they are recognized unless the subcontracted laboratory is also recognized under the EPA NLLAP program for the same analyses. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced.

### **4.10 PARTICIPATION AND MAINTENANCE OF RECOGNITION**

PJLA will participate in meetings with the EPA as scheduled and announced, or at least once every two years subject to EPA scheduling, to help in the evaluation, maintenance and improvement of the EPA NLLAP.