



DoD ELAP/DOECAP-AP 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 and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to Conformity Assessment Bodies (CABs) **for The Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP) and the Department of Energy Consolidate Audit Program Accreditation Program (DOECAP-AP). This is a Supplemental Procedure to PJLA's Accreditation Procedure (SOP-1). Both procedures shall be followed for the entirety of this accreditation program.**



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1.0 SCOPE/PURPOSE

- a) The DoD ELAP and DOECAP-AP are accreditation programs designed to assess the competency and capability of CABs to the DoD/DOE Consolidated Quality System Manual (QSM) for Environmental Laboratories (hereafter referred to as the DoD/DOE QSM) including any additional PJLA procedures and policies.
- b) This procedure includes:
 - i) The process for which PJLA carries out its accreditations in accordance with the DoD/DOE QSM and the DoD ELAP and DOECAP-AP Conditions and Criteria.
 - ii) Specific requirements of applicant and accredited CABs wishing to obtain and maintain accreditation to the DoD/DOE QSM for the DoD ELAP and/or the DOECAP-AP.
- c) PJLA offers this accreditation program to all interested CABs regardless of size, scope of accreditation, or membership in any organization unless otherwise directed by the DoD ELAP or DOECAP-AP.
- d) At no such time will PJLA operate or engage in the operation of an environmental testing laboratory.

2.0 REFERENCES

- a) International Standard ISO/IEC 17011 Conformity assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies, November 2017
- b) DoD/DOE QSM
- c) International Standard ISO/IEC 17025 General Requirements for the Competence of testing and Calibration Laboratories, November 2017
- d) The NELAC Institute (TNI) Environmental Laboratory Sector Standard Volume 1 Management and Technical Requirements for Laboratories Performing Environmental Analysis (2009)
- e) The NELAC Institute (TNI) Environmental Laboratory Sector Standard Volume 2 General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (2009)
- f) DoD Environmental Laboratory Accreditation Program (ELAP) Conditions and Criteria for the Recognition of Accreditation Bodies; Appendix A Suspending and Withdrawing DoD ELAP Recognition
- g) DOECAP-AP Procedure for Recognizing Accreditation Bodies; Appendix B Conditions and Criteria for the Recognition of Accreditation Bodies

3.0 SUBSTANCE OF THE AGREEMENT

- a) PJLA is recognized by the DoD ELAP Environmental Data Quality Workgroup (EDQW) and DOECAP-AP to accredit CABs to the DoD/DOE QSM by means of the continuation and good standing of the ILAC/APAC international MRAs and adherence to the Conditions and Criteria set forth by the DoD ELAP and/or DOECAP-AP.



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4.0 MANUAL/ORGANIZATION

- a) PJLA maintains a quality manual, operating procedures, and work instructions to document its quality system to comply with the ISO/IEC 17011 standard. These and other related documents (including this one) state the requirements for CABs seeking accreditation under the DoD ELAP and/or DOECAP-AP program.
- b) PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of an organization's accreditation status based on the organization's failure to meet requirements of the program on an ongoing basis or at the organization's request.
- c) PJLA maintains adequate financial resources for this accreditation program as required in the ISO/IEC 17011 standard.

Note: The DOECAP-AP requires PJLA to provide copies of any updates to quality management system documentation to the ASP DOECAP-AP Manager within 30 calendar days of the update; as related to DOECAP-AP.

5.0 TRAINING AND QUALIFICATION

- a) PJLA maintains a training, qualification and on-going continuing education program for assessors based on the requirements of ISO/IEC 17011 and the Conditions and Criteria set forth by the DoD ELAP and/or DOECAP-AP. New and experienced assessors are required to meet the requirements contained in this document.
- b) PJLA may utilize the training of another accrediting organization; however, that accrediting organization must also be recognized under the DoD ELAP and/or DOECAP-AP. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations.
- c) DoD ELAP and DOECAP-AP assessors will possess a bachelor's degree (or higher) in a scientific/technical discipline or have equivalent experience in environmental analysis.
- d) All assessors shall complete a basic training and work experience in accordance with PJLA Personnel Procedure (SOP-2). Training may include ISO/IEC 17025 training, National Environmental Laboratory Accreditation Council (NELAC) Training, and DoD/DOE QSM Training. PJLA will also provide assessors annual refresher training (e.g., regulations, accreditation processes, procedures, and requirements, records and documents, data analysis, reduction and reporting, measurement methods and techniques, other topics to improve assessment and communication skills). Curriculums for annual training will be provided to the DoD ELAP EDQW and DOECAP-AP for review and approval prior to execution. Any changes to PJLA's assessor training curriculum will be provided to the DoD ELAP EDQW and DOECAP-AP at least every two years. PJLA will notify and invite members of the DoD ELAP EDQW and DOECAP-AP to training activities 30 days in advance of the start of the training session.
- e) All qualifications and training will be documented in the assessor files. Evidence of training will be documented on a PJLA training record (LF-26) and provided to the DoD ELAP EDQW and DOECAP-AP, as required. Certificates of training will



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be provided for participation courses or when training with relevant exams for extensive standard changes take place. Assessors that are not in attendance at annual training sessions will be provided with the documented information to confirm their understanding and will be requested to sign a training record upon their review.

- f) Assessors will be assigned to each (CAB) based on their qualifications submitted and approved by PJLA.
 - i) DoD ELAP EDQW: Lead assessors may only be assigned to a client for a maximum period of two accreditation cycles. Once the two-year accreditation cycle has expired a new lead assessor will be assigned. The former lead assessor may be assigned with the new lead assessor as a technical assessor as necessary.
 - ii) DOECAP-AP: Lead Assessors may only be assigned to a client as the Lead Assessor for one consecutive accreditation cycle unless written approval from the ASP DOECAP-AP Manager is provided.
- g) Assessors shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by PJLA. The qualified assessor shall observe the candidate assessor performing:
 - i) at least one assessment, for those assessors that have previous documented experience performing environmental CAB assessments; or
 - ii) at least five assessments, for those assessors that have no documented experience performing environmental CABs assessments.

NOTE: A qualified assessor may evaluate the ability of an assessor to perform unsupervised assessments by direct observation, observing the assessor perform an assessment in its entirety; or by limited observation, observing the assessor performing parts of an assessment and allowing the assessor to conduct some parts of the assessment independently.

- h) Supervised assessments will be documented on an LF-100 Assessor Evaluation form as outlined in PJLA Personnel Procedure (SOP-2).

6.0 ASSESSMENTS AND DOCUMENTATION

- a) PJLA will perform on-site assessments of CAB laboratory systems to include the latest version of the DoD/DOE QSM and PJLA Policy Requirements. Each assessment will include the completion of a checklist and supplemental documents that provide sufficient evidence that all applicable elements of the DoD/DOE QSM have been assessed. The DoD ELAP EDQW and DOECAP-AP will be notified 30 days in advance (note: DOECAP-AP requires no later than 10 calendar days following the reported month) of any assessments scheduled including on-site or off-site assessments and scope expansions. A monthly updated list of pending assessments will be provided to the DoD ELAP EDQW and DOECAP-AP. PJLA will cooperate with the DoD ELAP EDQW and DOECAP-AP in all cases when CABs are selected to be witnessed.



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- b) Prior to each assessment, PJLA will require documentation to be submitted that includes: the quality manual, SOPs, PT listing/results/data packages, method validation results, mass calibration results (if applicable), previous audit reports, LOD/LOQs, Laboratory Control Limits/Charts for Laboratory Control Sample for each method, training records, standards traceability, technical justification for method modifications and a completed PJLA DoD/DOE QSM checklist. Assessors shall review the above documents prior to and during assessments.

7.0 PROFICIENCY TESTING (ACCREDITATION PROCESS)

- a) PJLA requires all CABs applying or maintaining accreditation under the DoD ELAP and/or DOECAP-AP program to comply with proficiency testing (PT) requirements outlined in PJLA Policy PL-1 and the DoD/DOE QSM. Applicant or accredited CABs shall ensure that all items on their scope of accreditation undergo proficiency testing in compliance with the DoD/DOE QSM.
- b) In the case, third party PT providers are not available, the CAB must be able to demonstrate proficiency by utilizing other sources as outlined in PJLA Policy PL-1 (i.e. inter lab comparison, intra lab comparison, repeatability studies).
- c) PT data from third party PT providers shall be submitted by the PT provider in an Excel based (.csv) format to pt@pilabs.com. Data shall be submitted within 15 days from the receipt of the completed study.

8.0 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

- a) PJLA accredits CABs for a two-year accreditation cycle, supplemented with yearly surveillance assessments. Accreditation assessments and reassessments involve a full system assessment of the CAB. Certificates cannot be extended past the expiration date unless approved by the DOD ELAP EDQW or DOECAP-AST Manager for extreme unforeseen circumstances. Requests shall be made within 5 days prior to the expiration date. CABs are strongly encouraged to schedule assessments well in advance to allow sufficient time for the new certificate to be re-issued. CABs that have a lapse in accreditation are considered non-accredited for the period the lapse occurs and can no longer claim accreditation until the certificate is renewed.

9.0 ANALYSIS OF FINDINGS AND REPORT

- a) PJLA will follow its documented procedures in the conduct of the assessments, documentation of findings (non-conformities/observations), and on-site reports. PJLA assessors are expected to leave the documentation of findings and the report with the CAB and PJLA Headquarters at the conclusion of the closing meeting.
- b) Assessment reports and findings (as applicable) will be submitted to the DoD ELAP EDQW and DOECAP-AP within 10 days of the on-site assessment.
- c) Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of



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corrective action, and objective evidence or an assessable plan with objective evidence of implementation of the plan within 60 days of the closing meeting. All non-conformities must be resolved prior to recommending accreditation.

Additional assessment material such as: corrective action plans, full corrective action taken for nonconformities and AB feedback will be provided to the DoD ELAP EDQW and DOECAP-AP upon request.

- d) PJLA will notify the ASP DOECAP-AP Manager in writing and update its website to document any action that adversely affects the status of a CAB's DOECAP-AP accreditation within 5 working days of the action.

10.0 SCOPE EXPANSION

- a) CABs may request that additional methods or analytes be added to their scope of accreditation. Typically, these can be added by conducting a documentation review by a competent assessor. In addition to the scope expansion process identified in PJLA's general Accreditation Procedure (SOP-1), the CAB will be required to submit the following information for a scope expansion.

- Method Validation Package
- Technical justification for any method modifications
- LOD/LOQ
- PT results
- DOC Training Records
- SOP Standards
- Traceability
- Full Data Package
- Control limits
- Copy of mass calibration (if applicable)

- b) Scope expansions for a technology that is not already on their scope of accreditation will require an on-site assessment.

11.0 CABS OBLIGATION IN REGARD TO PROHIBITED LABORATORY PRACTICES

- a) In accordance with the DoD/DOE QSM, laboratories shall report and submit the associated corrective action on any instances of inappropriate and prohibited laboratory practices discovered during any internal or external assessment or investigation to PJLA as soon as practicable. PJLA will be required to communicate this to the DoD ELAP EDQW and DOECAP-AP of the lab's deviation from the requirements of the DoD/DOE QSM no later than 10 days from the assessment.



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12.0 RECORD RETENTION (RECORDS)

- a) Assessment material and pertinent records will be retained for a minimum of five years. Specific program requirements may supersede these retention periods; however, only by increasing the retention period.

13.0 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

- a) PJLA will not delegate (whole, or in part) the responsibility of CAB assessment to another organization without the approval of the DoD ELAP EDQW and/or DOECAP-AP.

14.0 SUBCONTRACTING OF CAB ACTIVITIES

- a) CABs accredited by PJLA under the DoD ELAP and/or DOECAP-AP program will not subcontract activities described under the scope of their accreditation and for which they are recognized unless the subcontracted organization is also recognized under the DoD ELAP and/or DOECAP-AP program for the same activities. Other provisions of the ISO/IEC 17025 standard regarding subcontracting will also be enforced.

15.0 CERTIFICATES OF ACCREDITATION

- a) PJLA only issues certificates of accreditation upon the final approval of the Executive Committee. These certificates will contain the effective date, the scope of accreditation (matrices, method, technology, analyte), expiration date and date of last full on-site assessment.
- b) A listing of all accredited (CABs) will be published on the PJLA site to include the: CAB name, address, phone number, scope of accreditation. Any changes to the CAB's status will be indicated on the PJLA website and the DoD ELAP EDQW and/or DOECAP-AP will be notified within 5 business days of the change.
 - a) For the DoD ELAP, information from the scope of accreditation will be prepared on a Denix load sheet and submitted to the DoD ELAP EDQW for uploading onto their website.

16.0 PARTICIPATION AND MAINTENANCE OF RECOGNITION

- a) PJLA will comply, at all times, with the criteria and condition set forth by the DoD ELAP and/or DOECAP-AP for the administration of this program. PJLA will participate in DoD ELAP EDQW and DOECAP-AP annual meetings and conference calls as necessary and welcomes DOD or DOE observers to attend CAB on-site assessments.
- b) PJLA will maintain continuation of international recognition by ILAC and APAC for testing. The DoD ELAP EDQW and DOECAP-AP will be informed of PJLA's ILAC/APAC evaluation schedule at least 3-months prior to the scheduled date to



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invite a member to participate and will be notified within 30 days of any changes to our signatory status. Any documents developed for the evaluation will be submitted 30 days in advance. Reports resulting from the evaluation will be submitted to the DoD ELAP EDQW and DOECAP-AP for review within 30-days of receipt.

- c) PJLA will report any changes to DoD ELAP EDQW and DOECAP-AP of any major changes within 15 calendar days that affect PJLA such as: legal, commercial, organizational or ownership status, organizational and management (i.e. key managerial staff), quality management system policies or procedures where appropriate, location change, personnel, facilities, working environment or other resources, authorized representative for the program or any other matters that could affect the PJLA's capability, scope of recognized activities, or compliance with the DoD ELAP EDQW and/or DOECAP-AP requirements and relevant technical documents.
- d) Any disputes or appeals made regarding the requirements of the DoD/DOE QSM will be forwarded to the DoD ELAP EDQW and/or DOECAP-AP for resolution.
- e) Any CABs transferring to or from PJLA will be communicated to the DOD ELAP EDQW or ASP DOECAP-AP Manager within 10 days from the notification by the CAB.