



DoD ELAP-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 assessments bodies **for The Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP)**. **This is a Supplemental Procedure to PJLA's Accreditation Procedure (SOP-1). Both procedures shall be followed for the entirety of this accreditation program.**



DoD ELAP-Accreditation Procedure

1.0 SCOPE/PURPOSE

- 1.1 The Department of Defense Laboratory Accreditation Program (DoD ELAP) is an accreditation program designed to assess the competency and capability of (CABs) to the DoD Quality System Manual (QSM) including any additional PJLA policies.
- 1.2 This procedure includes the process for which PJLA carries out its accreditations in accordance with the DoD Quality Systems Manual for Environmental Laboratories (DoD QSM) and the Conditions and Criteria for DoD Environmental Laboratory Accreditation Program Recognition of Accreditation Bodies. This also includes specific requirements of applicant and accredited (CABs) wishing to obtain and maintain an accreditation to the DoD ELAP. This appendix only includes DoD ELAP 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 (CABs) as well as these requirements as necessary.
- 1.3 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 EDQW.
- 1.4 At no such time will PJLA operate or engage in the operation of an environmental testing laboratory.

2.0 REFERENCES

- 2.1 DoD Quality Systems Manual for Environmental Laboratories (DoD QSM)
- 2.2 International Standard ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, September 2004
- 2.3 DoD Environmental Laboratory Accreditation Program (ELAP) Conditions and Criteria for the Recognition of Accreditation Bodies; Appendix A Suspending and Withdrawing DoD ELAP Recognition
- 2.4 TNI EL Standard Volume 1 and 2 (2009)

3.0 SUBSTANCE OF THE AGREEMENT

- 3.1 PJLA is recognized by Department of Defense EDQW to accredit (CABs) to the DoD QSM by means of the continuation and good standing of the ILAC/APLAC international MRAs and adherence to the criteria and condition criteria and Appendix A Suspending and Withdrawing DoD ELAP Recognition set forth by the DoD for this program.

4.0 MANUAL/ORGANIZATION



DoD ELAP-Accreditation Procedure

- 4.1 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 (CABs) seeking accreditation under the DoD ELAP program. 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. PJLA maintains adequate financial resources for this accreditation program as required in the ISO 17011 standard.

5.0 TRAINING AND QUALIFICATION

- 5.1 PJLA maintains a training, qualification and on-going continuing education program for assessors based on the requirements of ISO/IEC 17011:2004 and the conditions and criteria set forth by the DoD for the administration of the DoD ELAP. New and experienced assessors are required to meet the requirements contained in this document. PJLA may, at its option, utilize the training of another accrediting organization. However, that accrediting organization must also be recognized under the DoD ELAP. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations.
- 5.2 DoD ELAP assessors will possess a Bachelor's degree (or higher) in a scientific/technical discipline or have equivalent experience in environmental analysis.
- 5.4 All assessors shall complete a basic training and work experience in accordance to PJLA Personnel Procedure (SOP-2) including basic ISO/IEC 17025:2005 training, NELAC Training and DoD QSM Training. Annual refresher training will be provided to address (for example): regulations; accreditation processes and procedures and requirements; records and documents; data analysis, reduction and reporting; and measurement methods and techniques; and other topics to improve assessment and communication skills. Curriculums for annual training will be provided to the EDQW for review and approval prior to execution. Any changes to our assessor training curriculum will be provided to the EDQW at least every two years. PJLA will notify and invite members of the EDQW to all training activities.
- 5.6 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 EDQW as required. Certificates of training will 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.



DoD ELAP-Accreditation Procedure

- 5.7 Assessors will be assigned to each client based on their qualifications submitted and approved by PJLA. 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.
- 5.8 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:
- a) at least one assessment, for those assessors that have previous documented experience performing environmental (CAB) assessments; or
 - b) at least five assessments, for those assessors that have no documented experience performing environmental (CAB) 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.

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

6.0 ASSESSMENTS AND DOCUMENTATION

- 6.1 PJLA will perform on-site assessments of (CABs) laboratory systems to include the latest version of the DoD 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 QSM have been assessed. The EDQW will be notified 30 days in advance 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 EDQW. PJLA will cooperate with the EDQW in all cases when (CABs) are selected to be witnessed. 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 ELAP checklist. Assessors shall review the above documents prior to and during assessments.



DoD ELAP-Accreditation Procedure

7.0 PROFICIENCY TESTING (ACCREDITATION PROCESS)

- 7.1 PJLA requires all (CABS) applying or maintaining accreditation under the DoD ELAP program to comply with PJLA Policy PL-1 and with the requirements of the DoD QSM. Applicant or accredited (CABs) shall ensure that all items on their scope of accreditation undergo a proficiency test at least every 6 months. These proficiency tests shall be conducted by competent providers as indicated in the DoD QSM or the TNI EL Standard Volume 1 and 2 (2009). In the case, third party providers are not available then the (CAB) must be able to demonstrate their adherence by utilizing other sources as outlined in PJLA Policy PL-1 (i.e. inter lab comparison, intra lab comparison, repeatability studies). This must be approved by PJLA. (CABs) are responsible for informing their PT providers of the format and distribution of whom PT data should be submitted to at PJLA headquarters. PT data shall be submitted in an Excel based (.csv) format to pt@pjilabs.com. Data shall be submitted within 15 days from the receipt of the completed study.

8.0 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

- 8.1 PJLA currently accredits (CABs) for a two-year accreditation cycle, supplemented with yearly surveillance assessments. Accreditation and re-accreditation assessments involve a full system assessment of the (CAB). Any extensions issued to (CAB's) certificate will be provided to the EDQW within 5 working days with the rationale of the expiration date of the extension.

9.0 ANALYSIS OF FINDINGS AND REPORT

- 9.1 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 organization at the conclusion of the closing meeting. Also, the lead assessor is expected to send this documentation to PJLA HQ within 10 days from the end of the assessment (with allowances for travel, weekends, etc.). Assessment reports and/or laboratory disclosures related to inappropriate practices as identified in the DoD QSM will be submitted to the EDQW within 10 days of the on-site assessment. Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of 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



DoD ELAP-Accreditation Procedure

action plans, full corrective action taken for nonconformities and AB feedback will be provided to the EDQW upon request.

10.0 SCOPE EXPANSION

10.1 Laboratories 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. At minimum PJLA will require the following information to be submitted:

- 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)

10.2 Laboratories requesting to expand their scope in regard to a new technique and or equipment will be required to apply for the extension in a similar manner, but will require an on-site assessment.

11.0 (CABS\LABS) OBLIGATION IN REGARD TO PROHIBITED LABORATORY PRACTICES

11.1 In accordance with the DoD ELAP 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 EDQW of the lab's deviation from the requirements of the QSM no later than 10 days from the assessment.

12.0 RECORD RETENTION (RECORDS)

12.1 DoD ELAP assessment material and pertinent recorder will be retained for at least five (5) years minimum. Specific program requirements may supersede these retention periods, but only by increasing them.

13.0 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

13.1 PJLA will not delegate (whole, or in part) the responsibility of (CAB) assessment to another organization without the approval of the EDQW. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.



DoD ELAP-Accreditation Procedure

14.0 SUBCONTRACTING OF (CAB) ACTIVITIES

- 14.1 (CABs) accredited by PJLA under the DoD ELAP program will not subcontract activities described under the scopes of their accreditation and for which they are recognized unless the subcontracted organization is also recognized under the DoD ELAP program for the same activities. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced.

15.0 CONFIDENTIALITY

- 15.1 PJLA at all times will keep records including the results of each assessment confidential. (CABs) will be informed to whom the report will be distributed to including the EDQW.

16.0 CERTIFICATES OF ACCREDITATION

- 16.1 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. Information from the scope of accreditation will be prepared on a Denix load sheet and submitted to the EDQW for uploading. 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 EDQW will be notified within 5 business days of the change.

17.0 PARTICIPATION AND MAINTENANCE OF RECOGNITION

- 17.1 PJLA will comply at all times with the criteria and condition set forth by the DoD for the administration of this program. PJLA will participate in EDQW annual meetings and conference calls as part of the continual improvements efforts for the DoD ELAP. PJLA will maintain continuation of international recognition by ILAC and APLAC for testing. The EDQW will be informed of PJLA's ILAC/APLAC evaluation schedule at least 3-months prior to the scheduled date to 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 EDQW for review within 30-days of receipt. PJLA will report any changes to EDQW 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



DoD ELAP-Accreditation Procedure

other matters that could affect the PJLA's capability, scope of recognized activities, or compliance with the EDQW requirements and relevant technical documents. Any disputes or appeals made in regard to the requirements of the DoD QSM will be forwarded to the EDQW for resolution.