



The California Environmental Laboratory Accreditation Program (CA ELAP)

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing Laboratories). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies for the **California Environmental Laboratory Accreditation Program (CA ELAP)**.



The California Environmental Laboratory Accreditation Program (CA ELAP)

1.0 SCOPE/PURPOSE

- 1.1 The Health and Safety Code Section 100837 allows California Environmental Laboratory Accreditation Program (ELAP) to “contract with approved third-party laboratory assessor bodies in accordance with the criteria developed by the NELAC Institute (TNI) or a federal agency to conduct the on-site assessments.” PJLA has a MoU with the State Water Resources Control Board (SWRCB) to perform on-site assessments of laboratories seeking accreditation to CA ELAP. PJLA is committed and obligated to follow the requirements outlined in the MoU. Any modifications or exceptions to the criteria outlined in the MoU will be subject to approval by the State Water Resources Control Board.
- 1.2 This procedure outlines PJLA’s criteria to assess laboratories in accordance with the Memorandum of Understanding (MoU) Services to be provided by a third-party laboratory assessor body. This procedure also includes assessment options to include an assessment to other standards or accreditation schemes offered by PJLA (i.e. TNI EL- NGAB, DoD ELAP, DOECAP AP, ISO/IEC 17025:2017). CABs applying for additional assessment activities other than the CA ELAP shall follow that program criteria.

2.0 REFERENCES

- 2.1 State Water Resources Control Board (SWRCB) Memorandum of Understanding (MoU) Services to be provided by a third-party laboratory assessor body.
- 2.2 California Code of Regulations 64802
- 2.3 TNI EL Volume 1 and Volume 2- 2016
- 2.4 ISO/IEC 17011:2017
- 2.5 ISO/IEC 17025:2017
- 2.6 DoD/DOE Quality System Manual (DoD/DOE QSM) Latest Version

3.0 DEFINITIONS

- 3.1 **Assessment:** systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.
- 3.2 **Conformity assessment:** demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled.
- 3.3 **Conformity assessment body (CAB):** body that performs conformity assessment services



The California Environmental Laboratory Accreditation Program (CA ELAP)

4.0 QUALITY MANAGEMENT SYSTEM

- 4.1 PJLA maintains a quality manual system in accordance to ISO/IEC 17011:2017 and TNI EL Volume II 2016 or latest version. Conformity assessment bodies are required to follow PJLA's standard operating procedures for accreditation programs being assessed (i.e. CA ELAP, ISO/IEC 17025, TNI EL, DoD ELAP, DOECAP-AP, etc.) Conformity Assessments bodies will be advised of all relevant SOPS or PJLA policies. In addition to PJLA policies, all CABs shall follow the CA ELAP criteria and applicable laws.

5.0 TRAINING AND QUALIFICATION

- 5.1 PJLA ensures that all assessors are qualified to the assess on behalf of the CA ELAP or additional standards as applicable.
- Drinking Water Assessments-Assessors shall obtain a US EPA certified officer for the applicable test field (chemistry organic/inorganic, microbiology, radiochemistry etc.). This certification must be renewed every 5 years.
 - TNI EL 2016- Assessors shall be trained on the TNI EL Volume 1 2016 as specified in SOP-1 NELAC.
 - DOD ELAP/DOECAP-Assessors must be trained on the DOD/DOE QSM latest version as specified in SOP-1 DOD/DOE.
- 5.2 All Assessors shall meet PJLA education and work experience criteria as outlined in SOP-2 Personnel Procedure.
- 5.3 Assessors shall participate in PJLA annual refresher training or any training required for CA ELAP.

6.0 ASSESSMENTS AND DOCUMENTATION

- 6.1 PJLA will only accept application from (CABs) for tests that PJLA is capable of assessing. (CABs) will be required to clearly inform PJLA of the standard (s) for which they would like to be assessed to. For CA ELAP laboratories may choose: 1) CA Regulations only (until 2023), 2) CA Regulations and TNI EL minus 2 (two exceptions listed in CCR section 64802.05(a)(1) or 62802.15(b)(1)), 3) CA Regulations and Full TNI EL standard 4) TNI EL Full or minus 2 and DOD ELAP QSM for PFAS criteria 5) Any other standard PJLA may offer such as ISO/IEC 17025:2017.

6.1.1 Option 1 - CA Regulation Assessment



The California Environmental Laboratory Accreditation Program (CA ELAP)

CAB(s) may be assessed to CA Regulations only. This will be allowed until 2023 to provide a transition period for all CABs to implement TNI EL (Minus 2) at a minimum. PJLA will utilize the CA Regulation checklist issued by the California Water Board for this assessment as well as the US EPA Drinking Water Quality Manual Checklist as applicable.

6.1.2 Option 2 - CA Regulations and TNI EL minus 2 (two exceptions listed in CCR section 64802.05(a)(1) or 62802.15(b)(1),3))

CAB(s) may be assessed to the TNI EL (Minus 2) criteria and the CA Regulations. This is the minimal standard all laboratories must adhere to by 2023. PJLA will utilize the CA Regulation/TNI EL Minus 2 checklist issued by the California Water Board for this assessment as well as the US EPA Drinking Water Quality Manual Checklist as applicable.

6.1.3 Option 3 – CA Regulations and Full TNI EL standard

CAB(s) may be assessed to the TNI EL Full standard with the CA Regulations. Laboratories will receive an accreditation under PJLA's TNI EL NGAB program and a certificate will be issued from PJLA and the CA Water Board. PJLA will utilize the CA Regulation/ Full TNI EL and the Drinking Water Quality Manual Checklists.

6.1.4 Option 4 – CA Regulations and TNI EL Full or minus 2 and DOD ELAP QSM for PFAS criteria.

CAB(s) may be assessed to the TNI EL Full standard or TNI EL (Minus 2) with the CA Regulations. Laboratories will receive an accreditation under PJLA's TNI EL NGAB, DoD ELAP, or DOECAP program and a certificate will be issued from PJLA and the CA Water Board. PJLA will utilize the CA Regulation/ Full TNI EL, DoD/DOE QSM (as applicable) and the Drinking Water Quality Manual Checklists.

6.1.5 Option 5 – CA Regulations and TNI EL Full or minus 2 and any other standard PJLA may offer such as ISO/IEC 17025:2017.

CAB(s) may be assessed to the TNI EL Full standard or TNI EL (Minus 2) with the CA Regulations. Laboratories will receive an accreditation under PJLA's TNI EL NGAB and other standard (e.g., ISO 17025:2017) program and a certificate will be issued from PJLA and the CA Water Board. PJLA will utilize the CA Regulation/ Full TNI EL, DoD/DOE QSM (as applicable) and the Drinking Water Quality Manual Checklists.

- 6.2 Prior to the on-site assessment, PJLA will request per the applicable (LF-116), that the laboratory submits documentation at least 30 days in advance. Failure to submit documentation 30 days in advance may result in a delay of the on-site assessment. This will include the following: Quality Manual (as applicable) and associated operating procedures, technical operating procedures for all test methods applied for, verifications of limit of detection and limit of



The California Environmental Laboratory Accreditation Program (CA ELAP)

quantitation for each analyte/method, proficiency testing data within the last 12 months (depending on the accreditation program more PT data may be requested), a completed self-assessment checklist provided by PJLA, management review and internal audit results from the last 12 months, corrective action plans from the last two CA ELAP assessments.

- 6.3 An opening meeting will take place prior to the start of the assessment to review the assessment plan, scope of accreditation or any other logistical details of the facility. Laboratories will be fully assessed to the standard(s) as specified in their application. Upon completion of the assessment a closing meeting will occur and a preliminary assessment report will be provided to the laboratory for review. No later than 30 days after completion of the on-site assessment, a final on-site assessment report will be provided to the laboratory by PJLA headquarters to include the following:
- a) A general description and overview of the laboratory and its condition.
 - b) Identification of any failures to comply with of the California Code of Regulations, title 22, chapter 19 or Health and Safety Code, sections 100825-100920, including citation to the specific sections of the Code of Regulations or the Health and Safety Code not followed.
 - c) Identification of any failures to follow the 2016 TNI Standard requirements, incorporated by reference into CCR section 64802.05(a) and section 64802.15(b)(1), including citation to specific sections of the 2016 TNI Standard that were not met by the laboratories' practices or quality system.
 - o for laboratories electively pursuing assessment to the TNI Standard prior to three years after the effective date of the regulation.
 - o for all laboratories three years after the effective date of the regulation.
 - d) Identification of any failures to follow test method requirements, identifying the specific provision of the method not followed.
 - e) Identification of any failures to implement or ensure effectiveness of the laboratories two most recent Corrective Action Plans (CAP).
 - f) Assessment checklists utilized
- 6.4. The laboratory will have **30 days** from date of receipt of the final on-site assessment report to respond directly to the PJLA with a corrective action plan, consistent with CCR section 64802.20(g) to include: Root Cause Analysis of the finding(s), Corrective actions that will take place, Date the finding(s) will be corrected. The laboratory shall address questions on the findings directly with



The California Environmental Laboratory Accreditation Program (CA ELAP)

PJLA within **30 days** of receipt of the assessment report. The deadline of the corrective action plan will not be extended by PJLA.

- 6.5 PJLA will review and approve or deny the corrective action plan within **30 days** and notify the laboratory of the decision. Should it be denied, the laboratory will be provided with **30 days** to submit an amended corrective action plan directly to the PJLA. When denied, the laboratory will be informed why the corrective action plan does not adequately address the finding(s). PJLA will review and approve or deny the amended corrective action plan within **30 days** and notify the laboratory of the decision. When denied, PJLA will inform the laboratory why the corrective action plan does not adequately address the finding(s). Should PJLA deny the amended corrective action plan, then ELAP will be contacted, in writing, within **15 days** of notification to the laboratory of the denial. PJLA will list Fields of Accreditation affected by the denial and the reason why the corrective action plan was denied.
- 6.6 Upon approval of the corrective action plan, PJLA will provide a completion letter to the laboratory (**Assessor Attestation Letter**) and supplemental information to include the following:
- A completion letter detailing all fields of accreditation reviewed, identifying, if any, fields of accreditation affected by a denial of the laboratory's amended corrective action plan. This letter should include the date of the assessment and timeframe of the corrective action approval.
 - on-site assessment report
 - approved corrective action plan
 - attestation from all assessment team members confirming the assessment report and CA plan development and approval
 - The state's and PJLA's checklist utilized for the assessment
 - The last corrective action plan submitted to ELAP

7.0 ADDITIONAL OBLIGATIONS TO THE MOU FOR CA ELAP

- 7.1 PJLA shall retain, for a minimum of **5 years**, all assessment-related records and documents and provide them to the State Water Board upon request.
- 7.2 PJLA shall meet with State Water Board staff biannually to review PJLA's work and adjust practices as requested by the State Water Board. PJLA will be responsible for any costs associated with this requirement.
- 7.3 PJLA shall annually participate in the ELAP Laboratory Conference, an educational event to help California laboratories improve and evolve. PJLA will give an educational presentation on at least one topic decided by ELAP each year. PJLA will be responsible for any costs associated with this requirement.



The California Environmental Laboratory Accreditation Program (CA ELAP)

- 7.4 PJLA shall forward any requests for remote assessments to ELAP for review and decision.
- 7.5 PJLA shall ensure that assessors are available, at no cost to the State Water Board, whenever internal audits, external audits, legal matters, or resolutions of other disputes require their presence.
- 7.6 PJLA shall schedule assessments when contacted by a laboratory to request services and contact ELAP, should PJLA identify a limitation to our availability which would exceed the allowable timeframe for an assessment as specified in CCR section 64802.20(b), or 64802.20(j).
- 7.7 PJLA shall maintain quantitative and qualitative metrics on the number and type of assessments, assessment findings, and corrective action plans. Provide such data to the State Water Board annually, or upon request.
- 7.8 PJLA shall immediately contact the State Water Board and provide evidence to its staff, if PJLA discovers evidence of laboratory fraud, negligence, or gross misconduct. If the assessor believes the data produced could present a risk to public or environmental health, PJLA shall document all findings, and upon completion of the assessment, immediately contact the State Water Board, and turn over all documents and evidence.
- 7.9 PJLA shall offer assessment services to laboratories within **30** days of ELAP posting an updated Field of Accreditation form to its website.
- 7.10 PJLA shall allow for Technical Review and Recommendation for Certification: State LCOs may conduct a technical review of PJLA's documentation for audits of drinking water laboratories when a laboratory applies for certification and make the final recommendations for certification as documented in program ELAP Standard Operating Procedure # SOP-035.
- 7.11 PJLA shall allow access to the state LCOs for Shadowing of On-Site Audits: State LCOs will accompany PJLA r assessors on 10% of on-site audits performed by PJLA.
- 7.12 PJLA shall utilize and make publicly available its current Dispute and Appeal Procedure SOP-10 to handle dispute resolution, both with individual assessor performance and with disputes regarding findings made during the on-site assessment. *Note-ELAP reserves the right to intervene at any point during or after the assessment process to investigate disputes.*
- 7.13 PJLA shall complete a State of California Form 700 Statement of Economic Interest each year.



The California Environmental Laboratory Accreditation Program (CA ELAP)

- 7.14 PJLA shall not assess a laboratory and receive any remuneration for technical assistance provided to laboratories for developing their quality systems to meet the new ELAP requirements.