
State Water Resources Control Board

MEMORANDUM OF UNDERSTANDING FOR THIRD-PARTY ASSESSMENT AGENCIES PROVIDING SERVICES TO LABORATORIES APPLYING FOR CALIFORNIA ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM ACCREDITATION

INCLUDING SPECIFIC REQUIREMENTS FOR THIRD-PARTY ASSESSMENT
AGENCIES RELATED TO DRINKING WATER PRIMACY

Revised June 2025

This Memorandum of Understanding is entered between _____
(Provider) and the California State Water Resources Control Board, Environmental
Laboratory Accreditation Program (State Water Board).

BACKGROUND

The Environmental Laboratory Accreditation Program (ELAP) regulations provide that laboratories may contract with approved third-party assessment agencies (TPA) to obtain an on-site assessment. The regulations require laboratories using the sophisticated instrumentation defined in the California Code of Regulations, title 22, division 2, chapter 19, article 1, section 64802.20(c)(1) to contract with an approved agency for their assessment service.

California maintains primacy under the Safe Drinking Water Act (SDWA), and ELAP is approved as the program of certification of laboratories conducting analytical measurements of drinking water contaminants. The US EPA's Manual for the Certification of Laboratories Analyzing Drinking Water describes how each certified laboratory should pass an on-site audit at least once every three years under an approved laboratory certification program. Additional requirements are addressed in this Memorandum that identify specific federal drinking water certification requirements the Provider must meet to conduct on-site audits of drinking water laboratories.

LEGAL AUTHORITY

California Health and Safety Code Section 100837 allows the California Environment 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." All TNI-

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approved or Department of Defense/Department of Energy-approved assessment agencies may be eligible to enter into an agreement with the State Water Board to conduct assessments for laboratories applying for California ELAP accreditation, specified in CCR section 64802.20(c)(2).

PURPOSE

The purpose of this Memorandum of Understanding is to establish an agreement between the State Water Board and the Provider for the services to environmental testing laboratories in California and ELAP as an approved third-party laboratory assessment agency.

TERM OF AGREEMENT

This Memorandum of Understanding will remain in place for a period of three years or until terminated by one of the parties. The parties may mutually agree to extend the length of this agreement.

PROVIDER ELIGIBILITY REQUIREMENTS

Eligibility for the Provider to assess California laboratories as an approved Third-Party Laboratory Assessor Body is contingent upon continual recognition by TNI, the United States Department of Defense, and/or the United State Department of Energy to accredit laboratories to the TNI Standard, Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016). Failure to continue to be recognized will nullify this agreement immediately. The Provider must notify ELAP immediately of any change to its recognition status.

Should recognition by TNI be delayed due to no fault of the Provider, ELAP may consider alternative evaluations, accreditations, or recognitions to establish eligibility.

ASSESSOR QUALIFICATIONS

The Provider shall maintain qualified laboratory Assessors capable of performing assessments for all Fields of Accreditation offered for accreditation by the State Water Board, and report to ELAP any changes in assessor qualifications by the 5th of the month following the change. These changes include:

1. Adding new assessors to the Provider's roster,
2. Removing an assessor from a Provider's roster,
3. Adding new capabilities to an individual assessor's qualifications list
4. Removing capabilities from an individual assessor's qualifications list

The Provider must notify ELAP in writing of the changes listed above using a spreadsheet ELAP has provided. The spreadsheet must have each specified field populated and changed information should follow these formatting rules:

- Add applicable information by typing in the new text and highlighting it **yellow**.
- Designate information to remove by changing the text to ~~red with strikethrough~~.

- The absence of either confirms the accuracy of the list as is.

Training Records

TNI V2M1, Section 6.0 requires maintenance of records of relevant qualifications, training, experience, and competence of each assessor as well as procedures for selecting, training, and formally approving the assessor. All documentation and records should be kept up to date and must be on file with ELAP. Anytime there is a change in an assessor's training files, the relevant files should be provided to ELAP within 30 days of the change.

Documentation and records on assessors must include at minimum:

- name and position;
- educational qualifications and professional status;
- work experience;
- training in management systems and assessment activities;
- competence for specific assessment tasks, including specialized training; and
- experience in assessment and results of their regular monitoring.

Upon acceptance of each on-site assessment report, ELAP verifies the competencies of the assessor performing the on-site. If the training records we have on file do not support the qualification of the assessor, ELAP will deny some or all the laboratory's request for accreditation due to not having an assessment performed by a qualified assessor.

Requirements for Assessors Performing Assessments of Drinking Water Laboratories

Assessors performing assessments of laboratories accredited or seeking accreditation for a Field of Accreditation in a Drinking Water matrix must be approved by the United States Environmental Protection Agency as a Laboratory Certification Officer. Laboratory Certification Officers must attend a US EPA sponsored refresher course once every five years.

Specialized Training

CA ELAP may offer specialized assessor training and require attendance to be approved to assess identified methods or technologies for the purpose of accreditation in California.

New and Novel Methods

While CA ELAP may offer specialized trainings for unique or novel methods, it remains the responsibility of the assessment provider to take whatever actions necessary to ensure assessors are appropriately trained and qualified to assess all methodologies for any assessment they are assigned to perform, including for new or novel methods CA ELAP may offer for accreditation. If the Provider is struggling to identify appropriate training opportunities, please notify CA ELAP so we can mutually discuss how to move forward. Assessors should not be assigned to assessments if they are not qualified for

the methods they will be assessing, as this will result in denial of the laboratory's application.

Monitoring the Performance of Assessors

Accreditation bodies are required to have procedures for monitoring the performance and competence of assessors, with monitoring conducted by:

- on-site observations,
- review of assessment reports,
- feedback from Conformity Assessment Bodies (CABs), and
- peer monitoring of assessors to evaluate an assessor's performance and to recommend appropriate follow-up actions to improve performance.

Each assessor shall be observed on-site every three years, unless there is sufficient supporting evidence that the assessor continues to perform competently. ELAP recommends that each assessment include an assessment appraisal form so that TPA firms are consistently monitoring the feedback of clients regarding their assessors' performances. ELAP may request these assessment appraisal forms at any time for review.

ELAP independently reviews assessor performance and reserves the right to request corrective action on behalf of the Provider or of individual assessors if it deems it necessary to do so. ELAP also reserves the right to disqualify individual assessors based on performance issues.

CONFLICTS OF INTEREST

An assessor may not have within the previous year any financial relationship with a laboratory it performs an assessment for on behalf of CA ELAP. This includes, but is not limited to, employment, consultation, training services, and/or investments. Any financial relationship represents a conflict of interest and disqualifies an approved assessor from providing the service of assessment for the purposes of accreditation by CA ELAP. Each assessment package must include the "Laboratory Third Party Assessor (TPA) Commitment and Qualification Statement and Conflict of Interest Form" in which the assessor must disclose any and all relationships, past and present, that exist with the laboratory they are assessing. Consistent with the requirements of the Fair Political Practices Act and the TNI "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories," be free from conflicts with those that they are assessing and have no other interests at play other than those of California ELAP.

Required State of California Forms

The requirements in this section will be provided directly to the assessor at their contact email from an automated State of California electronic system.

1. Annual Form 700 - All assessors are required to annually submit a Form 700 Statement of Economic Interest to the State of California to disclose economic interests

that may conflict with the nature of the work they are performing for CA ELAP. The form is due by April 1st each year.

2. Biannual Ethics Training – All assessors are required to biannually complete an ethics training provided by the California Secretary of State. Assessors will be notified directly to their contact email when the training is due.

3. Assuming Office - an Assuming Office Form must be completed within 30 days of the assessor's "start date", which is a date the Provider selects and notifies ELAP of its intent to initiate the process of onboarding a new assessor.

4. Leave Office - a Leaving Office Form must be completed within 30 days of an assessor discontinuing assessments in California. The Leaving Office date is a date the Provider selects and notifies ELAP of its intent to initiate the process of removing an assessor from its California work roster.

Failure to meet these requirements will result in referral of the individual to the Fair Political Practices Commission, disqualification of an assessor to work on behalf of CA ELAP, and the potential for personal and organizational fines.

SERVICES

The Provider shall offer assessment to analytical methods, the California regulations, and the incorporated 2016 TNI Standard, revision 2.1, minus exceptions listed in CCR section 64802.05(a)(1) or 62802.15(b)(1) to any laboratory located within the state of California for the purposes of California ELAP accreditation.

The Provider may also offer accreditation services, such as accreditation to the TNI Standard, which laboratories may electively pursue. Should a laboratory choose to pursue TNI accreditation through the Provider, the laboratory would be required to meet requirements established by the Provider to achieve accreditation, in addition to requirements of the California-specific regulations. Any additional accreditation services offered by the Provider are not substitutions for ELAP accreditation, and these services provided do not enable a laboratory to submit data for regulatory purposes, defined in the California Health and Safety Code, section 100825.

ACCREDITATION AUTHORITY

ELAP independently evaluates On-Site Assessment Reports and Corrective Action Plans when it reviews a laboratory's application for accreditation. ELAP retains the authority to approve or deny accreditation, regardless of the outcome of an assessment, if it disagrees with the determination made by the Provider. ELAP reserves the right to intervene at any point during or after the assessment process to investigate and make final determinations regarding any dispute between the Provider and the laboratory.

Exclusive authority to deny or approve accreditation falls with ELAP. The USEPA has delegated the drinking water laboratory certifying authority to the State of California

under the Safe Drinking Water Act primacy requirements. ELAP does not re-delegate this authority to the Provider. Although the Provider is recognized by as a “non-governmental accrediting body” by an accreditation authority, this recognition does not extend to drinking water certification for laboratories analyzing contaminants in drinking water samples. ELAP is the sole accreditation authority for all accreditation for all types of analyses in California, including certification of drinking water Fields of Accreditation.

PROCESS

1. Laboratories will schedule assessments directly with the Provider. The laboratory should be aware of the time frame in which the assessment must be completed to maintain or apply for accreditation. Requirements for laboratories to complete on-site assessments are identified in CCR section 64802.20(b). It is the responsibility of the laboratory to schedule an assessment sufficiently prior to deadlines for submitting its application for accreditation to ELAP.
 - a. Should the Provider identify a limitation to the Provider’s availability which would exceed the allowable timeframe specified in CCR section 64802.20(b), or 64802.20(j), such as the unavailability of assessors qualified to assess specific technical Fields of Accreditation, the Provider must contact ELAP in writing, detailing the cause of the delay.
 - b. Should the Provider identify a limitation on meeting the required timeframe due to a last-minute request on behalf of the laboratory, the Provider should notify ELAP at the time of scheduling.
2. The Provider shall conduct all assessment activities in accordance with its established procedures, and when assessing laboratories for drinking water, in conformance with the US EPA Manual for the Certification of Laboratories Analyzing Drinking Water. The Provider must use State Water Board specified assessment checklists where available.
3. The Provider shall provide to the laboratory, no later than 30 days after completion of the on-site assessment, an On-Site Assessment Report (OSAR). The OSAR must include, at a minimum:
 - a. A general description and overview of the laboratory and its condition.
 - b. Identification of all Fields of Accreditation assessed.
 - c. Identification of any failures to comply with the California Code of Regulations, title 22, chapter 19 (CCR) 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.
 - d. 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 laboratory’s practices or quality system.
 - e. Identification of any failures to follow test method requirements, identifying the specific provision of the method not followed.

- f. Identification of any failures to implement or ensure effectiveness of the laboratory's two most recent Corrective Action Plans (CAP).
 - g. All checklists used during the assessment as an addendum.
 - 4. The laboratory shall have 30 days from date of receipt of the OSAR to respond directly to the Provider with a CAP, consistent with CCR section 64802.20(g). The laboratory shall address questions on the findings directly with the Provider within 30 days of receipt of the OSAR. The deadline of the CAP shall not be extended by the Provider.
 - 5. The Provider shall review and accept or reject the CAP within 30 days and notify the laboratory of the decision.
 - a. Should it be rejected, the laboratory shall be provided with 30 days to submit an amended CAP directly to the Provider. When rejected, the Provider shall inform the laboratory why the CAP does not adequately address the finding(s).
 - i. The Provider shall review and accept or reject the amended CAP within 30 days and notify the laboratory of the decision. When rejected, the Provider shall inform the laboratory why the CAP does not adequately address the finding(s).
 - ii. Should the Provider reject the amended CAP, or should the laboratory fail to provide corrections within the limits identified, the Provider shall contact ELAP, in writing, within 15 days of notification to the laboratory. The Provider must list Fields of Accreditation affected by the rejection and the reason(s) why the CAP was rejected.
 - 6. The Provider shall provide a completion letter to the laboratory, detailing all Fields of Accreditation reviewed by the Provider and identifying, if any, Fields of Accreditation affected by a rejection of the laboratory's Amended CAP. The Provider shall additionally provide the OSAR and the accepted CAP, with a statement from the individual assessor(s) who provided or reviewed the OSAR and CAP(s) to ELAP. The statement shall attest that the assessor(s) created or reviewed the attached OSAR and CAP(s). All documents shall be collated into a single PDF or PDF portfolio, including at a minimum:
 - a. A close-out letter and summary of the assessment
 - b. The Assessor Commitment and Qualification Statement and Conflict of Interest Form
 - c. A finalized list of Methods or Fields of Accreditation assessed
 - d. The OSAR
 - e. The CAP(s), as submitted to the Provider, with an evaluation of each individual proposed corrective action
 - f. A copy of all checklists utilized during the assessment
 - 7. ELAP technical staff conduct a technical review of TPA Provider assessments when a laboratory applies for certification and make the final recommendations

for certification. Where the assessment was for a drinking water laboratory, the ELAP reviewer will be a USEPA LCO.

SPECIFIC REQUIREMENTS

Maintenance of Records

The Provider shall retain, for a minimum of 5 years, all assessment-related records and documents and provide them to the State Water Board upon request.

Participation in Biannual Guidance Meeting

The Provider shall meet with State Water Board staff biannually to review the Provider's work. The Provider will adjust practices as requested by the State Water Board. The Provider shall be responsible for any costs associated with this requirement.

Participation in Annual ELAP Laboratory Conference

The Provider shall annually participate in the ELAP Laboratory Conference, an educational event to help California laboratories improve and evolve. If requested, the Provider shall give an educational presentation on at least one topic decided by ELAP each year. The Provider shall be responsible for any costs associated with this requirement.

Remote Assessments

The State Water Board shall have exclusive authority to authorize a remote assessment in place of an on-site assessment. The Provider shall forward any requests for remote assessment to ELAP for review and decision. Remote assessments for drinking water methods are not allowed.

Assessor Availability

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. The State Water Board will make every effort to provide advanced notice to the Provider when possible.

Metrics

The Provider shall maintain quantitative and qualitative metrics on the number and type of assessments, assessment findings, and corrective action plans. This data will be provided to the State Water Board annually, or upon request.

Laboratory Fraud, Negligence, or Gross Misconduct

Should the Provider discover evidence of laboratory fraud, negligence, or gross misconduct, it shall immediately contact the State Water Board and provide any and all evidence to staff. If the assessor believes the data produced could present a risk to public or environmental health, the Provider shall document all findings, and upon completion of the assessment, the Provider shall immediately contact the State Water Board and shall turn over all documents and evidence.

Offering New Fields of Accreditation

The Provider is responsible for taking all necessary actions to be able to offer assessment services to laboratories within 30 days of ELAP posting an updated Field of Accreditation form to its website. ELAP will make every effort to provide advanced notice to the Provider when possible.

Conflict Resolution

The Provider must have a procedure in place to handle dispute resolution, both with individual assessor performance and with disputes regarding findings made during the on-site assessment and must make those procedures available to each laboratory as part of conducting its assessment. ELAP reserves the right to intervene at any point during or after the assessment process to investigate disputes.

Mediation of Disputes

ELAP reserves the right to intervene at any point during or after the assessment process to investigate and make final determinations regarding any dispute between the TPA Provider and the laboratory.

Observation of On-Site Audits

ELAP staff will observe Provider assessors on approximately 10% of on-site audits performed by the Provider. Provider assessors shall allow ELAP access to any audit they are conducting.

“Preassessment” Services

Preassessment services (providing a laboratory with an advanced list of findings based on a documentation review for an additional cost) are considered a consulting activity by California ELAP and thus are subject to consulting rules in the TNI Standard. All preassessments must be reported to ELAP as part of the requirements monthly assessment reporting.

Monthly Reporting

The Provider shall report to ELAP by the 5th of each month the status of ongoing assessments, a schedule of upcoming assessments, any preassessments performed, and an updated list of assessors with their qualifications.

AUTHORITY TO AMEND THIS AGREEMENT

The administrator of this Memorandum of Understanding, the Deputy Director at the Division of Drinking Water, State Water Resources Control Board, is granted authority to make changes to it at will to comply with new requirements that emerge during its term.

AUTHORIZING SIGNATURES

Each signatory must have the authority to bind their respective entity to the terms and conditions of this Memorandum of Agreement.

_____, on behalf of _____(Provider)

Title: _____

Date: _____

State Water Resources Control Board

_____, on behalf of the State Water Board

Title: _____

Date: _____