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

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

BACKGROUND

On May 5, 2020, the State Water Board adopted regulations for the Environmental Laboratory Accreditation Program and the laboratories it accredits. The regulations provide that laboratories may contract with approved third-party assessment agencies (TPA) to obtain an on-site assessment. The regulations also require laboratories using the sophisticated instrumentation and technologies listed in the California Code of Regulations, title 22, division 2, chapter 19, article 1, section 64802.20(c)(1) must contract with an approved agency for their assessment service.

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-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 as an approved third-party laboratory assessment body.

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.

E. JOAQUIN ESQUIVEL, CHAIR | EILEEN SOBECK, EXECUTIVE DIRECTOR

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 shall notify ELAP immediately of any change to its recognition status.

The Provider shall maintain qualified laboratory Assessors capable of performing assessments for all Fields of Accreditation offered for accreditation by the State Water Board. 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.

The Provider and each of its assessors must complete a State of California Form 700 Statement of Economic Interest each year, and 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.

SERVICES

The Provider shall offer the following assessment-only services to any laboratory located within the state of California for the purposes of California ELAP accreditation:

1. Assessment to the California-specific regulations adopted by the State Water Board on May 5, 2020 until three years after the effective date of the regulation.
2. Assessment to the California-specific regulations and assessment to the 2016 TNI Standard, revision 2.1, minus exceptions listed in CCR section 64802.05(a)(1) or 62802.15(b)(1), as adopted by the State Water Board on May 5, 2020.

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 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.

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. 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), the Provider must contact ELAP in writing, detailing the cause of the delay.

2. The Provider shall conduct all assessment activities in accordance with its established procedures. 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 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.
 - i. for laboratories electively pursuing assessment to the TNI Standard prior to three years after the effective date of the regulation.
 - ii. 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 provided by the State Water Board, 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 approve or deny the CAP within 30 days and notify the laboratory of the decision.
 - a. Should it be denied, the laboratory shall be provided with 30 days to submit an amended CAP directly to the Provider. When denied, the

Provider shall inform the laboratory why the CAP does not adequately address the finding(s).

- i. The provider shall review and approve or deny the amended CAP within 30 days and notify the laboratory of the decision. When denied, the Provider shall inform the laboratory why the CAP does not adequately address the finding(s).
 - ii. Should the Provider deny the amended CAP, the Provider shall contact ELAP, in writing, within 15 days of notification to the laboratory of the denied amended CAP. The Provider must list Fields of Accreditation affected by the denial and the reason why the CAP was denied.
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 denial of the laboratory's Amended CAP. The Provider shall additionally provide the OSAR and the approved CAP, with a statement from the individual assessor(s) who provided or reviewed the OSAR and CAP(s). The statement shall attest that the assessor(s) created or reviewed the attached OSAR and CAP(s).
7. 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.

ACCREDITATION AUTHORITY

Exclusive authority to deny or approve accreditation falls with the ELAP. ELAP will review On-Site Assessment Reports, Corrective Action Plans, and the recommendation made by the Provider 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.

SPECIFIC REQUIREMENTS

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. 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.

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.

AUTHORITY TO AMEND THIS AGREEMENT

The administrator of this Memorandum of Understanding is granted authority to make changes to it at will in order 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: _____

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

BACKGROUND

A key component of California's approved primacy program under the Safe Drinking Water Act (SDWA) is that the state establish and maintain a program of certification of laboratories conducting analytical measurements of drinking water contaminants. The California Environmental Laboratory Accreditation Program (ELAP) fulfills that requirement.

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. New regulations adopted by the State Water Resource Control Board in May 2020 require some laboratories to have a biannual on-site audit performed by a third-party assessment provider (TPA Provider). This addendum addresses requirements specific to federal drinking water certification requirements a TPA Provider must meet to conduct on-site audits of drinking water laboratories for certification by California ELAP.

ROLES AND RESPONSIBILITIES OF TPA PROVIDERS

1. 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.
2. Schedule assessments when contacted by a laboratory to request services. Should the TPA Provider identify a limitation to the TPA Provider's availability which would exceed the allowable timeframe for an assessment as specified in CCR section 64802.20(b), or 64802.20(j), the TPA Provider must contact ELAP in writing, detailing the cause of the delay.
3. The TPA Provider shall conduct all assessment activities in accordance with its established procedures and in conformance with the US EPA Manual for the Certification of Laboratories Analyzing Drinking Water. The TPA Provider must use State Water Board specified assessment checklists where available.
4. The TPA 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 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.

- i. for laboratories electively pursuing assessment to the TNI Standard prior to three years after the effective date of the regulation.
 - ii. 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 provided by the State Water Board, as an addendum.
5. The laboratory shall have 30 days from date of receipt of the OSAR to respond directly to the TPA Provider with a CAP, consistent with CCR section 64802.20(g). The laboratory shall address questions on the findings directly with the TPA Provider within 30 days of receipt of the OSAR. The deadline of the CAP shall not be extended by the TPA Provider without approval of ELAP.
6. The TPA Provider shall review and approve or deny the CAP within 30 days and notify the laboratory of the decision.
 - a. Should it be denied, the laboratory shall be provided with 30 days to submit an amended CAP directly to the TPA Provider. When denied, the TPA Provider shall inform the laboratory why the CAP does not adequately address the finding(s).
 - i. The TPA Provider shall review and approve or deny the amended CAP within 30 days and notify the laboratory of the decision. When denied, the TPA Provider shall inform the laboratory why the CAP does not adequately address the finding(s).
 - ii. Should the TPA Provider deny the amended CAP, the TPA Provider shall contact ELAP, in writing, within 15 days of notification to the laboratory of the denied amended CAP. The TPA Provider must list Fields of Accreditation affected by the denial and the reason why the CAP was denied.
7. Upon completion of an audit, the TPA Provider shall provide to the laboratory:
 - a. A completion letter detailing of all Fields of Accreditation reviewed by the TPA Provider and identifying, if any, Fields of Accreditation affected by a denial of the laboratory's Amended CAP
 - b. OSAR and the approved CAP, with a statement from the individual assessor(s) who provided or reviewed the OSAR and CAP(s)
 - c. The State's audit checklist(s)
 - d. The last corrective action plan (CAP) submitted to ELAP

8. The TPA 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.
9. Should the TPA 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 TPA Provider shall document all findings, and upon completion of the assessment, the TPA Provider shall immediately contact the State Water Board, and shall turn over all documents and evidence.

ROLES AND RESPONSIBILITIES OF ELAP

1. Accreditation Authority: USEPA has delegated the drinking water lab certifying authority to the State of California under SDWA primacy conditions. The State cannot re-delegate this authority to TPAs. Although a TPA Provider may be recognized by as a “non-governmental accrediting body” by an accreditation authority such as TNI, DoD, or DoE, this recognition does not extend to drinking water certification for laboratories analyzing contaminants in drinking water samples. ELAP is the sole accreditation authority for certification drinking water analyses (and all analyses) in California. The TPA Providers are only performing the audits.
2. Reviewer: ELAP reviews all audit documentation and the recommendations made by the TPA Provider at the time the laboratory applies for accreditation. ELAP makes final determinations about certification.
3. 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.

ROLE OF STATE LABORATORY CERTIFICATION OFFICERS (LCOS)

1. Technical Review and Recommendation for Certification: State LCOs conduct a technical review of TPA Provider documentation for audits of drinking water laboratories when a laboratory applies for certification and make the final recommendations for certification. This process is documented in program ELAP Standard Operating Procedure # SOP-035.
2. Shadowing of On-Site Audits: State LCOs will accompany TPA Provider assessors on 10% of on-site audits performed by the TPA Provider. TPA Provider assessors shall allow State LCOs access to any audit they are conducting.

REQUIRED DOCUMENTATION

This section is included to clarify Item #6 in the Process section of the body of the Memorandum. These requirements are applicable to all audits, including audits of all

drinking water laboratories. Upon completion of an audit, the TPA Provider shall provide to the laboratory:

1. A completion letter (also known as the Assessor Attest letter) detailing all Fields of Accreditation reviewed by the TPA Provider and identifying, if any, Fields of Accreditation affected by a denial of the laboratory's Amended CAP
2. OSAR and the approved CAP, with a statement from the individual assessor(s) who provided or reviewed the OSAR and CAP(s).
3. The State's and TPA's audit checklist(s)
4. The last corrective action plan (CAP) submitted to ELAP

All documents shall be locked so they are unable to be edited by the laboratory after receipt.

CONFLICTS OF INTEREST

TPA Providers shall not audit a laboratory and receive any remuneration for technical assistance provided to laboratories for developing their quality systems to meet the new ELAP requirements. Providing consultation services is a violation of the ISO 17011 Standard, Section 4.3. As set out in the MOU, recognition to the TNI Standard, Volume 2, which includes all ISO 17011 requirements, is the minimum requirement a TPA Provider must meet to be qualified to enter into the MOU. All TPA Providers are subject to those clauses.