

**STATE WATER RESOURCES CONTROL BOARD
RESOLUTION NO. 2020-0012**

ADOPTING REGULATIONS FOR ACCREDITATION OF ENVIRONMENTAL LABORATORIES IN TITLE 22, CALIFORNIA CODE OF REGULATIONS, SECTIONS 64801.00, 64802.00, 64802.05, 64802.10, 64802.15, 64802.20, 64802.25, 64803, 64805, 64806, 64807, 64808.00, 64808.05, 64808.10, 64808.15, 64809, 64810.00, 64810.05, 64810.10, 64811, 64812.00, 64812.05, 64813, 64814.00, 64814.05, 64814.10, 64815, 64816.00, 64816.05, 64816.10, 64817, 64819, 64821, 64823, 64825, 64827, and 64860

WHEREAS:

1. Effective stewardship of the environment and protection of public health requires quality data to inform state agencies of the effectiveness of regulatory actions. Such data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or the toxicity of sediments in rivers.
2. Field and laboratory methods are often complex and analytical instrumentation evolve as technology improves. Through the use of accreditation to oversee laboratories that provide these analytical services to the State, the State is able to ensure that laboratories generate data of a known minimum quality, that data obtained from different laboratories are comparable, and all laboratories comply with the same set of regulatory standards.
3. The 1994 Environmental Laboratory Accreditation Act (Health and Safety Code, Section 100825-10090), and Chapter 19 of Division 4 of Title 22 of the California Code of Regulations (CCR), provides the Environmental Laboratory Accreditation Program (ELAP) authority and structure to accredit laboratories for the analysis of environmental samples for regulatory purposes;
4. The federal Safe Drinking Water Act requires the state provide a program for the certification of laboratories and the authority to carry out such a program. (42 U.S.C. §300g-2 and 40 C.F.R. §142.10 (b)(3)(i).);
5. ELAP's current regulations have not been updated since 1994 and lack the specificity and details necessary for effectively regulating laboratory performance and creating standardized practices in laboratories to ensure data quality. These proposed regulations address those issues and will meet the statutory requirements and intent of the Environmental Laboratory Accreditation Act (Health and Safety Code, Section 100825-10090);

6. In 2015 an Expert Review Panel identified a number of fundamental weaknesses that hinder ELAP's ability to achieve its mission of ensuring the State has access to quality data for use in its environmental decision making and observed that these deficiencies have cost the program credibility among key constituencies – notably, the state agencies that rely on data generated by ELAP-accredited laboratories;
7. "Data quality" is defined by ELAP's regulatory agency partners, who are the primary users of the data created by the laboratories, as accuracy of results, consistency and comparability of results across laboratories, robust quality assurance requirements, and legal defensibility;
8. The adoption of these regulations will help ELAP implement a sustainable accreditation program that ensures laboratories generate environmental and public health data of known, consistent, and documented quality to meet stakeholder needs, and that California uses the highest quality scientific data as a foundation for its environmental and public health programs and decisions.
9. The proposed changes to the regulations will be contained in Title 22, California Code of Regulations, sections 64801.00, 64802.00, 64802.05, 64802.10, 64802.15, 64802.20, 64802.25, 64803, 64805, 64806, 64807, 64808.00, 64808.05, 64808.10, 64808.15, 64809, 64810.00, 64810.05, 64810.10, 64811, 64812.00, 64812.05, 64813, 64814.00, 64814.05, 64814.10, 64815, 64816.00, 64816.05, 64816.10, 64817, 64819, 64821, 64823, 64825, 64827, and 64860.
10. On October 11, 2019, the State Water Board published a notice of proposed rulemaking pursuant to the requirements of the California Administrative Procedures Act (APA), initiating a 70-day comment period, which ran from October 11, 2019 to December 20, 2019;
11. State Water Board staff held a public hearing on December 18, 2019. The purpose and intent of the public comment period and public hearing were to receive written and oral comments from the public on the proposed regulations in accordance with the APA;
12. An additional 15-day public comment period was provided from February 13, 2020 to February 28, 2020 to allow the public to comment on changes made to the proposed text of the regulations in response to comments received during the 70-day public comment period;
13. Prior to the adoption hearing, the State Water Board staff provided to the State Water Board summaries of, and response to, the comments received during the two comment periods, which was also made available to the public;
14. Final responses to all comments that were received during the public comment periods will be prepared and contained in the Final Statement of Reasons and submitted to the Office of Administrative Law (OAL) as part of the regulations package; and

15. With the exception of the 2016 TNI Standards, which was made available online through TNI, all elements of the regulatory package are posted on the program webpage at:
https://www.waterboards.ca.gov/drinking_water/certlic/labs/elap_regulations.html
16. As allowed per the OAL's regulations, the 2016 TNI Standard is being incorporated by reference into the proposed regulations. (Cal. Code Regs., tit. 1, § 20.) The TNI Standard contains relevant language from the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standards, which are copyright protected, and the 2016 TNI Standard is provided through a license agreement. During the development of the regulations, including during the public comment period, the State Water Board made the 2016 TNI Standard publicly available for viewing at the CalEPA Headquarters Office in Sacramento, each of the nine (9) Regional Water Quality Control Board Offices, and twenty-four (24) Division of Drinking Water District Offices. Interested parties were able to contact any of those offices to view the 2016 TNI Standard in the designated public record document review area. Additionally, The NELAC Institute provided access to a read-only, unlicensed version of the 2016 TNI Standard for all interested parties on the [TNI website](#). The 2016 TNI Standard was also available for purchase from TNI at a discounted rate.

THEREFORE BE IT RESOLVED THAT:

The State Water Board

1. Adopts the proposed ELAP Regulations, which will make modifications to Title 22, California Code of Regulations, sections 64801.00, 64802.00, 64802.05, 64802.10, 64802.15, 64802.20, 64802.25, 64803, 64805, 64806, 64807, 64808.00, 64808.05, 64808.10, 64808.15, 64809, 64810.00, 64810.05, 64810.10, 64811, 64812.00, 64812.05, 64813, 64814.00, 64814.05, 64814.10, 64815, 64816.00, 64816.05, 64816.10, 64817, 64819, 64821, 64823, 64825, 64827, and 64860, as appended to this Resolution;
2. Incorporates by reference into the regulations the 2016 TNI Standards – Revision 2.1, Volume 1, “Management and Technical Requirements for Laboratories Performing Environmental Analysis,” with two California-specific exceptions, and directs staff in the final statement of reasons to set out how it would otherwise be impractical to publish the TNI Standards in the California Code of Regulations and how the document was made available to the public during the public comment period. The standard will continue to be reasonably available to the public by purchase from TNI.
3. Water Code section 106.3 established a state policy that every human being has the right to safe, clean, affordable, and accessible water adequate for human consumption, cooking, and sanitary purposes, and requires the State Water Board to consider this policy when revising, adopting, or establishing regulations when those regulations are pertinent to the uses of water

described in the policy. This policy, which is referred to as the Human Right to Water, was considered by the State Water Board as part of the adoption of these regulations, and it was concluded that the regulations further the policy by setting specific requirements for laboratories that conduct analysis of water for regulatory purposes, helping to ensure that the laboratories are able to run the methods required by the regulations, and creating standardized practices to ensure that results are accurate, consistent and comparable between laboratories, reflect robust quality assurance requirements, and are legally defensible;

4. Adopts a single laboratory accreditation standard that incorporates quality management requirements. All data produced for regulatory environmental purposes and environmental decision-making are produced for the same broad purpose, and therefore will be subject to a single standard that will help provide data of equal quality regardless of a laboratory's size, type, geographic location, or community's economic status.
5. Directs State Water Board staff to:
 - a. Prioritize its resources to assist laboratories with transitioning to these regulations through a variety of tools and trainings throughout a 3-year Transition Period beginning upon the effective date of the regulations.
 - b. After the 3-year Transition period prioritize compliance assistance with the regulations and TNI for a one-year Implementation Period.
 - c. Continue seeking community input from Stakeholders such as State Regulatory Agencies, various California laboratory analyst and trade associations, TNI, and the Environmental Laboratory Technical Advisory Committee to identify areas in which the State Board can assist laboratories.
 - d. Use third-party assessments as allowed in statute to conduct laboratory assessments. After providing an opportunity for input from Stakeholders, bring back to the State Water Board for approval before the regulations go into effect the terms and conditions third party assessment firms must meet to provide services to laboratories in California, and the process and procedures that laboratories must follow for use of third-party assessors;

- e. Focus enforcement efforts, during the Transition and Implementation Periods, on compliance assistance and progressive enforcement. Progressive enforcement contemplates an escalating series of actions beginning with notification of violations and compliance assistance, followed by increasingly severe consequences, culminating in formal enforcement. During these periods of Transition and Implementation, formal enforcement actions such as suspension or revocation of accreditation or a monetary citation should be reserved for the most egregious violations, such as those violations resulting from intentional or grossly negligent misconduct, or violations that impact public health and the environment.
 - f. Ensure regulated entities can locate and access accredited laboratories by providing real-time access to accreditation data through an improved electronic database system and mapping tool.
 - g. After the 3-year Transition Period, assess laboratory progress in meeting the regulatory requirements and present this evaluation at a State Water Board Meeting.
6. Directs the Executive Director to sign Form 400 and submit the adopted regulations to OAL for filing with the Secretary of State; and
7. Authorizes the Executive Director or her delegee to make, prior to OAL filing the regulations with the Secretary of State, any non-substantive corrections to the language of the regulations or supporting documentation deemed necessary for clarity or consistency.

CERTIFICATION

The undersigned Clerk to the Board does hereby certify that the foregoing is a full, true, and correct copy of a resolution duly and regularly adopted at a meeting of the State Water Resources Control Board held on May 5, 2020.

AYE: Chair E. Joaquin Esquivel
 Vice Chair Dorene D’Adamo
 Board Member Tam M. Doduc
 Board Member Sean Maguire
 Board Member Laurel Firestone

NAY: None

ABSENT: None

ABSTAIN: None



 Jeanine Townsend
 Clerk to the Board

Title 22, CALIFORNIA CODE OF REGULATIONS

Division 4, Chapter 19

Article 1. Definitions.

Section 64801.00 Definitions.

The definitions listed in 2016 TNI Standard – Revision 2.1, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis apply throughout this regulation. Definitions used differently or that do not exist in 2016 TNI Standard – Revision 2.1, Volume 1, are defined below.

(a) “Acceptable Scores” means analytical results for a Proficiency Testing sample are within the specified acceptance criteria for that sample.

(b) “Accreditation” means the recognition of a laboratory by ELAP to conduct analyses of environmental samples for regulatory purposes.

(c) “Assessment Agency” means ELAP, or any entity that is contracted by ELAP to conduct laboratory assessments for ELAP.

(d) “CA-NV/AWWA” means California-Nevada Section of the American Water Works Association.

(e) “Citation” – means a monetary fine assessed to a laboratory due to non-compliance with a statute, and regulation or order issued or adopted pursuant to the Environmental Laboratory Accreditation Act.

(f) “Client” – means the entity for which the laboratory is performing analyses for regulatory purposes.

(g) “Complete Application Package” means an application package containing all the elements required in Section 64802.00.

(h) “Corrective Action Plan” – means the response to an onsite assessment report that contains a root cause analysis of the finding(s) identified in the onsite assessment report, the corrective actions that will take place to address the findings, and the date by which the finding(s) will be corrected.

(i) “CWEA” means California Water Environment Association.

(j) “Days” means calendar days, unless otherwise stated.

(k) “Denial” means a decision to reject an application for accreditation due to non-compliance with ELAP statutes and regulations.

(l) “ELAP” means the California Environmental Laboratory Accreditation Program, a program within the State Water Resources Control Board.

(m) "Field(s) of Accreditation" means the matrix, technology/method, and analyte combinations for which ELAP will offer accreditation, as defined in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2.

(n) "Owner" means a public agency, or any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

(o) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act on its behalf for purposes of complying with ELAP regulations or the statutes under which ELAP regulations are adopted.

(p) "Primary Accreditation Body" means the organization that actually executes the accreditation process, including but not limited to, receiving and reviewing applications, supporting documents, Proficiency Testing sample results, and conducting on-site assessments or reviewing on-site assessment reports.

(q) "Quality Manager" means a member of the laboratory staff who is responsible for ensuring the management system related to quality is implemented and followed at all times. Where staffing is limited, the technical manager and quality manager may be the same person.

(r) "Quality Manual" is defined in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2 and replaces the term Quality Assurance Manual.

(s) "Regulatory Purpose" is defined in Health and Safety Code, Section 100825.

(t) "Revocation" means the permanent loss of a certificate of accreditation due to non-compliance with ELAP statutes and regulations.

(u) "Root Cause Analysis" means an investigation by the laboratory to determine the underlying cause(s) of a finding identified in an onsite assessment report or a non-compliance identified by the laboratory.

(v) "Sophisticated Technology" means analytical instruments, detection systems, and/or preparation techniques requiring an advanced level of user understanding including gas chromatography/mass spectrometry (GC/MS), inductively coupled plasma spectrometry (ICP), inductively coupled plasma/mass spectrometry (ICP/MS), liquid chromatography/mass spectrometry (LC/MS), atomic absorption spectrophotometry (AA), gas chromatography (GC), alpha particle or gamma ray spectrophotometry, electron microscopy (EM), polarized light microscopy (PLM), high pressure performance liquid chromatography (HPLC), bioanalytical assays, and advanced molecular methods.

(w) "State Regulatory Agencies" means those state agencies whose statute or regulations require it to use laboratories that have been accredited by ELAP.

(x) "State Water Board" means the California State Water Resources Control Board, which includes ELAP.

(y) "Suspension" means the total or partial removal of a laboratory's accreditation to allow the laboratory to correct findings that identified non-compliance with ELAP statutes and regulations.

(z) "Technical Manager" is described in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.1.7.2 (with the exception of part [f]) and replaces the title of Laboratory Director.

(aa) "TNI" means The NELAC Institute.

(bb) "Trade Secret" means any information that meets the definition in Section 6254.7(d) of the Government Code.

(cc) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100837, 100870, 100872, 100880, 100905, 100907, 100910, 100915 Health and Safety Code.

Article 2. Accreditation Requirements.

Section 64802.00 Application Package.

(a) A complete application package for initial or renewal accreditation shall contain:

(1) Laboratory identifying information, which includes:

(A) Name of the laboratory;

(B) Details on the laboratory's type, location, ownership, contact information, and the regulatory agencies the laboratory reports to;

(C) Name and qualifications of Technical Manager(s), including copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;

(D) Name of Quality Manager;

(E) Signed declaration to comply with applicable ELAP statutes and regulations;

(F) Signature of the laboratory owner, corporate officer authorized to act on behalf of the laboratory, or owner's agent (include documentation of authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and

(G) Date of signature;

(2) A copy of the laboratory Quality Manual meeting the requirements of:

(A) 2016 TNI Standard Volume 1 – Revision 2.1, Module 2, Section 4.2.8.3 and 4.2.8.4; or

(B) Section 64802.05(b)(1);

(C) Subdivision (a)(2)(B), above, will become invalid three (3) years from the effective date of these regulations at which time accredited laboratories will be required to comply with subdivision (a)(2)(A), above;

(3) Signed and populated Field(s) of Accreditation tables for which accreditation is being requested;

(4) Proficiency Testing report(s) with acceptable scores for each Field(s) of Accreditation for which accreditation is requested in accordance with Section 64802.15;

(5) A copy of the most recently completed on-site assessment report from an Assessment Agency in accordance with Section 64802.20, including all findings and an approved corrective action plan; and

(6) For aquatic toxicity testing, a current reference toxicant control chart for each method, species, and endpoint requested.

(b) A complete application package for accreditation by reciprocity shall contain:

(1) Laboratory identifying information, which includes:

(A) Name of the laboratory;

(B) Details on the laboratory's type, location, ownership, contact information, and the regulatory agencies the laboratory reports to;

(C) Name and qualifications of Technical Manager(s), including copies of applicable degrees;

(D) Name of Quality Manager;

(E) Signed declaration to comply with applicable ELAP statutes and regulations;

(F) Signature of the laboratory owner, corporate officer authorized to act on behalf of the laboratory, or owner's agent (include documentation of authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and

(G) Date of signature;

(2) A copy of the laboratory Quality Manual meeting the requirements of:

(A) 2016 TNI Standard - Revision 2.1, Volume 1, Module 2, Section 4.2.8.3 and 4.2.8.4; or

(B) Section 64802.05(b)(1);

(C) Subdivision (b)(2)(B), above, will become invalid three (3) years from the effective date of these regulations at which time accredited laboratories will be required to comply with subdivision (b)(2)(A), above;

(3) Signed and populated Field(s) of Accreditation tables for which accreditation is being requested;

(4) Proficiency Testing report(s) with acceptable scores for each Field(s) of Accreditation for which accreditation is requested in accordance with Section 64802.15;

(5) A copy of the most recently completed on-site assessment report, including all findings and an approved corrective action plan;

(6) For aquatic toxicity testing, a current reference toxicant control chart for each method, species, and endpoint requested; and

(7) Proof of accreditation from a primary accreditation body, including:

(A) Official certificate of accreditation and scope of accreditation;

(B) Official on-site assessment report and findings; and

(C) Corrective action plan(s) reviewed and approved by the primary accreditation body.

(c) A complete amendment application package shall be submitted to ELAP in accordance with Section 64808.15.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100829, 100830, 100840, 100860.1, 100870, Health and Safety Code.

Section 64802.05. Quality Systems.

To ensure analytical data produced by the laboratory are of known and documented quality, and sufficient to evaluate the usability of the data for State Regulatory Agency needs, a laboratory shall:

(a) Comply with quality system requirements in accordance with 2016 TNI Standard – Revision 2.1, Volume 1:

(1) Module 2, with the following exceptions:

(A) Module 2, Section 4.1.7.2(f) – Technical Manager Qualifications; and

(B) Module 2, Section 5.2.6 – Technical Manager Requirements;

(2) Modules 3 through 7, where appropriate based on laboratory operations; or

(b) Develop and implement a quality assurance program. As evidence of such a program, the laboratory shall:

(1) Develop and maintain a Quality Manual. The Quality Manual shall address the quality assurance and quality control practices to be employed by the laboratory and shall include at a minimum:

(A) The quality assurance and quality control requirements specified in the test methods for which the laboratory seeks to obtain or maintain accreditation for; and

(B) Documents, or references to documents, that contain the following elements:

(i) Laboratory organization and job descriptions;

- (ii) Ethics and integrity clause;
- (iii) Quality assurance objectives for measurement data;
- (iv) Sampling procedures (when the laboratory performs the sampling);
- (v) Procedures for sample acceptance/rejection, custody, handling, and disposal of samples;
- (vi) Calibration procedures and frequency;
- (vii) Analytical procedures;
- (viii) Acquisition, reduction, validation and reporting of data;
- (ix) Internal quality control checks;
- (x) Performance and system audits;
- (xi) Preventive maintenance;
- (xii) Assessment of precision and accuracy;
- (xiii) Corrective action; and
- (xiv) Quality assurance reports;

(2) The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs:

- (A) Changes to laboratory equipment or instrumentation;
- (B) Changes to laboratory structure or physical arrangements; or
- (C) Changes in the laboratory organization;

(3) Perform annual quality assurance audits documenting compliance with subdivision (b)(1), above, including corrective actions for any noted findings. Audit reports shall be provided to ELAP upon request;

(4) Maintain records of the implementation of the quality assurance program. Records of the implementation of the quality assurance program shall be provided to ELAP upon request.

(c) Subdivision (b), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (a), above.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100829, 100830, 100840, 100860.1, 100865, 100870 Health and Safety Code.

Section 64802.10. Field(s) of Accreditation.

(a) ELAP will accredit laboratories in Field(s) of Accreditation required by State Regulatory Agencies for regulatory purposes.

(b) Field(s) of Accreditation offered for the purpose of drinking water analyses shall include United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations parts 141.21 through 141.42, 141.66, 141.89, and Appendix A of Subpart C, or as otherwise directed by the State Water Board.

(c) Field(s) of Accreditation offered for the purpose of compliance monitoring under the Clean Water Act shall include United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations part 136, or as otherwise directed by the State Water Board or other State Regulatory Agency.

(d) Field(s) of Accreditation offered for the purpose of solid and hazardous waste material analyses shall include United States Environmental Protection Agency approved methods as prescribed in SW-846, Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, or as otherwise directed by the State Water Board or other State Regulatory Agency.

(e) ELAP publishes the lists of Field(s) of Accreditation, called Field(s) of Accreditation tables, on the ELAP website. The Field(s) of Accreditation tables are updated, as needed, by publishing a revised Field(s) of Accreditation table on the ELAP website.

Note: Authority cited: Section 100830 Health and Safety Code; Reference: Sections 100825, 100830, 100840, 100850, 100852 Health and Safety Code.

Section 64802.15. Proficiency Testing.

(a) The Proficiency Testing requirements in this section shall not negate or supersede the Proficiency Testing requirements of other state or federal regulatory programs.

(b) When participating in a Proficiency Testing study, a laboratory shall:

(1) Comply with 2016 TNI Standard - Revision 2.1, Volume 1, Module 1 for each Field of Accreditation for which the laboratory is requesting accreditation, with the following exceptions:

(A) Volume 1, Module 1, Section 5.0 – Proficiency Testing Study Frequency Requirements for Accreditation; and

(B) Volume 1, Module 1, Section 8.0 – Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation; or

(2) Comply with the following Proficiency Testing requirements:

(A) Analyze Proficiency Testing samples in accordance with the laboratory's routine Standard Operating Procedure using the same quality control, acceptance criteria and staff as used for the analysis of routine environmental samples;

(B) Analyze Proficiency Testing samples of the same matrix as the Field(s) of Accreditation for which the laboratory holds or seeks accreditation;

(C) On or before the closing date of the study, direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP;

(D) Report in such a way that results of the Proficiency Testing study corresponds to the Field of Accreditation offered by ELAP; and

(E) Retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for Proficiency Testing samples for a minimum of five (5) years and provide them to ELAP upon request; and

(3) Not engage in the following activities:

(A) Send Proficiency Testing study samples, in which the laboratory is participating, to another laboratory for the analysis of a Field of Accreditation for which it seeks accreditation or is accredited;

(B) Knowingly receive or analyze any Proficiency Testing samples from another laboratory for which the results are to be used for accreditation;

(C) Communicate with any individual at another laboratory concerning the analysis of Proficiency Testing samples of an ongoing study;

(D) Attempt to obtain the assigned value of any portion of a Proficiency Testing study from the Proficiency Testing provider; and

(E) Request the Proficiency Testing provider to alter any portion of the laboratory's Proficiency Testing report after it was issued as final.

(c) Subdivisions (b)(2) and (b)(3), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (b)(1), above.

(d) If there are no available Proficiency Testing samples for a Field(s) of Accreditation, ELAP may require verification of quality control data as an alternative demonstration of capability.

(e) To obtain initial accreditation, within twelve (12) months prior to ELAP's receipt of the laboratory's initial application package, a laboratory shall achieve

acceptable scores in a Proficiency Testing study for each Field of Accreditation requested in the application.

(f) To maintain accreditation, a laboratory shall achieve acceptable scores in a Proficiency Testing study at least once per year for each Field of Accreditation for which the laboratory holds accreditation. Acceptable scores in Proficiency Testing studies shall be achieved:

(1) Within twelve (12) months from the accreditation date in year one of the accreditation period; and

(2) At least ninety (90) days prior to the expiration date of accreditation in year two of the accreditation period.

(g) To add or reinstate a Field of Accreditation, a laboratory shall achieve acceptable scores in a Proficiency Testing study for each Field of Accreditation for which the laboratory is requesting to add and submit an amendment application in accordance with Section 64808.15.

(h) If on the first attempt, a laboratory does not achieve an acceptable score for a Field of Accreditation, then within forty-five (45) days of receipt of the “Not Acceptable” score from the Proficiency Testing provider, the laboratory shall:

(1) Notify ELAP of the “Not Acceptable” score;

(2) Document the root cause of the failure;

(3) Take corrective action;

(4) Achieve an acceptable score in a subsequent Proficiency Testing study for that Field of Accreditation;

(5) Notify ELAP of the “Acceptable” score; and

(6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

(i) If a Proficiency Testing study for a Field of Accreditation is not available within forty-five (45) days of receipt of a “Not Acceptable” result, the laboratory shall:

(1) Submit a plan to ELAP that states when the next Proficiency Testing study will be completed, and;

(2) Achieve acceptable scores for the Field of Accreditation when the subsequent Proficiency Testing study becomes available and submit to ELAP.

(j) If on the second attempt, a laboratory does not achieve an acceptable score for a Field of Accreditation a laboratory shall:

(1) Notify ELAP of the “Not Acceptable” result within three (3) days;

(2) Be suspended for that Field of Accreditation;

(3) Cease reporting of results for regulatory purposes for that corresponding Field of Accreditation;

(4) Notify affected clients of second “Not Acceptable” Proficiency Testing result by registered mail, email with return receipt, or electronic signature document;

(5) Within thirty (30) days: investigate and document the root cause of the failure and take corrective action;

(6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action.

(k) To be reinstated after suspension of a Field(s) of Accreditation, the laboratory shall:

(1) Achieve acceptable scores in a Proficiency Testing study for the corresponding Field(s) of Accreditation; and

(2) Submit an amendment application package, in accordance with Section 64808.15.

(l) For toxicity bioassay analyses, each laboratory shall:

(1) Achieve acceptable scores in a Proficiency Testing study, where available, for each Field of Accreditation for which the laboratory is requesting accreditation, in accordance with (b), above;

(2) Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint; and

(3) Plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint.

(m) For pesticide residue in food, each laboratory shall obtain Proficiency Testing samples from a Proficiency Testing provider that meets TNI standards.

(n) If a laboratory has a financial interest, familial relationship, or contractual agreement for consultation with the provider of a Proficiency Testing study, then the results from that study shall not be used to meet the Proficiency Testing study requirements for accreditation.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100850, 100865, 100870, 100872 Health and Safety Code.

Section 64802.20. On-Site Assessment.

(a) An on-site assessment, either announced or unannounced, shall be conducted by an Assessment Agency to verify the information submitted with a laboratory's application and to verify a laboratory is in compliance with:

- (1) Quality system requirements, in accordance with Section 64802.05;
- (2) Analytical methods used for each Field of Accreditation for which the laboratory seeks to obtain or maintain accreditation;
- (3) Laboratory instrumentation, equipment, and facility requirements, in accordance with Section 64812.05; and
- (4) All applicable ELAP statutes and regulations.

(b) An on-site assessment shall be conducted:

- (1) For initial accreditation, no more than twelve (12) months prior to applying for accreditation;
 - (2) For renewal accreditation, once within the two years prior to the expiration date of accreditation;
 - (3) For amendment accreditation, in accordance with Section 64808.15;
- and
- (4) For enforcement purposes, when ELAP decides to conduct an assessment in accordance with Health and Safety Code 100865.

(c) An on-site assessment shall be conducted by ELAP or a third-party Assessment Agency contracted by ELAP to perform on-site assessments.

(1) A laboratory requesting assessment to Field(s) of Accreditation that utilizes sophisticated technology shall use a third-party Assessment Agency;

(2) A third-party Assessment Agency shall be one of the following:

(A) A National Environmental Laboratory Accreditation Program (NELAP)-recognized accreditation body;

(B) A NELAP-recognized non-government accreditation body; or

(C) An agency that is recognized by the Department of Defense or Department of Energy as an accrediting body.

(3) ELAP will publish a list of approved third-party Assessment Agencies on the ELAP website.

(d) The laboratory is responsible for requesting an on-site assessment through ELAP or a third-party Assessment Agency.

(e) When a scheduled on-site assessment is performed by ELAP, a laboratory shall pay an assessment fee in accordance with Section 64802.25.

(f) When an on-site assessment is performed by a third-party Assessment Agency contracted by ELAP to perform on-site assessments, a laboratory shall pay the third-party Assessment Agency its market rate for onsite assessments.

(g) Within thirty (30) days of the on-site assessment, a laboratory shall receive an on-site assessment report. If there are findings in the on-site assessment report, a laboratory shall:

(1) Within thirty (30) days of receipt of the on-site assessment report, submit a corrective action plan that contains a root cause analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected.

(2) Subsection (g)(1), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to submit, within thirty (30) days of receipt of the on-site assessment report, a corrective action plan that contains a root cause analysis of the finding(s), the corrective actions that will take place, and the date the finding(s) will be corrected in accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.11, 4.12, and 4.13.

(h) If a laboratory is notified that a corrective action plan does not address the finding(s) identified, then the laboratory shall have an additional thirty (30) days from the receipt of the notification to submit a revised corrective action plan. If the revised corrective action plan does not demonstrate the required corrections have been made, then ELAP will take action to deny, suspend or revoke accreditation for the Field(s) of Accreditation affected by the failure to take corrective action.

(i) If a subsequent on-site assessment, either announced or unannounced, reveals that a laboratory failed to take the corrective action(s) specified in a corrective action plan, then ELAP will take action to deny, suspend, or revoke accreditation for the Field(s) of Accreditation affected by failure to take corrective action.

(j) If a scheduled on-site assessment is not conducted within six (6) months from the scheduled assessment date and the delay is not a result of the Assessment Agency error or procedure, ELAP may take action to deny, suspend or revoke accreditation.

(k) If a laboratory has submitted a complete renewal or amendment application package in accordance with Section 64808.05 or 64808.15, respectively, and additional time is needed by the Assessment Agency to complete an on-site assessment, then the laboratory shall be issued an interim certificate of accreditation.

(1) A laboratory that holds an interim certificate of accreditation is accredited for Field(s) of Accreditation listed on the laboratory scope of accreditation.

(2) An interim certificate is non-renewable and shall be valid until one of the following occurs:

(A) An on-site assessment has been completed and a certificate of accreditation issued;

(B) The laboratory fails to meet the requirements for accreditation in accordance with Article 2; or

(C) The expiration date on the interim certificate of accreditation is reached.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100837, 100850, 100865, 100870, 100872 Health and Safety Code.

Article 3. Types of Accreditation.

Section 64808.00 Initial Accreditation.

(a) The period of accreditation for initial accreditation shall be twenty-four (24) months.

(b) To obtain initial accreditation, a laboratory shall:

(1) Submit a complete application package, in accordance with Section 64802.00; and

(2) Pay the required fees in accordance with Section 64802.25.

(c) If any of the elements in Section 64802.00 are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory of the missing elements. When reviewing for completeness of an application package ELAP will only ensure each element has been submitted with the application package, and not that each element meets minimum requirements.

(1) To resume processing, a complete application package shall be returned to ELAP within thirty (30) days from the date of ELAP's notification.

(2) If a complete application package is not returned to ELAP within thirty (30) days of receiving notice, then the application shall be denied by ELAP.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845 Health and Safety Code.

Section 64808.05 Renewal Accreditation.

(a) The period of accreditation following the renewal of accreditation shall be twenty-four (24) months.

(b) To renew accreditation, a laboratory shall:

(1) Submit a complete application package, in accordance with Section 64802.00, ninety (90) days prior to the expiration date of the certificate of accreditation; and

(2) Pay the required fees in accordance with Section 64802.25.

(c) If any of the elements in Section 64802.00 are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory. When reviewing for completeness of an application package ELAP will only ensure each element has been submitted with the application package, and not that each element meets minimum requirements.

(1) To resume processing, a complete application package shall be returned to ELAP within thirty (30) days from the date of ELAP's notification.

(2) If a complete application package is not returned to ELAP within thirty (30) days, the application shall be denied by ELAP.

(d) If a laboratory submits a renewal application package after the application due date, the laboratory shall be subject to a late fee equal to 15% of the accreditation fee.

(1) ELAP will use the date a complete application package is received as the submittal date.

(2) Submittal of late renewal application could result in a lapse in accreditation. If accreditation is not renewed by the expiration date on the certificate of accreditation, the laboratory shall cease all reporting of results for regulatory purposes and notify clients of the lapse in accreditation by registered mail, email with return receipt or electronic signature document.

(e) If a laboratory submits a renewal application package after the expiration date on its certificate of accreditation, the laboratory shall be subject to a late fee equal to 30% of the accreditation fee.

(1) ELAP will use the date a complete application is received as the submittal date.

(2) The laboratory shall cease all reporting of results for regulatory purposes on the expiration date on its certificate of accreditation and notify clients of the lapse in accreditation by registered mail, email with return receipt, or electronic signature document.

(f) If a laboratory submits a renewal application package ninety (90) days after the expiration date on its certificate of accreditation, then accreditation shall not be renewable.

(1) ELAP will use the date a complete application is received as the submittal date.

(2) The laboratory shall cease all reporting of results for regulatory purposes on the expiration date of its certificate of accreditation and notify clients of the lapse in accreditation by registered mail, email with return receipt, or electronic signature document.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845 Health and Safety Code.

Section 64808.10 Reciprocity Accreditation.

(a) Laboratories physically located outside of the State of California shall obtain accreditation through reciprocity.

(b) For laboratories physically located outside the State of California, the environmental laboratory accreditation program of another state or federal agency shall be recognized for the purposes of reciprocity if the accreditation program requirements related to quality systems, test methods, Proficiency Testing, on-site assessments, personnel, and laboratory facilities and equipment are at least as stringent as ELAP accreditation requirements.

(c) The environmental laboratory accreditation programs of other state or federal agencies shall be recognized for reciprocity through a written agreement with ELAP.

(d) For reciprocity accreditation, the period of accreditation shall be the time remaining on the certificate of accreditation provided by the primary accreditation body. If a laboratory submits a certificate of accreditation from more than one primary accreditation body, then the period of accreditation will be the time remaining on the certificate of accreditation that expires first.

(e) A laboratory applying for accreditation by reciprocity shall:

(1) Submit a complete application package in accordance with Section 64802.00(b); and

(2) Pay the required fees in accordance with Section 64802.25.

(f) A laboratory accredited through reciprocity may be subject to an on-site assessment. When ELAP conducts an on-site assessment for an out-of-state laboratory, the laboratory shall reimburse ELAP for all per diem and travel expenses incurred, in addition to the assessment fees in accordance with Section 64802.25.

(g) If a laboratory, accredited through reciprocity, is notified of suspension or revocation of its certificate of accreditation by its primary accreditation body, then the laboratory shall:

(1) Cease all reporting of results for regulatory purposes; and

(2) Notify ELAP within ten (10) days of the notification of suspension or revocation.

(h) If a reciprocity agreement with the accreditation program of another state or federal agency is revoked by ELAP, any certificate of accreditation issued by ELAP to an affected laboratory shall be valid until the expiration date on the certificate of accreditation.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference Sections 100825, 100829, 100895 Health and Safety Code.

Section 64808.15 Amendment Accreditation.

(a) When a certificate of accreditation is amended, the period of accreditation shall be the time remaining on the certificate of accreditation from the date it was amended.

(b) To amend accreditation, a laboratory shall:

- (1) Submit an amendment application package;
- (2) Pay the required fee in accordance with Section 64802.25.

(c) A laboratory shall submit an amendment application package for the following reasons:

(1) Change in laboratory name, except if the change in laboratory name is in connection with a sale or transfer of ownership, then the laboratory shall comply with Section 64814.05;

(2) Change in laboratory location;

(3) Addition of a satellite laboratory or mobile laboratory to the existing accreditation; or

(4) Addition or reinstatement of Field(s) of Accreditation to the laboratory's current certificate of accreditation.

(d) Amendments to a laboratory's accreditation are not accepted in the renewal application package. A separate amendment application package shall be submitted to amend accreditation.

(e) A laboratory applying for a change in laboratory name shall submit an amendment application package that includes the following:

- (1) Existing name of the laboratory;
- (2) Certificate number of the laboratory;
- (3) Address of the laboratory;
- (4) Proposed new name of the laboratory;
- (5) Signature of the laboratory owner, owner's agent, or officer; and
- (6) Signature date.

(f) A laboratory applying for a change in laboratory location shall:

(1) Within thirty (30) days prior to the change of location, submit a relocation plan to ELAP that includes the following laboratory identifying information:

- (A) Name of the laboratory;

- (B) Certificate number of the laboratory;
- (C) Existing address of the laboratory;
- (D) Address of the new location;
- (E) Description of the new location;
- (F) Timeline of the change in location;
- (G) Signature of the laboratory owner, owner's agent, or officer; and
- (H) Signature date;

(2) During the change in location, the laboratory shall:

(A) Comply with quality system requirements at the new location, in accordance with Section 64802.05; and

(B) Cease reporting data for regulatory purposes at the old location once the new location is reporting data for regulatory purposes;

(3) Within Ninety (90) days after the change of location, submit an amendment application package that includes the following:

(A) Laboratory identifying information, which includes:

(i) Name of the laboratory;

(ii) Certificate number of the laboratory;

(iii) Existing or previous address of the laboratory;

(iv) New address of the laboratory;

(v) Description of the new location;

(vi) Signature of the laboratory owner, owner's agent, or officer; and

(vii) Signature date;

(B) A copy of the laboratory Quality Manual, with updates necessitated by the change of location;

(C) A copy of new or revised Standard Operating Procedure(s) necessitated by the change of location;

(D) Proficiency Testing report(s) with acceptable scores for the Field(s) of Accreditation for which the laboratory is requesting accreditation, whereby analysis occurred at the new location; and

(E) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved corrective action plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20, whereby the assessment occurred at the new location;

(g) A laboratory applying to add a satellite or mobile laboratory to an existing accreditation shall:

(1) Prior to applying, ensure the laboratory meets the criteria for a satellite laboratory or mobile laboratory in accordance with Sections 64810.05 and 64810.10, respectively;

(2) Submit an amendment application package that includes the following:

(A) Laboratory identifying Information including:

(i) Name of the laboratory;

(ii) Details on the laboratory's type, size, location, business entity type, contact information and ownership;

(iii) Name and qualifications of the Technical Manager(s), including copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;

(iv) Name of the Quality Manager, if applicable;

(v) Agreement to comply with applicable ELAP statutes and regulations;

(vi) Signature of the laboratory owner, owner's agent, or officer; and

(vii) Signature date;

(B) Signed and populated Field(s) of Accreditation tables for which the satellite laboratory or mobile laboratory is requesting accreditation;

(C) Proficiency Testing report(s) with acceptable scores for each Field of Accreditation for which the satellite laboratory or mobile laboratory is requesting accreditation, whereby analysis occurred at the satellite or mobile laboratory; and

(D) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved corrective action plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20, whereby the assessment occurred at the new laboratory;

(3) Pay the required fee in accordance with 64802.25.

(h) A laboratory applying to add or reinstate Field(s) of Accreditation shall submit an amendment application package that includes the following:

(1) Laboratory identification information including:

(A) Name of the laboratory;

(B) Certificate number of the laboratory; and

(C) Address of the laboratory;

(2) Signed and populated Field(s) of Accreditation tables for which accreditation is being amended;

(3) A copy of the laboratory Quality Manual, with updates necessitated by the addition of Field(s) of Accreditation;

(4) Proficiency Testing report(s) with acceptable scores for each Field of Accreditation for which the laboratory is requesting to add; and

(5) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved corrective action plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20.

(i) The on-site assessment requirement for an amendment accreditation package may be waived if ELAP determines the amendment to accreditation would not affect the quality of the data.

(j) A laboratory is not required to submit an amendment application to remove Field(s) of Accreditation but may request an amended certificate of accreditation to remove Field(s) of Accreditation by submitting a written request to ELAP. Once a laboratory requests an amended certificate of accreditation, the laboratory shall cease reporting results for regulatory purposes of all removed Field(s) of Accreditation.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845, 100850, 100870 Health and Safety Code.

Article 4. Types of Laboratories.

Section 64810.00 Main Laboratory.

(a) A laboratory may apply for accreditation as a main laboratory, in accordance with Section 64808.00, if the laboratory is:

- (1) Designated as the primary location;
- (2) A fixed, permanent facility; and
- (3) May include fixed-in-place vehicles.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Section 100825, 100830 Health and Safety Code.

Section 64810.05 Satellite Laboratory.

(a) A satellite laboratory is a fixed, permanent facility (which includes fixed-in-place vehicles) that operates under a single scope of accreditation with a main laboratory.

(b) A main laboratory may apply for accreditation of a satellite laboratory under a single scope of accreditation, in accordance with Section 64808.15, if the following criteria are met:

- (1) The main laboratory and satellite laboratory operate under the same owner;
- (2) The satellite laboratory operates with oversight from the main laboratory;
- (3) The main laboratory and satellite laboratory are under the supervision of the same Technical Manager;
- (4) The main laboratory and satellite laboratory operate under the same quality management system and Quality Manual;
- (5) Reports identify which laboratory performed the analyses; and
- (6) A single contact person is identified to communicate with ELAP regarding accreditation activities for the main laboratory and satellite laboratory.

(c) Satellite laboratories shall comply with proficiency testing requirements in Section 64802.15 and on-site assessments in accordance with Section 64802.20.

Note: Authority cited: Section 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100830 Health and Safety Code.

Section 64810.10 Mobile Laboratory.

(a) A mobile laboratory is a portable, enclosed structure (such as a vehicle, vessel, aircraft, or trailer) designed and equipped with the necessary and appropriate accommodations and environmental conditions for the transportation and use of laboratory equipment to perform analyses in the Field(s) of Accreditation for which accreditation is requested.

(b) A mobile laboratory may operate under its own accreditation or operate under a single accreditation with a main laboratory.

(c) A mobile laboratory may apply for accreditation, in accordance with Section 64808.00, if the mobile laboratory operates autonomously without oversight from a main laboratory.

(d) A laboratory may apply for accreditation of a mobile laboratory under a single scope of accreditation, in accordance with Section 64808.15, if the following criteria are met:

(1) The main laboratory and mobile laboratory operate under the same owner;

(2) The mobile laboratory operates with oversight from the main laboratory.

(3) The main laboratory and mobile laboratory are under the supervision of the same Technical Manager;

(4) The main laboratory and mobile laboratory operate under the same quality management system and Quality Manual;

(5) Reports identify which laboratory performed the analyses; and

(6) A single contact person is identified to communicate with ELAP regarding accreditation activities for the main laboratory and satellite laboratory.

(e) Mobile laboratories operating under a single scope of accreditation as a main laboratory shall comply with proficiency testing requirements in Section 64802.15 and on-site assessments in accordance with Section 64802.20.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100830 Health and Safety Code.

Article 5. Laboratory Personnel, Facilities and Equipment.

Section 64812.00 Laboratory Personnel.

(a) A laboratory shall designate a Technical Manager. Except as provided in subdivisions (b) and/or (c), below, the Technical Manager shall have at minimum:

(1) A baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural or physical science, or environmental, sanitary or chemical engineering; and

(2) Three (3) years' experience in the analysis of chemical, biological, or microbiological samples in an environmental laboratory, prior to being designated Technical Manager, subject to the following allowances:

(A) A master's degree in chemistry, biochemistry, biology, microbiology, natural or physical science, or environmental, sanitary or chemical engineering, natural or physical science may be substituted for one (1) year of the required experience;

(B) A doctorate in chemistry, biochemistry, environmental, sanitary or chemical engineering, biology, microbiology, natural or physical science, or environmental, sanitary or chemical engineering, may be substituted for two (2) years of the required experience.

(b) An employee of a drinking water or wastewater treatment facility, who holds a valid CWEA Laboratory Analyst certification or CA-NV/AWWA Water Quality Analyst certification, shall be deemed to meet the qualifications of Technical Manager if the grade of certification has educational and experience requirements appropriate to the scope of analytical testing in the facility's laboratory. Table 3 below states the grades of certification and the required training or experience to obtain for each grade.

Table 3: Analyst Certification grades and Required Training or Experience

CA-NV AWWA	CWEA	Required Training or Experience
I	I	Microbiological Methods Solids Methods Biochemical Oxygen Demand (BOD)Methods Carbonaceous BOD Methods
II	II	Titrimetric Methods Methods using Specific Ion Electrode Technologies Colorimetric Methods

CA-NV AWWA	CWEA	Required Training or Experience
III	III	Methods using Ion Chromatography Methods using Flame Atomic Absorption Methods using Graphite Furnace Atomic Absorption
IV	IV	Methods using Gas or Liquid Chromatography Technologies Methods using Inductively Coupled Plasma Technologies

(c) The following shall be exempt from meeting the requirements in subdivisions (a) and (b), above:

(1) An individual who has continuously held the position of Technical Manager at an environmental testing laboratory since the laboratory was first accredited, provided that the accreditation date was on or before December 31, 1994; and

(2) A director of a public health laboratory, pursuant to Health and Safety Code Sections 101150 and 101160.

(d) The Technical Manager, and/or their designee, shall:

(1) Comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Sections 4.1.7.2 (with the exception of part [f]); or

(2) Be responsible for:

(A) All analytical and operational activities of the laboratory, including activities of satellite or mobile laboratories under the same certificate of accreditation;

(B) Supervision of all personnel employed by the laboratory, including personnel assigned to work in satellite or mobile laboratories under the same certificate of accreditation; and

(C) The accuracy and quality of all data reported by the laboratory, including data from satellite or mobile laboratories under the same certificate of accreditation.

(e) Subdivision (d)(2), above, will become invalid three (3) years from the effective date of these regulations, and laboratories will be required comply with subdivision (d)(1), above.

(f) If a Technical Manager is absent for a period of time exceeding:

(1) Fifteen (15) consecutive days, a person meeting the qualifications of the Technical Manager shall be designated to serve as a temporary Technical Manager; or

(2) Thirty-five (35) consecutive days, ELAP shall be notified in writing.

(g) Three (3) years from the effective date of these regulations, a laboratory shall designate a Quality Manager. The Quality Manager, and/or their designee, shall comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.1.5(i), 4.1.7.1, 4.2.6, 4.2.8.2 and 4.14.1.

(h) A laboratory shall designate a Principal Analyst(s) to be a user of sophisticated technology, defined in Section 64801.00(v), or a supervisor of the users of sophisticated technology. The Principal Analyst shall:

(1) Possess at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural and physical sciences, or environmental, sanitary, or chemical engineering; or

(2) Possess a certificate of completion in a course taught by the manufacturer of the sophisticated technology being used or supervised by the Principal Analyst; and

(3) Have at least six months experience in the operation of sophisticated technology in the analysis of environmental samples prior to obtaining the position of Principal Analyst.

(i) Subdivision (h), above, will become invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to meet 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 5.2 (excluding 5.2.6).

(j) Sophisticated technology in the laboratory shall be operated by either the Technical Manager, Principal Analyst, or other personnel designated by the Technical Manager.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100845 Health and Safety Code.

Section 64812.05 Laboratory Facilities and Equipment.

(a) A laboratory facility shall:

(1) Comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Sections 5.3, 5.5, and 5.6; or

(2) Be arranged and operated so that:

(A) Utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Field(s) of Accreditation for which the laboratory is accredited;

(B) Ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond established quality control limits as specified in the approved test methods or in the laboratory's Quality Manual;

(C) The design, arrangement, housekeeping, and operation of the laboratory minimizes the potential for sample contamination;

(D) Each piece of laboratory equipment meets all operational, quality assurance, quality control, and design criteria established in the approved method(s) employed by the laboratory;

(E) Each piece of laboratory equipment is operated and maintained by the laboratory as specified in the Quality Manual and Standard Operating Procedures; and

(F) Records are kept of all operational and maintenance activities associated with the operation of laboratory equipment.

(b) Subdivision (a)(2), above, will become invalid three (3) years from the effective date of these regulations, and laboratories will be required to comply with subdivision (a)(1), above.

(c) A laboratory shall store and handle hazardous materials in accordance with the California Code of Regulations, Title 8, Division 1, Chapter 4, Subchapter 7, General Industry Safety Orders.

(d) A laboratory shall dispose of chemical wastes and maintain records of disposal in accordance with Health and Safety Code Section 25200.3.1, and California Code of Regulations, Title 22, Division 4.5, Chapter 12, Standards Applicable to Generators of Hazardous Waste.

(e) When there is a change of sophisticated technology the laboratory shall:

(1) Update the Quality Manual necessitated by the change of sophisticated technology;

(2) Update or create Standard Operating Procedure(s) necessitated by the change of sophisticated technology;

(3) Submit an amendment application package in accordance with 64808.15(g), if the sophisticated technology is a new technology to the laboratory; and

(4) Retain all records necessary to determine compliance with this subdivision and provide these records to ELAP upon request.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100830 Health and Safety Code.

Article 6. Notification, Reporting, Records Retention, Change of Technical Manager or Ownership, and Trade Secrets.

Section 64814.00 Notification, Reporting, and Control of Records.

(a) State Regulatory Agencies and federal agencies to whom data is reported may have notification, reporting, and record retention requirements that are in addition to requirements here, and it is the responsibility of the laboratories to know those additional regulatory requirements.

(b) If an analytical result warrants a client notification, then the notification shall occur after the Technical Manager or designee, set forth in the laboratory's Quality Manual, has approved of the result.

(c) A laboratory accredited to perform analyses on drinking water samples shall notify a water supplier's designated contact person:

(1) Immediately within 24 hours, when the following results are confirmed:

(A) The presence of total coliforms, fecal coliforms, or *Escherichia coli* (*E. coli*);

(B) A bacterial sample result is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b);

(C) A nitrate sample result exceeds the maximum contaminant level; or

(D) A chlorite sample result collected at the entry point of a water distribution system exceeds the maximum contaminant level.

(2) Immediately within 48 hours, when the following results are confirmed:

(A) A perchlorate sample result exceeds the maximum contaminant level;

(B) A chlorine dioxide sample result exceeds the maximum residual disinfectant level; or

(C) A chlorite sample result exceeds the maximum contaminant level.

(d) If a laboratory is unable to make direct contact with a water supplier's designated contact person within 24 hours, in accordance with subdivision (c)(1), above, or within 48 hours, in accordance with subdivision (c)(2), above; then the laboratory shall immediately notify the State Water Board. If requested by the State Water Board, the laboratory shall provide a record of the time and method of attempts to contact the water supplier.

(e) If a water supplier is requesting the State Water Board invalidate bacteriological sample(s) due to laboratory accident or error, as described in Title 22, California Code of Regulations, Section 64425(a)(2), then the laboratory shall provide the water supplier with the following:

(1) A letter from the laboratory Technical Manager to the water supplier confirming the laboratory accident or error and agreeing to the invalidation request;

(2) Complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;

(3) Complete description of the error alleged to have invalidated the result(s);

(4) Copies of all analytical, operational, and quality assurance records pertaining to the incident in question;

(5) Any observations noted by the laboratory personnel when receiving or analyzing the sample(s) in question; and

(6) A corrective action plan that contains a root cause analysis of the laboratory accident or error, the corrective actions that will take place, and the date the finding(s) will be corrected.

(f) When a laboratory subcontracts work:

(1) The subcontracting laboratory shall comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.5; or

(2) The subcontracting laboratory shall comply with the following requirements:

(A) The subcontracting laboratory shall inform the customer(s) of arrangement with subcontractor(s);

(B) The subcontracting laboratory shall maintain a register of all subcontractors that are used for analytical testing;

(C) The subcontractor shall be accredited by ELAP in the Field(s) of Accreditation for analyses being performed for regulatory purposes;

(D) The subcontracting laboratory shall include the original of any report(s) prepared by the subcontractor; and

(E) The subcontracting laboratory shall provide the required notification in accordance with subdivision (c), above, unless there is an arrangement in writing that the subcontractor will provide the required notification.

(g) Subsection (f)(2), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (f)(1), above.

(h) A laboratory shall report to clients:

(1) In accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 5.10; or

(2) In accordance with the request for analysis, the full and complete results of all requested contaminants and pollutants from the analyses of the sample or components thereof.

(i) Subsection (h)(2), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (h)(1), above.

(j) A laboratory performing bacteriological analyses on drinking water samples shall submit a bacterial monitoring report with bacteriological results to the State Water Board in accordance with Title 22, California Code of Regulations, Section 64423.1(c)(2) and (c)(3).

(k) A laboratory performing chemical, radiological and microbiological analyses on drinking water samples in accordance with Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring shall report analytical results to the State Board by the 10th day of the month following the month in which the analyses were completed. The results for chemical and radiological analyses shall be reported electronically using subsection (k)(1) and the results for microbiological analyses should be mailed or emailed to the Water Board. Once the State Board notifies the laboratory that method (k)(2) is to be used for chemical, radiological, or microbiological analyses, the laboratory will have 3 months from the date of notification to fully implement the reporting under that subsection.

(1) Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001; or

(2) The California Laboratory Intake Portal (CLIP) using the EQEDD_CASWRCB_DDW data format with quality control elements related to individual sample results in PDF or electronic format.

(l) A laboratory performing chemical analyses on drinking water samples in accordance with Title 22, California Code of Regulations, Division 4, Chapter 15.5, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors, and Chapter 17.5, Lead and Copper, or other required monitoring shall report analytical results directly to the State Water Board by the 10th day of the month following the month in which the analyses were completed. If the State Water Board is unable to

accept results for these specific analytes electronically as set forth in subdivision (k), above, then results shall be submitted by hard copy or as otherwise directed by the State Water Board.

(m) A laboratory accredited for the analysis of pesticide residue in food shall verify the identity and concentration of a pesticide residue before reporting the results.

(n) A laboratory shall establish and maintain a system to control records:

(1) In accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.13; or

(2) That allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and or extracts. Records shall be retained for a minimum of five (5) years from generation of the last entry in the records.

(o) Subsection (n)(2), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to comply with subdivision (n)(1), above.

Note: Authority cited: Sections 100827 Health & Safety Code; Reference: Sections 100827, 100886, 116385 Health and Safety Code.

Section 64814.05 Notification of Change of Technical Manager, Quality Manager or Ownership.

(a) When there is a change of Technical Manager and/or Quality Manager, the laboratory shall, within thirty (30) days, submit notification to ELAP that includes:

(1) Name of the laboratory;

(2) Certificate number of the laboratory;

(3) Address of the laboratory;

(4) Name(s) of existing or previous Technical Manager and/or Quality Manager;

(5) Name(s) of new Technical Manager and/or Quality Manager;

(6) Qualifications of new Technical Manager in accordance with Section 64812.00;

(7) Copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;

(8) Signature of the laboratory owner, corporate officer authorized to act on behalf of the laboratory, or owner's agent (including authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and

(9) Signature date.

(b) When the ownership of a laboratory is changed or transferred, the new owner may request to operate under the laboratory's existing ELAP certificate of accreditation as stated in Health and Safety Code Section 100845 subdivisions (b) and (c):

(1) To request to operate under the laboratory's existing ELAP certificate of accreditation, the new owner shall, within thirty (30) days after the effective date of ownership change, submit a written request to ELAP and pay the fees in accordance with Section 64802.25. The written request shall include:

(A) Name(s) of the new owner(s) and the owner(s) designee, if applicable;

(B) Effective date of the change in ownership;

(C) Name(s) and qualifications of current Technical Manager;

(D) Name of current Quality Manager;

(E) Statement that the new owner will operate pursuant to the laboratory's existing Quality Manual. If changes to the laboratory are made that may adversely affect the quality of the analyses in Field(s) of Accreditation, the new owner shall submit:

(i) An updated Quality Manual; and

(ii) Proficiency Testing report(s) with acceptable scores for each Field of Accreditation affected by the change in ownership;

(F) Statement that the laboratory will remain in the existing location;

(G) Statement that the new owner has retained more than half of laboratory personnel upon assuming ownership;

(H) Statement that the new owner will retain all records and data from analyses performed under the previous ownership for a minimum of five (5) years;

(I) Statement that the new owner will comply with applicable laws and regulations;

(J) Signature of the new owner, corporate officer authorized to act on behalf of the owner, or owner's agent (including documentation of authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and

(K) Signature date.

(2) ELAP may conduct an on-site assessment in response to a change in ownership. If an on-site assessment is conducted, the laboratory shall comply with requirements in accordance with Section 64802.20.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100845, 100865 Health and Safety Code.

Section 64814.10 Trade Secrets.

(a) A laboratory shall notify ELAP if information provided to ELAP is designated as a trade secret. ELAP shall not release such information unless:

(1) The release is authorized under state or federal law; and

(2) ELAP has notified the laboratory of the impending release. Such notification shall be sent at least ten (10) days prior to releasing any information designated as a trade secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released.

Note: Authority cited Sections 100829, 100830 Health and Safety Code; Reference: Section 100825, 100840 Health and Safety Code.

Article 7. Reasons for Denial, Citation, Suspension, or Revocation.

Section 64816.00 Denial of Accreditation.

(a) Reasons for denying a laboratory's application for accreditation may include:

(1) A laboratory fails to submit a complete application package in accordance with Section 64802.00;

(2) A laboratory fails to implement a quality system in accordance with Section 64802.05;

(3) A laboratory fails to comply with the analytical method(s) listed on the laboratory's application for accreditation;

(4) A laboratory fails to analyze Proficiency Testing samples or report acceptable scores in accordance with Section 64802.15;

(5) A laboratory submits, as its own, Proficiency Testing sample results generated by another laboratory;

(6) A laboratory fails to complete a required on-site assessment in accordance with Section 64802.20;

(7) A laboratory fails to respond to an on-site assessment report with a corrective action plan in accordance with Section 64802.20;

(8) A laboratory fails to implement the corrective actions detailed in the corrective action plan within the required timeframe in accordance with Section 64802.20;

(9) A laboratory fails to pay fees in accordance with Section 64802.25;

(10) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;

(11) A laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;

(12) A laboratory knowingly makes any false statement or representation pertinent to receiving accreditation;

(13) A laboratory knowingly makes any false statement or representation in an application, record, or other document; and/or

(14) The laboratory fails to comply with any other provision of these regulations.

(b) A laboratory denied accreditation may petition for reconsideration pursuant to Health and Safety Code Section 100855.

Note: Authority cited: Sections 100829, 100830 Health and Safety Code; Reference: Sections 100825, 100840, 100850, 100855, 100865, 100870 Health and Safety Code.

Section 64816.05 Issuance of a Citation.

(a) Reasons for issuing a citation may include:

(1) A laboratory fails to maintain a quality system in accordance with Section 64802.05;

(2) A laboratory fails to comply with the analytical method(s) listed on the laboratory's certificate of accreditation;

(3) A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;

(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;

(5) A laboratory fails to respond to an on-site assessment report with a corrective action plan in accordance with Section 64802.20;

(6) A laboratory fails to implement the corrective actions detailed in the corrective action plan within the required timeframe in accordance with Section 64802.20;

(7) A laboratory fails to pay fees in accordance with Section 64802.25;

(8) A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15(d)(e) and (f);

(9) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;

(10) A laboratory makes consistent errors in analyses or erroneous reporting;

(11) A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;

(12) A laboratory knowingly makes any false statement or representation in an application, record, or other document;

(13) A laboratory fails to notify ELAP of a change in ownership; and/or

(14) A laboratory fails to comply with any other provision of these regulations.

(b) A laboratory that receives a citation may petition for reconsideration pursuant to Health and Safety Code Section 100880(f).

Note: Authority cited: Section 100830 Health and Safety Code; Reference: Section 100880 Health and Safety Code.

Section 64816.10 Suspension or Revocation of Accreditation.

(a) Reasons for suspending or revoking accreditation may include:

(1) A laboratory fails to maintain a quality system in accordance with Section 64802.05;

(2) A laboratory fails to comply with the analytical method(s) listed on the laboratory's certificate of accreditation;

(3) A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;

(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;

(5) A laboratory fails to respond to an on-site assessment report with a corrective action plan in accordance with Section 64802.20;

(6) A laboratory fails to implement the corrective actions detailed in the corrective action plan within the required timeframe in accordance with Section 64802.20;

(7) If, during an on-site assessment, ELAP determines that suspension is necessary to protect public interest, safety or welfare;

(8) A laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;

(9) A laboratory fails to pay fees in accordance with Section 64802.25;

(10) A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15(d)(e) and (f);

(11) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;

(12) A laboratory makes consistent errors in analyses or erroneous reporting;

(13) A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;

(14) A laboratory knowingly makes any false statement or representation in an application, record, or other document;

(15) A laboratory fails to notify ELAP of a change in ownership; and/or

(16) A laboratory fails to comply with any other provision of these regulations.

(b) A laboratory issued a notice of suspension or revocation may request a hearing within twenty days of notice pursuant to Health and Safety Code Sections 100910 and 100915.

(c) If a laboratory's accreditation for a Field(s) of Accreditation is suspended, the laboratory shall:

(1) Cease all reporting of results for regulatory purposes for the Field(s) of Accreditation that were suspended; and

(2) Notify all clients of the suspension status within three (3) days of receiving notice of suspension from ELAP. Notification shall be made by registered mail, email with return receipt, or electronic signature document.

(d) To reinstate a suspended Field(s) of Accreditation, a laboratory shall submit an amendment application in accordance with Section 64808.15.

(e) If a laboratory's accreditation has been revoked, the laboratory shall:

(1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, or materials that contain reference to their past accreditation status;

(2) Return its certificate of accreditation to ELAP;

(3) Cease all reporting of results for regulatory purposes;

(4) Notify all clients of the revocation status within three (3) days of receiving notice of revocation from ELAP. Notification shall be made by registered mail, email with return receipt, or electronic signature document;

(5) Provide ELAP with a list of clients affected by the revocation; and

(6) Discontinue use of subcontracting agreements for regulatory purposes with laboratories within seven (7) days of receiving notice of revocation from ELAP.

(f) To obtain accreditation after revocation, the laboratory shall apply for initial accreditation, in accordance with Section 64808.00, as if it were a new laboratory.

Note: Authority cited: Section 100830 Health and Safety Code; Reference: Section 100905, 100910, 100915 Health and Safety Code.