~~Strikethrough~~ – existing Title 22 CCR Chapter 19 regulation text

Underlined – second preliminary draft text

~~Strikethrough~~ – deletion to text

Underlined – addition to text

Article 1. § 64801 Definitions

Article 2. ~~Certification and Amendment Process~~ Accreditation Requirements

~~§ 64803~~ ~~Certification and Amendment~~

§ 64802.00 Accreditation Criteria

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§ 64802.25 On-Site Assessment

~~§ 64802.30. Accreditation Fees~~

Article 3. ~~Application Process~~ Types of Accreditation

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~~§ 64806~~ ~~Certification Fees~~

§ 64808.00 Initial Accreditation

§ 64808.05 Renewal Accreditation

§ 64808.10 ~~Amendment Accreditation~~ Reciprocity Accreditation

§ 64808.15 ~~Interim Accreditation~~ Amendment Accreditation

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Article 4. ~~Site Visits~~ Types of Laboratories

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§ 64810.00 Main Laboratory

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Article 6. ~~Required Test Methods~~ Notification, Reporting, ~~Records Retention~~ Control of Records, ~~and~~ Change of Technical Manager or Ownership, and Trade Secrets

~~§ 64811~~ ~~Test Methods~~

§ 64814.00 Notification, Reporting, and Records Retention

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Article 7. ~~Laboratory and Equipment~~ Reasons for Denial, Citation, Suspension, or Revocation

~~§ 64813~~ ~~Laboratory and Equipment~~

§ 64816.00 ~~Denying, Suspending, or Revoking~~ Denial of Accreditation

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~~§ 64827~~ ~~Sale or Transfer of Ownership~~

State Water Resources Control Board

Division of Drinking Water

Environmental Laboratory Accreditation Program

Accreditation of Environmental Laboratories

**Title 22. Social Security**

**Division 2. Environmental Health**

**Chapter 19. Certification of Environmental Laboratories**

**Article 1. Definitions.**

*Amend Section 64801 to read as follows:*

**§ 64801. Definitions.**

The definitions listed in 2016 TNI Standard – Rev 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 – Rev 2.1, Volume 1, are defined below.

~~(a) "Alternate Test Procedure" means an analytical test method, or procedure that is different in technic from the method(s) cited in Section 64811(a), (b), or (c), but detects and quantifies to the same degree of precision, accuracy, and level of detection.~~

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

~~(b) "Auxiliary Laboratory Facility" means any stationary place which:~~

~~(1) is operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination; and~~

~~(2) performs analyses in one or more of the same auxiliary; and Field(s) of Testing as the laboratory to which it is auxiliary; and~~

~~(3) is under the supervision of the same Laboratory Director as the laboratory to which it is auxiliary; and~~

~~(4) only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and~~

~~(5) is located such that the transport of samples to the auxiliary laboratory does not affect the quality of the analytical results.~~

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

~~(c) "A Complete Application" means a verified application for certification containing all the information required in Section 64805(a) or (b), and utilizing ELAP form 001 (dated 1/1/93).~~

(c) “Assessment ~~Firm~~ Agency” means ~~a private company~~ ELAP, or any entity that is approved by ELAP to conduct laboratory assessments for ELAP.

~~(d) "Contact Person" means an individual designated by the Laboratory Director to act as a contact between the laboratory and the Department for purposes of exchanging information between the Department and the laboratory.~~

~~(d) “California Analyte” means a substance, organism, physical parameter, property, or chemical constituent(s) regulated or with required monitoring in California only.~~

(d) Citation – means a monetary fine assessed to a laboratory due to non-compliance with ELAP statutes and regulations.

~~(e) "Laboratory" shall have the same meaning as given in Health and Safety Code Section 1010(c)(2).~~

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

~~(f) “Laboratory Director" means the person who, for the laboratory and its auxiliary or mobile laboratories, if any, is in charge of all analytical and operational laboratory activities; supervises all personnel, including those designated as Principal Analysts; and is the person responsible for the quality of reported data.~~

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

~~(g) "Facility or Facilities" means fixed or portable building(s), which contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the Field(s) of Testing for which a laboratory is certified accredited, and includes storage areas.~~

(g) “Complete Application Package” means an application package containing all the elements required in Section 64802.05.

~~(h) "Mobile Laboratory" means a vehicle, vessel, aircraft, or trailer, which is certified under Field of Testing 23, and is operated by the same owner as a certified stationary laboratory, and which is designed and equipped for the purpose of transporting and using laboratory equipment to perform analyses in one of the Fields of Testing for which the stationary laboratory is certified.~~

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

~~(i) "Owner" means 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.~~

(i) “Denial” means a decision ~~by ELAP~~ to reject an application for accreditation due to ~~not meeting the accreditation criteria in accordance with Section 64802.00~~ non-compliance with ELAP statutes and regulations.

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

(j) “Dismissed” means an application is denied without the opportunity to petition, but with opportunity to ~~refile~~ resubmit.

~~(k) "Principal Analyst" means a person who either supervises the activities of others in, or conducts, the analyses of environmental samples using sophisticated laboratory instruments. For these purposes, "sophisticated laboratory instruments" means: gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma spectrometers (ICP), direct current plasma spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), or high pressure liquid chromatographs (HPLC).~~

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

~~(l) "Stationary Laboratory" means a laboratory that is permanent and nonmovable and may include fixed-in-place vehicles.~~

(l) “Owner” means 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, or a public agency.

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

(m) "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.

~~(n) "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.~~

(n) “Primary Accreditation Body” means the organization that actually executes the accreditation process, including but not limited to, receiving and reviewing applications, documents, PT sample results, and on-site assessments.

~~(o) "Utility-Owned" means laboratories owned and operated by federal, state, city, or county agencies.~~

(o) “Quality ~~Assurance~~ Manual” ~~means quality manual as~~ is defined ~~by~~ in 2016 TNI Standard – Rev 2.1, Volume 1, Module 2 and replaces the term previously known as Quality Assurance Manual.

~~(p) "Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track. This definition is the same as the definition as given in Section 670, Vehicle Code.~~

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

~~(q) "Verified Application" means that the truth and accuracy of the information in the application has been attested to by the signature of a laboratory Owner.~~

(q) “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), ~~ion chromatography (IC)~~, 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), bioassay analyses utilizing aquatic organisms in toxicity testing, ~~or~~ and other similar instruments or technologies ~~including the use of aquatic organisms in toxicity testing of wastewater and hazardous waste~~.

~~(r) "Vessel" includes ships of all kinds, steamboats, steamships, canal boats, barges, sailing vessels, and every structure adapted to be navigated from place to place for the transportation of merchandise or persons. This definition is the same as given in~~

~~Section 21, Harbors and Navigation Code.~~

(r) “State Agency Partners” means those state agencies whose statute or regulations require it to use laboratories that have been accredited by ELAP.

(s) “State Board” means the California State Water Resources Control Board, which includes ELAP.

(t) “Suspension” means the total or partial removal of a laboratory’s accreditation ~~for a period of time~~ to allow the laboratory to correct findings that identified non-compliance with ELAP statutes and regulations.

(u) “Technical Manager” is described in 2016 TNI Standard – Rev 2.1, Volume 1, Module 2, Section 4.1.7.2 (with the exception of part [f]) and replaces the position previously known as Laboratory Director.

(v) “TNI” means The National Environmental Laboratory Accreditation Conference Institute.

(w) “Trade Secret” means any information that meets the definition in Section 6254.7(d) of the Government Code.

(x) "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 208. 1011 and 1012, Health and Safety Code. Reference: Sections 1010, 1014 and 1017, Health and Safety Code; Section 6254.7(d), Government Code; Sections 630 and 670, Vehicle Code; Section 21, Harbors and Navigation Code.~~

*Amend Title of Article 2 to read as follows:*

**Article 2. ~~Certification and Amendment Process~~ Accreditation Requirements.**

*Repeal Section 64803*

~~§ 64803. Certification and Amendment.~~

~~(a) A laboratory and its auxiliary or mobile laboratories shall be certified for a 24 month period in the Subgroups within each Field of Testing applied for when all the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation sample study sets have been received by the Department pursuant to Section 64809; and~~

~~(4) payment of the basic fee and per-Field-of-Testing fees published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) has been made to the Department.~~

~~(b) A laboratory desiring to add or remove one or more Subgroups within a Field(s) of Testing from its current certificate shall file a written request detailing the Field(s) of Testing or Subgroup(s) to be added or removed. Additions, which shall be effective for the remainder of the certification period, shall be made, and an amended certificate issued, when all of the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation samples have been received by the Department pursuant to Section 64809; and~~

~~(4) payment for a per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Sections 113 and 1017(a) for each Field of Testing to be added to the certificate has been made to the Department.~~

~~(c) Whenever there is an amendment to a certificate, the certificate number and the expiration date on the amended certificate shall be the same as the original certificate.~~

~~(d) Laboratories seeking an amendment to add one or more Subgroups within a Field(s) of Testing shall not perform analyses in the additional Field(s) of Testing, or Subgroup(s) of Field(s) of Testing, until approved by the Department as evidenced by the issuance of an amended certificate.~~

~~(e) Laboratories seeking removal of one or more Subgroups within a Field(s) of Testing shall not perform analyses in the Field of Testing, or Subgroup, after the date of its written request for removal.~~

~~(f) A laboratory desiring interim certification under authority of Health and Safety Code, Section 1015(d) shall file a written request for interim certification with its application. An interim certificate shall be issued after payment of the basic and per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) for each Field of Testing applied for, completion of the requirements of either Section 64807 or 64809, and after the Department has determined that the laboratory has submitted a complete application. In cases where reciprocity agreements exist, compliance with Section 64807 shall be based on a site visit report issued by the other government agency and conducted within 6 months prior to the request for interim certification.~~

~~(g) The Department's estimated schedule for processing a complete application for certification from the receipt of the complete application to the final decision regarding issuance or denial of a certificate is as follows:~~

~~(1) The median time is 6 months;~~

~~(2) The minimum time is 3 months;~~

~~(3) The maximum time is 12 months.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 113, 1012, 1013, 1014 and 1015, Health and Safety Code.~~

*Adopt Section 64802.00 to read as follows:*

**§ 64802.00 Accreditation Criteria.**

(a) A laboratory requesting ELAP accreditation shall meet the following minimum accreditation criteria:

~~(1) File a complete application package, in accordance with Section 64802.05;~~

(1) Comply with quality system requirements, in accordance with Section 64802.10;

(2) Achieve an acceptable score in a Proficiency Testing study for each Field~~(s)~~ of Accreditation for which the laboratory seeks to obtain or maintain accreditation, in accordance with Section 64802.20;

(3) Complete an on-site assessment conducted by an Assessment Agency, in accordance with Section 64802.25; and

(4) Pay the required fees ~~in accordance with Section 64802.30~~ as determined by the State Board.

~~(b) To add one or more Fields of Accreditation to its certificate:~~

~~(1) In between renewals, the laboratory shall submit an amendment application to ELAP and receive an amended certificate, in accordance with Section 64808.10; and~~

~~(2) At the time of renewal, the laboratory shall indicate the requested changes on its renewal application.~~

(~~c~~b) The period of accreditation shall be as follows:

(1) For initial and renewal accreditation, twenty-four (24) months;

~~(2) For amended accreditation, the time remaining on the certificate from the date it was amended;~~

(2) For reciprocity accreditation, the time remaining on the certificate provided by the primary accreditation body; and

~~(3) For reciprocity accreditation, the time remaining on the certificate provided by the primary accreditation body; and~~

(3) For amended accreditation, the time remaining on the certificate from the date it was amended.

~~(4) For interim accreditation, until accreditation is either granted or denied, but no longer than 12 months after the date of issuance.~~

(c) For initial accreditation requirements, refer to Section 64808.00.

(d) For renewal accreditation requirements, refer to Section 64808.05.

(e) For reciprocity accreditation requirements, refer to Section 64808.10.

(f) For amendment accreditation requirements, refer to Section 64808.15.

Note: Authority cited:

*Adopt Section 64802.05 to read as follows:*

**§ 64802.05. Application Package.**

(a) A complete application package for initial, renewal, or reciprocity accreditation ~~an application package~~ shall contain:

(1) Laboratory identifying information, which includes:

(A) Name of the laboratory;

(B) Details on the laboratory’s type, size, location, contact information, ownership, type of business structure and ~~for municipal laboratories~~ the regulatory agencies ~~that it~~ 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) ~~Agreement~~ 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 (~~including~~ include documentation of authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and

(G) Date ~~signed~~ of signature;

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

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

(B) Section 64802.10~~(a)(2)(A)~~(b)(1);

(C) Subdivision (a)(2)(B), above, will become invalid three (3) years after adoption of these regulations at which time accredited laboratories will be required to meet the TNI Standard in 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~~ Field(s) of Proficiency Testing scores for each Field(s) of Accreditation for which accreditation is requested ~~where Field(s) of Proficiency Testing exist. If there is no existing Field(s) of Proficiency Testing, ELAP may require an alternative demonstration of capability~~;

(5) A copy of the laboratory’s most recent on-site assessment report, including findings and approved corrective action report and/or corrective action plan;

(6) Accreditation fee payment;

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

(8) For reciprocity accreditation ~~only~~, proof of accreditation from a primary accreditation body, including:

(A) Official certificate and Scope of Accreditation;

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

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

~~(b) Subdivision (a)(2)(B), above, will become invalid three years after adoption of these regulations, and laboratories will be required to meet the TNI Standard in subdivision (a)(2)(A), above.~~

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

~~(c) An application package for renewal accreditation shall be received by ELAP no later than 90 days prior to the expiration date of the certificate.~~

~~(d) Subdivision (c), above, will become invalid three years after adoption of these regulations, and laboratories will be required to submit renewal application packages July 1 through August 31.~~

Note: Authority cited:

*Adopt Section 64802.10 to read as follows:*

**§ 64802.10. Quality Systems.**

To ensure analytical data produced by the laboratory is of known and documented quality, and sufficient to evaluate the usability of the data for State Agency Partner needs, ~~laboratories~~ a laboratory shall ~~comply with the following quality system requirements~~:

(a) ~~A laboratory shall~~ Comply with quality system requirements in accordance with 2016 TNI Standard – Rev 2.1, Volume 1:

(1) ~~Comply with quality system requirements in accordance with 2016 TNI Standard Volume 1, Modules 2 through 7, with the following exceptions~~ Module 2, with the following exceptions:

(A) ~~Volume 1,~~ Module 2, Section 4.1.7.2(f) – Technical Manager Qualifications; and

(B) ~~Volume 1,~~ Module 2, Section 5.2.6 – Technical Manager Requirements; ~~or~~

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

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

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

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

~~(1) Laboratory organization and personnel responsibilities; (2) Quality assurance objectives for measurement data;~~

~~(3) Sampling procedures (when the laboratory performs the sampling);~~

~~(4) Procedures for custody, handling, and disposal of samples;~~

~~(5) Calibration procedures and frequency;~~

~~(6) Analytical procedures;~~

~~(7) Acquisition and reduction, validation and reporting of data;~~

~~(8) Internal quality control checks;~~

~~(9) Performance and system audits;~~

~~(10) Preventive maintenance;~~

~~(11) Assessment of precision and accuracy;~~

~~(12) Corrective action; and~~

~~(13) Quality assurance reports.~~

~~(B) The Technical Manager or designee shall review, and amend if necessary, the quality assurance program and Quality Assurance Manual at least annually, and whenever there are changes in methods or laboratory equipment employed, laboratory structure or physical arrangements, or changes in the laboratory organization.~~

~~(C) Perform annual quality assurance audits documenting compliance with subdivision (a)(2), above, including corrective actions for any noted findings, and have the results available upon request by ELAP.~~

~~(D) Maintain records of the implementation of its quality assurance program, and provide those records upon request from ELAP. Records shall be maintained for a minimum of five years~~ Modules 3 through 7, where appropriate based on laboratory operations; or

~~(b) Subdivision (a)(2), above, will become invalid three years after adoption of these regulations, and laboratories will be required to meet the TNI Standard in subdivision (a)(1), above.~~

(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 all 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 personnel responsibilities;

(ii) Ethics and integrity clause;

(iii) Quality assurance objectives for measurement data;

(iv) Sampling procedures (when the laboratory performs the sampling);

(v) Procedures for 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 Standard Operating Procedures;

(B) Changes to laboratory equipment or instrumentation;

(C) Changes to laboratory structure or physical arrangements; or

(D) 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 after adoption of these regulations, at which time laboratories will be required to meet the TNI Standard in subdivision (a), above.

Note: Authority cited:

*Adopt Section 64802.15 to read as follows:*

**§ 64802.15. Field(s) of Accreditation.**

(a) ELAP will accredit laboratories ~~for environmental analyses~~ in Field(s) of Accreditation for use of environmental analyses required by State Agency Partners for regulatory purposes as identified in permits, orders, and other regulatory requirements.

(b) For laboratories that are conducting analyses for drinking water systems, Title 22 Section 64415 requires that the analyses be made in accordance with United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations parts 141.21 through 141.42, 141.66, and 141.89, unless otherwise directed by the State Board.

(c) 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:

*Adopt Section 64802.20 to read as follows:*

**§ 64802.20. Proficiency Testing.**

(a) A laboratory shall comply with ~~2016 TNI Standard, Volume 1, Module 1 for each Field of Accreditation for which the laboratory is requesting accreditation and where corresponding Field(s) of Proficiency Testing exist, with the following exceptions:~~

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

~~(2) Volume 1, Module 1, Section 8.0 – Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation.~~

all applicable Proficiency Testing requirements of state or federal regulatory agencies that are not covered in this section.

~~(b) To obtain initial accreditation, within one year prior to ELAP’s receipt of the laboratory’s initial application, a laboratory shall achieve acceptable scores in a minimum of one Proficiency Testing study for each Field of Accreditation on its application where a corresponding Field of Proficiency Testing exists. If there is no existing Field(s) of Proficiency Testing, ELAP may require an alternative demonstration of capability.~~

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

(1) Comply with 2016 TNI Standard - Rev 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) Direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP on or before the closing date of the study;

(D) Report in such a way that analytical results for the Field of Proficiency Testing is matched 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 the Proficiency Testing samples; and

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

~~(c) To maintain accreditation:~~

~~(1) A laboratory shall, within one year from the date of accreditation, achieve acceptable scores in a minimum of one Proficiency Testing study for each Field of Accreditation for which a laboratory holds accreditation and which a corresponding Field of Proficiency Testing exists.~~

~~(2) Subdivision (c)(1), above, will become invalid three years after adoption of these regulations. To maintain accreditation a laboratory shall, between September 1 of the year the laboratory applies for renewal accreditation and August 31 of the following year, achieve acceptable scores in a minimum of one Proficiency Testing study for each Field of Accreditation for which a laboratory holds accreditation and which a corresponding Field of Proficiency Testing exists.~~

~~(3) If a laboratory does not achieve acceptable scores for a Field of Proficiency Testing, within 30 days of receipt of the “Not Acceptable” result from the Proficiency Testing provider, the laboratory shall:~~

~~(A) Notify ELAP of the “Not Acceptable” result;~~

~~(B) Investigate and document the root cause of the failure;~~

~~(C) Take corrective action; and~~

~~(D) Achieve acceptable scores for that Field of Proficiency Testing in a subsequent Proficiency Testing study.~~

~~(4) If on the second attempt, a laboratory does not achieve acceptable scores for a Field of Proficiency Testing, a laboratory shall:~~

~~(A) Upon receipt of the “Not Acceptable” result from the Proficiency Testing provider, cease reporting of results for regulatory purposes, for that corresponding Field of Accreditation;~~

~~(B) Within 30 days, notify ELAP of the “Not Acceptable” result, and have its accreditation for that Field of Accreditation suspended effective upon receipt of the second “Not Acceptable” result from the Proficiency Testing provider;~~

~~(C) Within 30 days, investigate and document the root cause of the failure, and take corrective action; and~~

~~(D) Upon request from ELAP, provide documentation of the root cause investigation and corrective action to ELAP within 30 days.~~

~~(5) To be reinstated after suspension of a Field of Accreditation, the laboratory shall:~~

~~(A) Achieve acceptable scores for the corresponding Field of Proficiency Testing and submit to ELAP; and~~

~~(B) Submit an amendment application in accordance with Section 64808.10.~~

~~(6) If a Proficiency Testing study is not available within 30 days of receipt of a “Not Acceptable” result, the laboratory shall:~~

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

~~(B) Notify clients by registered mail, including:~~

~~(i) A statement of the root cause of the failure;~~

~~(ii) Corrective action taken; and~~

~~(iii) A plan that states when the next Proficiency Testing study will be completed.~~

~~(C) Achieve acceptable scores for that Field of Proficiency Testing when the subsequent Proficiency Testing study becomes available, and submit to ELAP.~~

(c) Subdivisions (b)(2) and (b)(3), above, will become invalid three (3) years after adoption of these regulations, at which time laboratories will be required to meet the TNI Standard in subdivision (b)(1), above.

~~(d) To renew accreditation:~~

~~(1) A laboratory shall, 90 days prior to expiration of accreditation, achieve acceptable scores in a minimum of one Proficiency Testing study for each Field of Accreditation for which a Proficiency Testing study exists.~~

~~(2) Subdivision (d)(1), above, will become invalid three years after adoption of these regulations. To renew accreditation, a laboratory shall, between~~

~~September 1 of the preceding year and August 31 of the year the laboratory submits its renewal application, achieve acceptable scores in a minimum of one Proficiency Testing study for each Field of Accreditation for which a laboratory holds accreditation and which a corresponding Field of Proficiency Testing exists.~~

~~(3) If a laboratory does not achieve acceptable scores for a Field of Proficiency Testing, within 30 days of receipt of the “Not Acceptable” result from the Proficiency Testing provider, the laboratory shall:~~

~~(A) Notify ELAP of the “Not Acceptable” result;~~

~~(B) Investigate and document the root cause of the failure;~~

~~(C) Take corrective action; and~~

~~(D) Achieve acceptable scores for that Field of Proficiency Testing in a subsequent Proficiency Testing study.~~

~~(4) If on the second attempt, a laboratory does not achieve acceptable scores for a Field of Proficiency Testing, a laboratory shall:~~

~~(A) Upon receipt of the “Not Acceptable” result from the Proficiency Testing provider, cease reporting of results for regulatory purposes, for that corresponding Field of Accreditation;~~

~~(B) Within 30 days, notify ELAP of the “Not Acceptable” result, and have its accreditation for that Field of Accreditation suspended effective upon receipt of the second “Not Acceptable” result from the Proficiency Testing provider; and~~

~~(C) Within 30 days, investigate and document the root cause of the failure, and take corrective action; and~~

~~(D) Upon request from ELAP, the laboratory shall provide documentation of the root cause investigation and corrective action to ELAP within 30 days.~~

~~(5) To be reinstated after suspension of a Field of Accreditation, the laboratory shall:~~

~~(A) Achieve acceptable scores for the corresponding Field of Proficiency Testing and submit to ELAP; and~~

~~(B) Submit an amendment application in accordance with Section 64808.10.~~

~~(6) If a Proficiency Testing study is not available within 30 days of receipt of a “Not Acceptable” result, the laboratory shall:~~

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

~~(B) Notify clients by registered mail, including:~~

~~(i) A statement of the root cause of the failure;~~

~~(ii) Corrective action taken; and~~

~~(iii) A plan that states when the next Proficiency Testing study will be completed.~~

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

(d) If there are no available Field(s) of Proficiency Testing for Field(s) of Accreditation, then ELAP may require an alternative demonstration of capability.

~~(e) For toxicity bioassay in any Field of Accreditation, each laboratory shall:~~

~~(1) Achieve acceptable scores in Proficiency Testing studies, where Proficiency Testing studies exist;~~

~~(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.~~

(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 minimum of one Field of Proficiency Testing for each Field of Accreditation requested in the application.

~~(f) For pesticide residue in food in any Field(s) of Accreditation, each laboratory shall participate in Proficiency Testing studies approved by ELAP.~~

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

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

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

~~(g) For a California Analyte for which there is no commercial Proficiency Testing study available, ELAP may require an alternative demonstration of capability.~~

(g) For amendment accreditation, when applicable, a laboratory shall achieve acceptable scores in a Field of Proficiency Testing for each Field of Accreditation for which the laboratory is requesting amended accreditation. For requirements of amendment accreditation package, refer to Section 64808.15.

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

(h) If a laboratory does not achieve an acceptable score for a Field of Proficiency Testing, then within thirty (30) 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) Investigate and document the root cause of the failure;

(3) Take corrective action;

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

(5) Notify ELAP of the “Acceptable” score.

(i) If on the second attempt, a laboratory does not achieve acceptable scores for a Field of Proficiency Testing, a laboratory shall:

(1) Be suspended for that Field of Accreditation effective upon receipt of the second “Not Acceptable” result from the Proficiency Testing provider;

(2) Cease reporting of results for regulatory purposes for that corresponding Field of Accreditation upon receipt of the “Not Acceptable” result from the Proficiency Testing provider;

(3) Notify clients of suspended status by registered mail;

(4) Within thirty (30) days:

(A) Notify ELAP of the “Not Acceptable” result; and

(B) Investigate and document the root cause of the failure and take corrective action;

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

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

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

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

(k) If a Proficiency Testing study for a Field of Proficiency Testing is not available within thirty (30) days of receipt of a “Not Acceptable” result, the laboratory shall:

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

(2) Notify clients of when the next Proficiency Testing study will be completed; and

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

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

(1) Achieve acceptable scores in a Field of Proficiency Testing 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 participate in Proficiency Testing studies approved by ELAP.

(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:

*Adopt Section 64802.25 to read as follows:*

**§ 64802.25. 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 ~~ELAP~~ application and to verify a laboratory is in compliance with:

(1) Quality system requirements, in accordance with Section 64802.10;

(2) Analytical methods used for each Field of Accreditation for which the laboratory seeks to obtain or maintain accreditation;

(3) ~~All applicable ELAP statutes and regulations~~ Laboratory instrumentation and equipment requirements, in accordance with Section 64812.05; and;

(4) ~~The laboratory’s instrumentation and equipment requirements in accordance with Section 64812.05~~ All applicable ELAP statutes and regulations.

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

(1) For initial accreditation, prior to obtaining accreditation;

(2) For renewal accreditation, once every ~~three~~ two years; ~~and~~

(3) For amendment accreditation, ~~at ELAP’s discretion~~ when required, in accordance with Section 64808.15; and

(4) For enforcement purposes, when necessary in accordance with Health and Safety Code 100865.

~~(c) When an on-site assessment is performed by ELAP, a laboratory shall pay an assessment fee in accordance with Section 64802.30.~~

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

~~(d) When an on-site assessment is performed by a third-party Assessment Firm approved by ELAP to perform on-site assessments, a laboratory shall pay an assessment fee in accordance with Section 64802.30.~~

(d) When a scheduled on-site assessment is performed by ELAP, a laboratory shall pay an assessment fee as determined by the State Board.

~~(e) If any findings are noted, within 30 days of the on-site assessment, the laboratory will receive an On-Site Assessment Report.~~

~~(1) Within 30 days of receipt of the On-Site Assessment Report, the laboratory shall submit a Corrective Action Report in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 4.11. The laboratory will be notified within 30 days whether the Corrective Action Report demonstrates the required corrections. If a finding is not correctable within 30 days, a laboratory shall submit a Corrective Action Plan as part of the Corrective Action Report, identifying the date by which the finding will be corrected.~~

~~(2) If the laboratory is notified that the Corrective Action Report does not demonstrate the required corrections, the laboratory shall have an additional 30 days from its receipt of the notification to submit a revised Corrective Action Report. If the revised report still does not demonstrate the required corrections, accreditation shall be denied, suspended or revoked for any Field(s) of Accreditation affected by failure to take corrective action.~~

~~(3) If in a subsequent on-site assessment, either announced or unannounced, ELAP determines that the laboratory failed to take any of the corrective action(s) specified by the laboratory, accreditation shall be denied, suspended, or revoked for any Field(s) of Accreditation affected by failure to take corrective action.~~

(e) When an on-site assessment is performed by a third-party Assessment Agency approved by ELAP to perform on-site assessments, a laboratory shall pay an assessment fee as determined by the third-party Assessment Agency.

~~(f) Unless otherwise approved by ELAP, if an on-site assessment is scheduled, but not conducted within six months from the scheduled assessment date and the delay is not a result of ELAP error or procedure, accreditation shall be denied, suspended or revoked.~~

(f) Within thirty (30) days of the on-site assessment, a laboratory will 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, the laboratory shall submit a corrective action report that contains a root cause analysis of the finding(s);

(2) If finding(s) are not correctable within thirty (30) days, a laboratory shall submit a corrective action plan, identifying the corrective actions that will take place and the date the finding(s) will be corrected;

(3) Subsection (f)(1), above, will be invalid three (3) years from the adoption 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 report in accordance with 2016 TNI Standard – Rev 2.1, Volume 1, Module 2, Section 4.11.

(g) If a laboratory is notified that a corrective action report does not demonstrate the required corrections, then the laboratory shall have an additional thirty (30) days from the receipt of the notification to submit a revised corrective action report. If the revised corrective action report does not demonstrate the required corrections, then accreditation shall be denied, suspended or revoked for the Field(s) of Accreditation affected by the failure to take corrective action.

(h) 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 report, then accreditation shall be denied, suspended, or revoked for the Field(s) of Accreditation affected by failure to take corrective action.

(i) Unless otherwise approved by ELAP, 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 ELAP error or procedure, accreditation shall be denied, suspended or revoked.

(j) 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 ELAP to complete an on-site assessment, then the laboratory shall be issued an interim certificate.

(1) A laboratory that holds an interim certificate 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 issued;

(B) The laboratory fails to meet the requirements for accreditation in accordance with Section 64802.00; or

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

Note: Authority cited:

~~Adopt Section 64802.30 to read as follows:~~

**~~§64802.30. Accreditation Fees (PLACE HOLDER).~~**

*Amend Title of Article 3.*

**Article 3. ~~Application Process~~ Types of Accreditation.**

*Repeal Section 64805*

~~§ 64805. Application.~~

~~(a) All laboratories seeking certification in any Subgroup as identified in Section 64823 within Field(s) of Testing 1 through 22, as listed in Health and Safety Code, Section 1017, shall file a complete application utilizing ELAP form 001, dated January 1, 1993, and containing the following information:~~

~~(1) complete name of the laboratory; and~~

~~(2) if the laboratory is stationary, the location, by street address, or map directions (if no street address exists), city, state, zip code, and county of the laboratory and any auxiliary laboratories; and~~

~~(3) if the laboratory is owned by a holder of a waste discharge permit issued by a California Regional Water Quality Control Board, the name or number of the Regional Board issuing the permit; and~~

~~(4) mailing address, parcel or package delivery address of the laboratory and any auxiliary laboratories; and~~

~~(5) if the laboratory is a vehicle or trailer, the vehicle identification and license plate number, including state of issue, or if the laboratory is a vessel, the vessel~~

~~identification number, vessel registration number, including state of issue, or if the laboratory is an aircraft, the aircraft identification number, aircraft registration number, including state of issue, of all mobile laboratories; and~~

~~(6) name, education, and experience for the person designated as the Laboratory Director; and~~

~~(7) name, education, and experience for each and every person designated as Principal Analyst; and~~

~~(8) name of a Contact Person; and~~

~~(9) phone numbers for the laboratory, fax devices, Laboratory Director, and Contact Person; and~~

~~(10) the name(s) of the Owner(s) of the laboratory. If the laboratory is owned by a corporation, the name of the officers, and stockholders owning 5% or more of the shares. If the laboratory is owned by a partnership, the name of all partners; and~~

~~(11) whether the laboratory seeks exemption from fees as allowed by Health and Safety Code, Section 1017(e). If exemption is claimed, it shall include evidences showing the laboratory to be established under the authority of Health and Safety Code, Section 1000, or that the laboratory meets the definition of a government- owned reference laboratory as established in Health and Safety Code, Section 1017(g); and~~

~~(12) the Field(s) of Testing for which the laboratory desires certification; and~~

~~(13) a quality assurance document meeting the requirements of Section 64815; and~~

~~(14) date of completion of the application and signature by an Owner.~~

~~(b) Laboratories seeking certification of a mobile laboratory under Field of Testing 23, shall file a complete application, which shall include the following information:~~

~~(1) the Subgroup within the Field of Testing to be employed in the mobile laboratory; and~~

~~(2) the name of the Owner(s) of the stationary laboratory that operates the mobile laboratory; and~~

~~(3) name, education, and experience for the person designated as Laboratory Director for the stationary laboratory that operates the mobile laboratory; and~~

~~(4) name, education and experience for each and every person designated as Principal Analyst for the mobile laboratory; and~~

~~(5) a quality assurance program meeting the requirements of Section 64815 covering the test methods to be employed in the mobile laboratory; and~~

~~(6) the location, by street address, or map directions (if no street address exists), city, state, zip code, and county of the certified stationary laboratory under the same owner as the mobile laboratory and the Subgroups within each Field of Testing for which that stationary laboratory is certified.~~

~~(c) All applications filed with the Department shall be considered complete unless within 30 days of receipt, the Department mails to the laboratory's mailing address a notice that the application is not complete. Any noted deficiencies in a submitted application must be corrected and the corrected application returned to the Department within ninety days from the date of the Department's notice of deficiencies or the application shall be considered null and void.~~

~~(d) An application for renewal of a certificate shall be received by the Department no later than ninety days prior to the expiration date of the certificate or it shall expire by operation of law on the stated expiration date as specified in Health and Safety Code Section 1014(a).~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Sections 1013, 1014 and 1017(e), Health and Safety Code.~~

*Adopt Section 64808.00 to read as follows:*

**§ 64808.00 Initial Accreditation.**

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

(1) Submit a complete application package, in accordance with Section 64802.05;

(2) Comply with quality system requirements, in accordance with Section 64802.10;

(3) ~~Be subject to an on-site assessment and comply~~ Complete an on-site assessment conducted by an Assessment Agency, in accordance with Section 64802.25; and

(4) Pay the required fees ~~in accordance with Section 64802.30~~ as determined by the State Board.

(b) If any of the elements in subdivision (a)(1), above, are missing ~~at the time~~ from the application ~~is filed~~ submission, then within thirty (30) days of the receipt ~~by~~ of the application, ELAP ~~the laboratory will be notified and the application will be returned~~ will notify the laboratory and return the application. ELAP will not review whether Proficiency Testing reports have acceptable scores for the appropriate Field(s) of ~~Accreditation~~ Proficiency Testing when reviewing ~~whether an application package is complete~~ the completeness of an application package, but ~~rather~~ will only ensure Proficiency Testing reports have been submitted with the application package.

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

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

Note: Authority cited:

*Adopt Section 64808.05 to read as follows:*

**§ 64808.05 Renewal Accreditation.**

(a) To renew accreditation, a laboratory shall:

(1) Submit a complete application package, in accordance with Section 64802.05;

(2) Comply with quality system requirements, in accordance with Section 64802.10;

(3) ~~Demonstrate successful completion of~~ Complete an on-site assessment conducted by an Assessment Agency in accordance with Section 64802.25, within ~~the previous three~~ two (2) years ~~from the date the renewal application was submitted~~ of the laboratory’s last on-site assessment; and

(4) Pay the required fees ~~in accordance with Section 64802.30~~ as determined by the State Board.

(b) If any of the elements in subdivision (a)(1), above, are missing ~~at the time~~ from the application ~~is filed~~ submission, then within thirty (30) days of the receipt ~~by~~ of the application, ELAP ~~the laboratory will be notified and the application will be returned~~ will notify the laboratory and return the application. ELAP will not review whether Proficiency Testing reports have acceptable scores for the appropriate Field(s) of ~~Accreditation~~ Proficiency Testing when reviewing ~~whether an application package is complete~~ the completeness of an application package, but ~~rather~~ will only ensure Proficiency Testing reports have been submitted with the application package.

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

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

~~(c) If a laboratory files its renewal application after the application due date, to continue the renewal process, the laboratory shall be subject to a late fee equal to 15% of its accreditation fee. If accreditation is not renewed by the certificate expiration date, the laboratory shall cease all reporting of results for regulatory purposes, and notify clients of its lapse in accreditation by registered mail.~~

(c) An application package for renewal accreditation shall be received by ELAP no later than ninety (90) days prior to the expiration date of the certificate.

~~(d) If a laboratory files its renewal application after the certificate expiration date, to continue the renewal process, the laboratory shall be subject to a late fee equal to 30% of its accreditation fee. On the certificate expiration date, the laboratory shall cease all reporting of results for regulatory purposes, and notify clients of its lapse in accreditation by registered mail.~~

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

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

(2) If accreditation is not renewed by the certificate expiration date, the laboratory shall cease all reporting of results for regulatory purposes and notify clients of the lapse in accreditation by registered mail.

~~(e) If a laboratory files its renewal application 90 days after the certificate expiration date, accreditation shall not be renewable. On the certificate expiration date, the laboratory shall cease all reporting of results for regulatory purposes, and notify clients of its lapse in accreditation by registered mail.~~

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

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

(2) The laboratory shall cease all reporting of results for regulatory purposes on the certificate expiration date and notify clients of the lapse in accreditation by registered mail.

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

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

(2) The laboratory shall cease all reporting of results for regulatory purposes on the certificate expiration date and notify clients of the lapse in accreditation by registered mail.

Note: Authority cited:

*Adopt Section 64808.10 to read as follows:*

**~~§ 64808.10 Amendment Accreditation.~~**

~~(a) To amend accreditation for the following reasons, a laboratory shall file an amendment application and pay the fee in accordance with Section 64802.30:~~

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

~~(2) Change its location;~~

~~(3) Add a satellite laboratory or mobile laboratory; and~~

~~(4) Add or reinstate a Field(s) of Accreditation to the laboratory’s current certificate.~~

~~(b) A laboratory applying to change its name shall:~~

~~(1) File an amendment application that includes the following:~~

~~(A) Existing name of the laboratory;~~

~~(B) Certificate number of the laboratory;~~

~~(C) Address of the laboratory;~~

~~(D) Proposed new name of the laboratory;~~

~~(E) Business entity type; and~~

~~(F) Signature of the laboratory owner, owner’s agent, or officer, and date signed.~~

~~(2) Pay the fee in accordance with Section 64802.30.~~

~~(c) A laboratory applying for a change of location shall:~~

~~(1) Have its accreditation suspended on the last day of operation at the old location, cease reporting of results for regulatory purposes, and notify clients by registered mail of suspended status; and~~

~~(2) To be reinstated, a laboratory shall:~~

~~(A) Within 30 days prior to the change of location, file an amendment application that includes the following:~~

~~(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) Business entity type;~~

~~(vii) Signature of the laboratory owner, owner’s agent, or officer; and~~

~~(viii) Date signed.~~

~~(B) Comply with quality system requirements at the new location, in accordance with Section 64802.10;~~

~~(C) Submit updates to the Quality Assurance Manual that are necessary because of the change of location;~~

~~(D) Submit any new or revised Standard Operating Procedure(s) necessitated by the change of location;~~

~~(E) Submit Proficiency Testing report(s) with acceptable scores for all Field(s) of Accreditation for which the laboratory is requesting accreditation, where Proficiency Testing studies exist; and~~

~~(F) If at ELAP’s discretion an on-site assessment is conducted, the laboratory shall comply with Section 64802.25.~~

~~(G) Pay the fee in accordance with Section 64802.30.~~

~~(d) A laboratory applying to add a satellite laboratory shall:~~

~~(1) Prior to applying, ensure the satellite laboratory meets the criteria for a satellite laboratory set forth in Section 64810.05;~~

~~(2) File an amendment application that includes the following:~~

~~(A) Name of the laboratory;~~

~~(B) Details on the laboratory’s type, size, location, business entity type, contact information and ownership;~~

~~(C) Name and qualifications of Technical Manager, 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) Agreement to comply with applicable ELAP statutes and regulations;~~

~~(F) Signature of the laboratory owner, owner’s agent, or officer; and~~

~~(G) Date signed.~~

~~(3) Identify the Field(s) of Accreditation for which the satellite laboratory is requesting accreditation;~~

~~(4) Submit Proficiency Testing report(s) with acceptable scores for each Field of Accreditation for which the satellite laboratory is requesting accreditation, where Proficiency Testing studies exist;~~

~~(5) If at ELAP’s discretion an on-site assessment is conducted, the satellite laboratory shall comply with Section 64802.25; and~~

~~(6) Pay the fee in accordance with Section 64802.30.~~

~~(e) A laboratory applying to add or reinstate a Field(s) of Accreditation shall:~~

~~(1) File an amendment application that includes the following:~~

~~(A) Name of the laboratory;~~

~~(B) Certificate number of the laboratory; and~~

~~(C) Address of the laboratory;~~

~~(2) Identify the Field(s) of Accreditation for which accreditation is being amended;~~

~~(3) Comply with quality system requirements, in accordance with Section 64802.10;~~

~~(4) Submit any portion of the Quality Assurance Manual that has been amended to address the additional Field(s) of Accreditation;~~

~~(5) Submit Proficiency Testing report(s) with acceptable scores for all Field(s) of Accreditation for which the laboratory is requesting to amend accreditation, where Proficiency Testing studies exist. If there is no existing Proficiency Testing study, ELAP may require an alternative demonstration of capability;~~

~~(6) If at ELAP’s discretion an on-site assessment is conducted, the laboratory shall comply with Section 64802.25; and~~

~~(7) Pay the fee in accordance with Section 64802.30.~~

~~(f) A laboratory is not required to file an amendment application to remove a Field(s) of Accreditation, but may request an amended certificate to remove a Field(s) of Accreditation by submitting a written request to ELAP. Once a laboratory receives an amended certificate, the laboratory shall cease reporting results for regulatory purposes for those Field(s) of Accreditation that were removed.~~

~~Note: Authority cited:~~

**§ 64808.10 Reciprocity Accreditation.**

(a) 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.

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

(c) Where reciprocity conditions exist, a laboratory applying for accreditation by reciprocity shall:

(1) Submit a complete application package in accordance with Section 64802.05;

(2) Comply with quality system requirements, in accordance with Section 64802.10; and

(3) Pay the required fees as determined by the State Board.

(d) For reciprocity accreditation, the period of accreditation shall be the time remaining on the certificate provided by the primary accreditation body.

(e) 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 determined by the State Board.

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

(1) Cease all reporting of results for regulatory purposes. The laboratory’s ELAP certificate shall be suspended or revoked effective the date of the action taken by the primary accreditation body; and

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

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

Note: Authority cited:

*Adopt Section 64808.15 to read as follows:*

**~~§64808.15 Interim Accreditation.~~**

~~(a) If a laboratory has filed a complete application in accordance with Section 64802.05, and additional time is needed by ELAP to complete an on-site assessment, the laboratory shall be issued an interim certificate.~~

~~(b) Interim accreditation is not renewable and shall be valid until one of the following occur:~~

~~(1) An on-site assessment has been completed and a certificate issued;~~

~~(2) The laboratory fails to meet the requirements for accreditation in accordance with Section 64802.00; or~~

~~(3) The expiration date on the interim certificate is reached.~~

~~Note: Authority cited:~~

**§ 64808.15 Amendment Accreditation.**

(a) To amend accreditation, a laboratory shall submit an amendment application package and pay the fee as determined by the State Board.

(b) 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.

(c) 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.

(d) 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) Business entity type;

(6) Signature of the laboratory owner, owner’s agent, or officer; and

(7) Signature date.

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

(1) Within thirty (30) days prior to 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) Business entity type;

(vii) Signature of the laboratory owner, owner’s agent, or officer; and

(viii) 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; and

(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;

(2) Comply with quality system requirements at the new location, in accordance with Section 64802.10;

(3) Complete an on-site assessment conducted by an Assessment Agency, in accordance with Section 64802.25; and

(4) Comply with the following conditions:

(A) A laboratory cannot report data for regulatory purposes at the new

location until ELAP approves the accreditation transfer;

(B) A laboratory cannot report data for regulatory purposes at the current and new locations under the same accreditation; and

(C) A laboratory shall cease reporting at the old location once the new location is reporting data for regulatory purposes.

(f) 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;

(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; and

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

(3) Complete an on-site assessment conducted by an Assessment Agency, in accordance with Section 64802.25.

(g) A laboratory applying to add or reinstate Field(s) of Accreditation shall:

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

(A) Laboratory identification information including:

(i) Name of the laboratory;

(ii) Certificate number of the laboratory; and

(iii) Address of the laboratory;

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

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

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

(2) Comply with quality system requirements, in accordance with Section 64802.10;

(3) Complete an on-site assessment conducted by an Assessment Agency, at ELAP’s discretion, in accordance with Section 64802.25; and

(4) If an amendment application is accepted by ELAP, then at the time of renewal, indicate the amendments on the renewal application package.

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

Note: Authority cited:

**~~§64808.20 Reciprocity Accreditation.~~**

~~(a) For laboratories physically located outside the state of California, another state or federal agency's environmental laboratory accreditation program shall be recognized for the purposes of reciprocity if the program’s 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.~~

~~(b) Another state or federal agency’s environmental laboratory accreditation program shall be recognized through a written agreement with ELAP.~~

~~(c) For reciprocity accreditation, the period of accreditation shall be the time remaining on the certificate provided by the primary accreditation body.~~

~~(d) Where reciprocity conditions exist, a laboratory applying for accreditation by reciprocity shall:~~

~~(1) File a complete application package in accordance with Section 64802.05;~~

~~(2) Comply with quality system requirements, in accordance with Section 64802.10; and~~

~~(3) Pay the required fees, in accordance with Section 64802.30.~~

~~(e) If a laboratory that is accredited through reciprocity has its certificate suspended or revoked by its primary accreditation body, it shall notify ELAP within 10 days of the suspension or revocation and its ELAP certificate shall be automatically suspended or revoked as of the effective date of the action taken by the primary accreditation body.~~

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

~~(g) 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 set forth in Section 64802.30~~

Note: Authority cited:

*Amend Title of Article 4*

**Article 4. ~~Site Visits~~ Types of Laboratories.**

*Repeal Section 64807*

~~§ 64807. Site Visits.~~

~~(a) Site visits shall be conducted by the Department to verify information contained in a laboratory's application for certification or when a laboratory requests the addition of one or more Subgroups within a Field of Testing. During the site visit, the Department shall verify the following:~~

~~(1) the laboratory uses only the analytical test methods identified in Section 64811 for each Subgroup within a Field of Testing for which the laboratory is seeking certification;~~

~~(2) the laboratory's instrumentation and equipment meet the requirements of Section 64813;~~

~~(3) the laboratory's quality assurance and quality control procedures meet the requirements of Section 64815; and~~

~~(4) the information contained in the application.~~

~~(b) Within 30 days of completion of a site visit, the Department shall notify a laboratory, in writing, of its deficiencies, if any, in complying with the requirements of (a)(1) through (a)(4) above. No laboratory shall be issued a certificate in any Subgroup within any Field of Testing applied for unless it has corrected all deficiencies noted, and has forwarded to the Department a statement, in writing, of all corrective actions taken. The statement of corrective actions shall be received by the Department within the time frame established in the Department's notice of deficiencies. If in a subsequent site visit the Department determines that the laboratory failed to take any of the corrective action(s) specified in the laboratory's statement, citation(s) as specified under the authority of Health and Safety Code, Section 1021, may be issued.~~

~~(c) A site visit shall be conducted within 6 months from the date of receipt by the Department of a laboratory's application. If a site visit is not conducted within this time period and the delay is not a result of Department error or procedure, certification shall be denied pursuant to Section 64803(a)(2).~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1015, 1018 and 1021, Health and Safety Code.~~

*Adopt Section 64810.00 to read as follows:*

**§ 64810.00 Main Laboratory.**

(a) A laboratory may apply for accreditation ~~of~~ as a main laboratory, in accordance with Section ~~64802.05~~ 64808.00, ~~provided that the main~~ if the laboratory is:

(1) ~~Is~~ Designated as the primary location;

(2) ~~Is~~ A fixed, permanent facility; and

(3) May include fixed-in-place vehicles.

Note: Authority cited:

*Adopt Section 64810.05 to read as follows:*

**§ 64810.05 Satellite Laboratory.**

(a) A laboratory may apply for accreditation of a satellite laboratory, in accordance with Section ~~64808.10~~ 64808.15, if ~~ELAP has determined that the laboratory applying for accreditation of a satellite laboratory meets the criteria below~~ the following criteria are met:

(1) The main laboratory and satellite laboratory operate under a single scope of accreditation that is divided among each ~~site~~ location;

(2) The ~~main laboratory provides oversight of the satellite laboratory and the~~ satellite laboratory does not operate autonomously;

(3) ~~All reports identify which laboratory performed the analyses and are submitted by the main laboratory only~~ The main laboratory provides oversight of the satellite laboratory;

(4) ~~A single contact person is identified, for the purpose of communicating with ELAP, regarding accreditation activities, for the main laboratory and the satellite laboratory~~ The main laboratory and satellite laboratory are under the supervision of the same Technical Manager;

(5) The main laboratory and satellite laboratory operate under the same quality management system and Quality ~~Assurance~~ Manual; ~~and~~

(6) Reports identify which laboratory performed the analyses and are submitted only by the main laboratory; and

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

Note: Authority cited:

*Adopt Section 64810.10 to read as follows:*

**§ 64810.10 Mobile Laboratory.**

(a) A laboratory may apply for accreditation as a mobile laboratory, in accordance with Section ~~64802.05~~ 64808.00, ~~provided that each mobile~~ if the laboratory is:

(1) A portable, enclosed structure (such as a vehicle, vessel, aircraft, or trailer); and

(2) ~~Is~~ Designed and equipped, with necessary and appropriate accommodation and environmental conditions, for the ~~purpose of transporting and using~~ transportation and use of laboratory equipment to perform analysis in the Field(s) of Accreditation for which accreditation is requested.

(b) A laboratory may apply to combine a main and mobile laboratory under a single accreditation, ~~provided that each mobile laboratory~~ in accordance with Section 64808.15, if the following criteria are met:

(1) ~~Is operated by the owner of the main laboratory~~ The main laboratory and mobile laboratory operate under the same owner;

(2) ~~Performs analyses in one or more of the same Field(s) of Accreditation as the main laboratory~~ The main laboratory and mobile laboratory operate under the same quality management system and Quality Manual;

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

(4) ~~Reports raw analytical data only to the main laboratory for its generation of the final report; and~~ The mobile laboratory performs analyses in one or more of the same Field(s) of Accreditation as the main laboratory;

(5) ~~The main laboratory and mobile laboratory operate under the same quality management system and Quality Assurance Manual~~ The mobile laboratory reports only raw analytical data to the main laboratory; and

(6) Reports identify which laboratory performed the analyses and are submitted only by the main laboratory.

Note: Authority cited:

*Amend Title of Article 5*

**Article 5. ~~Performance Evaluation Testing Process~~ Laboratory Personnel, Facilities and Equipment.**

*Repeal Section 64809*

~~§ 64809. Performance Evaluation Testing.~~

~~(a) No laboratory shall be certified to perform analyses in any Subgroup of any Field(s) of Testing as identified in Section 64823 unless the laboratory has submitted results for the analysis of performance evaluation sample study set(s) (where performance evaluation sample study set(s) exist) in each Subgroup within each Field of Testing for which certification is requested, and the results for the testing of the study set are in agreement with the criteria established below:~~

~~(1) within the 99% confidence limit of the mean computed by the Department for the collection of results received for the performance evaluation sample set for the following Subgroups: detection of total coliform or fecal coliform organisms in wastewater by Multiple Tube Fermentation technics; detection of total coliform or fecal coliform organisms in wastewater by Membrane Filter technics; Heterotrophic Plate Count technics; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics; Fecal streptococci and Enterococci by Membrane Filter technics of Field of Testing 1; all Subgroups in Fields of Testing 6, 9, 10, 12, 13, 16, 17, 18, and 19;~~

~~(2) positive/negative, present/absent, above/below, or other similar discrete response when the only result possible from a test is a discrete response for the following Subgroups in Field of Testing 1: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Membrane Filter technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by use of Clark's Presence/Absence medium; detection of both total coliforms and Escherichia coli (E. coli) organisms in drinking water by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside - 4- methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics;~~

~~(3) for all Subgroups in Field of Testing 8: within the 99% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set, or within the 95th percentile of a distribution of non-normal values. The choice determined by the Department through the application of standard tests that determine the normalcy of data;~~

~~(4) within the 95% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set for the following Subgroups: alkalinity, calcium, chloride, corrosivity, hardness, magnesium, MBAS, sodium, sulfate, total filterable residue and conductivity, iron (colorimetric methods only), manganese (colorimetric methods only), and ortho phosphate in Field of Testing 2; asbestos in Field of Testing 3;~~

~~(5) within a given percentage of a known or true value for the following Subgroups: cyanide, fluoride, nitrate and nitrite in Field of Testing 2; all Subgroups in Field of Testing 3, except asbestos; all Subgroups in Fields of Testing 4, 5, 20, 21, and 22.~~

~~(b) Each performance evaluation sample study set shall state the method of evaluation that shall be utilized to score results for that performance evaluation sample study set, and which requirements identified in (a) above, or (c) below must be met by the laboratory.~~

~~(c) If a performance evaluation sample study set contains one or more analytes that may be analyzed by a single test method that the Department recognizes and certifies as a Subgroup of a Field of Testing, the results shall meet one of the following:~~

~~(1) when 6 or fewer analytes are in the performance evaluation sample study set, all analytes are within the stated acceptance limits; or~~

~~(2) when more than 6 analytes are in the performance evaluation sample study set, eighty-five point zero percent (85.0%) of the analytes are within the stated acceptance limits.~~

~~(d) If a laboratory fails to submit results for the analysis of performance evaluation sample study sets, which meet the above requirements, the laboratory may, within 30 days, request that it be given a second, successive attempt to submit such results.~~

~~Failure of a laboratory to submit results for the analysis of performance evaluation sample study sets meeting the requirements of (a) or (c) within 6 months from the date of receipt by the Department of the laboratory's application for certification, or of its request for the addition of one or more Subgroups within a Field(s) of Testing shall result in the denial of the application or request.~~

~~(e) With the exception of Field of Testing 6, a certified laboratory shall, within 12 months from the date of certification, participate in at least one performance evaluation sample study set (where performance evaluation sample study set(s) exist) for each Subgroup within each Field of Testing as identified in Section 64823 for which certification is held. If the results from the study do not meet the requirements of (a) or (c), the laboratory shall be provided a second, successive attempt to submit such results. Irrespective of whether a second, successive attempt is provided, results meeting the requirements of (a) or (c) must be submitted by a certified laboratory to the Department at least 90 days prior to the expiration of its certificate or the laboratory's certificate may be restricted under Health and Safety Code, Section 1015(c).~~

~~(f) Laboratories holding certification in any Subgroup within Field of Testing 6 shall participate in all available performance evaluation test samples provided through the Environmental Protection Agency's Environmental Monitoring and Support Laboratory, Las Vegas inter-comparison cross check and performance evaluation studies. The laboratory must successfully complete a minimum of two inter-comparison cross check studies and one performance evaluation study each annual period from the date of certification. Failure to do so may be used by the Department as grounds for restricting the laboratory's certificate under Health and Safety Code, Section 1015(c).~~

~~(g) Laboratories seeking or holding certification in any Subgroup within Field of Testing 11 are exempt from compliance with the requirements of Health and Safety Code, Section 1015(b)(1).~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1015, 1017 and 1019, Health and Safety Code.~~

*Adopt Section 64812.00 to read as follows:*

**§ 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, ~~environmental~~ natural or physical science, or environmental, sanitary or chemical engineering~~, natural or physical science~~; 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, 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 may be substituted for two (2) years of the required experience.

~~(b) A Technical Manager employed by a laboratory owned by a public drinking water or wastewater utility may fulfill the requirements of Technical Manager by possession of the highest required Laboratory Analyst/Water Quality Analyst Certificate from CWEA or CA-NV/AWWA for performance of analytical techniques, in accordance with Table 64812, as follows:~~

**~~Table 64812~~**

**~~Laboratory Analyst/Water Quality Analyst Certification Required for Technical Manager~~**

| **~~Certificate Grade~~** | **~~Analytical Technique~~** | |
| --- | --- | --- |
| **~~Drinking Water~~** | **~~Wastewater~~** |
| **~~I~~** | ~~Calculation; Chlorine Analyzer; Colorimetric; Conductivity Meter;~~  ~~DPD; DPD-FAS; Electrode;~~  ~~Electrometric (Continuous);~~  ~~Enzyme Substrate; Hach;~~  ~~Presence-Absence~~ | ~~Automated Electrode; Colilert/Idexx;~~  ~~Colisure/Idexx; Conductivity Meter;~~  ~~HPC; Plate Count~~ |
| **~~II~~** | ~~Amperometeric;~~  ~~Auto Colorimetric;~~  ~~Cd Reduction Auto;~~  ~~Cd Reduction Manual;~~  ~~Electrometric; FIA;~~  ~~Gravimetric;~~  ~~Multiple Tube Fermentation;~~  ~~Nephelometric; Potentiometric;~~  ~~Titrimetric; Turbidimetric~~ | ~~Amperometric;~~  ~~Amperometric (low level);~~  ~~Auto Color no distill;~~  ~~Automated Colorimetric;~~  ~~Automated Reduction; Back titration;~~  ~~Colorimetric; DPD-FAS; Electrometric; Enterolert/Idexx; Gravimetric;~~  ~~Iodometric direct; MTF; MTF/EC-Mug;~~  ~~Nephelometric; Semi Auto Color no distill;~~  ~~Spectrophotometric; Thermometric;~~  ~~Titrimeteric; Titrimetric; Visual Comparison;~~  ~~Volumetric~~ |
| **~~III~~** | ~~AA Furnace; AA Manual Hydride; Automated Colorimetric; Cold Vapor (Automated); Cold Vapor (Manual); Cold Vapor AA;~~  ~~Combustion; Membrane Filter; Membrane Filter (Delayed); Membrane Filter (Two Step); Oxidation;~~  ~~Spectrophotometric; STGFAA~~ | ~~AA Chelation; AA Continuous Hydride;~~  ~~AA Direct Aspiration; AA Furnace;~~  ~~AA gaseous hydride; AA Manual Hydride;~~  ~~Adsorption and Coulometric Titration; Auto Ascorbic acid; Cd Reduction Manual;~~  ~~CIE/UV; Cold Vapor (Automated); Cold Vapor (Manual); CVAFS; Digestion & FIA;~~  ~~Electrode; Flame Photomteric; Gravimetric at 550°; Macro kjeldahl; Manual Ascorbic acid; Manual Colorimetric; Manual Distillation; Manual two reagent; MF; MF/mEI; MF/modified mTEC; Micro kjeldahl; MTF/A-1 media; MTF/LTB & EC media; Phenate Automated; Phenate Manual; Potentiometric; Purge & Trap CVAFS; Semi Auto Colorimetric; STGFAA~~ |
| **~~IV~~** | ~~ICP-AES; AA Direct Aspiration; AA or ICP; Filtration/IMS/FA; GC-ECD;~~  ~~GC-ELCD/PID; GC-MS;~~  ~~GC-NPD; HPLC; HRGC-HRMS; IC-ESI-MS/MS;~~  ~~IC-MS; IC-MS-MS; ICP-MS;~~  ~~Ion Chromatography; LC-MS; Semi Auto Colorimetric~~ | ~~AA or ICP; FIA; GC; GC-ECD; GC-ECD/ELCD; GC-ECD/FID; GC-ELCD;~~  ~~GC-ELCD; GC-FID; GC-FID/ECD; GC-FPD; GC-MS; GC-NPD; GC-PID; HPLC;~~  ~~HPLC or GC; IC; ICP-AES; ICP-MS;~~  ~~Ion Chromatography;~~ |

(b) An employee of a water or wastewater treatment facility, who holds a valid CWEA or CA-NV/AWWA Laboratory Analyst/Water Analyst certification, shall be deemed to meet the qualifications of Technical Manager if the level of certification has educational and experience requirements appropriate to the nature and size of the facility and the scope of analytical testing in the facility’s regulatory permit.

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

(1) A Technical Manager who was employed by an environmental testing laboratory at the time that the laboratory was 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 – Rev 2.1, Volume 1, Module 2, Sections 4.1.7.2 (with the exception of part [f]) ~~and 4.2.6~~; or

(2) Be responsible for:

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

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

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

(e) Subdivision (d)(2), above, will become invalid three (3) years after adoption of these regulations, and laboratories will be required to meet the TNI Standard in subdivision (d)(1), above.

~~(f) Sophisticated Technology in the laboratory shall be operated by either the Technical Manager or other personnel as designated by the Technical Manager.~~

(~~g~~f) If a Technical Manager is absent for a period of time exceeding ~~15 consecutive days, a person meeting the qualifications of the Technical Manager shall be designated to serve as a temporary Technical Manager~~:

(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) If a Technical Manager is absent for a period of time exceeding 15 consecutive days, a person meeting the qualifications of the Technical Manager shall be designated to serve as a temporary Technical Manager.~~

~~(1) If a Technical Manager is absent for a period of time exceeding 35 consecutive days, ELAP shall be notified in writing.~~

~~(h) A laboratory shall designate a quality manager. The quality manager, and/or their designee, shall comply with 2016 TNI Standard, 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~~g) Three (3) years from the adoption of these regulations, a laboratory shall designate a Quality Manager. The Quality Manager, and/or their designee, shall comply with 2016 TNI Standard – Rev 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 laboratory instruments, defined in Section 64801.00 (q), or a supervisor of the users of sophisticated laboratory instruments. The Principal Analyst shall:

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

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

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

~~(i) Laboratory personnel shall meet the education and experience requirements decided by laboratory management in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 5.2 (excluding 5.2.6).~~

(i) Subdivision (h), above, will become invalid three (3) years after adoption of these regulations, at which time laboratories will be required to meet 2016 TNI Standard – Rev 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:

*Adopt Section 64812.05 to read as follows:*

**§ 64812.05 Laboratory Facility and Equipment.**

(a) A laboratory facility shall:

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

(2) ~~The laboratory shall~~ 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 ~~Assurance~~ 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 ~~Assurance~~ 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 after adoption 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, General Industry Safety Orders, Department of Industrial Relations.

(d) A laboratory shall dispose of chemical wastes and maintain records of disposal in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for Management of Hazardous Wastes, State of California, Department of Health Services ~~and maintain records of disposal~~.

(e) When there is a change of Sophisticated Technology the laboratory shall:

(1) Update the Quality ~~Assurance~~ Manual ~~that differs because of~~ necessitated by the change of sophisticated technology;

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

(3) ~~Where applicable, comply with 2016 TNI Standard, Volume 1, Modules 3 through 7~~ Submit an amendment application package in accordance with 64808.15(g), if the sophisticated technology is new to the laboratory; and

(4) ~~Achieve acceptable scores in a Proficiency Testing study for any Field(s) of Accreditation affected by the change of instrumentation, where Proficiency Testing studies exist; and~~ Retain all records necessary to determine compliance with this subdivision and provide these records to ELAP upon request.

~~(5) Retain all records necessary to determine compliance with this subdivision and provide these records upon request from ELAP. Records shall be maintained for a minimum of five years.~~

Note: Authority cited:

*Amend Title of Article 6*

**Article 6. ~~Required Test Methods~~ Notification, Reporting, Records Retention, Change of Technical Manager or Ownership, and Trade Secrets.**

*Repeal Section 64811*

~~§ 64811. Test Methods.~~

~~(a) Laboratories certified for any Subgroup within Fields of Testing 1 through 6, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 141 as amended July 17, 1992, 57 Federal Register 31776.~~

~~(b) Laboratories certified for any Subgroup within Fields of Testing 9 through 14, as identified in Section 64823, shall employ those methods found in Article 5, Section 66260.11, Title 22, California Code of Regulations.~~

~~(c) Laboratories certified for any Subgroup within Fields of Testing 8 or 16 through 19, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 136, amended September 11, 1992, 57 Federal Register 41830, or methods stated in any permit issued by a California Regional Water Quality Control Board. If no method is stated in the permit and there is no method cited for the substance in Part 136, the laboratory is to seek approval for the use of the method from the Regional Board issuing the permit.~~

~~(d) Laboratories certified for any Subgroup within Fields of Testing 20, 21 or 22, as identified in Section 64823, shall develop and employ analytical confirmation procedures for the verification of pesticide identification and quantification.~~

~~(e) Laboratories certified in any Subgroup within Field of Testing 7, as identified in Section 64823, shall employ those methods found in either "Recommended Procedures for the Examination of Sea Water and Shellfish", 4th edition, 1970, American Public Health Association (APHA); or "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th edition, 1984, AOAC, Arlington, Virginia. Laboratories certified in any Subgroup within Filed of Testing 15, as identified in Section 64823, shall employ methods which were submitted to the Department at time of application for certification, or at time of request to add a Subgroup within a Field of Testing and which have been approved by the Department for use in the laboratory.~~

~~(f) Laboratories may substitute alternate test methods for those allowed by (a) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process, or shall obtain a waiver from the Environmental Laboratory Accreditation Program (ELAP), prior to implementing any substitution. ELAP may grant a waiver when a State Maximum Contaminant Level (MCL) is more stringent than a federal MCL or no State MCL exists and when ELAP determines that the test method the laboratory proposes to use is one for which that laboratory was previously ELAP certified. A waiver shall be valid until a~~

~~new State MCL is adopted for the analyte being detected by the method.~~

~~(g) Laboratories may substitute alternate test methods for those allowed by (b) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the California Environmental Protection Agency, Hazardous Materials Laboratory, Berkeley, California prior to implementing any substitutions.~~

~~(h) Laboratories may substitute alternate test methods for those allowed by (c) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process prior to implementing any substitution.~~

~~(i) Laboratories seeking certification for the subgroups consisting of fecal coliform or Escherichia coli (E. coli) organism technics, must also obtain, or hold, certification for the subgroups consisting of the same technic for total coliform organisms.~~

~~(j) To gain certification for individual radioactive elements or isotopes, except for uranium by fluorimetric technics, a laboratory shall obtain certification for gross alpha and beta radiation testing.~~

~~(k) A laboratory may seek certification, or hold certification for Field of Testing 11 without seeking or holding certification in Fields of Testing 10, 12, or 13. However, the laboratory shall submit all resulting preparations from the use of any of the subgroup members of Field of Testing 11 to a laboratory certified for Fields of Testing 10, 12, or 13.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1012, 1017 and 28503, Health and Safety Code; Section 12901, Title 22, California Code of Regulations; Appendices I, II and III of Article 5 (commencing with Section 66261.100), Title 22, California Code of Regulations.~~

*Adopt Section 64814.00 to read as follows:*

**§ 64814.00 Notification, Reporting, and Control of Records.**

(a) A laboratory shall comply with all applicable requirements of state or federal regulatory agencies that data is being reported to, including notification ~~and~~, reporting, and record retention requirements.

(b) ~~For the purposes of this Section “Approval” refers to the approval of the results by the laboratory’s Technical Manager or designee, as set forth in the laboratory’s Quality Assurance Manual~~ If an analytical result warrants a client notification, then the notification shall occur when the Technical Manager or designee, set forth in the laboratory’s Quality Manual, has approved of the result.

~~(c) Each laboratory shall establish and maintain records in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 4.13.~~

(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) A laboratory shall report to its clients in accordance with the request for analysis, the full and complete results of all detected contaminants and pollutants from the analyses of the sample or components thereof.~~

(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 Board. If requested by the State Board, the laboratory shall provide a record of the time and method of attempts to contact the water supplier.

~~(e) A laboratory shall comply with reporting requirements in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 5.10.~~

(e) If a water supplier is requesting the State 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 report with a root cause analysis of the laboratory accident or error. If finding(s) are not correctable within thirty (30) days, a laboratory shall submit a corrective action plan, identifying 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 – Rev 2.1, Volume 1, Module 2, Section 4.5; or

(2) ~~The subcontractor shall be accredited by ELAP in the Field(s) of Accreditation for the tests to be performed; and~~ 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) 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.~~

(g) Subsection (f)(2), above, will be invalid three (3) years from the adoption of these regulations, at which time laboratories will be required to meet the TNI Standard in subdivision (f)(1), above.

~~(h) A laboratory accredited to perform analyses on drinking water samples shall:~~

~~(1) Notify a water supplier's designated contact person immediately within 24 hours, whenever any of the following occur:~~

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

~~(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) Notify a water supplier’s designated contact person immediately within 48 hours, whenever any of the following occur:~~

~~(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.~~

~~(3) Notify the State Board if the laboratory is unable to make direct contact with the water supplier's designated contact person immediately within 24 hours, in accordance with subdivision (h)(1) of this Section, or 48 hours in accordance with subdivision (h)(2) of this Section. If requested by the State Board the laboratory shall provide a record of the time and method of attempts to contact the water supplier.~~

~~(4) Submit a Bacterial Monitoring Report to the State Board when reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1, including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3).~~

~~(5) Report to the State Board analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, electronically using the 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 as defined in the Environmental Information Exchange Network’s Electronic Drinking Water Report Version 3.0 (eDWR V3.0), or by means of Web services, Templates or On-Line Web forms as directed and approved by the State Board, by the 10th day of the month following the month in which the analyses were completed.~~

~~(6) Report directly to the State Board analytical results conducted pursuant to 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 by the 10th day of the month following the month in which the analyses were completed. In the event that the State Board is not able to accept those results for specific analytes electronically as set forth in subdivision (h)(5), above, results shall be submitted on paper or hard copy, or as otherwise directed by the State Board.~~

~~(7) Provide a water supplier with the following whenever a laboratory agrees to a request by the water supplier to invalidate a sample due to laboratory accident or error, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2):~~

~~(A) A letter from the laboratory Technical Manager to the water supplier agreeing to the invalidation request;~~

~~(B) 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;~~

~~(C) A complete description of the error alleged to have invalidated the result(s);~~

~~(D) Copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and~~

~~(E) A Corrective Action Report in accordance with 2016 TNI Standard, Volume 1, Module 2, Section 4.11. If a finding is not correctable within 30 days, a laboratory shall submit a Corrective Action Plan as part of the Corrective Action Report, identifying the date by which the finding will be corrected.~~

(h) A laboratory shall report to clients:

(1) In accordance with 2016 TNI Standard – Rev 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 adoption of these regulations, at which time laboratories will be required to meet the TNI Standard in subdivision (h)(1), above.

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

(k) A laboratory shall report analytical results to the State Board conducted in accordance with Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, by the 10th day of the month following the month in which the analyses were completed. The results shall be reported electronically using the following:

(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;

(2) A format defined by Environmental Information Exchange Network’s Electronic Drinking Water Report Version 3.0 (eDWR V3.0); or

(3) Web services, templates or on-line web forms as directed and approved by the State Board.

(l) A laboratory shall report directly to the State Board analytical results conducted pursuant to 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 by the 10th day of the month following the month in which the analyses were completed. If the State 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 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 – Rev 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 adoption of these regulations, at which time laboratories will be required to meet the TNI Standard in subdivision (n)(1), above.

Note: Authority cited:

*Adopt Section 64814.05 to read as follows:*

**§ 64814.05 Notification of Change of Technical Manager or Change of 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 ~~at a minimum~~:

(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; ~~and~~

(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) ~~Date signed~~ Signature date.

(b) When the ownership of a laboratory ~~has been~~ is sold or ~~otherwise~~ transferred, the new owner may request to operate under the laboratory’s existing ELAP certificate as ~~provided for~~ stated in Health and Safety Code Section 100845 subdivisions (b) and (c).

(c) To request to operate under the laboratory’s existing ELAP certificate ~~shall be granted when the following have occurred~~, 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 as determined by the State Board. The written request shall include:

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

~~(2) If ELAP, at its discretion, has conducted an on-site assessment, the laboratory has responded to any identified findings and received ELAP’s approval of the response.~~

(2) Effective date of the change ~~of~~ in ownership;

(3) ~~Final date requested for extension of existing ELAP certificate~~ Name(s) and qualifications of current Technical Manager;

(4) Name of current Quality Manager;

(5) Statement that the new owner will operate pursuant to the laboratory’s existing Quality ~~Assurance~~ 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:

(A) An updated Quality ~~Assurance~~ Manual; and

(B) Proficiency Testing report(s) with ~~acceptable scores for any Field(s) of Accreditation affected by the change, where Proficiency Testing studies exist. If there are no existing Proficiency Testing studies, ELAP may require an alternative demonstration of capability~~ Field(s) of Proficiency Testing scores for each Field of Accreditation affected by the change in ownership;

(6) Statement that the laboratory will remain in ~~its~~ the existing location;

(7) Statement that the new owner ~~will retain~~ has retained more than half of laboratory personnel upon assuming ownership;

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

(9) Statement that the new owner will comply with ~~all~~ applicable laws and regulations;

(10) Signature of the ~~laboratory~~ new owner, corporate officer authorized to act on behalf of the ~~laboratory~~ 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

(11) ~~Date signed~~ Signature date.

(d) 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 64802.25.

Note: Authority cited:

*Adopt Section 64814.10 to read as follows:*

**§ 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

*Amend Title of Article 7*

**Article 7. ~~Laboratory and Equipment~~ Reasons for Denial, Citation, Suspension, or Revocation.**

*Repeal Section 64813*

~~§ 64813. Laboratory and Equipment.~~

~~(a) A laboratory shall be arranged and operated so that:~~

~~(1) utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Subgroup within each Field(s) of Testing for which the laboratory is certified;~~

~~(2) ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond establish quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual;~~

~~(3) the design, arrangement, and operation of the laboratory minimizes the potential for sample contamination;~~

~~(4) the storage and handling of hazardous materials in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders, Department of Industrial Relations; and~~

~~(5) the disposal of chemical wastes is in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Wastes, State of California, Department of Health Services.~~

~~(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory.~~

~~(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory as required by the manufacturer's maintenance instructions for the equipment.~~

~~(d) Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Section 1012, Health and Safety Code; California Code of Regulations, Title 8; and Title 22, Division 4, Chapter 30, California Code of Regulations.~~

*Adopt Section 64816.00 to read as follows:*

**§ 64816.00 ~~Denying, Suspending, or Revoking~~ Denial of Accreditation.**

(a) Reasons for denying a laboratory’s application for accreditation shall include:

(1) A laboratory fails to submit a complete application package in accordance with Section 64802.05;

(2) A laboratory fails to implement a quality system ~~pursuant to~~ in accordance with Section 64802.10;

~~(3) The laboratory fails to analyze and report acceptable scores in Proficiency Testing samples in accordance with Section 64802.20;~~

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

~~(4) The laboratory fails to pass a required on-site assessment in accordance with Section 64802.25;~~

(4) A laboratory fails to analyze or report acceptable scores of Field(s) of Proficiency Testing samples in accordance with Section 64802.20;

~~(5) The laboratory fails to respond to an On-Site Assessment Report with a Corrective Action Report in accordance with Section 64802.25;~~

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

~~(6) The laboratory fails to implement the corrective actions detailed in the Corrective Action Report within the required timeframe in accordance with Section 64802.25;~~

(6) A laboratory fails to complete a required on-site assessment in accordance with Section 64802.25;

~~(7) The laboratory fails to pay fees in accordance with Section 64802.30;~~

(7) A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.25;

~~(8) The laboratory staff do not meet the personnel qualifications in accordance with Section 64812.00;~~

(8) A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.25;

~~(9) The laboratory submits, as its own, Proficiency Testing sample results generated by another laboratory;~~

(9) A laboratory fails to pay fees as determined by the State Board;

~~(10) The laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;~~

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

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

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

~~(12) The laboratory knowingly makes any false statement or representation in any application, record, or other document; and/or~~

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

~~(13) The laboratory fails to comply with any other provision of these regulations.~~

(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) Reasons for suspending or revoking accreditation shall include:~~

~~(1) The laboratory fails to maintain a quality system in accordance with Section 64802.10;~~

~~(2) The laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.20;~~

~~(3) The laboratory fails to pass an on-site assessment in accordance with Section 64802.25;~~

~~(4) The laboratory fails to respond to an On-Site Assessment Report with a Corrective Action Report in accordance with Section 64802.25(f);~~

~~(5) The laboratory fails to implement the corrective actions detailed in the Corrective Action Report within the required timeframe;~~

~~(6) If, during an on-site assessment, ELAP determines that suspension or revocation is necessary to protect public interest, safety or welfare;~~

~~(7) The laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;~~

~~(8) The laboratory fails to pay fees;~~

~~(9) The laboratory fails to complete Proficiency Testing studies as required;~~

~~(10) The laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.10(c)(d) and (e);~~

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

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

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

~~(14) The laboratory knowingly makes any false statement or representation in any application, record, or other document; and/or~~

~~(15) The laboratory fails to comply with any other provision of these regulations.~~

~~(c) If a laboratory’s accreditation for a Field(s) of Accreditation has been suspended, the laboratory shall cease all reporting of results for regulatory purposes for the Field(s) of Accreditation that were suspended.~~

~~(d) If a laboratory’s accreditation has been revoked, the laboratory shall:~~

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

~~(2) Return its original ELAP certificate;~~

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

~~(4) Notify all California regulatory clients of its revocation status within three days of receiving notice of revocation from ELAP;~~

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

~~(6) Discontinue use of subcontracting agreements with other ELAP accredited laboratories within seven days of receiving notice of revocation from ELAP.~~

~~(e) To be reinstated after revocation, the laboratory shall apply for initial accreditation as if it were a new laboratory.~~

*Adopt Section 64816.05 to read as follows:*

**§ 64816.05 Issuance of a Citation.**

(a) Reasons for issuing a citation shall include:

(1) A laboratory fails to maintain a quality system in accordance with Section 64802.10;

(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 64802.20;

(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.25;

(5) A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.25;

(6) A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.25;

(7) A laboratory fails to pay fees determined by the State Board;

(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.

*Adopt Section 64816.10 to read as follows:*

**§ 64816.10 Suspension or Revocation of Accreditation.**

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

(1) A laboratory fails to maintain a quality system in accordance with Section 64802.10;

(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 64802.20;

(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.25;

(5) A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.25;

(6) A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.25;

(7) If, during an on-site assessment, ELAP determines that suspension or revocation 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 determined by the State Board;

(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) If a laboratory’s accreditation for a Field(s) of Accreditation is suspended, the laboratory shall cease all reporting of results for regulatory purposes for the Field(s) of Accreditation that were suspended.

(c) To be reinstated from suspension of accreditation, a laboratory must submit a renewal application package in accordance with 64808.05.

(d) 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 accreditation certificate to ELAP;

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

(4) Notify all regulatory clients of the revocation status within three (3) days of receiving notice of revocation from ELAP;

(5) Provide ELAP with a list of regulatory 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.

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

Note: Authority cited:

*Repeal Article 8*

~~Article 8. Quality Assurance Documents.~~

~~§ 64815 Quality Assurance.~~

~~(a) Each laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality assurance program manual.~~

~~(b) The quality assurance program manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.~~

~~(c) The Laboratory Director shall review, and amend if necessary, the quality assurance program and quality assurance program manual at least annually. The Laboratory Director shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.~~

~~(d) A laboratory shall maintain records of the implementation of its quality assurance program, and provide those records upon request of the Department. Records shall be maintained for a minimum of three years.~~

~~(e) This section shall become inoperative January 1, 2022.~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Section 1012, Health and Safety Code.~~

*Repeal Article 9*

~~Article 9. Laboratory Personnel.~~

~~§ 64817. Laboratory Personnel.~~

~~(a) Each laboratory shall designate a Laboratory Director. Except as provided in (b) below, no person shall be designated as a Laboratory Director unless he or she meets the following educational and experience requirements.~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science.~~

~~(2) Has at least three years experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples. The experience requirement shall be satisfied from relevant work experience prior to the person having obtained the position of Laboratory Director. A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public hearing engineering, natural or physical science may be substituted for one year of the required experience. A doctorate in chemistry, biochemistry, environmental, sanitary or public hearing engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.~~

~~(b) Laboratory Directors of utility-owned water or wastewater treatment plant laboratories performing any of the analyses required under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Laboratory Director by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

~~Minimum Certificate Fields of Testing Grade Required 1, 2 [FNa1] and 16 [FNaa1] I~~

~~1, 2, 8 and 16 II 3, 5, 17 and 19 plus those~~

~~allowed for a grade II III 4, 6, and 18 plus those~~

~~allowed for a grade III IV~~

~~[FNa1] Limited to testing for: alkalinity, chloride, hardness, total filterable residue, and conductivity.~~

~~[FNa2] Limited to testing for: acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, nonfilterable residue, settleable residue, volatile residue, specific conductance, and turbidity.~~

~~(c) All Laboratory Directors of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (a) or (b) above.~~

~~(d) A Laboratory Director shall be responsible for:~~

~~(1) all analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities; and~~

~~(2) supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities, and those persons designated as Principle Analysts; and~~

~~(3) the accuracy and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.~~

~~(e) If, for any reason, a Laboratory Director leaves and is not replaced within 15 days by a person meeting the requirements specified in (a) or (b), whichever applies, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies the Department, pursuant to Section 1014(d) of the Health and Safety Code, describing the qualifications of the temporary director and receives written confirmation from the Department. An additional~~

~~extension of no more than ninety days beyond the original 90-day period may be granted by the Department, provided the laboratory can document that its good-faith efforts to recruit a qualified director were unsuccessful for reason beyond its control.~~

~~(f) A Laboratory Director shall assume the position of, or shall designate another person as Principal Analyst whenever there is use of a sophisticated laboratory instrument as defined in Section 64801(k). No person shall be a Principal Analyst for a laboratory unless he or she is:~~

~~(1) the user of the sophisticated laboratory instrument; or~~

~~(2) the supervisor of the users of the sophisticated laboratory instrument.~~

~~(g) Except as provided in (h) below, no person shall be a Principal Analyst unless he or she meets the following educational and experience requirements.~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science; or~~

~~(2) Possesses a certification of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used or supervised by the Principal Analyst; and~~

~~(3) Has at least six months experience in the operation of a sophisticated laboratory instrument in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples, or food. This experience requirement must be satisfied from experience gained prior to obtaining the position of Principal Analyst.~~

~~(h) Principal Analysts of utility-owned water or wastewater treatment plant laboratories performing any analyses under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Principal Analyst by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

~~Minimum Certificate~~

~~Fields of Testing Grade Required~~

~~1, 2 and 16 I~~

~~8 plus those allowed for~~

~~a Grade I II~~

~~3, 5, 17 and 19 plus those~~

~~allowed for a grade II III~~

~~4, 6, and 18 plus those~~

~~allowed for a grade III IV~~

~~(i) All Principal Analysts of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (g) or (h) above.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Section 1012, Health and Safety Code.~~

*Repeal Article 10*

~~Article 10. Notification and Reporting.~~

~~§ 64819. Notification and Reporting.~~

~~(a) Laboratories certified for Field of Testing 1, 2, 3, 4, 5, or 6 shall conform to the following reporting and notification requirements.~~

~~(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.~~

~~(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:~~

~~(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.~~

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

~~(C) A nitrate sample exceeds the MCL.~~

~~(3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraphs (2)(A) or (C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.~~

~~(4) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the 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, by the 10th day of the month following the month in which the analyses were completed.~~

~~(5) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:~~

~~(A) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;~~

~~(B) 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;~~

~~(C) complete description of the error alleged to have invalidated the result(s);~~

~~(D) copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and~~

~~(E) any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.~~

~~(b) Laboratories certified for Fields of Testing 20, 21, or 22 shall verify the identity and quantity of a pesticide residue before reporting the results. The confirmation procedures must conform to those in Section 64811(d) of this Chapter.~~

~~(c) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) prepared by all other laboratories who are party to the agreement.~~

~~Note: Authority cited: Sections 100275, 100830, 100835 and 116375, Health and Safety Code. Reference: Sections 100825(b) and 100835, Health and Safety Code.~~

*Repeal Article 11*

~~Article 11. Reciprocity Agreements.~~

~~§ 64821. Reciprocity Agreements.~~

~~(a) Another State's, or a United States agency's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if the program requires:~~

~~(1) periodic analyses of performance evaluation samples by the participating laboratories with the frequency of submittal, the method of evaluation, and the~~

~~established acceptance limits at least equal to those established in Section 64809 of this Chapter;~~

~~(2) on-site evaluation of participating laboratories during which the laboratory is reviewed under criteria at least equal to that established in Section 64807 of this Chapter;~~

~~(3) standards for quality assurance, laboratory facilities, test methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Sections 64811, 64813, 64815, and 64817 of this Chapter.~~

~~(b) Where reciprocity exists, each laboratory seeking California certification shall submit:~~

~~(1) an application pursuant to Section 64805(a) of this Chapter;~~

~~(2) copies of the results evaluated, or scored, from the last performance evaluation sample testing conducted by the laboratory for the other program;~~

~~(3) copies of the last on-site evaluation report prepared by the other program and the laboratory's response to any deficiencies noted;~~

~~(4) all applicable fees pursuant to Health and Safety Code, Section 1017(a); and~~

~~(5) a copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other agency.~~

~~(c) When a reciprocity agreement exists between the Department and another State, only those laboratories that reside within the boundaries of the other State shall be eligible for certification through reciprocity.~~

~~(d) If a reciprocity agreement with another State, or U.S. government agency is revoked, all certificates issued by the Department to all affected laboratories shall remain valid until the stated expiration date.~~

~~(e) No fees are waived where reciprocity exists.~~

~~(f) A laboratory certified under reciprocity may be visited or issued performance evaluation samples by the Department for the purposes of addressing questions or concerns on quality of results raised by any California government agency who has received a report from the laboratory. Applicable performance evaluation sample costs, pursuant to Section 1017(f) or travel costs pursuant to Section 1017(b) of the Health and Safety Code shall be paid.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1011 and 1017, Health and Safety Code.~~

*Repeal Article 12*

~~Article 12. Subgroups for Fields of Testing~~

~~§ 64823. Fields of Testing.~~

~~(a) Field of Testing 1 consists of those methods whose purpose is to detect the presence of microorganisms in the determination of drinking water or wastewater quality and encompasses the following Subgroups: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Membrane Filter technics; Heterotrophic Plate Count technics; detection of both total coliforms and Escherichia coli (E. coli) organisms by the Minimal Medium ortho-nitrophenyl-beta-D- galactopyranoside - 4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by use of Clark's Presence/Absence medium; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics, Fecal streptococci and Enterococci by Membrane Filter technics; detection of total coliforms and fecal coliforms other than for drinking water or wastewater quality.~~

~~(b) Field of Testing 2 consists of those analytes or methods whose purpose is to detect the presence of inorganic substances in the determination of drinking water quality and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technic; and encompasses the following Subgroups: alkalinity; calcium (titrimetric technics); chloride; corrosivity; fluoride; hardness (direct determination); magnesium (titrimetric technics); methylene blue active substances (MBAS); nitrate; nitrite; sodium (flame emission technics); sulfate; total filterable residue and conductivity; iron; manganese; orthophosphate; silica; cyanide; potassium (flame emission technics).~~

~~(c) Field of Testing 3 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of drinking water quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: arsenic; barium; cadmium; total chromium; copper; iron; lead; manganese; mercury; selenium; silver; zinc; aluminum; asbestos; antimony; beryllium; nickel; thallium; calcium; magnesium; sodium; potassium.~~

~~(d) Filed of Testing 4 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 524.2 for volatile organics; EPA method 501.3 for trihalomethanes; EPA method 525 for acid and base/neutral compounds; EPA method 513 for dioxins; EPA method 1613 for dioxins.~~

~~(e) Field of Testing 5 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 501.1 for trihalomethanes; EPA method 501.2 for trihalomethanes; EPA method 510 for total trihalomethanes; EPA~~

~~method 508 for chlorinated pesticides; EPA method 515.1 for chlorophenoxy herbicides; EPA method 502.1 for halogenated volatiles; EPA method 503.1 for aromatic volatiles; EPA method 502.2 for both halogenated and aromatic volatiles; EPA method 504 for EDB and DBCP; EPA method 505 for chlorinated pesticides and polychlorinated biphenyls; EPA method 507 for the haloacids; EPA method 531.1 for carbamates; EPA method 547 for glyphosate; EPA method 506 for adipates and phthalates; EPA method 508A for total polychlorinated biphenyls; EPA method 548 for endothall; EPA method549 for diquat and paraquat; EPA method 550 for polycyclic aromatic hydrocarbons; EPA method 550.1 for polycyclic aromatic hydrocarbons; EPA method 551 for chlorination disinfection byproducts; EPA method 552 for haloacetic acids.~~

~~(f) Field of Testing 6 consists of those methods whose purpose is to detect the presence of radioactive substances in drinking water, wastewater, or hazardous wastes; and encompasses the following Subgroups: gross alpha and beta radiation; total radium; radium 226; uranium; radon 222; radioactive cesium; iodine 131; radioactive strontium; tritium; gamma emitting isotopes; gross alpha by coprecipitation; radium 228; radioactive iodine; gross alpha and beta radiation in hazardous wastes; alpha emitting radium isotopes in hazardous wastes; radium 228 in hazardous wastes.~~

~~(g) Field of Testing 7 consists of those methods whose purpose is to detect the presence of microbial contamination or toxins in the determination of shellfish meat quality and encompasses the following Subgroups: shellfish meat microbiology; paralytic shellfish poison (PSP) and other marine biotoxins; microbiology of shellfish growing waters.~~

~~(h) Field of Testing 8 consists of those methods whose purpose is to detect the presence of toxins in the determination of wastewater quality, or in hazardous wastes and encompasses the following Subgroups: hazardous waste testing pursuant to Title 22, California Code of Regulations, Section 66261.24(a)(6); wastewater testing according to Kopperdahl (1976) using freshwater fish; wastewater testing according to EPA/600/4-85/013 using freshwater and/or marine organisms; wastewater testing by EPA method 1000.0; wastewater testing by EPA method 1002.0; wastewater testing by EPA method 1003.0; wastewater testing by EPA method 1006; wastewater testing by EPA method 1007; wastewater testing by EPA method 1009; wastewater testing according to Anderson, et al. (1990) using Giant Kelp (Macrocystis pyrifera); wastewater testing according to Anderson, et al. (1990) using red abalone (Haliotus rufescens); wastewater testing according to Dinnel and Stober (1987) using purple sea urchin (Strongylocentrotus purpuratus); wastewater testing according to Dinnel and Stober (1987) using red sea urchin (Strongylocentrotus franciscanus); wastewater testing according to Dinnel and Stober (1987) using sand dollar (Dendraster excentricus); wastewater testing according to procedure E 724-89 (ASTM, 1989) using Pacific oyster (Crassostrea gigas); wastewater testing according to procedure E 724-89 (ASTM, 1989) using California Bay Mussel (Mytilus edulis); wastewater testing according to procedure E 1218-90 (ASTM, 1990) using an alga (skeletonema costatum); wastewater testing according to EPA/600/4-90/027 using freshwater and/or marine organisms.~~

~~(i) Field of Testing 9 consists of those methods whose purpose is to detect physical~~

~~properties of hazardous wastes for regulatory purposes and encompasses the following Subgroups: ignitability; corrosivity by pH determination; corrosivity by corrosivity towards steel; reactivity.~~

~~(j) Field of Testing 10 consists of those methods whose purpose is to detect the presence of inorganic substances in hazardous waste samples and encompasses the following Subgroups: antimony; arsenic; barium; beryllium; cadmium; chromium, total; cobalt; copper; lead; mercury; molybdenum; nickel; selenium; silver, thallium; vanadium; zinc; chromium (VI); cyanide; fluoride; sulfide; total organic lead.~~

~~(k) Field of Testing 11 consists of those methods whose purpose is to prepare samples of hazardous wastes for further testing and encompasses the following Subgroups: California waste extraction test (WET); extraction procedure toxicity (EP TOX); toxicity characteristic leaching procedure (TCLP), all phases; TCLP, extraction of inorganics only; TCLP, extraction of semivolatile organics only; TCLP, extraction of volatile organics only.~~

~~(l) Field of Testing 12 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8240 for volatile compounds; EPA method 8250 for semivolatile compounds; EPA method 8270 for semivolatile compounds; EPA method 8280 for dioxins, EPA method 8290, EPA method 8260.~~

~~(m) Field of Testing 13 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8010 for halogenated volatiles; EPA method 8015 for nonhalogenated volatiles; EPA method 8020 for aromatic volatiles; EPA method 8030 for acrolein, acrylonitrile, acetonitrile; EPA method 8040 for phenols; EPA method 8060 for phthalate esters; EPA method 8080 for organochlorine pesticides or polychlorinated biphenyls; EPA method 8090 for nitroaromatics and cyclic ketones; EPA method 8100 for polynuclear aromatic hydrocarbon; EPA method 8130 for polynuclear aromatic hydrocarbons; EPA method 8120 for chlorinated hydrocarbons; EPA method 8140 for organophosphorus pesticides; EPA method 8150 for chlorinated herbicides; EPA method 632 for carbamates; total petroleum hydrocarbons - gasoline (LUFT manual); total petroleum hydrocarbons - diesel (LUFT manual); EPA method 8011; EPA method 8021; EPA method 8070; EPA method 8110; EPA method 8141; EPA method 8330; EPA method 8080 for PCBs only; EPA method 8080 for chlorinated pesticides only.~~

~~(n) Field of Testing 14 consists of those methods whose purpose is to detect the presence of asbestos for purposes of complying with the provisions of Title 22, California Code of Regulations, Section 66261.24(a)92)(A) and encompasses the following Subgroups: asbestos by polarized light microsopy.~~

~~(o) Field of Testing 15 shall be any method whose purpose is to detect the presence of any analyte found in the list of substances regulated by the California Safe Drinking~~

~~Water and Toxic Enforcement Act in drinking water, wastewater, hazardous wastes, and contaminated soils or sediments, but which method is not within any subgroup of any other Field of Testing cited in this section.~~

~~(p) Field of Testing 16 consists of those methods whose purpose is to detect the presence of inorganic substances, nutrients, physical or chemical demands, or physical properties in the determination of wastewater quality, and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technics and encompasses the following Subgroups: acidity; alkalinity (includes determination of bicarbonate, carbonate, & hydroxide); ammonia; biochemical oxygen demand (BOD); boron; bromide; calcium (titrimetric technics); carbonaceous biochemical oxygen demand (cBOD); chemical oxygen demand (COD); chloride; chlorine residual, total; cyanide; cyanide amenable to chlorination; fluoride; hardness (direct determination); kjeldahl nitrogen (includes determination of organic nitrogen); magnesium (titrimetric technics); nitrate; nitrite; oil and grease; organic carbon; oxygen, dissolved, pH; phenols; phosphate ortho; phosphorus, total; potassium (flame emission technics); residue, total; residue, filterable (total dissolved solids); residue, nonfilterable (total suspended solids); residue, settleable (settleable solids); residue, volatile; silica; sodium (flame emission technics); specific conductance; sulfate; sulfide (includes total and soluble); sulfite; surfactants (MBAs); tannin and lignin; turbidity; iron; manganese; total recoverable hydrocarbons by EPA method 418.1; total organic halides.~~

~~(q) Field of Testing 17 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of wastewater quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: aluminum; antimony; arsenic; barium; beryllium; cadmium; chromium (VI); chromium, total; cobalt; copper; gold; iridium; iron; lead; manganese; mercury; molybdenum; nickel, osmium; palladium; platinum; rhodium; ruthenium; selenium; silver; strontium; thallium; tin; titanium; vanadium; zinc; asbestos; calcium; magnesium; potassium; sodium.~~

~~(r) Field of Testing 18 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 624 for volatile organics; EPA method 625 for acid and base/neutral compounds; EPA method 1613 for dioxins; EPA method 1625 for dioxins; EPA method 613.~~

~~(s) Field of Testing 19 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 601 for halogenated volatiles; EPA method 602 for aromatic volatiles; EPA method 603 for acrolein, acrylonitrile, acetonitrile; EPA method 604 for phenols; EPA method 605 for benzidine; EPA method 606 for phthalate esters; EPA method 607 for nitrosoamines; EPA method 608 for organochlorine pesticides or polychlorinated biphenyls; EPA method 609 for nitroaromatics and cyclic ketones; EPA method 610 for polynuclear aromatics; EPA method 612 for haloethers; EPA method 632 for carbamates; EPA method 619; EPA method 608 for PCBs only; EPA method 608 for chlorinated pesticides only.~~

~~(t) Field of Testing 20 consists of those methods whose purpose is to detect the presence of inorganic pesticide residues in raw agricultural or bulk processed food and encompasses the following Subgroups: pesticide residues in processed foods detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in raw commodities detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in dairy products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in feed products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics.~~

~~(u) Field of Testing 21 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: chromatographic/mass spectrophotometric methods in either processed foods; raw commodities; dairy products; feed products.~~

~~(v) Field of Testing 22 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: halogenated compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in raw commodities detected by either gas chromatograph, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in feed products detected by either gas chromatography, high~~

~~pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics.~~

~~(w) Field of Testing 23 consists of the subgroup members appropriate to the Field of Testing stated by the laboratory, pursuant to Section 64805(b)(1).~~

~~Note: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Sections 1012, 1013, 1015, 1017 and 1019, Health and Safety Code.~~

*Repeal Article 13*

~~Article 13. Trade Secrets.~~

~~§ 64825. Trade Secrets.~~

~~(a) If a laboratory identifies information provided to the Department as a trade secret, the Department shall not release such information unless:~~

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

~~(2) the Department has notified the laboratory of the impending release. Such notification shall be at least ten days prior to releasing any information identified 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 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1012 and 1013, Health and Safety Code; Section 6254.7(d), Government Code.~~

*Repeal Article 14*

~~Article 14. Sale or Transfer of Ownership of a Laboratory.~~

~~§ 64827. Sale or Transfer of Ownership.~~

~~(a) A certificate shall be voided by operation of law if one or more of the following occurs.~~

~~(1) An original Owner fails to notify the Department, in writing, within 15 days after a change in ownership.~~

~~(2) A new Owner relocates the laboratory within 90 days of assuming ownership.~~

~~(3) If more than half the number of laboratory persons either quit or are terminated and replaced by a new Owner within 90 days of assuming ownership.~~

~~(4) If a new Owner submits an application to alter the laboratory's certificate as issued to the prior Owner by the addition of any Subgroup within any Field of Testing.~~

~~(b) A new Owner of a laboratory shall notify the Department, in writing, within 15 days after the sale or transfer of ownership and provide, at minimum, the following information.~~

~~(1) The name(s) of the new Owner(s).~~

~~(2) The date of sale or transfer of ownership.~~

~~(3) The name, education and laboratory related work experiences, as specified in Section 64817(a); or voluntary laboratory certificate grade as specified in Section 64817(b), of the person designated as the Laboratory Director.~~

~~(4) The names, education and laboratory related work experiences, as specified in Section 64817(g); or voluntary laboratory certificate grade as specified in Section 64817(h), of all persons who are designated as Principal Analysts.~~

~~(5) The names of all Principal Analysts who have quit, or were terminated and replaced; and the names of all Principal Analysts hired as replacements.~~

~~(6) A statement that there will be no changes in laboratory location, or in the certificate issued to the prior Owner(s) within 90 days of assuming ownership.~~

~~(7) A statement that all equipment, method, and quality assurance practices will not change within 90 days of assuming ownership.~~

~~(8) The notice shall be signed by one or more of the new Owner(s), or their Agents.~~

~~(c) New Owners that comply with the provisions of (b) above shall have use of the certificate issued to the prior Owner for a period of ninety days commencing with the date of the Department's notice of receipt of the information supplied by the new Owner.~~

~~(1) The certificate number and the laboratory name appearing on the certificate shall remain the same.~~

~~(2) The new Owner shall display, and provide a copy with all data reports, the Department's notice recognizing the sale or transfer of ownership.~~

~~(d) To obtain the use of the certificate to its original expiration date, the new Owner shall request such use in writing, and the laboratory shall be subjected to, and pass the following, within the 90 days use period granted by the Department.~~

~~(1) A site visit in accordance with Section 64807; and~~

~~(2) Performance evaluation samples in accordance with Section 64809.~~

~~Note: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Section 1014, Health and Safety Code.~~