

California Department of Public Health (CDPH)
Division of Drinking Water & Environmental Management (DDWEM)
Environmental Laboratory Accreditation Program (ELAP)

Certification of Environmental Laboratories
November 30, 2009 - Draft Regulations

These draft regulations reflect CDPH's current thinking on the modification of regulations dealing with the certification of environmental laboratories. Highlighted sections indicate changes made since the August 19, 2009 draft.

Any informal comments on this draft can be e-mailed to DDWEM's Dr. Steven Book (Steven.Book@cdph.ca.gov) and ELAP's Dr. George Kulasingam (George.Kulasingam@cdph.ca.gov).

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Title 22. Social Security

Division 4. Environmental Health

Chapter 19. Certification of Environmental Laboratories

Article 1. Definitions

§64801.05. Accredited College or University.

“Accredited College or University” means an educational facility which has met the standards of the United States of America Accrediting Commission for Senior Colleges and Universities or the Accrediting Commission for Community and Junior Colleges; or, if a non-United States college or university, one that is evaluated and found equivalent by the American Association of Collegiate Registrars and Admissions Officers.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.10. Days.

“Days” means calendar days, unless otherwise indicated.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.15. Deficiency.

“Deficiency” means not in compliance with certification requirements.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.20. ELAP.

“ELAP” means the Environmental Laboratory Accreditation Program.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.22. ELOPP.

“ELOPP” means the Environmental Laboratory Operations and Program Plan.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.25. Elaborate or Complex Laboratory Instrument or Procedure.

“Elaborate or Complex Laboratory Instrument or Procedure” means analytical instrumentation such as gas chromatograph/mass spectrometer (GC/MS), ion chromatography (IC), inductively coupled plasma spectrometer (ICP), inductively coupled plasma/mass spectrometer (ICP/MS), liquid chromatograph/mass spectrometers (LC/MS), atomic absorption spectrophotometer (AA), gas chromatograph (GC), alpha particle or gamma ray spectrophotometer, electron microscope (EM), polarized light microscope (PLM), high pressure liquid chromatograph (HPLC), or other similar instrument or other procedure including use of aquatic organisms in toxicity testing of wastewater and hazardous waste.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.30. Field of Accreditation or FoA.

“Field of Accreditation” or “FoA” means Field of Testing.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.35. Field of Testing.

“Field of Testing” means the testing category identified in Sections 100860.1 and 100862 of the Health and Safety Code.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.40. Group-of-Analytes.

“Group-of-Analytes” means some or all of the organic chemicals, **inorganic chemicals**, radionuclides, or micro-organisms that can be analyzed by a single analytical method for which a laboratory is seeking certification.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.45. Laboratory.

“Laboratory” means any place used, or any establishment, **including, but not limited to, a mobile laboratory**, or institution organized or operated for the analyses of environmental samples in any of the Field(s) of Testing listed in Section 100860.1 or Section 100862 of the Health and Safety Code and Unit(s) of Accreditation, or examinations or the practical application of any of the sciences or scientific disciplines used for the analyses of environmental samples or examination thereof.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.50. Method.

“Method” means an analytical process or procedure for use in the determination of the presence or quantitation of a pollutant or contaminant or regulated analyte in an environmental sample.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

§64801.55. National Program.

“National Program” means the entity that establishes national environmental laboratory accreditation standards, e.g., the National Environmental Laboratory Accreditation Conference (NELAC) or its successor, The NELAC Institute.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100847, 100862, Health and Safety Code.

§64801.60. Physical Property.

“Physical Property” means a measurement of the physical characteristics of an environmental sample.

~~Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.~~

§64801.65. Unit of Accreditation.

“Unit of Accreditation” means a component of the Field of Testing, including (a) the matrix, (b), a test method or technology, and (c) a designated analyte or analyte group. The Unit of Accreditation is specific to testing (e.g., analyte, matrix, method) for an individual regulatory requirement, such as is needed for compliance with the Safe Drinking Water Act or the Clean Water Act, or for specific agency requirements, such as those established by the Department of Toxic Substances Control or the Department of Food and Agriculture.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code. Reference: Sections 100825, 100845, 100847, 100860.1, 100862, Health and Safety Code.

Article 2. Application for State Accreditation.

§64802.010 Application for Initial Certification.

(a) A laboratory, including any auxiliary laboratories, shall meet the following requirements in order to be certified for any Field of Testing and Unit of Accreditation:

(1) submit for Department review and approval an application which includes all of the following:

(A) type of application;

(B) legal name of the laboratory;

(C) division, if appropriate;

(D) actual location of the laboratory (within USA address, city, state, zip code, or outside of USA, address, province, prefecture, city, country, mail code);

(E) mailing address for mail (within USA address or P.O. Box, city, state, zip_code, or outside of USA, address, province, prefecture, city country, mail code);

(F) shipping address for sample delivery (within USA address or P.O. Box, city, state, zip_code, or outside of USA, address, province, prefecture, city country, mail code);

- (G) telephone number (landline);
- (H) facsimile (FAX) number, if one is available;
- (I) E-mail address;
- (J) county
- (K) name and telephone number of the person(s) performing the functions as the director(s) of the laboratory;
- (L) name of the owner of the laboratory;
- (M) for a mobile laboratory, the make and model of the vehicle, the vehicle identification number, the vehicle license number, the state in which the vehicle is registered;
- (N) qualifications of the director(s), as provided in Section 64809;
- (O) Field of Testing and Unit of Accreditation for which certification is requested;
- (P) fees (if claim of exemption from fees pursuant to HSC 100860.1, include evidence for the claim), make check payable to "Environmental Laboratory Accreditation Program" pursuant to Article 13;
- (Q) the laboratory's Environmental Laboratory Operations and Program and Quality Assurance Plan (ELOPP) as described in Section 64808;
- (R) any other information about the laboratory that the laboratory considers may demonstrate competency;
- (S) signature of the owner or owner's designee of the laboratory on application form, date of signature, printed name of the owner or owner's designee verifying all information provided is true.

(2) Be subject to an on-site assessment by the Department to determine compliance with the laboratory's Operations and Quality Assurance Plan ELOPP, respond to any cited deficiencies, and ensure that the response to any cited deficiencies has been received and accepted by the Department;

(3) Successfully analyze proficiency testing samples and report acceptable results in the analysis of proficiency testing samples, pursuant to Section 64805, for each Field of Testing or Unit of Accreditation for which the certificate is requested; and

(4) Obtain the Department's approval of its ~~Laboratory Operations and Quality Assurance Plan~~ELOPP.

(b) For this Section and Section 64802.040, the auxiliary laboratory is any stationary place that is:

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

(2) where analyses in one or more of the same Field(s) of Testing and Unit(s) of Accreditation as the laboratory to which it is auxiliary is performed; and

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

(4) that 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) ~~identified as an auxiliary laboratory in the laboratory's Laboratory Operations and Quality Assurance Plan~~ELOPP.

Note: Authority cited: Sections 131200, 100830, 100840, 100845 and 100850, Health and Safety Code; and Section 15376, Government Code. Reference: Sections 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100850 and 100860.1, Health and Safety Code.

§64802.020. Application for Amendment of the Certificate.

(a) A laboratory must apply for and receive an Amendment of the Certificate in order to:

(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 64802.050;

(2) change its location;

(3) modify a Field of Testing and Unit of Accreditation for which it is certified or;

(4) add a Field of Testing and Unit of Accreditation.

(b) A laboratory's application for Amendment of Certificate for change of name will be approved provided that the laboratory has filed an application with the Department that has been signed by the owner or owner's designee and that includes the certificate number of the laboratory, name on existing certificate and proposed new name, and address of the laboratory;

(c) A laboratory's application for Amendment of Certificate for change of location will be approved provided that:

(1) The laboratory has filed an application with the Department that has been signed by the owner or owner's designee and that includes: the name of the laboratory, the certificate number of the laboratory, and address of current location and proposed new location;

(2) A description of the new location;

(3) If the Department at its discretion has conducted an on-site inspection, the laboratory has responded to any cited deficiencies, and the Department has accepted the response to any cited deficiencies.

(d) A laboratory's application for Amendment of Certificate to add a Field of Testing and Unit of Accreditation or modify a Field of Testing and Unit of Accreditation will be approved provided that:

(1) The laboratory has filed an application with the Department that has been signed by the owner or owner's designee and that includes: the name of the laboratory, the certificate number of the laboratory, the address of the laboratory, the identification of each Field of Testing and Unit of Accreditation to be added or modified, and the Field-of-Testing fee required by the regulations for each Field of Testing and Unit of Accreditation to be added or modified, and any portion of the Laboratory Operations and Quality Assurance Plan as described in 64815 that differs relating to the proposed amendment from the version of the Laboratory Operations and Quality Assurance Plan ELOPP most recently submitted to the Department;

(2) The laboratory has provided the Department with information necessary for the Department to determine whether the laboratory has the capability to conduct the analysis for each Field of Testing and Unit of Accreditation for which the amended certificate is requested. Examples of this information include:

(A) documentation that the laboratory has the necessary equipment and instrumentation;

(B) description of the laboratory's operating procedures to ensure conformance with the applicable analytical method(s);

(C) analyses of replicate quality control samples for which samples were obtained or prepared from a source that is different from the initial calibration standards, with quality control sample concentration as specified in the method;

(D) analyses of replicate quality control samples like those specified in Subsection C of this Section, but which lack a method-specified quality control sample concentration; in this case the laboratory shall propose to

the Department a quality control sample concentration, and if approved by the Department, shall use the proposed concentration.

(E) Method detection limit study according to 40 CFR Part 136, Appendix B, if required by the method; and

(F) Initial calibration results, if required by the method.

(3) If the Department at its discretion has conducted an on-site inspection, the laboratory has responded to any cited deficiencies, and the Department has accepted the response to any cited deficiencies; and

(4) The laboratory has successfully analyzed proficiency testing samples and reported acceptable results in the analysis of proficiency testing samples pursuant to Section 64805 for each Field of Testing and Unit of Accreditation for which the amendment has been requested.

(e) A laboratory is not required to file an application for Amendment to Certificate to remove a Field(s) of Testing and Unit of Accreditation and may request an Amendment for Certificate to remove a Field(s) of Testing and Unit of Accreditation by submitting a written request to the Department.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100847, 100850, 100851, and 100860.1, Health and Safety Code.

§64802.030. Application for Renewal of a Certificate.

(a) The certificate for a laboratory and its auxiliary laboratory shall be renewed for 24 months provided that:

(1) The laboratory has filed with the Department an application that has been signed by the owner or owner's designee and that includes: the name of the laboratory, the certificate number of the laboratory, the address of the laboratory; payment for all fees required by the regulations, including fees for which payment is past due; and any portion of the ~~Laboratory Operations and Quality Assurance Plan ELOPP~~ as described in 64815 that identifies differences from the version of the ~~Laboratory Operations and Quality Assurance Plan ELOPP~~ most recently submitted to the Department. A complete updated version of the current ~~Laboratory Operations and Quality Assurance Plan ELOPP~~ shall also be submitted to the Department.

(2) The application is submitted before the expiration of the laboratory's certificate;

(3) The laboratory shall participate annually in a minimum of one, **but not more than two** proficiency testing studies within a 12-month period, unless otherwise stated in Section 100870 of the Health and Safety Code.

(4) The laboratory has successfully analyzed proficiency testing samples and reported acceptable results in the analysis of proficiency testing samples, pursuant to Section 64805 for each Field of Testing or Unit of Accreditation for which the certificate is requested; and

(5) If the Department at its discretion has conducted an on-site inspection prior to the expiration date of the certificate being renewed, the laboratory has responded to any cited deficiencies, and the Department has accepted the response to any cited deficiencies.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100850, and 100860.1, Health and Safety Code.

§64802.040. Application for an Interim Certificate.

(a) A laboratory seeking interim certification may submit a written request, with or after submittal of an application for initial certification, certificate renewal or amendment of a certificate, for an interim certificate for a Field of Testing and Unit of Accreditation..

(b) An interim certificate shall be issued when the following have occurred:

(1) The laboratory has submitted a complete application pursuant to Section 64802.10, 64802.020, or 64802.030;

(2) The laboratory has successfully analyzed proficiency testing samples and reported acceptable results in the analysis of proficiency testing samples pursuant to Section 64805, for each Field of Testing and Unit of Accreditation for which the certificate is requested; and

(3) For an initial certification, the Department has approved the laboratory's **Laboratory Operations and Quality Assurance Plan ELOPP**.

(4) For an amended certification, the Department has determined that the laboratory has the capability to conduct the analysis for each Field of Testing and Unit of Accreditation for which the amended certificate is requested, as provided in section 64802.020 (d)(2).

(c) An interim certificate is not renewable and shall expire at the earliest of the following: (i) approval of the initial, renewal or amended certificate; (ii) denial of the initial, renewal or amended certificate; or (iii) one year after issuance of the **amended interim** certificate.

Note: Authority cited: Sections 131200 and 100830, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100830, 100840, 100845, 100847, 100850, 100851, and 100860.1, Health and Safety Code.

Article 3. Sale or Transfer of Ownership of a Laboratory

§64803. Sale or Transfer of Ownership.

(a) To apply to operate under the laboratory's existing ELAP certificate until its expiration date, the new owner shall submit a written request to ELAP to retain the certificate within thirty days of the effective date of the laboratory ownership change, be subject to an on-site assessment, pursuant to Health and Safety Code 100865, and provide the following in writing to ELAP:

- (1) the name of the new owner and owner's designee;
- (2) effective date of the change of ownership;
- (3) qualifications of laboratory director, addressing the requirements in Section 64809, if changed;
- (4) Statement that the new owner will operate pursuant to the laboratory's existing certificate and will not change anything in the ~~Laboratory Operations and Quality Assurance Plan-ELOPP~~ as described in Section 64808 without requesting and obtaining written approval from ELAP;
- (5) Statement that the new owner will retain all records and data of analyses performed by the previous owner for a minimum of five (5) years;
- (6) Statement that the new owner will comply with all applicable laws and regulations;
- (7) Signature of the new owner or owner's designee.

(b) To apply to operate after the expiration of the laboratory's existing ELAP certificate, the new owner shall submit an application pursuant to Section 64802.10, and may submit an application for an interim certificate pursuant to Section 64802.040.

Note: Authority cited: Sections 131200, 100825, 100830, Health and Safety Code. Reference: Section 100830 and 100845, Health and Safety Code.

Article 4. Suspension and Revocation of Certificate

§64804. Suspension and Revocation of Certificate

If the certificate of a laboratory is suspended or revoked in part, as provided for in Health and Safety Code, Division 101, Part 2, Chapter 4, Article 3 (commencing with Section 100825), including but not limited to, a temporary suspension, as provided for in Health and Safety Code Section 100915, the certificate may be revoked or suspended for any one or more Field of Testing and Unit of Accreditation, and the remainder of the certificate shall remain in effect.

Note: Authority cited: Sections ---, Health and Safety Code. Reference: Sections ----, Health and Safety Code. (Citations need to be completed)

Article 5. Proficiency Testing Process for State Accreditation

§64805. Laboratory Proficiency Testing and Reporting Requirements

(a) A laboratory that is required to analyze proficiency testing samples and report acceptable results in the analysis of proficiency testing samples shall meet the following requirements:

- 1) The laboratory shall successfully participate in a proficiency testing study for each Unit of Accreditation for which the laboratory is certified or applying for certification unless there is no proficiency test sample available for the Unit of Accreditation.
- 2) Each laboratory shall ensure that all proficiency testing study samples are analyzed in accordance with their quality assurance program as defined in Section 64808 by the laboratory staff that routinely perform the analysis and with the equipment that is routinely used in such analysis.
- 3) Each laboratory shall submit proficiency testing study results to the provider of the study samples by the closure date of the study. Submittal of study results after the study closure date shall be deemed a failed performance in said study.
- 4) For a laboratory applying for initial certification in a Unit of Accreditation, participate in a minimum of one proficiency testing study prior to issuance of the certificate. Where two proficiency testing studies are attempted, the studies shall be performed at a minimum of 30 days apart from the date of the first study closure and the date of commencement of the second study, except for laboratories doing analyses required by the California Department of Food and Agriculture. The laboratory shall participate in and pass one proficiency testing study, at the earliest, six months prior to the date of submittal of the application or, at the latest, six months from the date of application submittal. Should the

laboratory fail a proficiency testing study during this period, a subsequent study shall be performed. The study shall be performed at a minimum of 30 days but not more than ~~60-90~~ days apart from the date of the first study closure and the date of commencement of the second study, except for laboratories doing analyses required by the California Department of Food and Agriculture. A laboratory that fails ~~two~~ **both** proficiency testing studies during this period shall be denied certification for the pertinent Unit of Accreditation.

(5) For a laboratory that is certified, participate in a minimum of one proficiency testing study annually. ~~Should the laboratory fail a proficiency testing study, a subsequent study shall be performed. The study shall be performed at a minimum of 30 days but not more than 60 days apart from the date of the first study closure and the date of commencement of the second study, except for laboratories doing analyses required by the California Department of Food and Agriculture.~~ **Should the laboratory fail a proficiency testing study, a subsequent study shall be performed. The study shall be performed at a minimum of 30 days but not more than 90 days apart from the date of the first study closure and the date of commencement of the second study, except for laboratories doing analyses required by the California Department of Food and Agriculture, or unless proficiency test samples are unavailable, in which case the laboratory must participate in the next available study.** A laboratory that fails two or more proficiency testing studies in a year shall lose its accreditation for the pertinent Unit of Accreditation. **Reinstatement of certification requires that the laboratory apply for initial certification as set forth in section 64802.010 and complete proficiency testing as set forth in subsection (4) of this section.**

(6) For a laboratory that is certified and fails a proficiency test, but where no proficiency sample will be available for a second test within the year of certification, the laboratory shall within 60 days submit to ELAP a statement of deficiencies and a corrective action plan that addresses the basis or bases for those deficiencies. Unless the plan is rejected by ELAP, the laboratory may continue to operate until the second proficiency test is taken and successfully passed. A laboratory that fails the second proficiency test shall lose its accreditation for the pertinent Unit of Accreditation. Reinstatement of certification requires that the laboratory apply for initial certification as set forth in section 64802.010 and complete proficiency testing as set forth in subsection (4) of this section.

NOTE: Authority cited: Sections 131200, 100830, and 100850, Health and Safety Code.
Reference: Sections 100850, 100860.1, and 100870, Health and Safety Code.

[Existing Sections 64806 and 64860, fees for ELAP certification and NELAP accreditation, respectively, are not proposed to be amended in these regulations, but will be renumbered and placed in a new Article 13.]

Article 6. Conflict of Interest Prohibition

§64806. Conflict of Interest Prohibition

(a) No laboratory certified or seeking certification pursuant to this chapter shall submit results for evaluation in a proficiency testing study where the Department is the final recipient of the evaluated result, if the owner or director of the laboratory, the owner's or director's spouse, or dependent child(ren), or anybody acting on behalf of the owner or director, with regard to the entity that provides the proficiency testing study samples, either:

- (1) has an investment of 1% or more in investments in the entity not including mutual funds; or
- (2) is a director, officer, partner, trustee, employee or manager of that entity.

(b) No laboratory certified or seeking certification pursuant to this chapter shall submit results for evaluation in a proficiency testing study where the Department is the final recipient of the evaluated result, if the laboratory is providing services to an entity that is providing proficiency testing study samples. The laboratory's compliance with the conflict of interest requirements of **NELAC the National Program** regarding the use of proficiency testing study samples shall satisfy the requirements of this subsection.

NOTE: Authority cited: Sections 131200, 100830, and 100850, Health and Safety Code.
Reference: Sections 100850, 100860.1, and 100870, Health and Safety Code.

Article 7. Units of Accreditation.

§64807. Units of Accreditation.

(a) The laboratory shall use only the method for which it is certified and which is applicable for the detection and/or the quantitation of the analyte, or group-of-analytes. The method shall be Federal or State required for testing of environmental samples for the desired Unit of Accreditation, except for the following:

(1) Laboratories certified for Fields of Testing and Units of Accreditation involving drinking water and requesting use of alternate test procedures (ATP) for Federal regulated analytes, or group-of-analytes, shall be in compliance with Federal requirements, and shall be in possession of a document from the U.S. Environmental Protection Agency that shows approval for use of the procedures, prior to their use on environmental samples. Laboratories testing for analytes, or group-of-analytes that are not Federal regulated but are monitored by the State, shall utilize alternate methods approved by the State.

(2) Laboratories certified for Fields of Testing and Units of Accreditation involving wastewater and requesting use of ATP for Federal regulated analytes, or group-of-analytes shall be in compliance with the Federal requirements, and shall be in possession of a document from the U.S. Environmental Protection Agency that shows approval for use of the procedures, prior to their use on environmental samples. Laboratories testing for analytes, or group-of-analytes that are not Federal regulated but are monitored by the State, shall utilize alternate methods approved by the State.

(3) Laboratories certified for hazardous waste Fields of Testing and Units of Accreditation and requesting use of ATP for Federal or State regulated analytes, or group-of-analytes shall be in compliance with the California Code of Regulations, Title 22, Sections 66260.21(a) and 66260.21(b), and shall have been granted a variance by the California Department of Toxic Substances Control, Environmental Chemistry Laboratory (ECL) for the procedures, prior to their use on environmental samples.

(b) A laboratory certified for Fields of Testing and Units of Accreditation involving drinking water, wastewater, or ambient waters shall not use performance based methods, if prohibited by the U.S. Environmental Protection Agency.

Note: Authority cited: Section 131200, 100825, and 112165, 100830, Health and Safety Code. Reference: Sections 100830, 100845, 100850, 100860.1, and 112165, 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.

Article 8. Laboratory Operations and Quality Assurance Plan Environmental Laboratory Operations and Program Plan

§64808. Environmental Laboratory Operations and Quality Assurance Program Plan (ELOPP).

(a) The laboratory shall establish an ELOPP. Laboratory Operations and Quality Assurance Plan that ensures the production of reliable and valid data and ensures that the laboratory meets the proficiency testing requirements of Article 5. All the elements

of the ~~Laboratory Operations and Quality Assurance Plan~~ shall be documented in writing within the ~~Laboratory Operations and Quality Assurance Plan ELOPP~~, unless references to documents, as identified below, are included. The laboratory shall submit the ~~Laboratory Operations and Quality Assurance Plan ELOPP~~ to the Department for approval pursuant to Article 2. The laboratory shall review and update annually its ~~ELOPP~~ and, unless an earlier submittal is requested by the Department, ~~submit updates to the ELOPP biannually, update annually its Laboratory Operations and Quality Assurance Plan, and advise the Department of the updates with the exception of updates of changes in an operator of an elaborate or complex laboratory instrument or procedure, which shall include the operator's name, education, training, and experience, and which shall be submitted to the Department within 30 days of such change.~~ The laboratory shall operate in accordance with the ~~its~~ updated ~~Laboratory Operations and Quality Assurance Plan ELOPP~~, unless otherwise instructed by the Department.

(b) The ~~Laboratory Operations and Quality Assurance Plan ELOPP~~ shall include, and not be limited to, the following elements:

(1) table of contents;

(2) introduction;

(3) descriptions of:

(A) laboratory organization, including its personnel, numbers of staff in each position or category of position, education requirements, experience and training, and responsibilities; ~~including identification of those who oversee an elaborate or complex laboratory instrument or procedure;~~

(B) ~~the laboratory, including its physical structure and internal laboratory environmental controls, laboratory's facilities and environments,~~ which shall ensure that the operation of laboratory equipment enables analyses to be performed ~~as required~~ for the certified or requested Field(s) of Testing and Unit(s) of Accreditation;

(C) any auxiliary laboratory, including its physical structure and internal laboratory environmental controls, ~~which shall ensure that the operation of laboratory equipment enables analyses to be performed for the certified or requested Field(s) of Testing and Unit(s) of Accreditation;~~ ~~to ensure optimal function of laboratory equipment;~~

~~(4) The name of each individual who operates or performs an elaborate or complex laboratory instrument or procedure, along with his or her education, training, and, experience, pertinent to the operation or performance of such instrument or procedure.~~

(45) a list or lists of the matrix, test method or technology and analyte or group of analytes for each Unit of Accreditation for which the laboratory is accredited or seeks accreditation.

(56) a list or lists of (SOPs), including the date of each SOP's last revision;

(67) quality assurance procedures, unless they are included in specific SOPs listed in Subsection (b)(5) of this Section, or in specific methods listed in Subsection (b)(4) of this Section or in the specific methods identified in Subsection (b)(8)(B) of this Section.

~~(7) the laboratory's Quality Assurance Manual;~~

(8) All laboratory functions, operations, and practices, otherwise not included in the Subsections (b)(1) through(7), inclusive but not limited to the following in the Laboratory Operations and Quality Assurance Plan: ELOPP:

(A) laboratory internal environmental controls (for example separate ventilation, room temperature, humidity, dedicated power lines, fume hoods, filtration units, scrubbers, clean rooms, double-door systems), where applicable, for optimal equipment and analytical operation, minimizing and to minimize the potential for sample contamination;

(B) analytical methods which include the following, unless the methods and associated documentation are included in the SOPs of Subsection (b)(56):

1. title (method identification);
2. scope and application;
3. summary of method (includes a list of any modifications);
4. interferences;
5. apparatuses and materials;
6. reagents and standards;
7. sample collection, preservation, handling, chain-of-custody;
8. procedures which includes sample preparation, sample cleanup, calibration, calibration checks/verifications, qualitative/quantitative analyses, quality control, data review/validation, data acceptance, and/or corrective actions;

9. method performance (includes accuracy, precision, method detection levels, if applicable);

10. pollution control;

11. references;

12. applicable tables, diagrams, and/or flowcharts;

(C) equipment and instrument maintenance;

(D) training programs for personnel (includes demonstration of capability and ethics);

(E) internal audits;

(F) record control (namely, organization of records);

(G) record retention in compliance with State, federal, or local requirements established for laboratories for the environmental testing program;

(H) reporting and notification to the person or entity that submitted the material for testing, and, if applicable, to regulatory agencies;

(I) backup procedures in the absence of staff who oversee operate or perform an elaborate or complex laboratory instrument or procedure, or in the absence of the director;

(J) data integrity training;

(K) management procedures, including review and approval process for laboratory reports.

(c) In preparing the Laboratory Operations and Quality Assurance Plan ELOPP, the director of the laboratory shall refer to pertinent handbooks, other documents and regulatory requirements for laboratories prepared by the State of California or federal entities. The documents utilized by the laboratory shall be clearly referenced in the Laboratory Operations and Quality Assurance Plan ELOPP. Where a method is published and widely available, a reference citation is suitable and a physical copy of the method does not need to be included in the Laboratory Operations and Quality Assurance Plan ELOPP.

(d) The laboratory shall maintain the ELOPP and provide a copy of any or all of the ELOPP to the Department upon request. A list of the laboratory SOPs is to be

submitted as part of the Laboratory Operations and Quality Assurance Plan. At the Department's request an SOP shall be provided by the laboratory to the Department.

Article 9. Laboratory Personnel.

§64809. Director.

(a) Each laboratory shall have one or more persons who fulfill the responsibilities and duties of a director, and where the laboratory has more than one person who fulfills those responsibilities and duties, the laboratory shall ensure that each requirement of Subdivisions (b) and (c) of this Section is met by one of those persons.

(b) The director shall not serve as a director in name only and shall be responsible for the following:

(1) All analytical and operational activities of the laboratory, including those of any auxiliary laboratory;

(2) Supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary laboratory;

(3) Ensuring the accuracy and quality of all data reported by the laboratory, including any auxiliary laboratory.

(c) Except as provided in Subsections (d) (e) and/or (f), the owner(s) of the laboratory shall ensure that the person designated to serve as a director of the laboratory shall have as a minimum:

(1) Documentation of education and training that is applicable to the Fields of Testing and Units of Accreditation performed at the laboratory, including possession of at least a baccalaureate degree from an accredited college or university in chemistry, biochemistry, biology, microbiology, or environmental, chemical, or public health engineering, or natural or physical science; and

(2) Documentation of experience including at least three years work experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples that is applicable to each of the Fields of Testing and Units of Accreditation for performed at the laboratory. The following post-graduate degrees may be substituted for part of the required experience:

(A) A masters degree from an accredited college or university in chemistry, biochemistry, biology, microbiology, or environmental, chemical, or public health engineering, or natural or physical science may be substituted for one year of the required experience.

(B) A doctorate from an accredited college or university in chemistry, biochemistry, biology, microbiology, or environmental, chemical, or public health engineering, or natural or physical science may be substituted for two years of the required experience.

(d) In lieu of meeting the requirements specified in Subsection (c), a director employed by a laboratory owned by a government utility shall possess a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Environment Association or the California-Nevada Section of the American Water Works Association, pursuant to the Fields of Testing Conversion Table for Director Capacity. 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 table.

FIELDS OF TESTING CONVERSION TABLE FOR DIRECTOR CAPACITY	
Fields of Testing	Minimum Certificate Grade Required
101, 102 ^a , 107 and 108 ^b	I
101, 102, 107, 108, 113 and 119	II
103, 104 ^c , 105 ^c , 109, 110 ^c , 111 ^c and those allowed for a Grade II	III
104, 105, 106, 110, 111, 112 and those allowed for a Grade III	IV

Footnotes for the Fields of Testing Conversion Table for Director Capacity:

- a. Limited to testing for: alkalinity, chloride, hardness, total filterable residue, a
- b. Limited to testing for: acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, non-filterable residue, settleable residue, volatile residue, specific conductance, and turbidity.
- c. Excluding methods that require the use of GC/MS.

(e) The following shall be exempt from meeting the requirements of (c) and (d) above: ,

(1) Each person who is a director of a laboratory that possesses a current and valid certificate on the effective date of these regulations, but only so long as the person continues, without interruption, as the director of the laboratory of which he or she is director on the effective date of these regulations, and

(2) Each person who is a director of a Public Health Laboratory as described in Health and Safety Code Section 101155 and who meets the requirements of Health and Safety Code Section 101160 and any regulations promulgated pursuant to that Section.

(3) Each person who was a laboratory director as of December 31, 1994.

(f) The laboratory shall notify the Department in writing within 30 calendar days whenever the director ceases to be employed by the laboratory or there is otherwise a change of director or other person in charge of the laboratory, and shall include in the documentation either (1) the identity of a replacement director, and documentation that

the replacement director meets the requirements of this Section or (2) a request to the Department for approval of an interim director, and a description of qualifications of the interim director.

(g) The interim director may serve as director for a period not to exceed 90 days from the date the interim director first assumes the duties of director, provided that the laboratory has not received disapproval from the Department. The interim director may serve for more than 90 days if the Department approves a request from the laboratory to the Department. The request must be in writing and must document the steps the laboratory has taken to employ a replacement director who meets the requirements of this Section.

Note: Authority cited: Sections 131200, 100825, and 100830, Health and Safety Code. Reference: Section 100830, Health and Safety Code.

Article 10. Notification and Reporting.

§64810. Notification and Reporting to Meet ELAP Accreditation Purposes.

(a) A laboratory certified by the Department shall comply with the reporting requirements of its clients.

(b) The laboratory shall report in accordance with the request for analysis all detected pollutants and contaminants from the analyses of the sample or components thereof to its clients.

(c) The laboratory shall comply with all requirements of State or federal regulatory agencies, including but not limited to notification and reporting requirements.

(d) 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) (or copy of the original) prepared by all other laboratories who are party to the agreement.

(e) For notification and reporting for drinking water analyses for compliance with drinking water regulations and requirements, the following shall also apply:

(1) Laboratories certified by ELAP for Field of Testing E101, E102, E103, E104, E105, or E106, or by **NELAP the National Program** for Field of Testing N101, N102, N03, N104, N105, or N106 shall conform to the following reporting and notification requirements.

(A) 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.

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

1. The presence of total coliforms, fecal coliforms, or *Escherichia coli* (*E. coli*) is confirmed.
2. A bacterial sample result is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).
3. A nitrate sample result exceeds the MCL.

(C) The laboratory shall notify a water supplier's designated contact person as soon as possible following approval of sample results, but within 48 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:

1. A perchlorate sample result exceeds the MCL.

(D) If the laboratory is unable to make direct contact with the water supplier's designated contact person within 24 hours pursuant to subparagraph (1)(B) or 48 hours pursuant to subparagraph (1)(C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.

(E) With regard to notifying a water supplier's designated contact in subparagraph (1)(B) and subparagraph (1)(C):

1. "Approval" during the 24-hour period of subparagraph (1)(B) and the 48-hour period of subparagraph (1)(C) refers to the approval of the results by the laboratory's director or designee, as set forth in its Laboratory Operations and Quality Assurance Plan ELOPP.

2. If a laboratory subcontracts an analysis to a subcontractor laboratory, unless the subcontractor provides the required notification pursuant to subparagraph (1)(B) or subparagraph (1)(C), the subcontracting laboratory shall be responsible for providing the required notification pursuant to subparagraph (1)(B) or subparagraph (1)(C).

(F) 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.

(G) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15.5, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors, and Chapter 17.5, Lead and Copper, or other required monitoring shall be reported directly to the Department by the 10th day of the month following the month in which the analyses were completed. In the event that the Department is not able to accept those results for specific analytes electronically as set forth in subsection E of this section, results shall be submitted on paper or hard copy, or as otherwise directed by the Department.

(H) 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:

1. A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;
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, operating, and quality assurance records pertaining to the incident in question; and
5. Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.

(2) Laboratories certified for Fields of Testing E123, E124, or E125 shall verify the identity and quantity of a pesticide residue before reporting the results. The verification procedures must conform to those identified in SOPs or other documentation in the Laboratory Operations and Quality Assurance Plan ELOPP.

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

Article 11. Reciprocity Agreements.

§64811. Reciprocity Agreements.

(a) For ELAP to agree to recognize another state's environmental laboratory certification, accreditation, or licensing program for the purposes of reciprocity, the program must apply to ELAP for recognition of its program, and demonstrate in the application that the other state's program requires:

- (1) evaluation of participating laboratories through periodic analyses of proficiency testing study samples with the frequency of submittal, the method of evaluation, and the established acceptance limits at least equal to those in Article 3 of Chapter 4 of Division 101 of Health and Safety Code, and the provisions 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 Health and Safety Code 100865;
- (3) standards for quality assurance, laboratory facilities, methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Sections 64807, 64808 and 64809 of this Chapter.

(b) In states where ELAP has agreed to recognize a program for purposes of reciprocity pursuant to (a) above, a laboratory certified and audited by that state may seek California certification by submitting:

- (1) an application pursuant to Article 2 of this Chapter;
- (2) if requested by the Department, copies of the results evaluated, or scored, from the last proficiency testing study in which the laboratory participated for the other program;
- (3) if requested by the Department, 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 100860.1;
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) ELAP may rescind a reciprocity agreement with another State at any time at its sole discretion, and, if a reciprocity agreement is rescinded, no certificate issued by the Department under this agreement shall be revoked solely due to the rescission of the reciprocity agreement.

(d) No fees are waived where reciprocity exists.

(e) A laboratory certified under reciprocity may be visited or issued be required to analyze proficiency testing study 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 proficiency testing study sample costs, pursuant to Health and Safety Code 100870 or travel costs pursuant to the Health and Safety Code 100860.1 or Section 64805 of this Chapter shall be paid.

(f) If a laboratory that is accredited through reciprocity has its certificate suspended or revoked by the other State or Federal agency, the laboratory shall notify the Department within 10 days of the suspension or revocation.

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

Article 12. National Environmental Laboratory Accreditation Program Requirements.

§64812. NELAP National Program Application Process.

(a) A laboratory applying for or in possession of National Program accreditation or that is accredited by the Department under the National Program NELAP shall comply with the National Environmental Laboratory Accreditation Conference (NELAC) Standards, or the subsequent standards of the National Program.

~~(b) Should the National Program establish subsequent amendments or additions to, or replacements of the NELAC Standards, those standards shall be used to determine compliance for purposes of National Program accreditation.~~

(b) A laboratory applying for or possessing National Program accreditation in any Field of Testing listed in Health and Safety Code 100862 shall file a complete application pursuant to Article 2.

Note: Authority cited: Sections 131200, 100825, 100830, 100840, and 100862, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code;

Article 13. Fees for ELAP Certification and National Program Accreditation
(place holder)

[Existing sections 64806 and 64860, fees for ELAP certification and National Program accreditation, respectively, are not proposed to be amended in these regulations, but will be renumbered and placed in a new Article 13.]