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

Certification of Environmental Laboratories
March 8, 2010 - Draft Regulations

This draft reflects CDPH's current thinking on the modification of regulations dealing with the certification of environmental laboratories. Additions and deletions to existing regulations are indicated by underlines and strike-outs, respectively

Informal comments 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) until March 31, 2010.

When regulations are in the actual rulemaking process, there will be an opportunity for formal public comments.

Title 22. Social Security

Division 4. Environmental Health

Chapter 19. Certification of Environmental Laboratories

~~s 64801. Definitions.~~

~~(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.~~

~~(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.~~

~~(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).~~

~~(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.~~

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

~~(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.~~

~~(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, and includes storage areas.~~

~~(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.~~

~~(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.~~

~~(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.~~

~~(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).~~

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

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

~~(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.~~

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

~~(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.~~

~~(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.~~

~~(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.~~

~~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.~~

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.

§64801.65. 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 designated group of analytes. The Unit of Accreditation is specific to testing (*e.g.,* the matrix, the method, and the analyte or group of analytes) 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.

~~*s 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.~~

~~s 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, Heath and Safety Code. Reference: Sections 1013, 1014 and 1017(e), Health and Safety Code.~~

~~s 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, Heath and Safety Code. Reference: Sections 1015, 1018 and 1021, 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 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 ELOPP, respond to any cited deficiencies, and ensure that the response to any cited deficiencies has been received and accepted by the Department;

(3) Provide 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 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.

(4) 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

(5) Obtain the Department's approval of its 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 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 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 ELOPP as described in 64815 that identifies differences from the version of the ELOPP most recently submitted to the Department. A complete updated version of the current 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 successfully participate annually in a minimum of one proficiency testing study 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 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 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.

~~***s 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.~~

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 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 suspended or revoked 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)

~~s 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, Heath and Safety Code. Reference: Sections 1015, 1017 and 1019, Health and Safety Code.~~

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) In evaluating the successful participation of the laboratory in the proficiency testing study, the provider of study samples shall use proficiency testing acceptance criteria as set forth in the National Program's environmental laboratory accreditation standards.

(b) A laboratory applying for initial certification in a Unit of Accreditation, shall successfully participate in a minimum of one proficiency testing study for that Unit of Accreditation prior to issuance of the certificate. In this case, the following apply:

(1) The proficiency testing study shall occur, 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.
(2) If the laboratory fails the first proficiency testing study for initial certification, the laboratory may participate in a subsequent study, which will count as successful participation, provided it meets the proficiency testing acceptance criteria and is initiated and completed no sooner than 30 days but no later than 90 days from the date of the first study closure, except for laboratories doing analyses required by the California Department of Food and Agriculture.

(c) A laboratory that is certified in a Unit of Accreditation shall successfully participate in a minimum of one proficiency testing study for that Unit of Accreditation. In this case, the following apply:

(1) The proficiency testing study shall be completed within one year of the certification date.

(2) If the laboratory fails a proficiency testing study, the laboratory may participate in a subsequent study, which will count as successful participation, provided it meets the proficiency testing acceptance criteria and is initiated and completed no sooner than 30 days but no later than 90 days from the date of the first study closure, except for laboratories doing analyses required by the California Department of Food and Agriculture. If proficiency testing samples for the subsequent study cannot be provided by the sample provider such that testing cannot be completed within 90 days from the date of the first study closure, the laboratory shall within 90 days of the first study closure submit to ELAP for ELAP's review and approval a statement of deficiencies and a corrective action plan that addresses the basis or bases for those deficiencies, and shall comply with the corrective action plan as approved by ELAP.

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

~~s 64806. [to be moved to Article 13, and renumbered to Section 64813.010]~~ Certification Fees~~:~~

(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal Environmental Laboratory Accreditation Program certification:

(1) A non-refundable base or administrative fee of $959 payable at the time of initial and renewal application for certification and annually thereafter, and

(2) An additional fee of $432 for each Field of Testing specified in Health and Safety Code Section 100860.1 which the laboratory has requested in its

application, payable at the time of application for an initial, amended, or renewed ELAP certification, and annually thereafter.

(b) For a certificate issued between 01/01/02 and 12/31/02, the fee required at the time of the initial and renewal application shall be due and payable within the time period for which the certificate is valid and within 30 days notice by the Department.

Note: Authority cited: Sections 100830, 100835(a) and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

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 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.

~~***s 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, Heath 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.~~

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. Environmental Laboratory Operations and Program Plan

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

(a) The laboratory shall establish an ELOPP. All the elements shall be documented in writing within the ELOPP, unless references to documents, as identified below, are included. The laboratory shall submit the 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, The laboratory shall operate in accordance with its updated ELOPP, unless otherwise instructed by the Department.

(b) The 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, 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;

(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;

(4) 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.

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

(6) 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)(7)(B) of this Section.

(7) All laboratory functions, operations, and practices, otherwise not included in the Subsections (b)(1) through (6), inclusive but not limited to the following in the 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, 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)(6):

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 procedures in compliance with State, federal, or local requirements established for environmental laboratories;

(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 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 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 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 ELOPP.

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

~~s 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:~~

~~Fields of Testing~~	~~Minimum Certificate 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:~~

~~Fields of Testing~~	~~Mininimum Certificate 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.~~

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.

~~s 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.~~

(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 the National Program for Field of Testing N101, N102, N03, N104, N105, or N106 shall conform to the following reporting and notification requirements.

~~(1)~~ (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.

~~(2)~~ (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:

~~(A)~~ 1. The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.

~~(B)~~ 2. A bacterial sample result is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).

~~(C)~~ 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.
2. A chlorine dioxide sample result that exceeds the maximum residual disinfectant level (MRDL).

(D) If the laboratory is unable to make direct contact with the water supplier's designated contact person within 24 hours pursuant to subparagraph ~~(2)(A) or (C)~~ (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 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).

~~(4)~~ (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 F of this section, results shall be submitted on paper or hard copy, or as otherwise directed by the Department.

~~(5)~~ (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:

~~(A)~~ 1. A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;

~~(B)~~ 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;

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

~~(D)~~ 4. Copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and

~~(E)~~ 5. Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.

(2) Laboratories certified for Fields of Testing ~~20, 21, or 22~~ E123, E124, or E125 shall verify the identity and quantity of a pesticide residue before reporting the results. The ~~confirmation~~ verification procedures must conform to those ~~in Section 64811(d) of this Chapter~~ identified in SOPs or other documentation in the ELOPP.

~~(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.~~

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

s 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.~~

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 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. National Program Application Process.

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

(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;

~~s 64860~~. [to be moved to Article 13, and renumbered to Section 64813.020] NELAP Accreditation Fees.

(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal of a National Environmental Laboratory Accreditation Program (NELAP) primary or secondary accreditation:

(1) A non-refundable application fee of $3,000 payable at the time of initial and renewal application for accreditation, and
(2) An additional non-refundable fee for each Field of Testing specified in Health and Safety Code Section 100862 which the laboratory has requested in its application, payable at the time of application for an initial, amended, or renewed NELAP accreditation, as follows:

(A) A fee of $750 for each low complexity Field of Testing, identified as Fields of Testing number N115, N120, and N121.
(B) A fee of $1000 for each medium complexity Field of Testing, identified as Field of Testing number N101, N102, N103, N106, N107, N108, N109, N112, N114, and N118.
(C) A fee of $1,800 for each high complexity Field of Testing, identified as Field of Testing number N104, N105, N110, N111, N113, N116, N117 and N119.

(b) No environmental laboratory shall be approved as a NELAP accredited laboratory until fees provided by this section have been paid.

Note: Authority cited: Sections 100830, 100835(a) and 100862, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

Article 13. Fees for ELAP Certification and National Program Accreditation

§64813.010. ELAP Certifications Fees.

Reserved - existing regulations will be renumbered (see page 21).

§64813.020 National Program Accreditation Fees.

Reserved - existing regulations will be renumbered (see above).

~~***s 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 ofdrinking 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 ploychlorinated 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.~~

~~***s 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.~~