

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

Certification of Environmental Laboratories
May 5, 2008 Draft Regulations

This draft regulation reflects the California Department of Public Health's (CDPH's) current thinking on the modification regulations dealing with the certification of environmental laboratories. Additions and deletions from January 4, 2008 draft are indicated by underlines and ~~strikeouts~~, respectively.

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

Title 22. Social Security
Division 4. Environmental Health
Chapter 19. Certification of Environmental Laboratories

Article 1. Definitions

§64801.0114. Acceptable Results.

"Acceptable Results" means proficiency testing (PT) study data generated by a laboratory and in compliance with Sections 64809 ~~through 64809.010~~.

§64801.0116. 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.

~~§64801.0150. —Alternate Test Procedure.~~

~~—"Alternate Test Procedure" means an analytical test method, or procedure that is different in technic from the Federal or State required method(s) in Section 64811, and generates comparable results with accuracy, precision, and level of detection that are equivalent or better.~~

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

§64801.0410. 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.

§64801.0413. Deficiency.

“Deficiency” means not in compliance with certification requirements.

§64801.0552. 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.

§64801.0554. Elaborate or Complex Laboratory Instrument or Procedure.

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

§64801.0622. Field of Accreditation or FoA.

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

§64801.0642. Field of Testing.

“Field of Testing” means the testing category identified in Sections 100860.1 and 100862 of the Health and Safety Code. ~~Each testing category represents the collected sample type by matrix and testing type by discipline.~~

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

§64801.0765. Group-of-Analytes.

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

§64801.1210. Laboratory

“Laboratory” means any place used, or any establishment 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. — Matrix. (Is a definition needed?)~~

§64801.1315. 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.

~~§64801.1590. — Owner. (Question: should definition be amended in light of section 64803(a)(1)(X) and to conform to 64803(a)(1)(Q)? Or amend (x) to “owner or person authorized to sign on behalf of owner.” Add agent to represent cities. Consider dropping definition.)~~

~~—“Owner” means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.~~

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

~~**§64801.1620. — Performance Based Method.**~~

~~—“Performance Based Method” means a modified method from one that was initially approved by a government entity, and the modified method is not an alternate test procedure.~~

§64801.1630. Physical Property.

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

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

§64801.2082. Unit of Accreditation.

“Unit of Accreditation” means a component of the Fields of [Accreditation Testing](#), e.g., an analyte, the analytes, group-of-analytes, species, physical properties, and methods.

Article 2. Application for State Accreditation.

§64803. 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, zipcode, 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, zipcode, 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, zipcode, 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) laboratory web site, if laboratory has a web site;~~

~~(JK) county;~~

~~(L) Water Quality Control Board Region number;~~

~~(M) type of laboratory;~~

~~(KN) name and telephone number of the person performing the functions as the director of the laboratory;~~

~~(O) name and telephone number of the person who is the contact for the laboratory;~~

~~(P) name of the person to receive mail from the Department;~~

~~(LQ) name of the owner(s) of the laboratory;~~

~~(MR) 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;~~

~~(NS) qualifications of the director, as provided in Section 64817;~~

~~(QT) Field of Testing and Fields of Testing Unit of Accreditation requested for certification, which are listed in Health and Safety Code section 100860.1(a), including the analyte, group of analytes, physical property, or species, and the method for which certification is requested;~~

~~(PU) fees (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 3;~~

~~(QV) the laboratory’s in-house quality assurance manual Laboratory Operations Plan as described in Section 64815;~~

~~(RW) any other information about the laboratory that the laboratory considers may demonstrate competency;~~

(~~SX~~) signature of the owner(~~s~~) of the laboratory on application form, date of signature, printed name of the owner(~~s~~) verifying all information provided is true.

(2) an on-site assessment ~~pursuant to Health and Safety Code 100865 by the Department~~ has occurred and a response to any cited deficiencies has been received and accepted by the Department;

(3) acceptable results for proficiency testing sample study sets have been received by the Department pursuant to Sections ~~64809 and 64809.010~~; and

(4) the laboratory has received the Department's approval of its Laboratory Operations Plan ~~quality assurance manual~~.

(b) For this ~~section~~ Section and Section 64803.040, the auxiliary laboratory is any stationary place;

(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) located ~~at contiguous buildings on the same site and such that~~ the transport of samples to the auxiliary laboratory ~~is within a few minutes, and~~ does not affect the quality of the analytical results.

Note: Authority cited: Sections ~~208 and 1011, 1012~~ 131200, 100830, 100840, 100845 and 100850, Health and Safety Code; and Section 15376, Government Code. Reference: Sections ~~4013, 4014 and 4017(e)~~ 15376, Government Code; and Sections ~~413, 4012, 4013, 4014 and 4015~~ 100425, 100830, 100840, 100845, 100850 and 100860.1, Health and Safety Code.

§64803.020. 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 Ssection 64803.05027;

(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 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 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~~ 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 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 Plan as described in 64815 that differs from the version of the Laboratory Operations Plan 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, including, but not limited to:

(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 four replicate quality control samples for which samples were obtained or prepared from a different source than the initial calibration standards, with quality control sample concentration as specified in the method ^[GHY1]or, if unspecified, approximately ten times the laboratory-calculated MDL, and which includes an evaluation of accuracy (mean) and precision (standard deviation), if required by the method ^[GHY2] (NOTE: CDPH is still considering alternative language...);

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

(E) 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 Department has received acceptable results for proficiency testing study samples pursuant to Sections 64809 ~~and (or delete if two sections combined) 64809.010~~, if available, 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.

§64803.030. 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 ~~meets all the requirements of Section 64803~~ has been signed by the owner and that includes: the name of the laboratory, the certificate number of the laboratory, the address of the laboratory; and includes payment for all fees required by the regulations, including fees for which payment is past due; and any portion of the Laboratory Operations Plan as described in 64815 that differs from the version of the Laboratory Operations Plan most recently submitted to the Department;

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

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

(4) The Department has received acceptable results for applicable proficiency testing study samples, pursuant to Sections 64809 ~~and 64809.010~~, if available, for each Unit of Accreditation or Field of Accreditation for which the certificate is requested; and

(5) The Department has conducted an on-site inspection during the twenty-four months prior to the expiration date of the certificate being renewed, the laboratory has responded to any cited deficiencies, and the ~~department~~ 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.

§64803.040. 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 any Field of Testing and Unit of Accreditation, ~~or Field 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 64803, 64803.020, or 64803.030;

(2) The Department has received acceptable results for applicable proficiency testing study samples pursuant to Sections 64809 and 64809.010, if available, for each

Field of Testing and Unit of Accreditation or ~~Field of Accreditation~~ for which the certificate is requested; and

(3) For an initial certification, the Department has approved the laboratory's

Laboratory Operations Plan. ~~quality assurance manual.~~

~~(c) An interim certificate for a microbiology method will not be issued by the Department, unless the laboratory is already accredited for the same method for use in analysis of a similar matrix.~~

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

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

Article 3. Sale or Transfer of Ownership of a Laboratory

§64803.050. Sale or Transfer of Ownership.

(a) To apply to operate under the laboratory's existing ELAP certificate until its expiration date, ~~the~~ 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(~~s~~) of the new oOwner(~~s~~);

(2) effective date of the change of ownership;

(3) qualifications of laboratory director~~l~~, addressing the requirements in Section 64817, if changed;

(4) Statement that the new owner will operate pursuant to the laboratory's existing certificate and will not change any thing in the Laboratory Operations Plan as described in Section 64815 of the following without requesting and obtaining written approval from ELAP;

~~—(A) laboratory location;~~

~~—(B) equipment;~~

~~—(C) methodology;~~

~~—(D) quality assurance practices;~~

(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 ~~one or more of~~ the new owner(~~s~~).

(b) To apply to operate after the expiration of the laboratory's existing ELAP certificate, the new owner shall submit an application pursuant to Ssection 64803, and may submit an application for an interim certificate pursuant to Section 64803.040.

Note: Authority cited: Sections 131200, 100825, 100830~~208, 1011 and 1012~~, Health and Safety Code.
Reference: Section 100830 and 100845~~1014~~, Health and Safety Code.

Article 4

§64803.060 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), the certificate may be revoked or suspended for any one or more Field of Testing and Unit of Accreditation~~or field of accreditation~~, and the remainder of the certificate shall remain in effect.

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

Article 5. Proficiency Testing Process for State Accreditation

§64809. Laboratory Proficiency Testing Evaluation Requirements.

- (a) 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.
- (b) Each laboratory shall ensure that all proficiency testing study samples are analyzed in accordance with their quality assurance program as defined in Section 64815 by the laboratory staff that routinely perform the analysis and with the equipment that is routinely used in such analysis.
- (c) 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.
- (d) A laboratory failing to produce proficiency testing study results that meet the scoring requirements provided to the laboratory after the conclusion of the study, shall take corrective action(s), maintain records of such actions, and submit a corrective action summary for each failed analyte to the Department within 30 days of receipt of the evaluation report from the provider of the proficiency testing study. The corrective action summary shall include the laboratory's determination of the cause(s) for each "not acceptable" evaluation, and actions taken to improve future data quality. If the Department at its discretion has conducted an on-site inspection, the laboratory shall include its corrective action summary, a response to any cited deficiencies noted during the on-site inspection.

(e) A laboratory applying for initial certification in a Field of Testing and Unit of Accreditation shall participate in a minimum of one, but not more than two proficiency testing studies prior to issuance of the certificate. Where two proficiency testing studies are attempted, the studies shall be performed at a minimum of 30-days apart from the date of the first study closure and the date of commencement of the second study, except for laboratories doing analyses required by the California Department of Food and Agriculture. The laboratory shall participate in and pass one proficiency testing study, at the earliest, six months prior to the date of submittal of the application or, at the latest, 6 months from the date of application submittal.

(f) 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, either: (1) has an investment of \$2,000-1% or more in investments not including mutual funds; or (2) is a director, officer, partner, trustee, employee or manager of the entity that provides the proficiency testing study samples.

(g) 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. (or alternatively, "The laboratory shall assure it complies with the conflict of interest requirements of NELAC regarding the use of proficiency testing study samples.")

NOTE: Authority cited: Sections ~~208, 1011 and 1012~~, 131200, 100830, and 100850, Health and Safety Code. Reference: Sections ~~1015, 1017 and 1019~~, 100850, 100860.1, and 100870, Health and Safety Code.

~~(This Section is deleted because it's covered in section 64809.)~~

~~§64809.010.— Proficiency Testing Studies.~~

~~—(a) Each laboratory shall analyze proficiency testing study samples by each certified method routinely used on samples received and analyzed at the laboratory for regulatory purposes.~~

~~—(b) The laboratory staff, who routinely perform analysis of samples that are received at the laboratory for regulatory purposes, shall analyze the proficiency testing study samples using equipment that is routinely used in such analysis.~~

~~—(c) 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.~~

~~—(d) A laboratory applying for initial certification in a Field of Testing shall participate in a minimum of one, but not more than two proficiency testing studies prior to issuance of the certificate. Where two proficiency testing studies are attempted, the studies shall be performed at a minimum of 30 days apart from the date of the first study closure and~~

~~the date of commencement of the second study. The laboratory shall pass one proficiency testing study, at the earliest, six months prior to the date of submittal of the application or, at the latest, 6 months from the date of application submittal.~~

~~— (e) A laboratory certified or applying for renewal of certification shall participate in a minimum of one, but not more than two proficiency testing studies within a 12-month period, unless otherwise stated in Section 100870 of the Health and Safety Code.~~

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

Article 6. Fields of Testing Units of Accreditation.

§64811. Fields of Testing Units of Accreditation.

~~(a)~~ **(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, group-of-analytes, or physical property. The method shall be Federal or State required for testing of environmental samples for the desired Field of Testing Unit of Accreditation, except for the following:

~~(b1)~~ **(b1)** Laboratories certified for ~~the Fields of Testing~~ Fields of Testing and Units of Accreditation involving drinking water and requesting use of alternate test procedures (ATP) for Federal regulated analytes, group-of-analytes, or physical properties 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, group-of-analytes, or physical properties, that are not Federal regulated but are monitored by the State, shall utilize alternate methods approved by the State.

~~(e2)~~ **(e2)** Laboratories certified for Fields of Testing and Units of Accreditation involving wastewater and requesting use of ATP for Federal regulated analytes, group-of-analytes, physical properties, or species 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, physical properties, or with species that are not Federal regulated but are monitored by the State, shall utilize alternate methods approved by the State.

~~(d3)~~ **(d3)** Laboratories certified for hazardous waste Fields of Testing and Units of Accreditation and requesting use of ATP for Federal or State regulated analytes, group-of-analytes, physical properties, or species shall be in compliance with the California Code of Regulations, Title 22, Ssections 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.

(eb) 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 ~~208, 1011, and 1012,~~ **131200, 100825, and 112165, 100830,** Health and Safety Code. Reference: Sections ~~1012, 1017 and 28503,~~ **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 7. Laboratory Operations Plan Quality Assurance

§64815. Quality Assurance Laboratory Operations Program Plan.

(a) The laboratory shall establish a quality assurance program Laboratory Operations Plan that ensures the production of reliable and valid data and ensures that the laboratory meets the proficiency testing requirements of Article 5. All the elements of the Laboratory Operations Plan shall be documented in writing in the The Laboratory Operations Plan. quality assurance program shall be documented in the laboratory's quality assurance manual. The laboratory shall submit the Laboratory Operations Plan to the Department for approval pursuant to Section 64803. The laboratory shall update annually - its Laboratory Operations Plan, and advise the Department of the updates. its notify the Department prior to making any change to the laboratory operations quality assurance manual, and shall have available for Department review and approval or submit obtain for approval from the Department prior to making the change. The laboratory shall operate in accordance with the approved updated Laboratory Operations Plan, unless otherwise instructed by the Department quality assurance manual.

(b) The quality assurance manual Laboratory Operations Plan 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; and each principal analyst, including his or her education, training and experience;

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

(C) any auxiliary laboratory, including its physical structure and internal laboratory environmental controls to ensure optimal function of laboratory equipment;

(4) Standard Operating Procedures (SOP) and quality assurance procedures for all laboratory functions, operations, and practices inclusive but not limited to the following may appear as a citation in the manua Laboratory Operations Plan:

(A) laboratory internal environmental controls (for example separate ventilation, room temperature, humidity, dedicated power lines, fume hoods, filtration units,

scrubbers, clean rooms, double-door systems) where applicable for optimal equipment and analytical operation, minimizing potential for contamination;

(B) analytical methods which include the following:

(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) procedure 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, ~~NELAC ethics standards~~);

(E) internal audits;

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

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

(H) report and notification to clients;

(I) management and backup procedures for key staff (NOTE: this is to address what happens when director or principal analysts are out of office);

(J) data integrity training ~~as provided in NELAC standards, chapter 5, section 5.5.27~~^[GHY3];

(K) management procedures requirements, including the review and approval process who signs laboratory reports.

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

Article 8. Laboratory Personnel.

§64817. Director.

(a) Each laboratory shall have one or more a-persons who fulfills 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 Subdivisons (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 (fe), 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 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 are-is applicable to each of the Fields of Testing and Units of Accreditation for the types of work performed by-at the laboratory. The following post-graduate degrees may be substituted for part of the required experience:

(A) A masters degree 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 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 , 1089 , 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, and conductivity.
- 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) ~~All The following directors of laboratories that possess a current and valid certificate on the effective date of these regulations~~ shall be exempt from meeting the requirements of (c) ~~and/or~~ (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 ~~director 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.~~

~~—~~(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-director~~ meets the requirements of this ~~S~~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 ~~S~~section.

Note: Authority cited: Sections ~~208, 1011 and 1012~~ **131200, 100825, and 100830**, Health and Safety Code. Reference: Section ~~4042~~ **100830**, Health and Safety Code.

Article 9. Notification and Reporting.

§64819. Notification and Reporting to Meet ELAP Accreditation Purposes.

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

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

(c) The laboratory shall comply with all requirements of notification requirements by State or federal regulatory agencies, including but not limited to notification and reporting requirements. ~~that pertain to the samples and analyses being performed.~~

(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 analysis for compliance with drinking water regulations and requirements, the following shall also apply (NOTE: the following text is from existing regulations, but was omitted from the prior draft):

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

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

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

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

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

3. A nitrate sample exceeds the MCL.

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

(D) 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.

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

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

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

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

4. copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and

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

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

(f) 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. (Note: This language is now Subsection (d).)

Note: Authority cited: Sections 131200 ~~100825 and~~ 100830, ~~400835 and~~ 116375, Health and Safety Code. Reference: Sections 100825(b) and ~~400835~~ 100830, Health and Safety Code.

Article 10. Reciprocity Agreements.

§64821. Reciprocity Agreements.

(a) For reciprocity in another state, the other state needs to apply for reciprocity agreement. Another ~~s~~State's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if that 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 Divison 101 of Health and Safety Code, and the provisions established in Sections 64809 and 64809.010 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 64811, 64815 and 64817 of this Chapter.

(b) In states where a reciprocity agreement exists, 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)

~~(d)~~ If a reciprocity agreement with another State is rescinded, no certificate issued by the Department under this agreement shall be revoked solely due to the rescission of the reciprocity agreement.

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

~~(f)~~ A laboratory certified under reciprocity may be visited or issued 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 Sections 64809 and 64809.010 of this Chapter shall be paid.

~~(g)~~ 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. The laboratory's certificate, issued by the Department, may be suspended or revoked according to Government Code ~~s~~Section XXXX.

Note: Authority cited: Sections ~~208, 1011 and 1012~~ 131200, 100830, Health and Safety Code.
Reference: Sections ~~1011 and 1017~~ 100825, 100860.1, 100865, 100870,, Health and Safety Code.

Article 11. National Environmental Laboratory Accreditation Program Requirements.

§64859. NELAP Application Process.

(a) A laboratory applying for NELAP accreditation or is accredited by the Department under NELAP shall comply with the 2003 NELAC Standards EPA publication number 600/R-04/003. Where the NELAC Standards do not specify, the laboratory shall comply with requirements of the Department.

(b) A laboratory seeking NELAP accreditation in any Field of Testing listed in Health and Safety Code 100862 shall file a complete application.

Note: Authority cited: Sections 131200, 100825, 100830, 100840, and 100862, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 100425, 100825, 100830, 100840, 100847, 100850, and 100851, Health and Safety Code.