*March 25, 2009*

# Frequently Asked Questions – Draft ELAP Regulations

CDPH invited informal comments on the December 5, 2008 draft Environmental Laboratory Accreditation Program (ELAP) regulations. We received a number of comments and have made some changes in the draft regulations currently posted on the CDPH website (March 5, 2009 version) in response to these comments, as well as other changes we made on our own initiative, primarily for clarity.

Although we are not responding to all informal comments provided by interested parties, there were several Frequently Asked Questions brought up by commentors that we believe would be helpful to address, namely:



## *1. Why don't the regulations address procedures for revoking certifications and other enforcement actions?*

Several commenters raised the issue of why the regulations do not, in general, address the procedures for denying, reinstating, suspending and revoking certifications, and for taking enforcement actions. The reason that those matters are not addressed in the regulations is that if a matter is addressed in the law, then the regulations cannot conflict with that law. The regulations can only add specificity or clarity to the law.

The Environmental Laboratory Accreditation Act (ELAA) has a number of provisions that describe the basis for denying, suspending, or revoking certificates or accreditations, including sections 100850, 100851, 100865, 100870, 100905, and 100907. However, the ELAA does not in general, describe the procedures for suspensions or revocations. That is because the administrative adjudication portions of the California Administrative Procedures

Act (APA), which are contained in sections 11500 through 11529 of the Government Code, set out the procedure for hearings to address denials, suspensions and revocations. (The APA itself, ELAA, and Health and Safety Code section 131071 require that the APA be followed.)

Under the APA, a proceeding to deny an application is commenced by the Department's serving on the laboratory a Statement of Issues, and a proceeding to suspend or revoke a certificate is begun by the Department's filing of an Accusation. Because the CDPH contracts with the Department of Health Care Services (DHCS) to have CDPH hearings heard by administrative law judges within DHCS's Office of Administrative Hearings and Appeals, after the proceeding is initiated, the case will be transferred to the DHCS Office of Administrative Hearings and Appeals. That office, and the assigned administrative law judge within it, are responsible for issuing orders to the laboratory as to briefs to file, when the hearing is to be held, explicit procedures governing the hearing, etc.

It is worth noting a particular section of the ELAA that does specifically regulate hearings, namely section 100915. That section authorizes the Department to temporarily suspend a certification or accreditation without a hearing when it is necessary to protect the public health. Then, the law provides that the Department is to notify the laboratory of the suspension, following which the laboratory can request a hearing.

In addition, the law also provides for expiration of a certificate or accreditation if the laboratory fails to submit a completed application, which includes submission of fees, as described in the regulations, within the specified time period. (Health and Safety Code sections 100840 and 100847.) The laboratory would not have a hearing in that situation.

Finally, the ELAA lists a number of enforcement actions, other than suspension or revocation of a certification or accreditation, which may be taken by the Department against a laboratory, and the ELAA also makes certain actions criminal. Those provisions appear in HSC sections 100875 through 100885, and sections 100890 through 1009000. The Department's proposed regulations do not further specify the basis for when the Department or a law enforcement agency may take an enforcement action, nor the procedures to be followed. That is because the ELAA and other laws grant the Department and law enforcement agencies the power to take enforcement actions and describe the procedures to be followed. Furthermore, in California, even if it were possible to do so, a regulatory agency is not required to specify in the regulations the particular enforcement action that an agency is to take for each specific violation of the law or regulations. Each enforcement action is based on the individual circumstances of the violation by the laboratory.

## *2. Why isn't CDPH using the 2004 version of draft regulations coordinated by Alexis Milea, then a senior engineer with the Drinking Water Program, which had input from ELTAC and other interested parties?*

In drafting the various versions of the regulations, the Department considered the version drafted by Alexis and also considered the existing regulations. The Department's decision to reject various provisions in the Alexis version rests on several factors. First, a number of the proposed regulations are inconsistent with certain provisions in the law. For example, the Alexis version (section 64803) provides that a renewal application must be submitted 90 days before it expires. However, the law requires that an application be accepted as long as it is submitted before expiration. The Alexis version also provides that a laboratory's certificate remains in operation after expiration, but that it cannot operate until it does certain things, and also requires the lab to pay a late penalty. However, the law provides that the certificate expires; the law would not permit the certificate to remain valid, nor does it allow for a penalty. Another example is that the Alexis version provides, in section 64811, that a lab's certificate can be revoked if more than 50% of employees quit. However, the law does not provide for revocation on the basis that a certain percentage of employees quit. Also, the Alexis version unnecessarily lists the Fields of Accreditation, as the law lists all the Fields of Testing. The reciprocity agreement section also conflicts with law, and is poorly written. It does not adequately address how reciprocity is to be applied for and approved, and it confuses reciprocity to be granted to the other state with the Department's approval of the laboratory.

Another reason for rejecting some of the regulations proposed in the Alexis version is the fact that the regulations are written in such a fashion that they would not be approved by either the Department's Office of Regulations or the Office of Administrative Law. For example, a number of the definitions contain language that belongs in the regulations themselves, not in the definitions. Definitions are not to contain regulatory language. In the Alexis version, the lab director, demonstration of technical capability, and interim certificate definitions, for example, contain language that is not appropriate for definitions. There are problems with other of the definitions.

The Alexis version also does not clearly spell out the various application processes. It also contains some application requirements in sections of the regulations other than the application sections, e.g. proficiency testing. It also addresses the fees in several different places, and does not make clear when fees must be paid. The Department's version addresses the various instances

where an interim certificate is appropriate, while the Alexis version does not address those applications. Also, the Alexis version does not have a complete application process for a lab that changes ownership. The Department's draft regulation clearly lays out what the lab must do to obtain a new certificate in its own name.

In addition to failing to address a number of matters that should be included in the regulations, the Alexis version erroneously includes others. It purports to amend existing law by including regulations that are inconsistent with provisions in the Health and Safety Code and Government Code. Most notably, the Alexis version improperly addresses the Department's enforcement process. As is more fully described elsewhere in the FAQs, the law establishes the basis and procedure for denial, suspension, and revocation of certificates. The law also provides the Department with the tools that it may use in enforcing the law and regulations. The program, just like other Department programs, then exercises its enforcement authority on a case by case basis, as it deems appropriate, and within the bounds of the law. Regulations are not intended to circumscribe the Department's enforcement authority. Regulations cannot amend the law, and if they conflict with the law, they would be void, even assuming that Office of Regulations or Office of Administrative Law would approve regulations that conflicted with the law.

Certain regulations in the Alexis version also would require frequent updating of the regulations because they incorporate other existing requirements, which may well change. For example, the Alexis version states in section 64813(g), that laboratories must meet certain methods, and lists those methods and the date of the document that describes that method. However, methods are continually updated and new methods are published. Therefore, the Department's version instead generally requires laboratories merely to comply with state and federally required methods, and does not identify them by name or date.

Also, with regards to methods, the Alexis version in section 64808(c) requires the lab to use PT samples approved by ELAP in conjunction with California Food and Ag and US FDA. However, there are no requirements in law for those agencies to work with ELAP, and the Department cannot, via regulations, impose requirements upon other public agencies.

Certain other provisions of the Department's draft regulations differ from the Alexis version, but they do so because ELTAC, at meetings and regulation drafting and discussion sessions in 2007 and later, recommended those revisions. For example, the Alexis version imposes a number of personnel requirements on the laboratory. As can be seen, the Alexis version, in sections 64804, 64811, 64813 and 64814 imposes requirements on laboratories relating to their personnel, including personnel at non-management levels. The

Department's version is limited chiefly to imposing requirements on the laboratory director.

The Alexis version also was deficient in a number of other aspects. One of the most notable of those is that the Alexis version does not use proper language to regulate the laboratory. Thus, the Alexis version at times places requirements on the owner or the laboratory director. However, neither owners nor laboratory directors are certified; it is the laboratory that is certified, and the regulations must always be directed at requiring the laboratory to act.

## *3. Why not use the 2004 (Alexis) version of the draft regulations as a basis for revisions, rather than starting over?*

The Department used the Alexis version as a starting point in revising the draft regulations.

A number of the provisions of the December 5, 2008 draft regulations are quite similar to the 2004 version. However, the December 5, 2008 draft addresses areas in which the 2004 version was inconsistent with state statutes. In addition, the December 5, 2008 version provides needed detail on the requirements for the several kinds of applications that a laboratory may file. Other changes are discussed elsewhere in the FAQs.

The Department has prepared a comparison of the December 5, 2008 and the 2004 draft regulations, which follows.

**COMPARISON OF ELAP'S DEC. 5, 2008 VERSION TO VERSION PREPARED BY ALEXIS MILEA, NOVEMBER 2004**

NOTE:
TEXT FROM MILEA IS IN TIMES NEW ROMAN FONT AND IS NOT UNDERLINED, AND IF REMOVED IN ELAP VERSION IS ~~STRUCK-THROUGH~~.

TEXT FROM ELAP 2008 IS IN ARIAL FONT AND IS UNDERLINED.

**§64801.~~05.~~0114. Acceptable Results**.
"Acceptable Results" means proficiency testing (PT) study ~~findings that the PT study provider or ELAP has determined meet acceptance criteria specified for the study undertaken.~~data generated by a laboratory and in compliance with Section 64809.

**§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.

~~**§64801.07. Analyte Group.**~~

~~"Analyte group" means some or all of the chemicals or substances that can be analyzed by a single analytical method for which a laboratory is seeking accreditation.~~

~~**§64801.10. Analytical Specialist.**~~

~~"Analytical Specialist" means a person who either supervises the activities of others in, or is otherwise responsible for the results produced by, the analysis of environmental samples using sophisticated laboratory instruments, such as gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma atomic emission spectrometers (ICP-AES), inductively coupled plasma mass 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), high performance liquid chromatographs (HPLC), ion chromatography (IC), or liquid scintillation counter (LSC), or bioassay testing.~~

~~**§64801.15. California Analyte.**~~

~~"California analyte" means a chemical or substance for which monitoring is required by a State regulatory program, but may not be by any federal government program.~~

**§64801.0410. Days.**

"Days" means calendar days, unless otherwise indicated.

**§64801.~~20~~.0413. Deficiency.**

"Deficiency" ~~mean a deviation from test method procedures or practices that has not been authorized by ELAP.~~means not in compliance with certification requirements.

~~**§64801.23. Demonstration of Technical Capability.**~~

~~"Demonstration of technical capability" means a document that provides to ELAP the information necessary to determine whether a laboratory has the capability to conduct the analysis for a specific UoA, including:~~

~~(a) Documentation that the laboratory has the necessary equipment/instrumentation;~~
~~(b) Documentation describing the laboratory's operating procedures to ensure conformance with the analytical method(s);~~
~~(c) Four replicates analysis of quality control samples, as follows:~~
~~(1) Samples obtained or prepared from a different source than the initial calibration standards;~~
~~(2) An evaluation of accuracy (mean) and precision (standard deviation); and~~
~~(3) Quality control sample concentration as specified in the method or, if unspecified, approximately ten times the laboratory-calculated MDL;~~
~~(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).~~

**~~§64801.25. Designated Analyte.~~**
~~"Designated analyte" means a substance that can occur in the materials regulated by a State regulatory program that requires the analysis of environmental samples by accredited laboratories.~~

**§64801.~~30~~.0552. ELAP.**
"ELAP" means the ~~California~~ Environmental Laboratory Accreditation Program.

**§64801.0554. 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), 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.

**~~§64801.35. Environmental Sample.~~**
~~"Environmental sample" means a collected volume of potable or not-potable surface or ground water, soil, sediment, hazardous waste, or any other material analyzed for a State regulatory program.~~

**~~§64801.40. Facilities.~~**
~~"Facilities" means fixed or portable building(s), including storage areas, that contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the FoAs for which a laboratory is accredited.~~

**§64801.~~45~~.0622. Field of Accreditation or FoA**.
"Field of Accreditation" or "FoA" means ~~a group~~ Field of ~~UoAs.~~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.

**§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.

~~**§64801.50. Interim Certificate.**~~
~~"Interim certificate" means a temporary certificate of accreditation listing UoAs that a laboratory has requested be added to its existing certificate, that allows the laboratory to report analyses for regulatory purposes for the additional UoAs.~~

**§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.

~~**§64801.55. Laboratory Director.**~~
~~"Laboratory director" means the laboratory staff person who is responsible for actual day-to-day supervision of all technical, analytical and data reporting operations in the laboratory for the fields of accreditation listed on the laboratory's certificate.~~

~~§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.

~~**64801.60. Not Acceptable.**~~
~~"Not Acceptable" means that the PT study provider or ELAP has determined that the PT study findings do not meet acceptance criteria specified for the study undertaken.~~

~~**§64801.65. Owner.**~~
~~"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.~~

~~**§64801.70. Owner's Agent or Agents of Owners or Officer.**~~
~~"Owner's agent" or "agents of owners" or "officer", means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with this chapter or the statutes under which this chapter has been adopted.~~

**§64801.1630. Physical Property.**
"Physical Property" means a measurement of the physical characteristics of an environmental sample.

~~**§64801.75. State Regulatory Program.**~~
~~"State regulatory program" means a program that requires the analysis of environmental samples that has been established under regulatory and/or statutory requirements by the State Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCBs), the Department of Toxic Substances Control (DTSC), the California Environmental Protection Agency (Cal/EPA), the Department of Health Services (DHS), the Department of Food and Agriculture (DFA), or any successor agencies.~~

~~**§64801.80. Test Method.**~~
~~"Test method" means an analytical testing technique or procedure that a State regulatory program requires to be used to determine the level of a designated analyte in an environmental sample for the purposes of assessing compliance with its statutes, regulations and/or permits.~~

**§64801.~~85.~~2082. Unit of Accreditation ~~or UoA~~.**
"Unit of accreditation" ~~or "UoA"~~ means a ~~specific combination of: (a) for ELAP accreditation, a State regulatory program, or for NELAP accreditation, a matrix, (b) a test method or technology, and (c) a designated analyted or analyte group for which accreditation may be obtained~~. component of the Field of Testing, e.g., an analyte, the analytes, group-of-analytes, species, physical properties, and methods.

**§64803. Application for Initial Certification.**

**§64803. ~~Basic Accreditation Requirements for ELAP and NELAP.~~**
~~(a) To obtain a certificate of accreditation (certificate), a laboratory shall meet the following requirements:~~
~~(1) Submit an application, pursuant to Section 64804;~~

~~(2) Except for interim and reciprocal certificates, complete an on-site assessment, pursuant to Section 64808 for ELAP accreditation or NELAC Standards for NELAP accreditation;~~

~~(3) Achieve Acceptable Results in the required proficiency testing studies (PT studies) pursuant to Section 64808 for ELAP accreditation or NELAC Standards for NELAP accreditation; and~~

~~(4) Pay the required fees pursuant to Section 64805.~~

~~(b) The period of the certificate shall be based on the anniversary of the initial certificate of accreditation and shall be as follows:~~

~~(1) For an ELAP certificate, two years;~~

~~(2) For a NELAP certificate, one year, and~~

~~(3) For an amended ELAP or NELAP certificate, the time remaining on the certificate from the date it was amended.~~

**~~§64804. Application for ELAP and NELAP Certificates.~~**

(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)(~~a) To apply for an initial, renewed, or amended ELAP or NELAP certificate, a laboratory shall~~ submit for Department review and approval ~~-~~an application ~~to ELAP that~~ which includes all of the following:

~~(1) Details on the laboratory's type, location, contact information and ownership;~~

(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) county

~~(2) Qualifications of personnel, addressing the requirements in Section 64812:~~
~~(A) For an ELAP certificate, Laboratory Director and Analytical Specialist(s); or~~
~~(B) For a NELAP certificate, Technical Director and Quality Assurance Officer;~~

(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 64817:

(O) ~~(3) FoA(s) and/or UoA(s)~~ Field of Testing and Unit of Accreditation for which ~~accreditation~~ certification is ~~being~~ requested;
~~(Q) (4) Quality assurance manual pursuant to Section 64813 for ELAP accreditation and NELAC Standards for NELAP accreditation;~~ the laboratory's Laboratory Operations and Quality Assurance Plan as described in Section 64815;

(P) ~~(5)~~ ~~F~~fees ~~, pursuant to Section 64805 and, for renewals, Subsection 64803(c); and~~
(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;

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

(S) (6) ~~S~~signature of the ~~Laboratory~~ ~~O~~owner~~, owner's agent, or officer~~, or owner's designee of the laboratory on application form~~,and~~ date

~~signed~~ of signature, printed name of the owner or owner's designee verifying all information provided is true~~.~~

**~~[§64809. On-Site Assessment.]~~**

~~(a) Each laboratory shall be subject to an on-site assessment to obtain its initial certificate and every two years thereafter by ELAP to verify the information submitted with its ELAP certificate application pursuant to Section 64803(a), including compliance with requirements in:~~

~~(1) Methods used for each UoA for which the laboratory seeks accreditation;~~
~~(2) Section 64812 (Laboratory and Equipment);~~
~~(3) Section 64813 (Quality Assurance); and~~
~~(4) Section 64814 (Personnel)~~

~~(b) Within 30 days of the on-site assessment, the laboratory will receive a notice of deficiencies related to compliance with Subsection(a) from ELAP.~~

~~(1) Within 30 days of receipt of the deficiencies notice from ELAP, the laboratory shall submit a corrective action report to ELAP that details how each identified deficiency has been investigated and corrections initiated and/or completed; the laboratory will be notified within 30 days whether the corrective action report demonstrates the corrections;~~

~~(2) If the laboratory is notified by ELAP that the corrective action report does not adequately address the identified deficiencies, the laboratory shall have an additional 30 days from its receipt of the notification to submit a revised corrective action report; if the revised report still does not demonstrate the required corrections, accreditation shall be denied or revoked for any UoAs affected by failure to take corrective action~~

~~(3) Prior to the deadline for report submission, a laboratory may request in writing that ELAP allow additional time to complete the report. The laboratory will be notified within 10 days of ELAP's receipt of such a request whether the extension has been approved, based on an evaluation of the reasons provided by the laboratory.~~

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

(3) acceptable results for applicable proficiency testing study samples, pursuant to Section 64809, if available, for each Field of Testing or Unit of Accreditation for which the certificate is requested; and

(4) the laboratory has received the Department's approval of its Laboratory Operations and Quality Assurance Plan.

(b) For this Section and Section 64803.040, the auxiliary laboratory is any stationary place that is:

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

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

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

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

(5) identified as an auxiliary laboratory in the laboratory's Laboratory Operations and Quality Assurance Plan.

**§64803.020. Application for Amendment of the Certificate.**

~~[(64804)(c)] To remove one or more UoAs or FoAs from its certificate:~~

~~(1) In between renewals, the laboratory shall submit a written request to ELAP and receive an amended certificate.~~

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

(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 64803.050;

(2) change its location;

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

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

(b) A laboratory's application for Amendment of Certificate for change of name will be approved provided that the laboratory has filed an application with the

Department that has been signed by the owner or owner's designee and that includes the certificate number of the laboratory, name on existing certificate and proposed new name, and address of the laboratory;

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

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

(2) A description of the new location;

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

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

(1) The laboratory has filed an application with the Department that has been signed by the owner or owner's designee and that includes: the name of the laboratory, the certificate number of the laboratory, the address of the laboratory, the identification of each Field of Testing and Unit of Accreditation to be added or modified, and the Field-of-Testing fee required by the regulations for each Field of Testing and Unit of Accreditation to be added or modified, and any portion of the Laboratory Operations and Quality Assurance Plan as described in 64815 that differs relating to the proposed amendment from the version of the Laboratory Operations and Quality Assurance Plan 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 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 Department has received acceptable results for proficiency testing study samples pursuant to Section 64809, 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.

~~§64803.030. Application for Renewal of a Certificate.~~

~~[SECTION 64803]~~

~~(c) To renew a certificate, at least ninety days prior to its expiration date, a laboratory shall submit a renewal application pursuant to Section 64804(a).~~

~~(1) A renewal application submitted prior to the expiration date, but less than 90 days prior to that date, shall be subject to a late fee of $300 in addition to the accreditation fee.~~

~~(2) If it does not submit its renewal application by the certificate expiration date, as of that date, the laboratory shall cease all reporting of analytical work for regulatory purposes until it has been notified in writing that its application has been received by ELAP. When it submits its renewal application, the laboratory shall pay a penalty in addition to its accreditation and late fees as follows:~~

~~(A) 10% of its accreditation fee, if application submitted within 30 days after the expiration date;~~

~~(B) 25% of its accreditation fee, if application submitted 31 to 60 days after the expiration date; or~~

~~(C) 50% of its accreditation fee, if application submitted 61 to 90 days after the expiration date.~~

~~(3) If a laboratory fails to submit its renewal application by 90 days after its certificate expiration date, the certificate shall not be renewable. To obtain a certificate, the laboratory shall be required to apply as for an initial certificate, pursuant to Subsection (a).~~

~~(4) A laboratory that has submitted a renewal application shall be subject to an on-site assessment within six months after being notified by ELAP of the requirement for the assessment. If the assessment is not completed within this time period and the delay is not due to ELAP error or procedure, the laboratory's certificate shall be subject to revocation.~~

[(64804)(c) ~~To remove one or more UoAs or FoAs from its certificate:~~]

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

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

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

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

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

(4) The Department has received acceptable results for applicable proficiency testing study samples, pursuant to Section 64809, if available, for each Field of Testing or Unit 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 has accepted the response to any cited deficiencies.

~~§64803.040. Application for an Interim Certificate.~~

~~(64804)(b) A laboratory may submit a written request at any time for an interim certificate, if it is an accredited laboratory that is applying for an amended certificate to add UoAs and wishes to report analyses for regulatory purposes for the new UoAs while its amendment application is being processed. A laboratory shall not submit a request for an interim certificate for a microbiological test procedure, unless it is already accredited for one or more equivalent microbiological methods.~~

~~(1) Prior to the laboratory's conducting and/or reporting any analytical work for regulatory purposes, Acceptable Results for PT studies for the UoAs in the application shall be received by ELAP and an interim certificate issued.~~

~~(2) The interim certificate shall be valid until:~~

~~(A) A site visit has been completed and an amended certificate issued; or~~

~~(B) An amended certificate has been issued based on ELAP's review of an equivalent demonstration of technical capability by the laboratory for the UoAs on its application.~~

~~(C) ELAP notifies the laboratory that the interim certificate has expired due to failure to meet either of the requirements in (b)(2)(A) or (B) or at the end of one year from its issue date, whichever comes first.~~

(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 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 for which the certificate is requested; and

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

(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 64803.020 (d)(2).

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

**§64803.050. ~~§64811. Change~~ Sale or Transfer ~~of Laboratory~~ Ownership.**

(a) To apply to operate under the laboratory's existing ELAP certificate until its expiration date ~~and to temporarily operate while the application is being processed,~~ 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 ~~Section 64808~~ Health and Safety Code 100865, and provide the following in writing to ELAP~~, as a minimum:~~:

(1) the n~~Name(s)~~ of the new owner~~(s);~~ and owner's designee;

(2) E~~e~~effective date of the change of ownership;

~~(3) Names of all Analytical Specialists who quit, or were terminated and replaced as of the effective date of the ownership change; and the names of all Analytical Specialists hired as replacements.~~

(3) ~~(4)~~ Qualifications of ~~personnel~~ laboratory director, addressing the requirements in Section ~~64814 for laboratory director and analytical specialist;~~64817, if changed;

~~(5)~~ (4) Statement that the new owner will operate pursuant to the laboratory's existing certificate and will not change ~~any of the following~~ anything in the Laboratory Operations and Quality Assurance Plan as described in Section 64815 without requesting and obtaining written approval from ELAP:

~~(A) laboratory location,~~

~~(B) equipment~~

~~(C) methodology~~

~~(D) quality assurance practices~~

~~(6)~~ (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), or their agents~~ or owner's designee~~.~~

~~(b) The laboratory under new ownership shall have its certificate revoked as of the effective date of the ownership change if:~~

~~(1) It does not comply with the requirements in Subsection (a);~~

~~(2) If the new owner relocates the laboratory without ELAP approval; or~~

~~(3) If more than half the laboratory's technical staff either quit or are terminated and replaced by the new owner upon assuming ownership.~~

~~(c) The laboratory under new ownership shall be subject to having its certificate revoked upon ELAP notification if an on-site assessment indicates inconsistencies with the information provided pursuant to Subsection (a);~~

(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 64803, and may submit an application for an interim certificate pursuant to Section 64803.040.

## Article 4. Suspension and Revocation of Certificate

### §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, and the remainder of the certificate shall remain in effect.

(THE DEPARTMENT IS NOT PROPOSING TO AMEND EXISITING 64806)

~~**§64805. Accreditation Fees for ELAP and NELAP Certificates.**~~

~~(a) Fees for ELAP accreditation shall be paid as follows:~~

~~(1) An administrative fee of $1250 with the submittal of an application for initial, renewed, or reinstated accreditation, and annually thereafter;~~

~~(2) An FoA fee determined as follows with the submittal of an application for initial, amended, renewed, or reinstated accreditation, and annually thereafter:~~

~~(A) $500 each for FoAs 102, 109, 115, and 119;~~

~~(B) $750 each for FoAs 101, 103, 105, 107, 108, 110, 112, 113, 116, 118, 120, 121, 122, and 123; and~~

~~(C) $1100 each for FoAs 104, 106, 111, 114, 117, and 124.~~

~~(3) Except for UoAs in FoA 119, a UoA fee of $5 for each UoA (single analyte) listed on the application for initial, amended, renewed, or reinstated accreditation, and annually thereafter. If a laboratory seeks accreditation for an analyte group by a single method, the UoA fee for that analyte group shall be $5 for each chemical or substance in the group up to a maximum of $400.~~

~~(b) Fees for NELAP accreditation shall be paid as follows:~~

~~renewed, or reinstated accreditation, and annually thereafter;~~

~~(2) An FoA fee determined as follows with the submittal of an application for initial, amended, renewed, or reinstated accreditation, and annually thereafter:~~

~~(A) $750 each for FoAs 102, 109, 115, and 119;~~

~~(B) $1000 each for FoAs 101, 103, 105, 108, 110, 112, 113, 116, 118, 120, and 121; and~~

~~(C) $1200 each for FoAs 104, 106, 111, 114, and 117.~~

~~(3) Except for UoAs in FoA 119, a UoA fee of $5 for each UoA (single analyte) listed on the application for initial, amended, renewed, or reinstated accreditation, and annually thereafter. If a laboratory seeks accreditation for an analyte group by a single method, the UoA fee for that analyte group shall be $5 for each chemical or substance in the group up to a maximum of $400.~~

~~(c) When the new owner of a laboratory that has changed ownership requests to retain the ELAP or NELAP certificate, it shall submit FoA fees pursuant to Section 64805 for the FoAs on the certificate.~~

~~(d) A laboratory that has, or is applying for, both ELAP and NELAP accreditation shall pay only one administrative fee, i.e., the NELAP fee specified in Paragraph (b)(1).~~

§64859~~**§64807. Requirements for NELAP Certificates.**~~

~~NELAP Application Process.~~

~~Unless otherwise specified in this Chapter,~~

(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.

**~~§64808.~~ §64809. Laboratory Proficiency Testing ~~(PT) Studies~~Evaluation Requirements**

~~(b) To maintain accreditation, each laboratory shall:~~

~~(1) Each calendar year, achieve Acceptable Results in a PT study for each UoA for which it is accredited, as follows:~~

~~(A) If the results for the first PT study for a UoA are Not Acceptable, the laboratory shall:~~

~~1. Within 30 days of receipt of the evaluation report from the PT study provider, take corrective action(s), and maintain records of such actions; and~~

~~2. Conduct a second PT study before the end of the calendar year.~~

~~(B) If the results for both PT studies for a UoA are Not Acceptable, the laboratory shall:~~

~~1. Have its accreditation for that UoA suspended on receipt of written notification from ELAP;~~

~~2. Cease all analytical work for regulatory purposes for that UoA upon receipt of the "Not Acceptable" results;~~

~~3. Conduct two sets of PT studies for the UoA; and~~

~~4. Have its accreditation reinstated upon receipt of Acceptable Results for both PT studies, or if either or both sets of PT study results are Not Acceptable, apply for an amended certificate pursuant to Section 64804(a).~~

(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.

~~(c) Each laboratory shall conduct PT studies as follows:~~

~~(1) Except for UoAs in FoAs 122, 123, and 124, using PT samples that:~~

~~(A) Meet the design, execution, and reporting requirements in the NELAC Standards; and~~

~~(B) Have been obtained from a provider designated by ELAP, based on a demonstration that the provider meets the requirements contained in the NELAC~~

~~Standards, and/or has been accredited by a NELAC-designated Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA).~~

~~(2) For toxicity bioassay PT studies for any FoA, using PT samples prepared and scored pursuant to the "National Standards for Water Proficiency Testing Studies, Criteria Document, Toxicity Studies", Part 3, January 31, 2001.~~

~~(3) For UoAs in FoAs 122, 123, and 124, using PT samples approved by ELAP in conjunction with the California Department of Food and Agriculture.~~

~~(4) For UoAs in FoAs 101 and 108, using PT samples approved by ELAP in conjunction with the Federal Food and Drug Administration.~~

~~(e)~~ [sic]~~A laboratory conducting PT studies for UoAs in FoAs 115 through 118, shall conduct PT studies that match their accreditation by phase, as follows:~~

~~(1) For aqueous phase, by analyzing a liquid PT sample; or~~

~~(2) For aqueous/solid phase, by analyzing a solid phase PT sample.~~

~~(f) A laboratory conducting PT studies for UoAs in FoAs 122, 123, and 124 shall complete all PT studies provided by ELAP up to four studies, if available, within twelve months from the date of receipt by the laboratory and achieve Acceptable Results in a minimum of two.~~

~~(g) For a California analyte for which there is no PT study available that meets the requirements in Subsection (c)(2)(A and B), a laboratory shall conduct a PT study that has been provided to it by ELAP along with the acceptance criteria and concentration ranges for the study. The criteria and ranges will have been based on the Environmental Laboratory Technical Advisory Committee recommendations.~~

(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.

~~(a) If a PT study that meets the requirements in Subsection (c)(2)(A and B) is available, to obtain an initial or amended ELAP certificate, each laboratory shall achieve Acceptable Results for at least one PT study for each UoA on its application within three months prior to, or subsequent to, the Department's receipt of the laboratory's application.~~

~~(1) With the exception of UoAs in FoAs 119, 122, 123, and 124, each laboratory shall conduct up to a maximum of two PT studies for each UoA;~~

~~(2) If it does not achieve Acceptable Results in the first PT study for a UoA, the laboratory shall conduct a second study within the same calendar year and achieve Acceptable Results; and~~

~~(3) If it does not achieve Acceptable Results in either of the two PT studies for a UoA, the laboratory shall not be accredited for that UoA.~~

(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, six months from the date of application submittal.

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

(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, 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.

(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. The laboratory's compliance with the conflict of interest requirements of NELAC regarding the use of proficiency testing study samples shall satisfy the requirements of this subsection.)

**~~§64810.~~§64821. Reciprocity Agreements**.

(a) For reciprocity in another state, the other state needs to apply for reciprocity agreement. Another ~~S~~state's ~~or federal agency's~~ environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if ~~the program's requirements related to proficiency testing, on-site assessments, quality assurance, laboratory facilities and equipment, test methods, and personnel are at least as stringent as the ELAP accreditation requirements in this chapter.~~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 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 64811, 64815 and 64817 of this Chapter.

(b) In states where a reciprocity agreement exists, ~~each~~a laboratory certified and audited by that state may seek~~ing accreditation shall~~ California certification by submitting:

(1) ~~A~~an application pursuant to ~~Section 64804(a); (~~Article 2~~) Copies~~ of ~~the~~ this Chapter;

(2) if requested by the Department, c~~C~~opies of the ~~PT study~~ results evaluated, or scored, from the ~~most recent~~ last proficiency testing study ~~conducted by~~ in which the laboratory participated for the other program;

(3) if requested by the Department, ~~C~~copies of the ~~most recent~~ last on-site ~~assessment~~evaluation report prepared by the other program and the laboratory's response to any deficiencies noted;

(4) all applicable f~~F~~ees pursuant to Health and Safety Code, Section ~~64805;~~ Section 100860.1; and

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

(c) 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.

(d) No fees are waived where reciprocity exists.

~~(f) When ELAP conducts a site assessment for an out-of-state laboratory accredited, the laboratory shall reimburse ELAP for all per diem and travel expenses incurred.~~

(e) 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.

~~(d)~~
(f) If a laboratory that is accredited through reciprocity has its certificate suspended or revoked by the other State or ~~f~~Federal agency~~'s environmental, laboratory accreditation program, it~~ the laboratory shall notify ~~ELAP~~the Department within 10 days of the suspension or revocation ~~and its ELAP certificate shall be~~ . The laboratory's certificate, issued by the Department, may be suspended or revoked ~~as of the effective date of the action taken by the other program.~~ according to Government Code Section XXXX.

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

## Article 7. Laboratory Operations and Quality Assurance Plan

### ~~§64813.~~ §64815. Laboratory Operations and Quality Assurance Plan.

(a) ~~To obtain and maintain ELAP accreditation, each~~ The laboratory shall ~~(1) Implement a~~ establish a Laboratory Operations and qQuality aAssurance ~~program for all UoAs for which it seeks, or is maintaining, accreditation;~~ Plan that ensures the production of reliable and valid data and ensures that the laboratory meets the proficiency testing requirements of Article 5. All the elements of the Laboratory Operations and Quality Assurance Plan shall be documented in writing within the Laboratory Operations and Quality Assurance Plan, unless references to documents, as identified below, are included. The laboratory shall submit the Laboratory Operations and Quality Assurance Plan to the Department for approval pursuant to Section 64803. The laboratory shall update annually its Laboratory Operations and Quality Assurance Plan, and advise the Department of the updates. ~~(3) On request, provide documentation to ELAP that demonstrates compliance with the quality assurance program for each UoA for which it seeks, or is maintaining, accreditation.~~The laboratory shall operate in accordance with the updated Laboratory Operations and Quality Assurance Plan, unless otherwise instructed by the Department.

(b) ~~As a minimum, t~~The ~~l~~Laboratory~~'s manual~~ Operations and ~~q~~Quality ~~a~~Assurance Plan shall include ~~the following:~~ and not be limited to, the following elements:

(1) table of contents;

(2) introduction;

~~[b](3) For each staffperson;~~

~~1. Job description;~~

~~2. For each analytical specialist, training record and/or description of experience demonstrating capability to analyze each UoA for which the analyst is responsible; this may include classes, acceptable results from performance testing sample analysis, and completion of a Demonstration of Technical Capability.~~

~~(c) In addition to the requirements in Subsection (b), the quality assurance manual for a laboratory with 10 or more employees shall include the following:~~

~~(1) Organization and management structure of the laboratory, including the technical director, quality assurance officer, supervisors, and the laboratory's approved signatories; and~~

(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;

**~~§68412. Laboratory and Equipment.~~**

~~A laboratory shall be arranged and operated so that:~~

~~(a) Utilities are maintained to allow the laboratory equipment to function and produce analyses for each UoA for which the laboratory is accredited;~~

~~(b) Ventilation and environmental control are maintained to ensure that analytical results do not exceed quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual; and~~

~~(c) The potential for sample contamination is minimized.~~

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

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

~~(1)~~ (4) lists of ~~Standard Operating Procedures~~ (SOPs) ~~for all UoAs,~~ including ~~a~~ ~~description of the steps used for the analysis, as well as the following:~~

~~(A) Instruments;~~

~~(B) Standards;~~

~~(C) Reagents;~~

~~(D) Calibration Procedures; and~~

the date of each SOP's last revision;

(5)~~(E) Q~~quality Control assurance procedures ~~as found in the analytical method or described in Section 64813(f) and (g)~~, unless they are included in specific SOPs listed in Subsection (b)(4) of this Section;

(6) ~~(2) Prepare a~~ the laboratory's ~~q~~Quality ~~a~~Assurance manual ~~documenting the elements of its quality assurance program~~;

(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 Laboratory Operations and Quality Assurance 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. ~~(2) Procedures for the following:~~

~~(A)~~ Sample ~~receipt, storage, tracking, and disposal;~~ collection, preservation, handling, chain-of-custody;

8. procedure which includes sample preparation, sample cleanup, ~~(D) Recording the preparation of calibration standards, reagents, media, calibration check solutions, quality control samples, and other relevant materials;~~ calibration, calibration checks/verifications, qualitative/quantitative analyses, quality control, data review/validation, data acceptance, and/or ~~(E)~~ c~~C~~orrective actions ~~when quality control requirements are not met;~~

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 ~~(C) I~~nstrument maintenance;

~~(f) Each laboratory shall maintain up-to-date records for every technical staffperson and contracted personnel documenting that each:~~

~~(1) Reads annually, understands, and uses the laboratory's most current quality assurance procedures that pertain to his/her responsibilities;~~

~~(2) Has been trained at least annually in the procedures; and~~

~~(3) Has been annually reviewed for a demonstration of capability.~~

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

(E) internal audits;

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

~~(B)~~ (G) r~~R~~ecord~~s retention, storage, and disposal;~~ in compliance with State, federal, or local requirements established for the environmental testing program;

(H) report and notification to clients;

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

~~[c] (2)~~ (J) Data integrity ~~procedures signed and dated by senior laboratory management that include, as a minimum: Data integrity training; signed data integrity documentation for all employees; in-depth, periodic monitoring of data integrity; and data integrity procedure documentation;~~
training.

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

~~(e) Each laboratory accredited for UoAs in FoAs 101 – 106 shall demonstrate compliance with the requirements in the Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-B-97-001) (Chapter IV-Chemistry; Chapter V Microbiology; Chapter VI-Radiochemistry). If a regulation has established more stringent requirements for any of these UoAs, the laboratory shall demonstrate compliance with those requirements."~~

~~(g) If an analytical method does not have quality control procedures, a laboratory shall use the following:~~

~~(1) For UoAs in FoAs 101, 107, and 108, Standard Methods for the Examination of Water and Wastewater, 20th edition (1998), or Standard Methods Online (), April 2004; www.standardmethods.org, Sections 9020, 9030, 9040, and 9050. For UoAs in FoA 101, Section 9060 B is also required;~~

~~(2) For UoAs in FoA 102 and 109, Standard Methods for the Examination of Water and Wastewater, 20th edition (1998), or Standard Methods Online (),April 2004;www.standardmethods.org, Sections 2020 for general physical and aggregate property tests, 3020 for non-spectroscopy method for elements, 4020 non-ion chromatography methods for inorganic analytes, and 5020 for non-specific organic substances;~~

~~(3) For UoAs in FoA 103 and 110, Standard Methods for the Examination of Water and Wastewater, 20th edition (1998), or Standard Methods Online (), April 2004; www.standardmethods.org, Section 3020 for spectroscopy methods and 4020 for ion chromatography methods.~~

~~(4) For UoAs in FoA 104 and 111, Standard Methods for the Examination of Water and Wastewater, 20th edition (1998), or Standard Methods Online (), April 2004; www.standardmethods.org, Section 6020.~~

~~(5) For UoAs in FoA 105 and 112, Standard Methods for the Examination of Water and Wastewater20th edition (1998), or Standard Methods Online (), April 2004; www.standardmethods.org, Section 7020.~~

~~(6) For UoAs in FoA 113, Standard Methods for the Examination of Water and Wastewater, 20th edition (1998), or Standard Methods Online (), April 2004; www.standardmethods.org, Section 8010 and 8020.~~

~~(7) For UoAs in FoAs 115 through 121, Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, (SW-846) U.S.E.P.A., third edition; and~~

~~(8) For UoAs in FoAs 122 through 124, the quality control procedures specified by the Department of Food and Agriculture, on the basis of the intended use of the analytical data.~~

(c) In preparing the Laboratory Operations and Quality Assurance 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 Operations and Quality Assurance 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 and Quality Assurance Plan.

~~(d) Prior to accepting and instituting a test method, and at any time that there is a change in the type of instrument, personnel or method, the laboratory shall perform a demonstration of technical capability and maintain records for ELAP review on request.~~

(d) A list of the laboratory SOPs is to be submitted as part of the Laboratory Operations and Quality Assurance Plan. At the Department's request an SOP shall be provided by the laboratory to the Department.

## ~~§64814.~~Article 8. Laboratory Personnel.

### §64817. Director.

(a) Each laboratory shall ~~designate a laboratory director~~ 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) ~~(e)~~ The director shall not serve as a director in name only and ~~A laboratory director, or his/her designee,~~ 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;

~~(2)~~ (3) Ensuring the accuracy and quality of all data reported by the laboratory, including any auxiliary laboratory.

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

~~sanitary~~ chemical, or public health engineering, or natural or physical science; and

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

(2) Documentation of experience including at least three years work experience in the analysis of ~~chemical and microbiological samples, prior to being designated laboratory director, subject to the following allowances~~ 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 master's degree from an accredited college or university in chemistry, biochemistry, biology, microbiology, or environmental, ~~sanitary or~~ 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, ~~sanitary or~~ chemical , or public health engineering, ~~biology, microbiology~~, or natural or physical science may be substituted for two years of the required experience.

~~(b) Except as provided in Subsections (c) and/or (d), prior to being designated an analytical specialist, a person shall have as a minimum a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science; and, if working for the laboratory, be under the supervision of a laboratory director or analytical specialist; and have:~~

~~(1) A certification of completion for a course taught by the manufacturer of the sophisticated laboratory instrument which is being used or supervised by the analytical specialist; or~~

~~(2) Six months experience operating a sophisticated laboratory instrument to analyze water, wastewater, solid waste, hazardous waste or other environmental samples, or food.~~

~~(c)~~ (d) In lieu of meeting the requirements specified in Subsections ~~(c), (a) or (b), a laboratory~~ director ~~or analytical specialist(s)~~ employed by a laboratory owned by a ~~public drinking water or wastewater~~ government utility shall ~~have and~~ possess a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Environment Association ~~(CWEA)~~ or the California-Nevada Section of the American Water Works Association ~~(CA-NV/AWWA)~~ , pursuant to the Fields of Testing Conversion Table ~~64814, as follows:~~

~~(1) A laboratory director shall have the highest certificate grade required~~ for Director Capacity. The minimum grade of the ~~performance of any FoA~~ above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory ~~is accredited.~~ seeks certification as noted in the table.

~~(2) An analytical specialist shall have the certificate grade required for the FoA(s) and UoAs for which the analytical specialist conducts analyses or supervises others conducting analyses for the laboratory.~~

**~~Table 64814~~**
**~~Minimum Personnel Certification~~**

| ***~~Fields of Accreditation (FoAs)~~*** | ***~~Minimum Certificate Grade~~*** | ***~~UoAs Allowed~~*** |
|---|---|---|
| ~~101, 108~~ | ~~I~~ | ~~All~~ |
| ~~102, 109~~ | ~~I~~ | ~~Alkalinity, Hardness, Total Filterable Residue, Conductivity, Chloride~~ |
| ~~109~~ | ~~II~~ | ~~Acidity, BOD, COD, Chlorine Residual, DO, pH, Turbidity, Residues~~ |
| ~~102, 109~~ | ~~III~~ | ~~All~~ |
| ~~103, 110~~ | ~~III~~ | ~~All, except those using ICP-MS~~ |
| ~~104, 111~~ | ~~III~~ | ~~All, except those using GC-MS or LC-MS~~ |
| ~~103, 104,105, 110, 111, 112, 113~~ | ~~IV~~ | ~~All~~ |

| **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) ~~(d)~~ The following shall be exempt from meeting ~~Subsections (a), (b) and (c):~~ 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 ~~or analytical specialist who was employed by an environmental testing laboratory at the time that the laboratory was first accredited, provided that the accreditation date was on or before~~ as of December 31, 1994.

~~(f) A laboratory director shall assume the position of, or shall designate another person as, the analytical specialist responsible for the use of each sophisticated laboratory instrument in the laboratory.~~

~~(g) If a laboratory director leaves and is not replaced within 15 days by a person meeting the laboratory director requirements in this section, a person or persons with lesser qualifications may serve as a temporary~~ (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 ninety days from the date the interim director first assumes the duties of director, provided that the laboratory ~~notifies ELAP, describing the qualifications of the temporary director and receives written approval from ELAP. An additional extension of no~~ has not received disapproval from the Department. The interim director may serve for more than ninety days ~~beyond the original 90-day period may be granted by ELAP, provided the laboratory can document that its good-faith efforts to recruit a qualified director were not successful for reasons beyond its control.~~ 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.

**~~§64815.~~ §64819. Notification, and Reporting~~, and Records Retention.~~ to Meet ELAP Accreditation Purposes.**

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

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

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

(d) ~~(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) (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:

~~(a)~~ (1) ) Laboratories certified for ~~FoAs 101, 102, 103, 104, 105 and/or 106~~ Field of Testing 1, 2, 3, 4, 5, or 6 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, 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 is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).

~~(C)~~ 3. A nitrate sample exceeds the MCL.

(C) The laboratory shall notify a water supplier's designated contact person as soon as possible, 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 exceeds the MCL.

~~(3)~~ (D) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraph~~s (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.
~~(4)~~ (E) 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.

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

~~(5)~~ (G) 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. ~~C~~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. ~~C~~ complete description of the error alleged to have invalidated the result(s);
~~(D)~~ 4. ~~C~~ copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and
~~(E)~~ 5. ~~A~~ any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.

~~(b)~~ (2) Laboratories certified for ~~FoAs 122 and 123~~ 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.

~~(d) Each laboratory shall maintain comprehensive records of all laboratory activities, including original observations, calculations and derived data, calibration records and copies of test reports for a minimum of five (5) years.~~

## *4. Why doesn't the "intent" of the co-authors of AB 1317, as described in their 2005 letter to the Assembly Journal, support adoption of the draft regulations prepared in 2004?*

One commentor supported the prior (Alexis Milea) version, because "it was the intent of the sponsors of the bill that Alexis' regulations … be adopted." This refers to a September 8, 2005 letter to the Assembly Journal regarding AB 1317, and the commentor's interpretation that it demonstrates "intent" by the authors that the regulations and statutes be coordinated. The letter is from the Chair and Vice Chair of the Assembly Committee on Environmental Safety and Toxic Materials (Assemblymembers Ruston and Tran, respectively). The letter is reproduced below.

<Letterhead>
Assembly
California Legislature

Assembly Committee on Environmental Safety and Toxic Materials

September 8, 2005

Honorable Fabian Nunez
Speaker of the Assembly
Sate Capitol, Rm 219
Sacramento, CA 95814

Re: Letter to the Assembly Journal regarding AB 1317 (Ruskin)

Dear Speaker Nunez:

AB 1317 updates and restructures the statutory framework that govern the Environmental Laboratory Accreditation Program (ELAP) which is run by the Department of Health Services (DHS). ELAP is the program that accredits the state environmental program that accredits the state environmental laboratories that conduct the tests need for regulatory compliance.

AB 1317 was designed to maintain, in statue, the existing authority of DHS to certify ELAPs, to set the fees to cover the actual costs of the program by regulations, to recognize accreditation form others states for ELAPs, and to establish third –party laboratory assessor bodies.

The bill moved, to the regulatory process, the functional elements of the program that need to adapt and change on a regular basis (such as listing of the fields for certification) so that they can keep up with changes in regulatory performance as required by changes in the law.

Lastly it maintains, in statute, the procedures and penalties for the denial, suspension, or revocation of laboratory accreditation, including authorization to inspect an accredited laboratory.

As originally written, it was designed to work tightly with a set of draft regulations that had been formed through an extensive and collaborative process between the Department of Health Services and the regulated community. Amendments were taken in the Senate to address some concerns expressed by the Department of Health Services about how to "blow up this box" and make the proper transition. Those amendments were not tied to those draft regulations. Some conflicts will remain between existing statute and regulations. For instance, current regulations have two fields of testing for microbiological tests, one for drinking water wastewater, and one for shellfish. Proposed regulations have four fields of accreditation for microbiological tests: drinking water, shellfish, wastewater and food. Current statute has two different sets of fields of accreditation (ELAP and NELAP) with seven individual fields. ELAP has: drinking water, wastewater, food, recreational and shellfish. NELAP has: drinking water and wastewater.

We much appreciate the cooperation of all the parties to get this far.

This letter is submitted to the Assembly Journal to memorialize commitments made by the undersigned authors, representatives of the regulations community and the Department of Health Services. Even though the remaining language of the bill as introduced gives enough borad authority to revamp the conflicting regulations, we pledge to stay involved in this reorganization effort to make sure that the process goes forward in a timely fashion, and that the concerns of the stakeholders, regulated community and the agency continue to get dedicated focus.

Sincerely

<signed by> <signed by>

Ira Ruskin
Chair

Van Tran
Vice Chair

The commentor points out that Ms. Milea's effort resulted in a set of draft regulations that had wide support among those who participated in its preparation and that was supported by ELTAC, the Environmental Laboratory Technical Advisory Committee.

However, no matter how much consensus or support there is for that draft, it cannot proceed into the regulatory process, because, as the commentor mentions, and as his "supporting" letter from the Assembly Members mentions, the 2004 draft regulations conflict with state statutes.

This disparity between draft regulations and statutes resulted because of timing related to the development of the two sets of documents. The draft regulations were intended to coordinate and be consistent with a bill (Assembly Bill 1317), as introduced in 2005. However, the bill was amended from its original language in the Assembly, and further amended in the Senate, passed

by both houses and signed into law in September 2005. It became effective January 1, 2006.

As a result, the draft regulations developed prior to the bill's adoption as a statute contain language that was no longer suitable for those regulations, given the final statutory language.

The commentor considers the letter to have some significance in his recommended approach to using the Nov 2004 (same as ELTAC Jan 2005) draft ELAP regulations. A careful reading of the letter, however, does not find the support the commentor believes is there. In fact, the letter mentions there are conflicts. ("Some conflicts will remain between statute and regulations.")

It seems more that the letter supports the CDPH's point of view, since in the last paragraph, it states, "Even though the remaining language of the bill as introduced gives enough broad authority to revamp the conflicting regulations, ..."

Thus, if this letter has any significance it may be that the authors envisioned the conflicting regulations need to be changed so that they would not conflict with the statute. That they appreciate the "cooperation of all parties to get this far" suggests that they recognized that were still further efforts needed before regulations were completed. That is what we are attempting to do in the current draft regulations.

In addition, the significance of this letter appears to be a memorialization of commitments by the Assembly Committee, analytical laboratory representatives, and DHS (the precursor to CDPH), although, it is unclear what commitments are being made. The sentence of the last paragraph appears to be a pledge to remain involved in the reorganization effort leading to the formation of CDPH (hence the earlier reference to "blow up this box"), and not necessarily to the effort of adopting ELAP regulations.

Further, an Assembly committee's letter about the original design of the bill does not have the same weight as the statute signed into law. (Also, as mentioned above, it is difficult to identify the "intent" of the authors, with regard to the bill.) Other members of the Assembly and Senate appeared to have preferred the amended versions better, and thus had their own, different "intent." Apparently the Governor did, too, since he signed it into law on September 20, 2005.

Finally, whether or not the letter provides the authors' intent, the Department can only adopt regulations based on actual signed-into-law statutory language, and that quite often is not in the same form as it was introduced (or intended).