CALIFORNIA
Water Boards
STATE WATER RESOURCES CONTROL BOARD
REGIONAL WATER QUALITY CONTROL BOARDS

California Environmental Laboratory Accreditation Program (ELAP)

Environmental Laboratory Technical Advisory Committee (ELTAC) Meeting

December 13, 2018

Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

ELTAC Meeting

December 13, 2018

Sacramento and Riverside

REVISED

NOTICE OF ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC) MEETING

December 13, 2018
10:00 a.m. – 3:00 p.m.
(or until completion of business)

Location 1	Location 2
California Environmental Protection Agency Building	~~TBA Southern California~~ Santa Ana Regional Water Quality Control Board
~~2540, 25th Floor~~ 1001 I Street, Sierra Room	~~TBA~~ 3737 Main Street Alvarado Room (Rm 207 Second Floor)
Sacramento, CA 95814	~~TBA~~ Riverside, CA 92501

The Environmental Laboratory Accreditation Program (ELAP) will host a meeting of its technical advisory committee, as noted above. The notice and agenda for this meeting and others can be found at www.waterboards.ca.gov/elap. For further information regarding this agenda, see below or contact ELAP at elapca@waterboards.ca.gov.

This meeting is available via webcast at https://video.calepa.ca.gov/.

AGENDA

ITEM 1 – Call to Order/Roll Call
ITEM 2 – Proposed Alternative Draft Regulations Text for Laboratory Accreditation
- **a.** ELAP Presentation
- **b.** Presentation of Alternative
- **c.** Committee Group Discussion

ITEM 3 – Adjournment

The time and order of agenda items are subject to change at the discretion of the ELTAC Chair and may be taken out of order. The meeting will be adjourned upon completion of the agenda, which may be at a time earlier or later than posted in this notice.

In accordance with the Bagley-Keene Open Meeting Act, all meetings of ELTAC are open to the public.

Members of the public will be provided appropriate opportunities to comment on any issue before ELTAC, but the ELTAC Chair may, at his or her discretion, apportion available time among those who wish to speak.

The meeting locations are accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Eric Yee at (916) 341-6024 or emailing eric.yee@waterboards.ca.gov. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Webcast Information

Webcast	**https://video.calepa.ca.gov/**

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
ELTAC MEETING

Thursday, December 13, 2018 – 10:00 a.m.
1001 I Street, Sierra Room
Sacramento, CA 95814
And
Santa Ana Regional Water Quality Control Board
3737 Main Street
Alvarado Room (Rm 207 Second Floor)
Riverside, CA 92501

Meeting Agenda

TIME	AGENDA ITEM	PRESENTER(S)
10:00am	**Call to Order/Roll Call** *Objective: Roll call.*	Stephen Clark, *Chairperson*
10:05am	**ELAP Presentation** *Objective: Provide program perspective.*	Christine Sotelo, *DELAPO* Jacob Oaxaca, *ELAP*
10:35am	**Presentation of Proposed Alternative Draft Regulations Text for Laboratory Accreditation** *Objective: Provide information to committee members on proposed alternative.*	Amber Baylor, *SOCWA* Bill Ray, *William Ray Consulting, LLC* Steve Jepsen, *SCAP*
11:05am	**Public Comments/Committee Discussion**	
12pm-1:15pm	Lunch	
1:15pm	**Committee Discussion**	
2:30pm	**Close – Review Action Items** *Objective: Review any assignments generated during the meeting and adjourn.*	Stephen Clark, *Chairperson*

ROLL CALL

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
ELTAC MEETING
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1001 I Street, Sierra Room
Sacramento, CA 95814
And
3737 Main Street
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Riverside, CA 92501

MEETING PACKET

Roll Call

Name	Affiliation	Member Type	Present
Diane Anderson	APPL, Inc.	Rep	
Mindy Boele	CWEA	Rep	
Jill Brodt	Brelje and Race Laboratories	Rep	
Gail Cho	CA Dept. of Fish and Wildlife	SRAE	
Stephen Clark	Pacific EcoRisk	Rep	
Ronald Coss	CWEA	Rep	
Huy Do	CASA	Rep	
Andy Eaton	Eurofins Eaton Analytical	Rep	
Miriam Ghabour	Metropolitan Water District of Southern California	Rep	
Bruce Godfrey	ACIL	Rep	
Anthony Gonzales	CAPHLD	Rep	
Rich Gossett	Physis Environmental	Rep	
David Kimbrough	Pasadena Water and Power	Rep	
Mark Koekemoer	Napa Sanitation District	Rep	
Bruce LaBelle	Dept. of Toxic Substances Control	SRAE	
Allison Mackenzie	Babcock Laboratories	Rep	
Sean McCarthy	Division of Drinking Water	SRAE	
Christine Sotelo	CA ELAP	DELAPO	
Renee Spears	State Water Resources Control Board	SRAE	

Abbreviation	Member Type
DELAPO	Designated ELAP Officer, nonvoting
Scribe	Minutes (non-member)
SRAE	State Regulatory Agency Employee, nonvoting
Rep	Representative Member, voting

PROGRAM PERSPECTIVE

Christine Sotelo, ELAP
Jacob Oaxaca, ELAP

PROPOSED ALTERNATIVE DRAFT REGULATIONS TEXT FOR LABORATORY ACCREDITATION

Amber Baylor, SOCWA
Bill Ray, William Ray Consulting, LLC
Steve Jepsen, SCAP

Proposed Parallel Laboratory Certification Program Regulations

Comparable Quality System Requirements

Amber Baylor, Bill Ray, & Steve Jepsen
ELTAC Meeting on 12/13/2018

Goals for Today

- Provide ELTAC with the framework of the CA QMS for discussion.
- Continue to work with ELTAC, ELAP, and the Summit Partners in the development of Title 22 Regulations that includes a parallel accreditation system.
- Request ELTAC to form a sub-committee for the creation of the parallel accreditation system.

Utility Management Perspective

- Committed Staff Training for Transition to TNI
- Identified More Staffing Needed
- GASB 75 Cost Driver
- Need for Administrative Efficiency

Background

- In 2005, ELAP sought legislation to allow implementation of NELAP requirements
- Legislation allowed ELAP to run parallel programs – NELAP and current requirements
- Operated parallel programs until discontinuing the NELAP program

Issues With Prior Parallel System

- Number of labs seeking NELAP accreditation stayed about 10% of total labs
- Many who stayed out saw no value in NELAP – was for interstate commerce
- NELAP labs complained about the significant effort to become accredited versus everyone else
- A perception that NELAP produce better quality data

Other Problems

- ELAP never updated regulations – even though an attempt was made in 2005
- There was no uniformity in quality system components between various method sources

Current State

- Although attempts have been made, there still exists a lack of uniformity in quality system components
- Standard Methods has made improvements
- Older EPA methods are no longer cited
- Inclusion of 40CFR Part 136.7 Quality Control
- Still no creation of a uniform program

Why Not Full TNI?

- Proponents state it is an extensive management system
- TNI claims it provides data of "known and documented quality"
- It is an existing set of standards that could be dropped in
- TNI is even looking into PT frequency and alternate Technical Manager requirements

Issues Created by TNI

- Uses an international standard for all types of labs
- Added a significant number of additional requirements – some have issues in implementation
- Focus is on records – almost exclusively
- Includes both quality system and laboratory management requirements

TNI Standards Are

- Designed around a medium to large self-contained commercial lab
- Demands documentation (Documents and Records) for all aspects of the laboratory including purchasing and employment
- Has duties and requirements that are not exempted based on lab size – a single person may have to be Management, Technical Manager, and Quality Manager

V1M2 4.3 Document Control

- These are documents
- Regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions, manuals, policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc.
- May be on various media, whether hard copy or electronic, and may be digital, analog, photographic or written.

V1 M2 4.13 Control of Records

- 4.13.3.f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory.
- What follows are 19 specific records to be kept

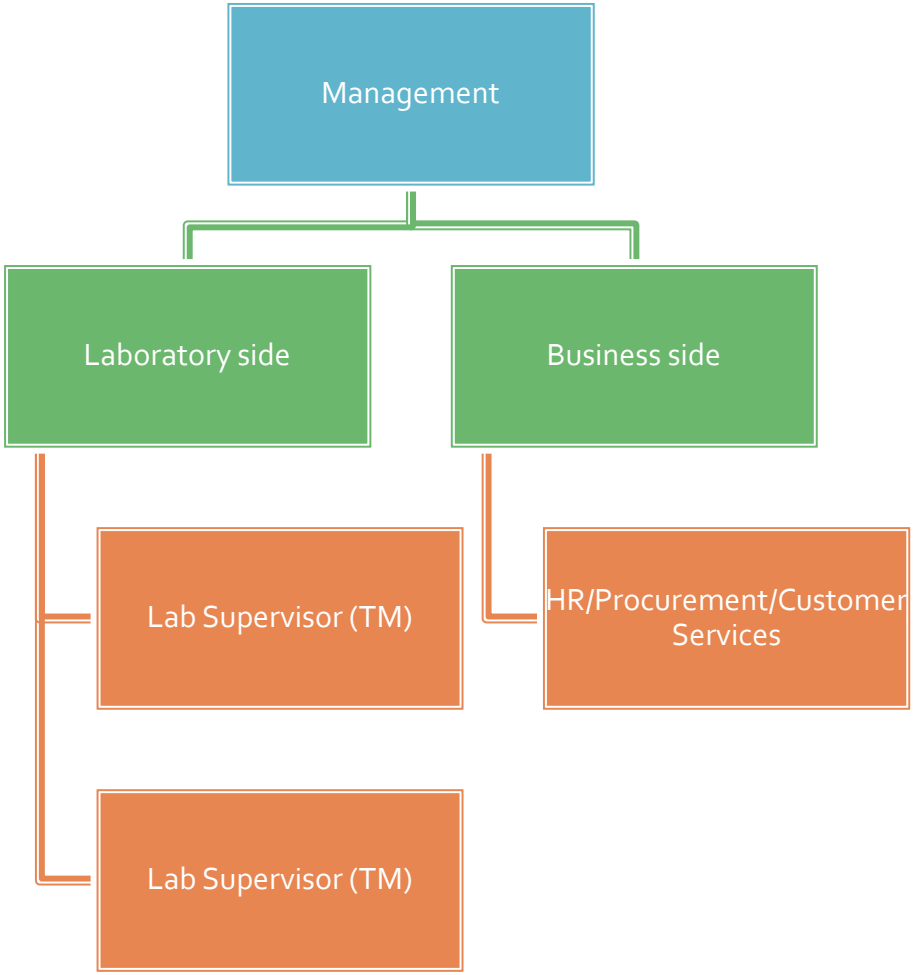
Policies and/or Procedures

- There are 30 required Policies and/or Procedures
- Although some can be combined it still leaves approximately 10 documents

Duties and Responsibilities

- Management including Top Management
- Technical Managers
- Quality Managers
- Authorized persons

TNI's View of Management



Current View

Issues to Resolve

- Is Laboratory Director = to Technical Manager or Management
- If Management then NO Qualifications but who would be Technical Manager in 1-person lab
- If Technical Manager who takes on Management duties/responsibilities/ authorities

Assigning Authorities

- 4.1.5.f) personnel who manage, perform, or verify work
- 4.1.5.i) QM authority
- 4.2.8.5.c) SOP approving
- 4.3.2.3 document issuing authority
- 4.3.3.3 amending documents by hand
- 4.9.1.a) nonconforming work authority
- 4.11.1 corrective action

Some other Things

- TNI cannot replace an existing regulation – must defer to the regulation
- TNI uses the same quality system framework as currently in place in labs
- TNI does not alter any quality system criteria making it more stringent
- TNI allows in Module 4 permission to report data even if quality system component failed (1.7.1.2.f).iii; 1.7.3.1; 1.7.3.2.a); 1.7.3.3.a) and b))

Create equivalency in data quality system components

Any Parallel Program Should

Creating Equivalency

- Adopt TNI standards as necessary to complete what is already in regulations (approved methods)
- Add other standards to round out laboratory operations (sample collection/handling/etc.)
- Review with an eye to reduce duties and responsibilities for truly small labs (1-4 persons)

Other Considerations

- Keep Quality System Manual and Analytical SOP formats (V1M2. 4.2.8.3; 4.2.8.4; and 4.2.8.5.f) – with consideration for what Policies/Procedures to keep)
- Add definitions especially for the Matrix portion of a Field of Accreditation

Review Action Request

- Seek feedback on the parallel system proposed.
- Request ELTAC to form a sub-committee for the creation of the parallel accreditation system.

Questions?

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The California Quality Management System

The California Quality Management System (CA QMS) is a proposed quality management system within the framework of the California Code of Regulations[1] that reduces extensive documentation requirements with a focus on production of high quality data from environmental testing laboratories in California. The CA QMS utilizes management components from Volume 1 of the Nelac Institute (TNI) 2016 standard. The CA QMS is a parallel accreditation system as envisioned under the Environmental Laboratory Accreditation Act, Health and Safety Code § 100829(a), and Assembly Bill 1438 (2016, Committee on Environmental Safety and Toxic Materials), which authorizes the State Water Board to "[o]ffer both state accreditation and TNI accreditation.

The CA QMS provided below is a first draft version and should not be intended to be used as a final version. The CA QMS is being developed in a transparent, collaborative fashion with the intent to produce a robust standard that protects public health and the environment. A work group consisting of representatives from water and wastewater utilities has been created to facilitate the development of the CA QMS found in the draft version of this document. Included in Appendix A is a Interested parties who would like to contribute to the development of the CA QMS should reach out to Amber Baylor at abaylor@socwa.com.

This document is being produced for public distribution for the Environmental Laboratory Technical Advisory Committee meeting on December 13, 2018.

Article 1. Definitions

[1] California Title 22 Division 4, Chapter 19

Article 1. Definitions.

§64801. Definitions.

a) Definitions found in *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev 2.1, September 1, 2016, Volume 1, Modules 1 thru 7 apply to these standards. Any definition that does not exist in the standard are defined below. Any clarification to the definition in the above standard is cited below.
   1) “California analyte” means a substance, organism, physical parameter, property, or chemical constituent required only by California statute or regulation.
   2) “Field of Accreditation Matrix” is defined as the same as that listed for Quality System Matrix in Volume 1, Module 2, section 3.0 for the matrix portion of the complete Field of Accreditation definition (Matrix-Method/Technology-Analyte).
   3) "Laboratory Director" means the person who, for the laboratory is the person designated to perform the duties described in Volume 1 Module 2 for management and top management. Where staff is limited the position of Laboratory Director may be combined with the position of Technical Manager and/or Quality Manager. If combined then the person must perform all duties as required by Volume 1 Module 2 for each position.
   4) "Owner" means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.
   5) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with these regulations or the statutes under which these regulations are adopted.
   6) "Trade Secret" means any information that meets the definition in Section 6254.7(d) of the Government Code.
   7) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.
   8) "Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track. This definition is the same as the definition as given in Section 670, Vehicle Code.
b) All references to days, weeks, months or years are calendar based.

Article 2. Accreditation Process

§64802. Accreditation Process.

a) All laboratories seeking Initial or Renewal accreditation shall state unequivocally whether they wish accreditation under the *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev 2.1, September 1, 2016; or under the requirements for parallel accreditation as stated in section 64808 and 64810 below.
b) All on-site assessments will be conducted in accordance with the requirements found in General Requirements for Accreditation Bodies Accrediting Environmental Laboratories 2009 Rev. 0.1 V2M3 Section 6.

64802.05 Initial Accreditation

a) A laboratory shall:
   1) Submit a complete application package in accordance with 64804;
   2) Submit performance test sample result in compliance with 64812;
   3) Submit a Quality System manual in compliance with 64808; and
   4) Submit fee payment in accordance with 64806
b) The laboratory shall be assessed compliance with 64808 through an on-site assessment.
c) A laboratory may be granted interim accreditation prior to the on-site assessment in accordance with H&SC 100850.(d) if ELAP finds sufficient information is available from the Quality System document or performance test results.

64802.10 Renewing Accreditation

a) A laboratory shall:
   1) Submit a notice of intent to renew and information as required by 64802..b) below;
   2) Submit a Quality System document if there has been changes since the last submission;
   3) Submit fee payment in accordance with 64806; and
b) The laboratory shall be assessed compliance with 64812 performance test sample results.

64802.15 Amending Accreditation before Renewal

a) If amending accreditation by the addition of one or more Fields of Accreditation a laboratory shall:
   1) Submit a notice of intent to amend by addition listing the requested Field(s) of Accreditation and any information that has changed since the last application;
   2) Submit an amended Quality System document;
   3) Submit performance test sample results in compliance with 64812. If performance test sample(s) do not exist then submit data and documents showing the following
      A) The results of the initial demonstration of capability if the addition(s) are Field(s) of Accreditation consisting of analytical methods and analytes approved for regulatory use by state or federal regulation.
      B) The results of the method validation as found in Volume 1, Module 2 section 5.4 as well

as the initial demonstration of capability if the method is a laboratory developed method or a method modified outside of those allowed by the analytical method reference or allowed by federal regulation.

4) Submit fee payment in accordance with 64806

b) If amending accreditation by the removal of one or more Fields of Accreditation a laboratory shall:
   1) Submit a notice of intent to amend by removal and a list of Field(s) of Accreditation to be removed.
   2) The effective date with regards to accreditation is the date of the laboratory's notice.

64802.20 Acceptance of Another State or Federal Government Agency's Accreditation

a) A laboratory may submit an accreditation issued by another State or by a federal government agency and request accreditation without submitting performance test sample results and going through an onsite assessment if any of the following conditions exist
   1) There is a Reciprocity agreement between the issuing agency and the State of California;
   2) The issuing agency is recognized by The NELAC Institute as an Accrediting Body; or
   3) The issuing agency is the federal Department of Defense or Department of Energy. This includes any third-party accrediting bodies employed by either agency.
b) The other agency's accreditation must be submitted with an application.
c) The requested Field(s) of Accreditation must match those cited on the other agency's accreditation

Article 3. Application Packages

64804 Application Packages

a) A laboratory applying for initial accreditation shall submit an application package with the following information
   1) Laboratory Name
   2) Laboratory location address
   3) Contact information including at least a mailing address; phone number and e-mail address for the person designated the Laboratory Director. The laboratory may supply contact information for other persons within the laboratory
   4) Name of person(s) identified as Technical Manager(s) and information supporting meeting the qualifications in section 64814.
   5) A complete list of Field(s) of Accreditation sought for accreditation
   6) The application must be signed by an Owner or an Owner's agent
b) Laboratories submitting for renewal shall provide only that information cited above that has changed since its last submission. If nothing has changed then the renewal request must include a statement to that effect.

Article 4. Accreditation Fees

64806. Accreditation Fees (fees are place-holders only)

a) Laboratories shall pay the following fees when required by this standard
   1) Application fee for initial applications required by 64802.05: $1000
   2) Application fee for filings required by 64802.10, 64802.15, or 64802.20: $500
   3) Annual fee as required by H&SC 100860.1.(a): $2000
   4) Onsite assessments, whether conducted by ELAP or an approved third-party will be billed for the following costs:
      A) Travel including air/rail; rental car; hotel at receipted costs
      B) Mileage at federal rate for the year the on-site conducted
      C) Up to 24 hours at the prevailing hourly charge for on-site assessment preparation
      D) The hours taken to conduct the on-site assessment
      E) Up to 16 hours to submit the final assessment report and evaluate the laboratory's submission

Article 5. Quality System Standards

§64808. Quality System Standards

a) Laboratories seeking or holding accreditation under the TNI standard shall comply with all provisions found in the 2016 Revision 2.1 standard Volume 1, Module 2 and Modules 3 through 7 as applicable for the test methods.
b) Laboratories seeking or holding parallel accreditation shall develop a quality management system and create a quality system manual that is reflective of the quality management system. The contents of the quality management system shall include, at a minimum, the following
    1) The quality system component (quality assurance and quality control) requirements specified in the test methods for which the laboratory seeks, or holds, accreditation.
    2) The quality system components found in applicable state and federal regulations.
    3) Incorporate the contents of *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev. 2.1, September 1, 2016, Volume 1, Modules 3 through 7 (as appropriate for the test method) where the test method or federal regulation are silent on the requirement.
    4) The laboratory is to employ requirements of the above TNI standard as found in Volume 1, Module 2 sections 4.2.8.4.a) through r); except j), m), n), o), p), q), and r)
    5) In addition, the laboratory is to employ the requirements in Volumn 1, Module 2 sections 5.3; 5.5; 5.6; 5.8; and 5.9. The laboratory is to incorporate the requirements of Volume 1, Module 2, section 5.7 if it collects samples.
c) The format for the quality system document shall follow Volume 1 Module 2, section 4.2.8.3.a) through i); except e), and g). For 4.2.8.3.h) the laboratory shall substitute “accreditation standards” for “the Standard”.
d) The format for all analytical Standard Operating Procedures (SOP) shall contain discussion on the topics found in Volume 1 Module 2, section 4.2.8.4.f).i) through xxiii. The SOP must state that a topic is not applicable and provide justification.

Article 6. PT Study Requirements

§64810. PT Study Requirements.

a) Laboratories seeking accreditation under the TNI standard shall comply with all provisions found in the 2016 Revision 2.1 standard Volume 1, Module 1.
b) Laboratories seeking parallel accreditation are exempt from the provisions in Volume 1 Module 1, section 5.0.
c) All laboratories shall comply with H&SC 100870.(d) including use of providers meeting TNI standards; payment of any fees charges; and the release of study results directly to ELAP.
d) The following table cross-references Fields of Accreditation matrices with Fields of Proficiency Testing matrices

Field of Proficiency Testing Matrix	Field of Accreditation Matrix
Drinking Water	Drinking Water
Non-Potable Water	Aqueous and Saline/Estuarine
Solids	Solids
Oil and Solvent	Non-Aqueous Liquid

e) All laboratories shall select PT samples that match the method/technology-analyte within the matrix cross-reference above for which the laboratory is seeking or hold accreditation
f) PT results submitted for initial accreditation under 64802.05 above shall have a closing date of the study more than six months before the application date.
g) Laboratories accredited under parallel accreditation shall meet the following.
    1) Accredited laboratories shall analyze PT samples within the first 12 months from the date of issue of the accreditation or renewed accreditation and achieve acceptable results for all PT Fields of Proficiency Testing analyzed. If any result is marked unacceptable, then the laboratory shall obtain samples from the next available PT sample study set. If any result from the second set is also unacceptable, then the laboratory is subject to revocation per H&SC 100850.(b).(1).
    2) Accredited laboratories shall within the second 12 months of accreditation but before one month from the stated expiration date analyze and achieve acceptable results for all PT Fields of Proficiency analyzed. If a second set is necessary, it must be completed and results available before 1 month from the stated expiration date. A failure to achieve acceptable results in the second set or a failure to provide results before 1 month from the expiration date shall be grounds for denial of that Field(s) of Accreditation per H&SC 100850.(b).(1)

Article 7. Alternate Technical Manager Qualifications

§64812. Alternate Technical Manager Qualifications.

a) All laboratories seeking or holding either form of accreditation shall comply with the provisions found in the 2016 Revision 2.1 standard Volume 1, Module 2, section 5.2 regarding Technical Manager qualifications; except water or wastewater treatment plant laboratories seeking or holding accreditation for any Field of Accreditation associated with analyses required under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code.
b) Excepted laboratories may fulfill the requirements for Technical Manager by the Technical Manager possessing a Laboratory Analyst or 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). The minimum grade of the above certificate acceptable shall be based on the Field(s) of Accreditation as noted in the conversion table set out below:

Field of Accreditation Method/Technology under Matrices Drinking Water and Non-Potable Water	CA-NV AWWA water quality analyst certificate	CWEA laboratory analyst certificate
All microbiological methods/All technologies All solids methods/all technologies	I	I
All methods/titrimetric technologies All methods/specific ion electrode technologies All methods/colorimetric technologies	II	II
All methods/ion chromatography All methods/flame atomic absorption All methods/graphite furnace atomic absorption	III	III
All methods/all chromatography technologies including those using mass detectors All methods/ICP All methods/ICPMS	IV	IV

Article 8. Notification and Reporting

§64814. Notification and Reporting.

a) Laboratories accredited for Fields of Accreditation where the Matrix is Drinking Water shall conform to the following reporting and notification requirements.
b) 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.
c) 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.
d) 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.
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 current at the time reporting is made and Data Dictionary concurrent with that version, by the 10th day of the month following the month in which the analyses were completed.
f) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:
    1) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;
    2) complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;
    3) complete description of the error alleged to have invalidated the result(s);
    4) copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and
    5) any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.
g) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) prepared by all other laboratories who are party to the agreement.

Article 9. Reciprocity Agreements

§64816. Reciprocity Agreements.

a) Another State's, or a United States agency's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if the program requires:
   1) periodic analyses of performance evaluation samples by the participating laboratories with the frequency of submittal, the method of evaluation, and the established acceptance limits at least equal to those established in Sections 64802 and 64809;
   2) On-site assessments are at least three years apart.
   3) standards for quality assurance, laboratory facilities, test methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Section 64802.
   4) The other agency shall accept California accreditation. If not, then the laboratory may seek accreditation under the conditions of 64802.20 above.
b) Where reciprocity exists, each laboratory seeking California certification shall submit:
   1) an application pursuant to Section 64805(a);
   2) fees pursuant to 64811; and
   3) a copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other agency.
c) When a reciprocity agreement exists between the Department and another State, only those laboratories that reside within the boundaries of the other State shall be eligible for certification through reciprocity.
d) If a reciprocity agreement with another State, or U.S. government agency is revoked, all certificates issued by the Department to all affected laboratories shall remain valid until the stated expiration date.
e) A laboratory certified under reciprocity may be visited or issued performance evaluation samples by the Department for the purposes of addressing questions or concerns on quality of results raised by any California government agency who has received a report from the laboratory. Applicable fees pursuant to 64811 shall be paid.

Article 10. Trade Secrets

§64818. Trade Secrets.

(a) If a laboratory identifies information provided to the Department as a trade secret, the Department shall not release such information unless:
(1) the release is authorized under state or federal law; and
(2) the Department has notified the laboratory of the impending release. Such notification shall be at least ten days prior to releasing any information identified as a trade secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released.

Article 11. Sale or Transfer of Ownership of a Laboratory

§64820. Sale or Transfer of Ownership.

(a) A certificate shall be voided by operation of law if one or more of the following occurs.
(1) An original Owner fails to notify the Department, in writing, within 15 days after a change in ownership.
(2) A new Owner relocates the laboratory within 90 days of assuming ownership.
(3) If more than half the number of laboratory persons either quit or are terminated and replaced by a new Owner within 90 days of assuming ownership.
(4) If a new Owner submits an application to alter the laboratory's certificate as issued to the prior Owner by the addition of any Subgroup within any Field of Testing.
(b) A new Owner of a laboratory shall notify the Department, in writing, within 15 days after the sale or transfer of ownership and provide, at minimum, the following information.
(1) The name(s) of the new Owner(s).
(2) The date of sale or transfer of ownership.
(3) The name, education and laboratory related work experiences, as specified in Section 64817(a); or voluntary laboratory certificate grade as specified in Section 64817(b), of the person designated as the Laboratory Director.
(4) The names, education and laboratory related work experiences, as specified in Section 64817(g); or voluntary laboratory certificate grade as specified in Section 64817(h), of all persons who are designated as Principal Analysts.
(5) The names of all Principal Analysts who have quit, or were terminated and replaced; and the names of all Principal Analysts hired as replacements.
(6) A statement that there will be no changes in laboratory location, or in the certificate issued to the prior Owner(s) within 90 days of assuming ownership.
(7) A statement that all equipment, method, and quality assurance practices will not change within 90 days of assuming ownership.
(8) The notice shall be signed by one or more of the new Owner(s), or their Agents.
(c) New Owners that comply with the provisions of (b) above shall have use of the certificate issued to the prior Owner for a period of ninety days commencing with the date of the Department's notice of receipt of the information supplied by the new Owner.
(1) The certificate number and the laboratory name appearing on the certificate shall remain the same.
(2) The new Owner shall display, and provide a copy with all data reports, the Department's notice recognizing the sale or transfer of ownership.
(d) To obtain the use of the certificate to its original expiration date, the new Owner shall request such use in writing, and the laboratory shall be subjected to, and pass the following, within the 90 days use period granted by the Department.
(1) A site visit in accordance with Section 64807; and
(2) Performance evaluation samples in accordance with Section 64809.

Appendix A

Policy & Procedure Quick Reference Guide for the California Quality Management System

Element	Policy/Procedure	Contents found in V1M2 unless otherwise noted
Quality system	Policy	4.2.2
Customer confidentiality	Policy and procedures	4.1.5
Confidence	Policy and procedures	4.1.5
Feedback and corrective action re. departures from documented procedures	Policy and procedure	4.2.8.4
Permitted departures from documented procedures	Policy and procedure	4.2.8.4
Electronic signatures	Policy	4.2.8.4
Review of requests, tenders, contracts	Policy and procedure	4.4.1
Selection and purchasing of services and supplies	Policy and procedure	4.6.1
Complaint resolution	Policy and procedure	4.8
Assigned authorities for implementing corrective action for nonconforming work	Policy and procedure	4.11.1
Client notification timeframe regarding doubts on validity of data	Policy	4.14.5
Work does not conform to requirements	Policy and procedure	4.9.1
Personnel training and training needs	Policy and procedure	5.2.2
Sample acceptance policy	Policy	5.8.6

Element	Policy/Procedure	Contents found in V1M2 unless otherwise noted
Handling of PTs	Procedure	V1M1 4.2
Data integrity	Procedure	5.2.7
Impartiality	Procedure	4.1.5
Define requirements for Technical Manager (ascension)	Procedure	5.2
Generate data	Procedure	4.2.8.5
Document control	Procedure	4.3
Review work	Procedure	4.4
Internal audits	Procedure	4.14
Management reviews	Procedure	4.15
Method SOP contents	Procedure	5.4
Uncertainty	Procedure	5.4.6.2
Electronic data protection	Procedure	5.4.7.2
Traceability	Procedure	5.6
Sampling	Procedure	5.7
Sample handling	Procedure	5.8
Quality control	Procedure	5.9

PUBLIC COMMENTS

Public Comments on the Agenda Item

Members of the public may address the Environmental Laboratory Technical Advisory Committee (ELTAC) after the scheduled presentations.

Depending on how many people are interested in speaking, the Chairperson may limit comments to 3 minutes. To avoid redundant comments, persons with similar concerns may be asked to have a single spokesperson address their concerns.

COMMITTEE DISCUSSION

CLOSE – REVIEW ACTION ITEMS

Stephen Clark, Chairperson