



December 20, 2019

Ms. Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
P.O. Box 100. Sacramento, CA 95812-2000

Via email: commentletters@waterboards.ca.gov

Subject: Comments – Proposed Environmental Laboratory Accreditation Program Regulations.

Ms. Townsend,

The Bay Area Clean Water Agencies (BACWA) appreciates the opportunity to comment on the proposed ELAP Draft Regulations (proposed Regulations). BACWA is a joint powers agency whose members own and operate publicly-owned treatment works (POTWs) and sanitary sewer systems that collectively provide sanitary services to over 7.1 million people in the nine-county San Francisco Bay Area. BACWA members are public agencies, governed by elected officials and managed by professionals who protect the environment and public health. BACWA supports a Laboratory Committee with participants who will be responsible for implementing the proposed Regulations, once adopted.

BACWA continues to support dual track accreditation option with the California Quality Management System (QMs) proposed by the public laboratory community. The comments herein include recommendations on modifications to the proposed Regulations regardless of whether ELAP chooses to implement a TNI-based standard as part of a single, or a dual track accreditation system.

The estimated cost of compliance is underestimated in the Initial Statement of Reasons primarily because it does not properly reflect the cost of labor in California. As BACWA and other public laboratories around the State have previously commented, the high cost of compliance will force the closure or drop of accreditation by several small laboratories. However, having a public agency laboratory certified, especially in remote locations of the state, affords that agency a much faster response time on obtaining data results, and thus a more effective response to any potential problems. The purpose of the public agency laboratory is to ensure treatment and distribution operations are protective of public and environmental health. Loss of certification

and potential closure of laboratories detracts from this primary purpose. To limit the closure of small laboratories, it is imperative that ELAP make a commitment to budget and allocate resources to support small laboratories, and incentivize them to continue accreditation under the new regulations.

The remainder of our comments pertain to specific sections in the Regulation, as listed below.

1. Section 64816 - Enforcement Provisions

BACWA appreciates that the opening language in sections 64816.00(a) and 64816.05(a) was rephrased slightly to improve clarity. Our comments on the enforcement section pertain to the fairness and transparency in assigning enforcement actions. Proposed redline edits are provided in the attached document and described below.

BACWA recommends limiting the list of violations that may result in the denial of a laboratory's *application* for accreditation to only those relevant to ELAP's review of the sufficiency of that application, plus potentially a documented history of difficulty complying with the regulations. Because the decision to deny an application is made before an accreditation is issued/renewed, the items that may result in such a denial should be focused on issues apparent in the application. Accordingly, we suggest removing several items from the list, as shown in the attached redline.

Subdivision (b) is added to section 64816.05 to include a reference to reconsideration provisions in Health & Safety Code section 100880(f) for citations and penalties assessed on environmental laboratories. Including this reference provides additional clarity for laboratories regarding their rights under statute in the event they are aggrieved by the issuance of a citation.

A sentence is added to section 64816.10(a) that directly refers to the due process provisions in Health & Safety Code section 100910 and 100915 for the suspension or revocation of a laboratory's accreditation. Including this reference provides additional clarity for laboratories regarding their rights under statute, and reflects statutory direction that suspension and revocation of a laboratory's accreditation cannot be completed with providing adequate notice and opportunity for a hearing to the affected laboratory.

In addition to the suggested redlines, improvements should be made to the language governing the violations that may result in the issuance of a citation and those that may result in the suspension or revocation of accreditation. As the Proposed Regulations currently read, the same violation could qualify for either a citation or suspension/revocation of accreditation. This leaves significant discretion to ELAP staff to determine which punishment to pursue for any given violation, and prevents laboratories from understanding what penalties they might face for even a minor instance of noncompliance. Because suspending or revoking a laboratory's accreditation represents a severe punishment, the Proposed Regulations should indicate that only severe violations will result in this penalty in order to ensure that punishments are proportional to the regulatory violation. This also comports with the State Water Resources Control Board's

commitment to consistent, fair, and progressive enforcement as stated in its Water Quality Enforcement Policy.

ELAP should add language to section 64816.10 governing suspension and revocation to clearly state that ELAP would suspend or revoke accreditation only where failures to comply are material, repeated, and/or grossly negligent or intentional.

2. **64801.00 Definitions** - *“(r) “Sophisticated Technology” means analytical instruments, detection systems, and/or preparation techniques requiring an advanced level of user understanding including gas chromatography/mass spectrometry (GC/MS), inductively coupled plasma spectrometry (ICP), ... bioanalytical assays, advanced molecular methods and other similar instruments or technologies.”*

The current regulations include bioassays under “sophisticated instruments”. BACWA requests that ELAP clarify whether they intend the term “bioanalytical assays” to include chronic and acute toxicity bioassays.

3. **64802.05.b.2** - *The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs:*
 - (A) *Changes to Standard Operating Procedures;*

The Quality Manual (QM) is a high-level document that normally references a list of Standard Operating Procedures (SOPs). Changing the QM for every change in an SOP (for example, if Quality Control limits change) would be extremely burdensome, since such changes happen all the time. BACWA recommends that the text be updated to read: “changes to the list of Standard Operation Procedures”.

4. **64802.10.e** - *ELAP publishes the lists of Field(s) of Accreditation, called Field(s) of Accreditation tables, on the ELAP website. The Field(s) of Accreditation tables are updated, as needed, by publishing a revised Field(s) of Accreditation table on the ELAP website*

ELAP plans to maintain the list of Fields of Accreditation (FOA) on its website. This allows flexibility for ELAP, but not much certainty for labs, since these changes (which are really changes to the regulation) will not have a public process where unintentional consequences can be identified before the changes go into effect. A laboratory could find their accreditation FOA

removed without any warning or recourse. BACWA recommends that ELTAC approve FOA updates prior to posting on ELAP's website.

5. 64812.00.a - *Laboratory Personnel -- Technical Manager qualification*

This is one of the two exceptions to the TNI standards in the proposed Regulations. ELAP will allow qualification as a Technical Manager based on CWEA or AWWA certification, as requested by the laboratory community at the beginning of the ELAP reform process.

The only "grandfather" clause in the draft regulations is to allow a person who has been continuously employed for 25 years at the same lab as a technical manager since 1994 to continue in that position. The 2016 TNI standards have more reasonable "grandfather" clauses. BACWA recommends that the TNI qualification be added as an option, by adding: "d) qualifies as a Technical Manager under the 2016 TNI Standards."

The regulation as written recognizes only a single technical manager per laboratory. Larger laboratories will have more than one technical manager, as defined by TNI. BACWA recommends adding "a) A laboratory shall designate one or more Technical Managers".

6. 64812.05.c - *A laboratory shall store and handle hazardous materials in accordance with the California Code of Regulations, Title 8, Division 1, Chapter 4, Subchapter 7, General Industry Safety Orders.*

It is unclear whether ELAP staff or 3rd-party assessors are trained and qualified to write findings against this regulation. BACWA recommends that this language be dropped from the regulation, since ELAP auditors may include written recommendations to laboratories in an On-Site Assessment report that will document the existence of a potential problem without involving the issue in accreditation renewal.

7. 64812.05.d - *A laboratory shall dispose of chemical wastes and maintain records of disposal in accordance with the California Code of Regulations, Title 22, Division 4.5, Chapter 12, Standards Applicable to Generators of Hazardous Waste.*

It is unclear whether ELAP staff or 3rd-party assessors are trained and qualified to write findings against this regulation. BACWA recommends that this language be dropped from the regulation, since ELAP auditors may include written recommendations to laboratories in an On-Site Assessment report that will document the existence of a potential problem without involving the issue in accreditation renewal, or may make referrals to the Certified Unified Program Agency (CUPA) with jurisdiction.

If this section must be retained, BACWA recommends adding “*or California H&S Code Section 25200.3.1*” to the above text, since Laboratories are permitted to handle hazardous waste under California H&S Code Article 9 Section 25200.3.1. This statute has provisions similar to the Satellite Accumulation provisions of the cited Title 22 regulation, but is specific to laboratories.

- 8. 64814.00.b** - *If an analytical result warrants a client notification, then the notification shall occur after the Technical Manager or designee, set forth in the laboratory’s Quality Manual, has approved of the result.*

From the context of sections (a) and (c), it is clear this is intended to apply to required notifications under drinking water regulations. It is common in wastewater labs to provide preliminary results to Operations for timely process control. To clarify that this language does not apply to all analytical results, we recommend updating the above text to read: “(b) If an analytical result warrants a regulatory client notification...”

- 9. 64802.20 and 64808.05.c** - *On-Site Assessment*

ELAP must verify that there is an adequate pool of qualified assessors to conduct the audits of all laboratories within the two year certification cycle. ELAP has only audited 105 laboratories in the past two years, even with the reduction of required ELAP assessments to the 60% of laboratories w/o sophisticated technology, they are currently far short of capably auditing 400+ labs during a two year period. In addition, ELAP needs to ensure there are sufficient third party assessors to accomplish the complex level of audits for the remaining 40% of laboratories.

BACWA recommends adding the following language to Section 64808.05.c: “If the application submission is complete, except for a completed OSA report, and the lack of a completed OSA is due to a lack of available approved third-party assessors or ELAP auditors, the laboratory may request that ELAP issue an interim certificate. If ELAP concludes that a lack of available auditors was the reason that the laboratory’s was unable to schedule an OSA prior to submitting the application, ELAP shall issue an interim certificate to the laboratory, valid for one year.”

- 10. 64802.20.c.2.D** - *“An agency that is contracted by ELAP.”*

Any agency to be used for assessment should be certified at the level of the Quality Management System adopted for use by the laboratories seeking accreditation. We recommend the language in this section be changed to “An agency contained in an approved list maintained by ELAP,”

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We appreciate your consideration of our comments.

Respectfully Submitted,

A handwritten signature in cursive script that reads "David R. Williams".

David R. Williams
Executive Director

Attachment: Proposed edits to enforcement provisions

cc: BACWA Executive Board
Jason Mitchell, BACWA Laboratory Committee Chair
Dan Jackson, BACWA Laboratory Committee Vice-Chair