



February 8, 2019

Environmental Laboratory Accreditation Program (ELAP)  
Preliminary Draft Regulations Comments  
P.O. Box 100, Sacramento, CA 95814

VIA EMAIL: [elapca\\_comments@waterboards.ca.gov](mailto:elapca_comments@waterboards.ca.gov)

**Subject: ELAP Preliminary Draft Regulations Comments**

The Bay Area Clean Water Agencies (BACWA) appreciates the opportunity to comment on the proposed ELAP Preliminary 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 also supports comments submitted by the California Association of Sanitation Agencies, and the Central Valley Clean Water Association.

BACWA continues to support dual track accreditation proposed by Summit Partners, as described most recently in the letter submitted to State Water Board Chair Marcus on January 29, 2019. 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.

There are areas in the proposed Regulation that would benefit from additional clarity. While we understand there is a limit to the level of detail that can be included in the body of the regulations, supporting fact sheets could fill the gap. We recommend that ELAP work with Environmental Laboratory Technical Advisory Committee (ELTAC) to prepare the fact sheets before the proposed Regulations are finalized.

Our specific comments are listed below.

**1. Definitions, §64801 (v)**

Under definitions, the draft regulation states: “TNI” means The National Environmental Laboratory Accreditation Conference Institute. The TNI-2016 standard, in their definition, states the following:

*TNI: The NELAC Institute*

In the context of TNI, the word NELAC is not an acronym; it is a contrived word. The acronym NELAC is copyrighted, and therefore TNI-2016 clarifies that “NELAC” is not used as an acronym in this case. We suggest ELAP revise its definition to match the TNI-2016 standard.

## **2. Quality Systems, §64802.10 (a)**

The paragraph on Quality Systems references the 2016 TNI standard specifically, which is based on the ISO 17025-2005 standard. After the development of the 2016 TNI standard, ISO published an updated version in 2017, and TNI is working to adopt that standard. The 2017 ISO standard emphasizes risk-based action, rather than listing prescriptive directions. We recommend that ELAP incorporate flexibility into the regulations to allow for implementing updated versions of TNI standards in the future, after outreach to stakeholders, and a public comment process. This would allow for appropriate updates as laboratory standards evolve.

## **3. Fields of Accreditation, § 64802.15(b)**

The Field of Accreditation section references drinking water analyses listed in 40 CFR (Code of Federal Regulations) parts 141.21 through 141.42, 141.66, and 141.89. We recommend including 40 CFR part 136 to also address wastewater methods.

## **4. Fields of Accreditation, §64802.15 (c)**

ELAP proposes publishing Fields of Accreditation (FOAs) on ELAP’s website, but does not include them in the body of the regulations. While we understand the flexibility this provides in updating FOAs, this raises several issues that will need to be addressed:

- How ELAP will notify laboratories that changes have been made.
- How much time will ELAP allow laboratories to adopt these new/updated methods.
- If the update drops an existing method and adopts a newer version of the same method, (for example, dropping EPA 608 and adopting EPA 608.3), whether laboratories are expected to submit Initial Demonstration of Capabilities (IDOC) to be certified in the newer version.
- Whether the above would be considered a new application or application amendment, or whether a laboratory would work under the certificate issued for the previous version.
- How ELAP will coordinate with its regulatory partners so that utilities are complying with permit requirements where previous version of the method is referenced.

BACWA recommends that these, and other questions, be addressed through supplemental fact sheets.

## **5. On-Site Assessment, § 64802.25 (c)**

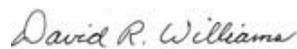
The On-Site Assessment section states that “The laboratory is responsible for scheduling an on-site assessment through ELAP or a third-party Assessment Agency”. BACWA recommends that ELAP schedule the laboratory on-site assessment using either ELAP staff or a third party

assessor. A fact sheet clarifying what is meant by ‘assessment agency’ and what are the qualifications for an acceptable assessor needs to be explained. ELAP also must verify that there is an adequate pool of qualified assessors before the regulations are passed.

Hiring assessors does not represent a known, fixed cost to agencies; as the demand for assessors goes up, the cost of service will increase. BACWA requests that ELAP consider how to control costs to make required audits fair for all laboratories. Laboratories who must hire assessors should not pay more than those audited by ELAP staff. Also, laboratories should not be penalized because there are insufficient qualified assessors available, both within and outside of ELAP.

We appreciate your consideration of our comments.

Respectfully Submitted,



David R. Williams  
Executive Director

cc: BACWA Executive Board  
Nirmela Arsem, BACWA Laboratory Committee Chair