



CVCWA

Central Valley Clean Water Association

Representing Over Fifty Wastewater Agencies

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September 16, 2016

Via Electronic Mail Only

Felicia Marcus, Chair
State Water Resources Control Board
1001 I Street
Sacramento, CA 95814
commentletters@waterboards.ca.gov

RE: Comment Letter on ELAP Regulations Development/Laboratory Standard

Dear Ms. Marcus:

The Central Valley Clean Water Association (CVCWA) appreciates this opportunity to comment on the California Environmental Laboratory Accreditation Program's (ELAP) recommendation to adopt Volume 1 of The NELAC Institute's (TNI) 2016 standard as the basis for laboratory accreditation as the California laboratory standard. CVCWA is a non-profit association of public agencies located within the Central Valley region that provide wastewater collection, treatment, and water recycling services to millions of Central Valley residents and businesses. We approach these matters with the perspective of balancing environmental and economic interests consistent with state and federal law. Many of our members operate environmental laboratories to ensure proper operation of their wastewater treatment plants in a manner that is protective of public health and the environment. Additionally, others rely on small local laboratories to perform basic testing. In this letter, we provide comments on ELAP's proposal to use the 2016 TNI as the California laboratory standard, including our concerns about the unintended consequences of adopting this standard and the lack of a real stakeholder process leading up to this proposal.

CVCWA acknowledges the need to update ELAP regulations and supports efforts to do so. However, the 2016 TNI standards that ELAP is proposing for the State Board to adopt present significant hurdles for municipal laboratories to overcome in order to comply, despite the fact that these hurdles do not correspond to an environmental or public health benefit. While ELAP's

proposal was available for comment for only a very brief time, the following comments attempt to identify the areas of concern for municipal and small laboratories with regard to the adoption of the 2016 TNI standard in full.

1. Request That the October 6, 2016 Workshop Be Delayed and the Public Review and Comment Period Extended

On September 6, 2016, the State Water Resources Control Board (State Board) gave notice that it would be holding a Workshop on proposed changes to the laboratory accreditation regulations on October 6, 2016. The deadline for the submittal of comments is noon on Friday, September 16, 2016, thereby giving the affected laboratory community less than ten days to comment. Additionally, the 2016 TNI standard and other related supporting material is not publicly available without individual purchase¹ and therefore not readily available to all those that would be impacted by this recommendation to review and provide comment on.

This comment period is too short given the complexity and comprehensive nature of the 2016 TNI document, its lack of availability for review, and the importance of the matter at hand. Adoption of this standard represents a comprehensive change to existing procedures and policies, with potentially enormous unintended consequences. Written comments provide an extremely important opportunity for members of the affected laboratory community and other stakeholders to review these standards and raise specific concerns. Travelling in person to the workshop may be difficult or impossible for many, especially for those from smaller agencies. The written comment period may be their only opportunity to participate in this phase of the stakeholder process, voice their concerns about specific unintended consequences of adopting this standard, and advise ELAP on their areas of greatest compliance concern.

Given the importance of this proposal to the laboratory community, a ten-day window in which to prepare comments is too short and the comment deadline should be extended to further accommodate stakeholders wishing to provide comments on this item. In the same vein, holding a workshop on October 6, 2016 to consider the 2016 TNI standard as a potential regulation is premature and the workshop should be postponed until the laboratory community has had sufficient opportunity to provide meaningful comments. CVCWA suggests that the workshop be delayed to provide stakeholders with at least a 30-day comment period and that the State Board provide a means for the public to access the standards under consideration without purchase.

¹ The 2016 TNI documents are not available to the public without first purchasing them from the NELAC Institute. Other quality management systems are available to the public, such as the U.S. Environmental Protection Agency's standards and the 2003 NELAC Institute standards.

2. Compliance with the 2016 TNI Standards Is Overly Burdensome and Could Result in Many Small Municipal Laboratories Dropping Their ELAP Certifications and Closing

California has over 700 certified environmental testing labs, and over 60 percent of these are small laboratories with fewer than five full-time staff, and many with less than two. CVCWA represents many public agencies that have ELAP-certified laboratories with less than two staff members, and in some cases, operators at water and wastewater treatment plants perform the compliance sampling. These laboratories are small, but perform very important water quality and plant performance testing. Many of these municipal labs provide real-time and quick turnaround results for various regulated entities, which enables treatment plant operators to respond quickly to any environmental or public health concerns. Municipal labs, particularly small ones like one-person labs, face unique challenges if the 2016 TNI standard is adopted. Some provisions in the 2016 TNI standard are overly burdensome for municipal labs, which could cause these labs to close. The testing these labs perform is difficult – if not impossible – to do offsite and is best performed onsite to provide timely results for process control and regulatory compliance.²

The onerous and burdensome requirements of the 2016 TNI standard could result in smaller labs hiring additional staff or requiring additional resources just to deal with TNI compliance issues, with possible detrimental effects on the quality and timeliness of results. The 2016 TNI standard includes requirements that are burdensome for municipal labs generally and small labs specifically, such as:³

- Over 500 documented policies and procedures are required, with no corresponding water quality benefit. The technical methods used for analytical testing will remain the same.
- Elevated educational requirements for key positions, e.g., four-year degree for laboratory Technical and Quality Control (QC) Managers that may be beyond the resources of many small labs.
- Additional staffing requirements for Technical and QC Managers that are beyond the financial means of many small labs.
- Public agencies with multiple labs will be required to staff each lab with a Technical Director, with no improvement in efficiency or quality.

² Many permits require constituent sampling where the holding time is short and is not conducive to sending the sample to an outside laboratory.

³ Additionally, there has not yet been any significant external vetting or review of these standards, because NELAC finalized this set of standards only one month ago and this document is not available to our members, unless they decide to purchase it. Given that, and the extremely short comment period on this proposal, the above is not an exhaustive list of the requirements that are unnecessarily burdensome on municipal labs. Further in-depth review could reveal additional issues with the 2016 TNI standard.

- Conflicts between 2016 TNI standards and public agencies' policies governing such activities as procurement and purchasing, contract selection and formation, job description requirements, and personnel employment procedures, among others.

Particularly problematic provisions for one-person laboratories are as follows:

- Additional staff, specifically Technical and Quality Control Managers
- Annual internal audits
- Data integrity system
- Customer feedback
- Demonstration of continual improvement

These requirements will overload existing employees with additional clerical tasks that will adversely impact quality and efficiency. Many smaller communities do not have the resources to add staff or hire consultants to comply with these onerous requirements, and this would result in the closure of those environmental labs. These cost increases are both short-term and long-term, since compliance with the 2016 TNI standards requires ongoing oversight and reporting, which in turn requires additional staff time.

Small lab closure is a frequent result of a state's adoption of TNI standards. For example, when Florida adopted an earlier version of the TNI standards, approximately 30 percent of the environmental laboratories dropped their certifications and closed, resulting in job losses. Many were small municipal laboratories. New York saw similar closures when it began requiring TNI compliance.

One-person and other small labs perform many functions in addition to analytical testing. The retention of in-house laboratory skills is an important aspect of operating a robust water and wastewater system for communities. These laboratories have the ability to respond quickly and effectively to meet treatment challenges. They protect public health and water quality for the communities they serve and the environment. The real-time feedback provided by onsite laboratory personnel is essential to maintaining water quality and public safety. For these reasons, the State Board should carefully consider whether the burdens inherent in the 2016 TNI standard are worth the risks to California's municipal laboratory community.

3. There Has Been a Lack of Any True and Transparent Stakeholder Process

From the beginning of the California accreditation standard review process, TNI has been the preferred standard of ELAP. ELAP created and selected an Expert Review Panel (ERP) consisting of five panel members who were TNI-affiliated or associated with TNI-accredited laboratories. Accordingly, their recommendation for ELAP to adopt TNI standards was biased and should be considered an extreme conflict of interest.

In response to the ERP report, the ELAP Work Plan included an extremely aggressive timeline for standards adoption that limited opportunity for stakeholders to comment and provide input to only two occasions. The two stakeholder meetings conducted were heavily biased toward TNI because of the limited number of stakeholder participants, particularly from the smaller laboratories most heavily impacted by these regulations. The first “stakeholder meeting” was merely a TNI-sponsored training session, and the second meeting’s purpose was ill-defined, which resulted in greater confusion for the stakeholders; and again, it gave little consideration to other viable lab standard alternatives aside from TNI.

There is also concern about the inconsistent messaging from ELAP regarding the use of the 2016 TNI standards. The State Board’s notice for the October 6, 2016 workshop states that ELAP is recommending adoption of the 2016 TNI standards. However, ELAP has indicated to members of the Environmental Laboratory Technical Advisory Committee (ELTAC) that ELAP intends to consider ELTAC’s suggestions for modification or removal of the more onerous requirements in the 2016 TNI when it develops new ELAP regulations. Thus, it is not clear to the public or the regulated community what ELAP’s proposal truly is: adoption of 2016 TNI as it reads, or a further customization of 2016 TNI standards. This impedes the public’s ability to meaningfully comment on ELAP’s proposal. Additionally, if ELAP does intend the latter, stakeholder involvement in the process of identifying problematic provisions is very important, as is public access to the 2016 TNI standards.

The public’s opportunity to provide verbal comments and engage in meaningful discussions during ELTAC meetings is non-existent. The continued lack of opportunity for stakeholder involvement creates wider communication gaps between ELAP and the laboratories it inspects and accredits.

4. ELAP’s Proposal Does Not Reflect the Recommendation of the Affected Laboratory Community, as Represented by the Environmental Laboratory Technical Advisory Committee

The ELTAC was established by California Health and Safety Code section 100863 “to assist, advise, and make recommendations regarding technical, scientific, and administrative matters concerning the accreditation or certification of environmental laboratories” to California’s ELAP. Despite its establishment in statute, ELTAC was disbanded by ELAP in 2015, only to be resurrected by ELAP in early 2016 with mostly new members. The new ELTAC has only had five meetings since March 2016 to discuss and deliberate on the options for ELAP’s new quality management system (QMS), technical standards, and annual Proficiency Tests. ELTAC’s formal consideration of QMS options did not occur until August 24, 2016. Ultimately, ELTAC recommended to ELAP that: (1) laboratories would perform one annual Proficiency Test; (2) the technical standards would be the same as the approved analytical methods; and (3) the QMS

would be the California Plus option.⁴ Critically, ELTAC did not recommend consideration of the full 2016 TNI standard.

ELAP's recommended adoption of full 2016 TNI standards (not a modified version) has set aside all of ELTAC's recommendations, effectively rejecting the majority of the laboratory community as represented by ELTAC. ELAP has not made it clear in the notice for the October 6, 2016 workshop that a majority of ELTAC members do not recommend adoption of the 2016 TNI standards. Instead, the notice would seem to indicate that all of ELAP's advisory bodies support this proposal.

To date, there has been no thorough review of how the current codified laboratory standards are lacking or how the 2016 TNI standards would address the failings of the current regulations. For that reason, it is difficult to determine why the 2016 TNI standard is preferable to any other possible standard, including the California Plus option favored by ELTAC or even a TNI "Lite" option.

5. ELAP Regulations Should Be Updated with Standards That Protect Public Health and the Environment, and Ensure the Survival of Municipal Environmental Laboratories

CVCWA appreciates and concurs that it is necessary to update ELAP regulations and standards. The State Board and ELAP should adopt a standard that achieves this goal and is applicable to all laboratories. It is important to note that the TNI standards are designed for medium-to-large commercial laboratories, and to facilitate their marketability across state lines. The 2016 TNI standards are not the proper standard for California because they are overly burdensome; do not increase data accuracy, quality, or defensibility; and could result in the closure of many small municipal and commercial labs. Closure of these small labs would result in lost jobs, as well as higher analytical costs with loss of competition and increased ELAP fees to cover the additional inspection requirements in the 2016 TNI standard. Most municipal onsite laboratories conduct analytical testing for optimal operations of water or wastewater treatment plants and for regulatory compliance purposes. Closure of smaller labs and municipal labs could

⁴ At its July 7, 2016, ELTC took a straw poll vote on whether to recommend the TNI Standard as a foundation for ELAP's quality management system requirement for accreditation. This Straw Polled failed (8-5 against using the TNI Standard). At its August 24, 2016 meeting, votes were taken on both the California Plus option and a TNI "Lite" option (actual voting results were 7-5 in favor of California Plus and 6-6 for TNI "Lite"). The results of ELTAC's votes on both the California Plus and TNI "Lite" options were to be presented to the State Water Board. "California Plus" refers to a proposed option in which ELTAC and ELAP would start with analyzing the shortcomings in the current California environmental lab accreditation regulations and add in provisions that would enhance the regulatory scheme using EPA-based standards. TNI was also mentioned as a source of potential additions to the California Plus standard. "TNI Lite" refers to a proposed option in which ELTAC and ELAP would start with the TNI standards and pare them down as burdensome and unnecessary provisions are identified, to create a customized standard for California.

result in a shift of the focus of lab testing from maintaining Water Quality Objectives to commerce, thereby endangering public health and the environment in California.

In conclusion, CVCWA strongly encourages the State Board to consider the serious impact that adopting the full 2016 TNI standard would have on small laboratories and the communities they serve. CVCWA does not believe that the proposal from ELAP is in the best interests of the protection of public health, the environment, the majority of environmental testing laboratories, or the goals of ELAP, and therefore opposes the adoption of the full 2016 TNI Volume 1 Standard.

We appreciate your consideration of these comments. If you have any questions, or if CVCWA can be of any further assistance, please contact me at (530) 268-1338, or eoofficer@cvcwa.org.

Sincerely,



Debbie Webster,
Executive Officer

cc: Frances Spivy-Weber, Vice Chair, State Water Resources Control Board
Tam M. Doduc, State Water Resources Control Board
Steven Moore, State Water Resources Control Board
Dorene D'Adamo, State Water Resources Control Board