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May 1, 2017

Via Electronic Mail Only

Ms. Jeanine Townsend
State Water Resources Control Board
1001 I Street, 24th Floor, Sacramento, CA 95814
commentletters@waterboards.ca.gov

Subject: Comment Letter – ELAP Year 2 ERP Report and Additional Comments on ELAP's Consideration of Lab Standards

Dear Ms. Townsend:

The Central Valley Clean Water Association (CVCWA) appreciates this opportunity to comment on the Final Recommendations by the Expert Review Panel for the State of California's Environmental Laboratory Accreditation Program (ELAP) Year 2 Final Report (ERP Report). CVCWA would also like to take this opportunity to provide additional comments on ELAP's continued consideration of adopting Volume 1 of The NELAC Institute's (TNI) 2016 Standard as the basis for the quality management system (QMS) for California laboratory accreditation. CVCWA believes it is appropriate to incorporate comments on the 2016 TNI standard as a California Regulation in this letter, as the ERP Report is largely focused on ELAP's adoption of this standard. CVCWA appreciates the opportunity to partner with ELAP to further explore strategies, options, and implementation plans related to the new California lab accreditation standards and regulations.

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 provide

compliance monitoring and ensure proper operation of their wastewater treatment plants in a manner that is protective of public health and the environment. Others rely on small, local laboratories to perform basic testing. In this letter, we provide comments on the ERP Report and on ELAP's proposal to base forthcoming regulations on the 2016 TNI Standard, and its potential impact on publically-owned treatment works (POTWs) in the Central Valley.

A. The ERP Report Correctly Identifies That ELAP has Made Significant Improvements, but More Improvement Must Occur Before ELAP Can Administer the 2016 TNI Standard

CVCWA appreciates the services of the Expert Review Panel (ERP) and concurs with its assessment that ELAP has made significant progress since November 2015, and that ELAP still lacks adequate staff to properly perform onsite assessments of accredited laboratories which resulted in significant programmatic backlog. However, we strongly believe that ELAP still lacks expertise with the 2016 TNI Standard, and therefore will need more time for staff training prior to the adoption and implementation of this standard as the California accreditation standard. Thus, CVCWA has reservations about the ERP Report's recommendation that the 2016 TNI Standard be adopted in California regulations as quickly as possible.

CVCWA disagrees with ERP's rush to adopt 2016 TNI without more modifications. Of the 58 modifications ELAP proposed, ERP only endorsed two modifications to incorporate into regulations, and recommended that the rest be clarifications contained in a guidance document. We believe that the number of proposed modifications still does not meet the direction given by the State Water Resources Control Board (State Board) in October 2016. The State Board directed ELAP to work with the laboratory community to whittle down the 2016 TNI Standard into a workable version that can be applicable to all laboratories, regardless of size. Furthermore, the 2016 TNI Standard is still under review by TNI and it will take time for this standard to reach final form. Therefore, adoption of the 2016 TNI Standard is premature at this time. Modifying the standard will also lower the burden on ELAP in terms of training and staffing.

CVCWA agrees that ELAP needs to be held accountable for continuing to make progress with laboratory accreditation. However, forming another ERP without also forming a Stakeholder Advisory Group or other group to increase communication between laboratory stakeholders and ELAP would fail to bring in useful perspectives. If another ERP is formed, CVCWA recommends that a fully-vetted selection procedure be followed to prevent bias in terms of the experience the panel members have with other laboratory quality management systems, including TNI.[1] A Stakeholder Advisory Group

[1] The present ERP members are all currently (or have recently been) associated with TNI and larger commercial laboratories.

would need to be comprised of members that are proportionately allocated from all types and sizes of laboratories that ELAP accredits.

Related to stakeholder involvement going forward, ELAP's means of communication with stakeholders requires significant improvement to reach all laboratory stakeholders in California. ELAP has depended heavily upon Environmental Laboratory Technical Advisory Commission (ELTAC) members' input. ELTAC is not a stakeholder group, and is not necessarily representative of all laboratory stakeholders. For example, ELAP has held two listening sessions (April 5 and 6, 2017) soliciting feedback from the laboratory community with a focus on three questions to support ELAP's plan in response to the ERP report. The announcement was unclear, contained incomplete information, and did not reach all stakeholders. As a result, the sessions were poorly attended. It was a one-way discussion for those who attended via webcast, as comments submitted electronically were not monitored or responded to during the sessions. Back-and-forth discussions were limited only to those who attended in person (a total of less than ten persons attended both sessions).

B. Adopting the 2016 TNI Standard Without Meaningful Modifications Imposes Undue Burdens on California's Small and Municipal Laboratories

As CVCWA has noted in its past comments, the 2016 TNI standard will likely increase cost and personnel burdens on small laboratories and municipal laboratories, without a corresponding increase in data quality or defensibility. This is why CVCWA has advocated for a modified standard that will achieve real benefits for state agencies in terms of ensuring the quality of laboratory data without imposing overly burdensome requirements on laboratories. CVCWA's main concerns with the 2016 TNI standard and its impacts on smaller and municipal laboratories are that the standard presents auditing challenges for municipal laboratories (as a division within a larger public agency), that the combination of all requirements in the standard is a significant burden to smaller laboratories, that existing regulation is not acknowledged or incorporated into the standard, and that the technical manager requirements do not reflect current regulations regarding certifications.

1. Some Provisions in the 2016 TNI Standard Present Auditing Challenges for Municipal Laboratories

Each municipal laboratory is only a department or section within a larger agency. Because of this, the TNI standard presents unique implementation and auditing challenges for municipal laboratories. To increase efficiency within the parent agency, there is a division of labor in which laboratories are primarily responsible for running tests and reporting results to the parent agency, Regional Water Quality Control Boards (Regional Boards), or the State Board. Due to this division of labor, departments outside

of the laboratory are responsible for IT, human resources, and purchasing for the entire public agency. These other departments have their own policies and procedures already in place. Unlike commercial laboratories, municipal laboratories are required to follow agency (i.e., city, county, special district, or city *and* county) policy.

It is unreasonable to require municipal laboratories to maintain copies of the policies, procedures, and records of other agency departments. This will cause inefficiency and unnecessary busywork in laboratory operations without any benefit to legal defensibility or data quality. These documents are outside of the laboratories' control, and it is therefore nearly impossible for laboratories to have control over these processes and corresponding documentation. Since these documents are outside of a municipal laboratory's control, they should not be included or audited as part of a municipal laboratory's management system. The draft regulations should expressly include an exemption for TNI requirements that are addressed by the parent agency or other agency departments. This is because laboratory accreditation assessments should be *laboratory* assessments, not agency assessments.

TNI policy, procedure, and record requirements that are typically delegated to other agency departments and are outside of municipal laboratory control include, but are not limited to:

Human Resources Department
Job Descriptions (TNI V1M2 4.2.8.4.g and 5.2.4)
Hiring and Firing (TNI V1M2 5.2.7)
Disciplinary Action as a Result of Data Integrity Investigations (TNI V1M2 5.2.7)
Employee Education and Training Goals (TNI V1M2 5.2.2)
Educational and Professional Qualification records (TNI V1M2 5.2.5)
Ethics (TNI V1M2 5.2.7)

Purchasing Department
Purchasing Services and Supplies (TNI V1M2 4.6.1)
Reception and Inspection of Supplies (TNI V1M2 4.6.1 and 4.6.2)
Purchasing Documents (TNI V1M2 4.6.3)
Evaluation of Suppliers (TNI V1M2 4.6.4)

IT
Software Documentation and Verification (TNI V1M2 4.13.3.f.xv)
Electronic Data Security and Data Backups (TNI V1M2 4.13.3.f.xv)
Protection of Confidential Information (TNI V1M2 4.1.5.c)

Records Management
Indexing, Access, and Filing of Records (TNI V1M2 4.13.1.1)
Records Retention Schedules and Records Storage Facilities (TNI V1M2 4.13.1.2)
Access to Records (TNI V1M2 4.13.1.4)

2. Provisions Within the 2016 TNI Standard Are Individually Attainable, but Collectively Are a Significant Burden on Laboratories

The 2016 TNI Standard Volume 1 Module 2 contains over 580 general quality system requirements for laboratories. Laboratories must comply with over 1,100 requirements for the entire 2016 TNI Standard (Volume 1, Modules 1 through 7).[2] If ELAP selects an unmodified version of the 2016 TNI standard as the accreditation standard, the total burden of the standard will require laboratories to reorganize staff and/or hire additional staff in order to maintain California accreditation. This is particularly problematic for small laboratories, which generally lack the financial resources necessary to make these changes and accordingly bring their laboratories into compliance with this new standard.

In order to develop a TNI-compliant quality management system, laboratories will need to hire consultants, add additional short-term and long-term staff, attend numerous training sessions,[3] and draft the policies and procedures required by the 2016 TNI Standard. According to our members' estimates, accomplishing these changes will take at least three to five years, even with significant implementation assistance from ELAP. Training and consulting resources for implementation are limited since TNI does not currently offer templates or training materials for their 2016 TNI Standard, which has not yet been formally adopted by TNI's voting body, and there are not enough consultants to meet anticipated demand. The list of consulting firms on the TNI website includes a total of 12 in the entire United States, and only one of those is located in California.

After each laboratory develops a TNI-compliant Quality Management System (QMS), a significant amount of staff time will be needed to meet ongoing TNI requirements. Even after the transition has occurred, the additional documentation maintenance activities will require staff time that would otherwise be spent on performing sample analyses. Staff time will be needed for maintaining required documents, document control, records management, and ongoing QMS training. The increased documentation under the 2016 TNI Standard will require hiring additional personnel to maintain the lab's level of service, reducing process control testing, and/or

[2] This number is based on the 2009 TNI Audit Checklist posted on the NELAC Institute website. A checklist for 2016 TNI is currently unavailable.
[3] The per-person cost of the TNI training series (Small Laboratory TNI Standard Implementation) offered by TNI consists of ten two-hour webinars (20 hours total). Each webinar costs $50 (plus $15 for training documentation), or $450 for the series (plus $15 for training documentation).

increasing the amount of samples sent to commercial laboratories for testing. Regardless of laboratory size, resources will either need to be increased or reallocated from sample analysis, sampling, analytical standard operating procedures (SOP) maintenance, and analytical training to TNI management system requirements. In total, this amounts to a significant increase in laboratory resources.

As stated at the April 5, 2016 training provided by ELAP, the 2016 TNI Standard itself does not improve data quality, because the TNI lacks the method-specific requirements that would ensure that tests are being performed correctly. Since the intent of ELAP accreditation is to ensure data quality,[4] CVCWA recommends further reducing the overall number of TNI requirements beyond the ELAP and ERP recommendations, and/or allowing laboratories up to five years to implement TNI requirements in order to make the burden of complying with new accreditation regulations more proportional to the limited benefits associated with this standard in regard to data quality.

In addition, laboratories performing basic approved microbiology and wet chemistry tests should be granted an exemption from TNI requirements, similar to the field test exemption in Water Code section 13176. Alternatively, these laboratories should be given an extended compliance period of five to seven years in order for these laboratories to make the needed changes while avoiding increased cost.

3. The 2016 TNI Standard Does Not Adequately Address or Incorporate Existing Water Quality and Laboratory Regulations

The 2016 TNI Standard only vaguely refers to regulatory requirements, which is not useful to laboratories within the regulated community. There are multiple sections in TNI that have this type of language. Some examples are:

- "The laboratory shall use methods which meets the needs of the customer and which are appropriate." (2016 TNI Volume 1, Module 2, section 5.4.2.)
- "If a mandated test method or applicable regulation includes protocols for determining detection limits they shall be followed. If the method or regulation does not contain specific directions the following requirements shall apply. . . ." (2016 TNI Volume 1, Module 4, section 1.5.2.1.)

The regulations adopted by ELAP should clearly state when water quality regulatory requirements exist and apply to laboratory procedures. For method modifications and selection of methods, wastewater compliance laboratories should be

[4] ELAP Program Information (http://www.waterboards.ca.gov/drinking_water/certlic/labs/program_info.shtml).

referred to the United States Environmental Protection Agency's (EPA) Alternate Test Procedure found at 40 C.F.R. Part 136 (sections 136.4, 136.5, 136.6), and drinking water compliance laboratories should be referred to Appendix A to Subpart C of 40 C.F.R. Part 141, 40 C.F.R. Part 141.28, and the EPA's Drinking Water Alternate Test Procedure Program website. For method detection limit (MDL) requirements, the 2016 TNI Standard puts little emphasis on 40 C.F.R. Part 136 Appendix B,[5] but 40 C.F.R. Part 136 is required for wastewater compliance testing and it is the only procedure allowed for drinking water compliance testing when the mandated method lacks an MDL procedure.[6] EPA does not recognize any MDL procedure applicable to hazardous waste testing.[7]

In some cases, the 2016 TNI Standard conflicts with existing regulations. For example, the 2016 TNI Standard (Volume 1, Module 2, section 5.4.2) states that a "laboratory shall use the last valid edition of a standard unless it is not appropriate to do so." Again, this language is vague and does not cite applicable regulations to aid laboratories. Using the latest edition of a standard conflicts with EPA regulations, which specify method editions or publication year for compliance testing at 40 CFR Part 136 (wastewater) and 40 CFR Part 141 (drinking water).

CVCWA recommends clarifying language in the new regulation for these and other vague 2016 TNI provisions that have a serious impact on compliance with EPA regulations, particularly for those laboratories associated with discharges permitted under the National Pollutant Discharge Elimination System (NPDES).

4. CVCWA Supports Broadening Technical Manager Requirements to Include Laboratory Analyst Certifications

CVCWA strongly supports adopting existing California laboratory personnel requirements in the new regulation. (Cal. Code Regs., tit. 22, art. 9.) CVCWA appreciates that in the past, ELAP and the State Board have also been supportive of this change. In lieu of modifying the 2016 TNI standard in this regard in regulations, the Expert Review Panel (ERP) recommends that ELAP clarify Technical Manager criteria to include laboratory analyst certifications, but then mentions that ELAP might eventually transition away from this to "rejoin the national program." (ERP Report, pp. 11-12.) Note that the term "national program" refers to TNI, which is a nonprofit corporation, and only 13 states are accrediting bodies through TNI. These important certifications should remain part of the California regulations to ensure that laboratories can find qualified personnel to manage laboratory work.

[5] 2016 TNI Volume 1, Module 4, 1.5.2.1.1 notes that 40 CFR Part 136 is merely one option for determining MDL.
[6] Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-R-05-004, 2005.
[7] Federal Register Notice - Waste Management System; Testing and Monitoring Activities; Notice of Availability of Final Update V of SW–846, 80 FR 48522.

ELAP and ELTAC have discussed this issue at length and have agreed that the qualifications for technical managers should be expanded to include California Water Environment Association (CWEA) and American Water Works Association (AWWA) certifications. In current regulations, CWEA and AWWA certifications are equivalent to the experience and education requirements for laboratory directors.[8] Technical managers under the 2016 TNI Standard are roughly equivalent to laboratory directors under current California regulations. These certifications facilitate upward mobility within laboratories and promote ongoing educational training specific to wastewater or drinking water programs to maintain the certification.[9]

CWEA and AWWA certifications are crucial for small municipal laboratories, particularly in rural areas, which have difficulty attracting staff who have two years of experience and meet the college unit and degree requirements in the 2016 TNI Standard.[10] Most of these laboratories typically perform relatively simple approved tests. Incorporating CWEA and AWWA certifications ensures that laboratory staff have the required technical skill to manage a laboratory and conduct analytical testing with robust quality assurance and quality control practices. It also ensures that municipalities have the necessary flexibility to find and hire staff to operate their laboratories.

In closing, CVCWA recommends that ELAP seriously consider the costs and further ELAP staff trainings that will be required in order for ELAP to adopt the 2016 TNI Standard as California's laboratory accreditation system. A more robust stakeholder involvement process will ensure that ELAP keeps making progress in laboratory accreditation, even following the disbanding of the current ERP.

CVCWA also urges ELAP to follow State Board direction to adapt this standard to fit California's needs, rather than force a cumbersome standard onto the state's laboratories. To the extent that the ERP Report contemplates and advocates ELAP's adoption of the 2016 TNI Standard as California's laboratory accreditation system, CVCWA is concerned that an adoption of the 2016 TNI Standard places unnecessary burdens on laboratories - particularly small and municipal laboratories - without a corresponding benefit to data quality and defensibility.

[8] Current California regulations require three years of experience and a Baccalaureate degree or an appropriate CWEA/AWWA certificate for Laboratory Directors (Title 22 Division 4 Chapter 19 Article 9).
[9] CWEA certification has specific education and experience requirements for each certificate level, and certificate holders must pass an examination and complete 12 hours of ongoing training each year.
[10] TNI Technical Manager requirements: two years of experience and an Associate degree or two years of college with 16 college units in chemistry for inorganic tests; an Associate degree and four college units in biology for limited microbiology testing; a Baccalaureate degree with 16 college units in biology or microbiology; a Baccalaureate degree with 24 college units in chemistry for metals and organic chemistry testing; or a valid treatment plant operator's certificate.

We appreciate your consideration of these comments. CVCWA continues to encourage ELAP to engage its stakeholders in a truly collaborative effort and to provide additional opportunities for stakeholder engagement and input. If you have any questions, or if CVCWA can be of any further assistance, please contact me at (530) 268 1338, or eofficer@cvcwa.org.

Sincerely,

Debbie Webster

Debbie Webster,
Executive Officer

cc: Ms. Christine Sotelo, Chief, Environmental Laboratory Accreditation Program
Ms. Felicia Marcus, Chair, State Water Resources Control Board
Mr. Steven Moore, State Water Resources Control Board
Ms. Tam Doduc, State Water Resources Control Board
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