

October 19, 2016

Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
Commentletters@waterboards.ca.gov (delivered via email)

Subject: Comment Letter – ELAP Regulations Development / Laboratory Standard

Members of the State Water Resources Control Board:

Thank you for the opportunity to provide comments in response to the Environmental Laboratory Accreditation Program (ELAP) recommendation to adopt the 2016 *The NELAC Institute* (TNI) regulations and for extending the deadline to allow for adequate review of those documents. Palo Alto would prefer a “California plus” alternative for our State’s municipal laboratories. The majority of the participants at the State Water Resources Control Board TNI workshop on October 6th, including ELAP’s Environmental Laboratory Technical Advisory Committee (ELTAC), Bay Area Clean Water Agencies (BACWA), the California Water Environment Association (CWEA), the Pasadena coalition, and the California Department of Fish and Wildlife, all were opposed to a “full TNI” adoption of California lab accreditation.

A portion of the 2016 TNI Volume 1 requirements will have a negative effect on the staffing, budget, efficiency, and mistake potential in our laboratory, without necessarily improving data quality. If TNI standard development is not revised to be more compatible with the smaller California municipal lab community (note that 40% of state labs are five or fewer employees), then our lab analyses would need to be contracted to larger commercial labs, increasing our costs and reducing responsiveness. We want to provide excellent service to the water, wastewater, and recycled water decision makers in the operational, regulatory, and environmental protection community. The City does not want to see what happened in Florida and New York, where many small laboratories were forced to close as a result of trying to comply with TNI. We understand that there are concerns with the quality rather than quantity of labs in California, but the small labs play a vital role in preserving the Bay and protecting public health.

Background

The City of Palo Alto’s lab supports a Palo Alto drinking water system that serves a residential population of approximately 67,400 with 20,000 service customers and the wastewater treatment system that serves approximately 220,000 people in six agencies, including Palo Alto, Mountain View, Los Altos, Los Altos Hills, Stanford University, and the East Palo Alto Sanitary District. The Palo Alto laboratory employs eight staff members (three lab technicians, three chemists, a senior chemist, and a lab manager). The laboratory is located onsite at the wastewater treatment plant, where approximately 20 million gallons of wastewater is treated each day. The laboratory supports the compliance for NPDES permits for the wastewater operation as well as for recycled water, industrial waste, potable water, process samples and special studies. The laboratory is certified for over 30 methods for wastewater and drinking water, including 9 fields of testing in the areas of microbiology, inorganic chemistry, toxic chemicals, volatile organics, and whole effluent toxicity.

Overview of Concerns

The City of Palo Alto has five main concerns; (1) increased cost for ratepayers to implement the changes with little added benefit, (2) increased documentation that is not likely to improve data quality, (3) the need to send out samples to contract commercial laboratories to address the increased documentation requirements and costs of the proposed changes, (4) burdens on existing resources and already busy staff to implement the proposed changes with efficiency loss and increased mistakes by analysts and reviewers due to changing workloads; and (5) the lost opportunity to evaluate alternative state accreditation standards (e.g., Virginia, Texas, and Oregon).

Concern over Cost

The TNI requirements will increase lab costs, especially for the implementation and sustainability required by the program. Additional staff must be considered to accommodate this increased work load, but Palo Alto has no intentions of adding staff. The city will more than likely experience cuts to their existing potable water and wastewater programs in order to handle the implementation and ongoing costs. The California ELAP program has already increased their fees by approximately 25% annually to account for budget shortfalls, auditor training, and other related services bought about by the possibility of implementing TNI. At the October 6, 2016 workshop, the Water Board asked us to provide specific suggestions where regulations should be revised; those suggestions will be provided in the upcoming months. We request a reduction in the frequency for proficiency testing certified samples for water pollution (i.e., WP for wastewater treatment) and water supply (i.e., WS for drinking water). The extra WP/WS requirement adds no value to the overall data quality, a statement mentioned in ELAP's Expert Review Panel report, dated October 2015, that recommended ELAP do a better job evaluating the current once per year proficiency testing results instead of increasing proficiency testing frequency to twice per year (as required by TNI). We understand that increasing costs for the implementation, training, and staff time is not something that is going to deter the implementation of this program, but we do worry that the additional cost to our ratepayers will bring about no real benefit to the data quality that already exists.

Concern over Level of Documentation and Data Quality

Lab documentation increases substantially with TNI 2016, which will not only decrease lab efficiency on bench work but will also burden staff reviewing and updating the material. The current lab documentation is adequate to ensure legally and defensible data; therefore the increased documentation is burdensome and requires increased staff to handle the workload, without dramatically improving data quality. Our current standard operating procedure (SOP) book contains 40 procedures totaling approximately 140 pages. TNI Module 2 Section 4.2.8.5 requires that 23 sections be included in each of these individual SOPs where applicable and that SOPs be prepared for all phases of current laboratory activities. Documenting all activities in the lab in this manner is going to be both cumbersome and a drain on staff resources, especially for smaller labs that do not always encounter the same issues as larger ones. For example, creating an SOP for document control in a commercial lab would be much more crucial than for a smaller one, seeing that there are less people to review and handle paperwork. SOPs may be helpful, but they become counterproductive as they get longer and longer with redundant references to provisions already covered in prescribed standard methods. Another example of excessive documentation is evident in the quality assurance (QA) manual template for TNI (115 pages). The QA template has areas that are typically duplicative of an individual municipality's existing policies and procedures. Some of those chapters that could be deleted, including Section 4.2 *Conflict of Interest and Undue Pressure*, Section 7 *Review of Requests, Tenders and Contracts*, and Section 10 *Service to The Client*.

Concern over Greater Use of Contract Laboratories

A long and extensive implementation with ongoing follow-up will change our lab operation. TNI may lead to lab closures (e.g., as occurred in New York and Florida). Without staff additions, some analyses would be contracted out to commercial labs or reduced in frequency when lab staff reach the limits of

doing more quality assurance/quality control without additional team members to pick up extra workload. I am concerned that those contracted samples may not meet hold time limits, samples could break in transport, and untimely results from contract labs (where samples are sometimes batch processed at opportune times for cost effectiveness) will impact timely public health and environmental protection decision making. The delay in receiving data, especially for drinking water and process control, may impact environmental and public health management decisions.

Concern over Staffing, Efficiency, and Greater Mistake Potential

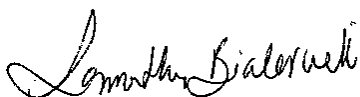
The amount of work associated with the multiple regulations will dramatically increase for all lab staff, causing an efficiency decrease and a potential increase in mistakes. Analysts will be forced to focus on extraneous documentation, instead of their bench work, which could lead to more errors with the actual data. In the TNI quality manual template (Section 5.2) job titles for lab director, quality manager, and technical manager have lists of responsibilities that are assumed to be completed by three people. Although it states for smaller labs that these titles could be shared with one person, there could be conflicts of interest and a great burden on that person to manage all of the associated tasks. Switching the critical focus from the quality of supplied client data over to excessive paperwork will impact mistake potential, decrease lab efficiency, and create unneeded burdens.

Concern over Other States Approach to National TNI

Only 13 US states have adopted NELAC standards, and 3 of the 13 (i.e., VA, TX & OR), are using modified TNI requirements (the so-called TNI-lite) to meet lab accreditation needs. More research needs to be done understanding the benefits of other accreditation standard pathways that are short of full TNI standards. In addition, it would be beneficial to explore a two tiered program for commercial and municipal labs for California, so that the “reciprocity” option (full TNI) that ELAP is wanting could be made available to those interested labs hoping to do business with other states. The municipal labs could continue to do their important work with a partial TNI program, selecting regulations that still uphold the quality control standards you want to see, yet practical enough to sustain our California laboratories. The Water Board should also evaluate and understand why some states chose not to adopt TNI.

For more information please contact me at Samantha.bialorucki@cityofpaloalto.org.

Thank you for your consideration,



Samantha Bialorucki
Manager of Laboratory Services / ELAP Designated Laboratory Director
ELAP Certification # 1087
NPDES Permit # CA0037834¹
Drinking Water System #4310009

¹ NPDES Board Order R2-2014-0024 (NPDES Permit No. CA0037834); pH Cease and Desist Order R2-2015-0011 (NPDES Permit No. CA0037834); Board Order R2-2016-0008 Alternate Monitoring and Reporting Requirements to Support SF Bay RMP (NPDES Permit No. CA0037834); Watershed Nutrient Order R2-2014-0014 (NPDES Permit No. CA0038873); Watershed Mercury and PCB Order R2-2012-0096 (NPDES Permit No. CA0038849); Recycled Water Board Order R2-93-160; ELAP Certification No. 1087; EPA Lab Code CA00179