Public Comment ELAP Year 2 ERP Report Deadline: 5/1/17 by 12 noon





April 28th, 2017

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

Subject: Comment Letter - ELAP Year 2 ERP Report

Members of the State Water Resources Control Board:

Thank you for the opportunity to provide comments for the May 3, 2017 public workshop in response to the latest Expert Review Panel's (ERP) year two final report assessment of progress and final recommendations for the State of California's Environmental Laboratory Accreditation Program's (ELAP) and their mission to adopt the 2016 *The NELAC Institute* (TNI) regulations.

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

At the October 6th, 2016 workshop, the State Water Board listened to a packed room of concerned California ELAP accredited laboratory personnel, all frustrated about how the full adoption of TNI would negatively affect their jobs. The general consensus with all of the speakers was that this type of full scale program would place a great deal of emphasis on documentation rather than the quality of the data, adversely affecting staffing, budgets, training and efficiency for the majority of these non-commercial labs. By the end of the discussions it was pretty apparent that although worried about the repercussions of a "full TNI" adoption your staff had left us feeling somewhat optimistic and reassured that ELAP would work together with the ELTAC (Environmental Laboratory Technical Advisory Committee), to come up with a solution. The solution, you advised was for ELAP and ELTAC to work through all of the TNI regulations and include only the essential elements from the standards that actually protected data quality and to avoid those that really did not improve the quality and were not practical for California's laboratories.

After many discussions between ELTAC and ELAP regarding possible modifications to the current TNI regulations (see attachment #1), ELTAC voted in favor of modifying and in some cases deleting certain sections. As a member of the lab committee it was comforting to know that these decisions were being discussed with both parties and that our highly qualified committee's voice would be heard. After our last update from ELTAC the outcome of those meetings did not seem to align with the majority of opinions on that committee, evident in ELAP's direction to retain the full 2016 TNI requirements except two (having labs analyze one set of proficiency annual tests instead of two and the education/experience criteria for laboratory supervisors in California). In the ERP two year report it was stated that "ELAP cannot neglect to consider the laboratory perspective in ELAP policy decisions", which seemed like this was already being done. The fact that ELAP decided to add clarification to 58 pre-existing requirements and ignore the recommendations from ELTAC to delete certain TNI sections, makes it seem that the committee member's votes did not count.

It is difficult to fathom how the recommended "full TNI", adoption will take place without elevating accreditation fees even more, given the number of requirements and assessments. The regulations alone are already going to add costs to the laboratories, by forcing the laboratories to buy their copyrighted protected templates and regulations not to mention the cost of any future regulations we may need. The ERP identified ELAP as having lack of staffing, funding and training resources currently to maintain their program and that is not even the start of what is going to be needed for the future transition or sustainability of this type of program. ERP has suggested in their latest report that ELAP will more than likely have to outsource for their third party onsite assessments due to backlogs, field of testing [FOT] assessments and cross training, even though increased fees have already gone into effect to help pay for them. The "full TNI" requirements will definitely drain our laboratories resources without any real benefit to the quality of the data.

The City of Palo Alto has five major concerns with the outcome of "full TNI"; (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 possibility of having laboratory closures in California.

Our laboratory wants to provide excellent service to the water, wastewater, and recycled water decision makers in the operational, regulatory, and environmental protection community, but agrees with ELTAC that not all of the proposed TNI requirements are required in order to achieve this. We recognize that change is inevitable and that ELAP is doing their best to make those changes align with the goals set by the ERP, but we just want the outcome to make sense for California. "Full TNI" has policies and regulations geared too much larger commercial labs where they can independently make decisions for some of the regulations like purchasing and security where that level of detail may be necessary. For Palo Alto's sized laboratory and others like it, some of the TNI requirements in fact will take away efficiency and quality by redirecting focus to areas that will not necessarily improve our quality of data. I encourage the board to listen to the ELTAC members and laboratory communities on May 3rd so that the best choice can be made for the quality of California's data and resources.

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

NPDES Permit # CA00378341

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; Drinking Water System #4310009; ELAP Certification No. 1087; EPA Lab Code CA00179

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PROPOSED MODIFICATIONS TO TNI VOLUME 1 PREPARED BY: ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE

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TNI Section	Summary	Modification	Rationale	# in Agreement
Module 2				
2.0	references other documents	defer to SAPC to judge if the documents are indispensable	not indispensable	9 (in favor) 2 (against) 1 (absent)
4.1.4	requires lab to make a list of potential conflicts of interest	delete	no definition of what conflict of interest is. Covered under mandatory ethics training	8 (in favor) 2 (against) 2 (absent)
	requires lab to have documentation	delete	too broad	8 (in favor) 2 (against) 2 (absent)
4.1.5 (b)	ensuring mgmt. and personnel are tree from undue influence	modify - strike "have arrangements to"	is necessary to avoid fraudulent actions	9 (in favor) 1 (against) 2 (absent)
4.1.5 (c)	requires procedures for protecting customer information	delete	outside regulatory authority of ELAP	9 (in favor) 1 (against) 2 (absent)
		delete		
4.1.7.1 (d)	additional requirements for lab	delay until ELAP can offer better definition of expectation	Difficult for 1-2 person lab to comply with. Problem with "documented training"	10 (in favor) 2 (against)
4.1.7.2 (d)	requires that separate facilities have separate technical managers	delete	expense to muni labs, cause small labs to revoke ELAP cert (labs won't be overseen by the state), doesn't solve the problem	8 (in favor) 4 (against)
4.1.7.2 (e)	requirements for when tech. mgr. is out	delete timeframe for notification, require an alternate when on leave		10 (in favor)
	for extended period of time	delete and replace with current ELAP language	ELAP language is more stringent	z (against)
4.3	document control	delay for 3 years	excessive effort	11 (in favor) 1 (abstained)

Attachment 1

in Agreement 10 (in favor) 2 (against) (abstained) 9 (in favor) 2 (against) (abstained) 8 (in favor) 3 (against) (abstained) (abstained) (abstained) (abstained) 9 (in favor) 2 (against) 8 (in favor) 2 (against) 9 (in favor) 2 (against) 8 (in favor) 3 (against) 7 (in favor) 5 (against) 7 (in favor) 4 (against) 7 (in favor) 5 (against) 1 (absent) 1 (absent) 12 qualified candidates. CWEA/AWWA require approval from State Agency labs should not be able to use non-CA certified labs should be able to send samples to other CA certified requiring a B.S. degree eliminates not applicable - ELAP labs are not methods already have policies to standard methods without prior non-standard methods should certificates would not be valid imperative for implementation ensure quality of supplies already in the method excessive effort calibration labs PREPARED BY: ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE Rationale too broad too broad approval labs PROPOSED MODIFICATIONS TO TNI VOLUME 1 any place where ref to ISO, replace delete - use current CA language delay - ELAP provide training and ELAP/SAPC/EPA can approve modify - striking ref. to ISO and modify - require internal audits if not deleted then modify - add delete sentence that precedes delete sentence that precedes replacing with CA standard during years ELAP is not performing assessment support documents subsection (a) subsection (a) Modification with Title 22 methods delete delete delete delete requires all labs used for subcontracting being technical manager or lab director sentence that proceeds subsection (a) requires documentation of procedures sentence that proceeds subsection (a) requires B.S degree as a condition of for transport and storage of reference conditions for approval of use of nonrequires documenting purchasing process for services and supplies requirements for calibration labs requires annual internal audits documentation requirements standard methods to be ISO certified Summary standards is broad is broad 4.8, 4.11, 4.12, 4.13, 5.6.2.1 and related TNI Section 4.14.5 (c) 5.2.6 (all) sections 5.6.4.2 5634 564.1 4.5 etc. 4.15 4.6 5.4

in Agreement 1 (abstained) 1 (abstained) 10 (in favor) 2 (against) 2 (absent) 8 (against) 8 (in favor) 4 (against) 3 (against) 2 (against) 3 (in favor) 8 (in favor) 8 (in favor) 2 (against) 4 (in favor) 8 (against) 2 (absent) 8 (in favor) outside regulatory authority of ELAP standards should not be used after minimum number of calibration method already specifies when method already specifies the confusing and non-productive too specific, should be broad nvestigation/corrective action surrogates are appropriate any failure should require PREPARED BY: ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE expiration date Rationale points PROPOSED MODIFICATIONS TO TNI VOLUME 1 remove any reference to LOQ and does not specify then the section needs (for example DLR for DW) modify - require use of EPA MDI. specific to CA regulatory agency modify - only when the method modify - delete "if reliablility is modify - strike "such as use of replace with something more **ELTAC will work with SAPC** delete last sentence of first linear regression" paragraph 1.7.1 Modification procedure delete verified" applies delete delete requires labs to use a minimum number analytes outside of acceptance range of requires documentation for procedure requires that lab determine an LOQ for requires documentation of procedure method and still report results without gives lab the option to use EPA MDL expiration date if reliability is verified requires surrogates for all samples, allows labs to use standards after allows LCS to have certain # of of calibration standards standards, and blanks of sample disposal for data reduction corrective action every analyte procedures Summary 4.3.5, 4.3.7 (a,b,c); Module 4 - 1.5.2.1, **Multiple Modules** Module 2 - 5.9.3; Module 1 - 4.2.4, 1.5.2.1.1 (Notes) TNI Section 5642(f) 17.1.1(f) 1.7.3.2 (b) Module 4 17.2.3.3 5.8.9 (c) 1724 1.7.1

PROPOSED MODIFICATIONS TO TNI VOLUME 1 PREPARED BY: ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE

TNI Section	Summary	Modification	Rationale	# in Agreement
Module 2 - 3.1 Module 4 - 1.5.2.1.2, 1.5.2.2.2, 1.7.1.2	verification requirements	remove any reference to MDL as currently specified; work with SAPC to come up with solution that more adequately meets their needs		8 (in favor) 2 (against) 2 (absent)