



May 1, 2017

Main Office

10060 Goethe Road
Sacramento, CA 95827-3553
Tel: 916.876.6000
Fax: 916.876.6160

Treatment Plant

8521 Laguna Station Road
Elk Grove, CA 95758-9550
Tel: 916.875.9000
Fax: 916.875.9068

Board of Directors

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www.regionalsan.com

Jeanine Townsend, Clerk to the Board
State Water Resource Control Board
P.O. Box 100
Sacramento, CA 95812-0100

Delivered via e-mail to commentletters@waterboards.ca.gov

SUBJECT: Comment Letter – ELAP Year 2 ERP Report

Dear Ms. Townsend and Members of the Board:

The Sacramento Regional County Sanitation District (Regional San) appreciates the opportunity to comment on the Assessment of Progress and Final Recommendations by the Expert Review Panel (ERP) for the State of California's Environmental Laboratory Accreditation Program (ELAP). Regional San provides wastewater collection, conveyance and treatment for over 1.4 million people in the Sacramento region. On average, we safely treat and discharge 150 million gallons of wastewater per day in accordance with our National Pollutant Discharge Elimination System (NPDES) permit. We take our mission very seriously to protect public health and the environment. Many of our NPDES permit requirements are tied to the conditions in the Sacramento River and the Delta ecosystem. As a result, Regional San also has a state-of-the-art laboratory facility that helps us meet critical analytical needs to ensure we are in compliance with our permit and helps us achieve our mission. Regional San's Environmental Laboratory has been in operation since 1982. The laboratory employs trained, professional environmental scientists and technical staff committed to providing quality services to meet both routine and challenging analytical needs for studies or monitoring and compliance programs.

Regional San has participated in the efforts related to the ELAP regulations development and has, along with other stakeholders including Publically Owned Treatment Works (POTWs), provided input related to the ERP and the proposed ELAP regulations. However, the changes are significant and the notices often give a short lead time for review and input to the documents. We encourage the State Water Board (SWB) members and staff to consider the input that has been provided to date from stakeholders who have a significant interest in the successful implementation of the ELAP and proposed incorporation of the 2016 NELAC Institute (TNI) Standard, including Regional San.

Attached, is a letter submitted on April 5, 2017, in response to a request for comments for the ELAP Regulations Development/Laboratory Standard Listening Sessions. We request that this letter be incorporated into the SWB public comment record and would like to reiterate our main concerns related to the following.

ELAP regulation implementation and the recommendations made in the ERP Report, including:

- Conducting beta testing prior to full implementation of ELAP changes
- Prioritization of the ELAP requirements with a phased implementation
- Incorporation of certain tools, training, and templates on the ELAP website
- Reconsideration of the requirements and implementation of the third party assessments
- Use of an open and transparent stakeholder process
- Improvement of communication between ELAP, ELTAC, and affected stakeholders.

The process of choosing and evaluating the potential impacts of implementing a new lab standard as described in the ERP Report should be carefully and thoughtfully undertaken, without being rushed through the public review period. The impact on laboratory staff, wastewater treatment plant process control, regulatory monitoring and reporting, and the environment would be better served by a thorough review and comment period. We again appreciate the opportunity to provide our comments and look forward to working with the SWB staff through these issues.

If you have any questions, please feel free to contact Srivi Ramamoorthy, Regional San's Laboratory Manager at (916) 875-9020 (Ramamoorthys@sacsewer.com) or myself at (916) 876-6092 (mitchellt@sacsewer.com).

Sincerely,



Terrie Mitchell
Manager Legislative and Regulatory Affairs

Attachment: Regional San Comment Letter for ELAP Regulations Development/Laboratory Standard
Listening Sessions dated April 5, 2017

cc: SWRCB Board Members: Felicia Marcus, Steven Moore, Tam M. Doduc, Dorene D'Adamo
Srivi Ramamoorthy - Regional San Laboratory Manager
Amy Saylor - Regional San Environmental Laboratory Quality Assurance Officer



REGIONALSAN

TAKING THE WASTE OUT OF WATER

Sacramento Regional County Sanitation District

April 5th 2017

Main Office

10060 Goethe Road
Sacramento, CA 95827-3553
Tel: 916.876.6000
Fax: 916.876.6160

Christine Sotelo
State Water Resources Control Board
Division of Drinking Water/ELAP

Treatment Plant

8521 Laguna Station Road
Elk Grove, CA 95758-9550
Tel: 916.875.9000
Fax: 916.875.9068

SUBJECT: Comment Letter – ELAP Regulations Development/Laboratory Standard Listening Session

Regional San’s Response to Questions Posed by ELAP Regarding the Expert Panel Report

Board of Directors

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1. We agree with the Panel that we need to clearly define an implementation path and timeline for laboratories to adopt the TNI Standard. What plan or strategy would work best for your laboratory?

Regional San’s Recommendation:

- Conduct beta testing prior to full implementation (preferred approach): One approach would be for ELAP to work in partnership with a group of laboratories voluntarily selected based on their size (1-2 person lab, 6-8 person lab, 10+) and their type (commercial, municipal, drinking water, wastewater etc.) to develop procedures, templates and other necessary documents for TNI 2016 implementation. Beta testing would help troubleshoot the process in a small controlled environment before rolling it out for full implementation. Implementing TNI 2016 is a very large undertaking for both ELAP and the lab community. Full implementation all at once can potentially overwhelm ELAP’s resources and the laboratory community with questions, complaints, training, and consultation.

We believe beta testing the implementation with a handful of laboratories (including Regional San) might help with creation of training materials, documents, and templates that are customized and more meaningful to the California lab community and the state agency partners (SAPC).

- Prioritize the requirements then use a combination of document and requirement phasing: ELAP should have a well laid out plan for implementation with timelines attached to each of the identified requirements. A flow chart outlining the order of implementation along with deadlines and expected deliverables might be useful for labs to see the big picture. Begin with the easiest requirements to help a lab get

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started. It may also be beneficial to phase the TNI Program. For instance, Phase 1 could include commercial labs, Phase 2 could include larger agency labs and Phases 3 & 4 could include smaller agency labs. This phased implementation would provide an opportunity to address issues and develop educational materials to help the smaller labs.

Example: Implementation for Corrective Action:

Date 1- ELAP provides examples, templates, and a guidance document for the Policy and Procedure for Corrective Action

Date 2- ELAP provides training on the Policy and Procedure for Corrective Action

Date 3- ELAP provides a list of records that must be retained to prove that the Policy and Procedure for Corrective Action is followed.

Date 4- Laboratories write their Policy and Procedure for Corrective Action

Date 5- Laboratories implement their Policy and Procedure for Corrective Action and maintain corrective action records.

Date 6- ELAP begins assessing Corrective Action.

Laboratories have their regular work that must be conducted in addition to implementing the 2016 TNI standard. In order to help the lab community, ELAP should clearly outline the implementation schedule with a reasonable time period for compliance. At a minimum, ELAP should consider providing the lab community up to 5 years for full implementation. In addition, since many labs are not subscribed to the Lyris list serve, ELAP needs to develop a more inclusive way of communicating and educating laboratories on the new TNI standards and the implementation schedule.

2. What tools do you need to be successful?

Regional San recommends that the following information be available on ELAP's website for each TNI requirement as it is phased in:

- a. ELAP expectations for each 2016 TNI module. Define the minimum required for compliance.
- b. Timely training to meet the set expectations provided at no additional cost.
- c. Provide examples/templates of 2016 TNI compliant Quality Systems (preferably in Word format) for a 1 person lab, a 10 person lab, and a 50 person lab. This would include all quality system policies and procedures, as well as example management review reports, corrective action reports, data integrity investigation reports, internal audit reports, and test reports. Laboratories do not want to reinvent the wheel. A procedure and policy that works for a lab of similar size can be adapted to work for other labs. The TNI Standard is a not prescriptive standard. Unfortunately, this leaves laboratories confused about how to address each TNI requirement. Examples of each procedure, policy, and QMS requirement will steer labs in the right direction and ease some of the confusion.

- d. Provide a list of records that must be retained for each item listed in the table of contents for each module. Since a list of required records is not laboratory specific, it makes sense for the accrediting body to provide a list of records that must be retained and readily available during onsite inspections.
- e. Provide a 2016 TNI audit checklist similar to the 2003/2009 TNI checklists available from NELAP. This will allow labs to check if they are in compliance with TNI requirements.
- f. Create a place on ELAP's website for labs to post implementation questions. This would provide a forum for ELAP, ELTAC, or another lab to share their experiences and help answer the questions. ELAP could then review the questions and provide ELAP approved answers in an FAQ on ELAP's webpage.

3. We agree that ELAP should accept third-party assessments to reduce our backlog. How would you like to see this done?

Regional San strongly opposes the use of third party assessors to fulfill this basic function of laboratory certification. However, it appears ELAP has already decided to move forward with third party assessments. Based on this direction, we have the following suggestions.

ELAP should identify and contract with third party assessors (similar to NPDES inspection process by the Water Board) that ELAP has determined to meet certain criteria and who do not have a conflict of interest. In addition, ELAP will need to develop an assessment protocol/process to ensure audits are being conducted consistently based on the type of laboratory (e.g., commercial vs agency). There also needs to be a process established to respond to audit recommendations, as well as an appeal process. This will ensure that laboratories are audited at the prescribed frequency using qualified assessors. It also stabilizes the cost of third party assessment. California lacks a supply of qualified third party assessors. Additionally ELAP is creating new demand for assessment services. If laboratories arrange their own assessment services, they may have a hard time scheduling assessments due to lack of assessors and inflated pricing (supply vs demand). ELAP will have to track the frequency of assessment regardless of who hires the assessor. It makes more sense for ELAP to schedule assessors in a way that works with their resources for reviewing third party assessment reports. In addition, third party assessment creates a potential for conflict of interest if laboratories choose their own. Labs should not be allowed to shop around for auditors.

General Comments

- There must be an open and transparent stakeholder process

The Sacramento Regional County Sanitation District (Regional San) has tried to engage and provide meaningful comments on the California Environmental Laboratory Accreditation Program (ELAP). Unfortunately, there has been very little time provided for interested stakeholders to review and comment on released documents. An example is the most recent release of the Expert Panel Report which was only made available on the SWRCB's website on Monday April 3rd, with a listening session

scheduled 2 days later to provide comments. This short review time does not provide adequate time to have meaningful dialogue.

- There is a need to improve communication between ELAP, ELTAC and affected stakeholders
Regional San has encouraged a more robust dialogue with affected stakeholders. It was our impression from the last Water Board workshop that ELAP would be working with the affected stakeholders to develop a “lighter” more reasonable version of the TNI standards for agency laboratories, such as ours. In fact, ELAP, ELTAC, and SAPC spent considerable time and effort developing and voting on modifications to the proposed TNI standard. Unfortunately, it appears that those stakeholder recommendations may be ignored and not included in the final regulations. For instance, the latest announcement regarding the April 5th & 6th Listening Sessions implies that the Expert Panel Report recommendations are supported by ELAP. The announcement also gave only two business days for affected stakeholders to evaluate and comment on the Expert Panel Report. Many laboratories may not even be aware of the release of this Expert Panel Report if they are not subscribed to the Water Board Lyrus List Serve. This change in direction and short comment period is very disappointing.

We appreciate the opportunity to provide our comments and look forward to working through these issues in the coming months. If you have any questions, please feel free to contact us.

Sincerely,

Srivi Ramamoorthy

Regional San Laboratory Manager

916-875-9020

Amy Saylor

Regional San Laboratory QA Officer

916-875-9023