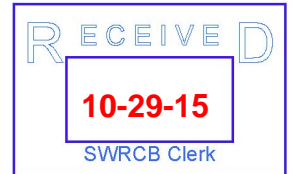


## **commentletters**

---



**From:** Cindy Ziernicki <Cindy.Ziernicki@HELIXWATER.org>  
**Sent:** Thursday, October 29, 2015 10:33 AM  
**To:** commentletters  
**Subject:** Attention to all SWRCB Members for consideration on Item 4 – Findings and Recommendations of the Expert Review Panel of the State of California – ELAP  
**Attachments:** ERP Letter\_Helix Water District (002).pdf

Dear SWRCB:

Please accept the attached re-submission of a comment letter date 8/28/2015 for consideration.

Also please note below comments for consideration:

It has been brought to my attention that in the new TNI documents, either the 2009 and/or 2012 (which is not yet finalized) there is a requirement that every lab have a director, a QA officer, who cannot be the same person and has to be different from the analyst. This would mean that every lab, even the smallest, has to have a minimum of three (3) employees. This could drive lots of utility labs out of business and could affect hundreds of small lab employees with regards to employment and pension.

If there are potential future standards which may be implemented by ELAP, such as the one cited above, which we are unable to view because they are behind a pay wall, I kindly request that they be made available to all potentially affected parties. I would like to be able to read the TNI guidance **as written** so I can understand the full impact of TNI, without waiting for a gap analysis or summary performed by ELAP which may take months and may not even fully address all concerns. As a small lab this could have MAJOR impacts on our operations.

Before any standards get adopted, please fully evaluate the impact they will have on labs of all sizes, paying particular attention to the fact that over 50% of the 800+ ELAP-certified laboratories have less than 5 employees and the majority of those labs are utilities that are not near any other laboratory. Please include the laboratory community so that we may have an intelligent conversation about this prior to implementing such a radical change.

In summary:

- **Is there a TNI requirement that every lab have a director, a QA officer, who cannot be the same person and has to be different from the analyst?**
  - **If so, what are the requirements for the director and the QA officer? Is a college degree required?**
- **Make TNI and/or ISO 17025 and ISO 17011 standards available to stakeholders.**

Please **do not rush** this decision-making process. It is critically important that all recommendations and changes to current ELAP procedures be a fully reviewed by stakeholders. Thank you for your consideration.

Regards,

Cindy Ziernicki  
Helix Water District  
Stakeholder Advisory Committee (SAC) member



## Helix Water District Water Quality Laboratory

Setting standards of excellence in public service

9550 Lake Jennings Park Road  
Lakeside, CA 92040-3513

(619) 443-1031  
FAX (619) 443-0134  
www.hwd.com

Cindy Ziernicki  
Helix Water District  
9550 Lake Jennings Park Road  
Lakeside, CA 92040

August 28, 2015

Dear Expert Review Panel (ERP) for ELAP:

My name is Cindy Ziernicki, I am the Senior Chemist for the Helix Water District. Helix Water District has a laboratory accredited for compliance analysis under the Safe Drinking Water Act by the Environmental Laboratory Accreditation Program (ELAP). I served as a member of the Environmental Laboratory Technical Advisory Committee (ELTAC) and then was nominated to be a member of the Stakeholders Advisory Committee (SAC). The SAC was tasked with coming up with a set of questions for the Expert Review Panel (ERP) to respond to in order to help ELAP become a functioning program in the Division of Drinking Water. The final eight (8) charge questions that were agreed upon for the ERP to address and answer are attached. As part of this collaborative process, I attended the two face-to-face hearings in March and August 2015 and one teleconference/webinar in June on Quality Systems.

I would like to thank the Expert Review Panel for their tireless efforts to date. The panel was not tasked with an easy job; in fact, it is a very complicated process. First and most important in my opinion, is to understand the underlying issues of what happened to ELAP to cause dysfunction. And then with that knowledge, address the charge questions in a manner that can be implemented with the limitations of staff, time and budget. In the past, the ELAP organization was dysfunctional due to lack of leadership, personnel have been poorly trained in the use of standards and requirements for accreditation, and ELAP's former managers did not hold the staff accountable when they failed to apply standards correctly or uniformly. ELAP management did not keep their regulations up to date so it was difficult even for those staff who wanted to do a good job to hold laboratories to a standard. On site assessments and simple office tasks were mismanaged and auditors were not skilled. While there are plenty of other examples of how the core problems expressed themselves, it all came down to management and training.

I am concerned about the direction of the ERP especially after the August 2015 session. Mainly, it appears that most of the discussion has revolved about how The NELAC Institute (TNI) standards can be implemented, either partially or fully into the current California laboratory accreditation process. Of the eight charge questions, there is one sub-question (3a) that states "Should CA rejoin NELAP?" This question **doesn't** ask "Should ELAP require labs to become NELAP compliant?" I am certainly not alone in this concern. My laboratory is small, with two principal analysts. Small laboratories make up over 80 percent of all ELAP-certified labs in the state of California. What we want, and why my employer feels it is important for me to participate in this process for change, is a functioning ELAP. We want the program that is in place to become more efficient, transparent and with a uniform standard of



procedures amongst auditors. We do not want the laboratories to be burdened with more paperwork, unnecessary additional PTs and a cumbersome internal audit program. Being part of the SAC that created the eight charge questions, it is clear that converting ELAP to NELAP will not solve the original issues.

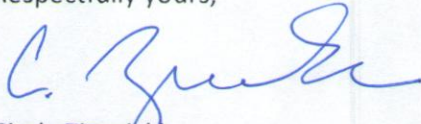
The problem with the recommendations to date of the ERP is that they do not address the lack of staff or other internal issues within ELAP. For instance, disbanding ELTAC was a first priority for ELAP based on ERP recommendation. ELTAC was inefficient not due to lack of concern, ideas or commitment from the laboratory community or committee members, but due to the fact that all of ELTAC's recommendations, designed checklist as a tool for ELAP and even draft regulations were ignored by ELAP. Disbanding ELTAC was premature as evident of current checklists being revised by ELAP staff with no clear peer and technical review plans in the process. ELTAC members are technical experts and have more hands-on laboratory experience than ELAP staff. Now the entire make-up of new ELTAC has been modified according to the new draft ELTAC by-laws and the proposed seat assignments are mainly from regulatory bodies and not the lab community. I am uncertain how changing the make-up of the committee will change how ELAP responds to the suggestions from ELTAC. It is understood that the new language in the proposed bylaws will impose more structure on ELAP to respond to ELTACs recommendations but this could have occurred with the current make-up of ELTAC as well as long as ELAP commitment is there to collaborate and respond.

ELAP was TNI compliant for a long time and it did not solve any of ELAPs problems. The same is true for Third Party Assessors--whatever the merits or demerits of this idea, it does not provide either leadership or training to ELAP personnel. The presentations from the August meeting were lacking in specificity to ELAP, generic, and none detailed to how to solve the specific problems of ELAP.

ELAP clearly needs more auditors, training and tools to conduct uniform audits across the board. I appreciate the ERP recognizing the lack of staff available to perform audits. As a tool and another audit type option, the idea of a 'virtual' on-site assessment in certain situations could help tremendously with the amount of time an auditor spends at each facility by freeing up auditor time and requiring no travel time; this concept deserves consideration.

May I kindly suggest that the ERP take a look at the charge questions again and begin addressing them before the first 'findings' draft is submitted. The eight charge questions are the basic reasons why the ERP was needed and formed.

Respectfully yours,



Cindy Ziernicki  
SAC member  
Helix Water District  
Senior Chemist  
9550 Lake Jennings Park Road  
Lakeside, CA 92040  
cindy.ziernicki@helixwater.org

(See next page for the Eight Charge Questions for the ERP )

### Charge questions for the ELAP Program Review

- 1) What should the State's role be in the accreditation process?
  - a. Are the philosophies, objectives and scope of ELAP clearly defined?
  - b. Are they appropriate?
  - c. Does ELAP have the capacity to support the program?
  
- 2) How can California's accreditation standards be improved?
  
- 3) What should California's approach be to recognizing accreditation by other states, national entities or private accreditation services?
  - a. Should CA rejoin NELAP?
  
- 4) How can ELAP's laboratory inspection program be made more robust?
  - a. What are the appropriate qualifications for auditor/inspector team members in each of the specialty areas that ELAP certifies laboratories?
  
- 5) How can California improve its proficiency testing program for quantifying laboratory quality?
  
- 6) How can California improve its process for responding to concerns expressed by: a) laboratories that have concerns about the certification process, or b) clients who have concerns about the quality of a laboratory that has been certified by ELAP?
  
- 7) How should ELAP plan for future programmatic, testing and management needs?
  
- 8) Which program improvements are most urgent and can be accomplished within existing resources and authorities?
  - a. Which are the highest priority longer-term program improvements?