February 8, 2019

Environmental Laboratory Accreditation Program (ELAP)
Preliminary Draft Regulations Comments
P.O. Box 100, Sacramento, CA 95814

VIA EMAIL: elapca_comments@waterboards.ca.gov

Subject: ELAP Preliminary Draft Regulations Comments

The Bay Area Clean Water Agencies (BACWA) appreciates the opportunity to comment on the proposed ELAP Preliminary Draft Regulations (proposed Regulations). BACWA is a joint powers agency whose members own and operate publicly-owned treatment works (POTWs) and sanitary sewer systems that collectively provide sanitary services to over 7.1 million people in the nine-county San Francisco Bay Area. BACWA members are public agencies, governed by elected officials and managed by professionals who protect the environment and public health. BACWA supports a Laboratory Committee with participants who will be responsible for implementing the proposed Regulations, once adopted. BACWA also supports comments submitted by the California Association of Sanitation Agencies, and the Central Valley Clean Water Association.

BACWA continues to support dual track accreditation proposed by Summit Partners, as described most recently in the letter submitted to State Water Board Chair Marcus on January 29, 2019. The comments herein include recommendations on modifications to the proposed Regulations regardless of whether ELAP chooses to implement a TNI-based standard as part of a single, or a dual track accreditation system.

There are areas in the proposed Regulation that would benefit from additional clarity. While we understand there is a limit to the level of detail that can be included in the body of the regulations, supporting fact sheets could fill the gap. We recommend that ELAP work with Environmental Laboratory Technical Advisory Committee (ELTAC) to prepare the fact sheets before the proposed Regulations are finalized.

Our specific comments are listed below.

1. **Definitions, §64801 (v)**

Under definitions, the draft regulation states: "TNI" means The National Environmental Laboratory Accreditation Conference Institute. The TNI-2016 standard, in their definition, states the following:

TNI: The NELAC Institute

In the context of TNI, the word NELAC is not an acronym; it is a contrived word. The acronym NELAC is copyrighted, and therefore TNI-2016 clarifies that "NELAC" is not used as an acronym in this case. We suggest ELAP revise its definition to match the TNI-2016 standard.

2. **Quality Systems, §64802.10 (a)**

The paragraph on Quality Systems references the 2016 TNI standard specifically, which is based on the ISO 17025-2005 standard. After the development of the 2016 TNI standard, ISO published an updated version in 2017, and TNI is working to adopt that standard. The 2017 ISO standard emphasizes risk-based action, rather than listing prescriptive directions. We recommend that ELAP incorporate flexibility into the regulations to allow for implementing updated versions of TNI standards in the future, after outreach to stakeholders, and a public comment process. This would allow for appropriate updates as laboratory standards evolve.

3. **Fields of Accreditation, § 64802.15(b)**

The Field of Accreditation section references drinking water analyses listed in 40 CFR (Code of Federal Regulations) parts 141.21 through 141.42, 141.66, and 141.89. We recommend including 40 CFR part 136 to also address wastewater methods.

4. **Fields of Accreditation, §64802.15 (c)**

ELAP proposes publishing Fields of Accreditation (FOAs) on ELAP's website, but does not include them in the body of the regulations. While we understand the flexibility this provides in updating FOAs, this raises several issues that will need to be addressed:

- How ELAP will notify laboratories that changes have been made.
- How much time will ELAP allow laboratories to adopt these new/updated methods.
- If the update drops an existing method and adopts a newer version of the same method, (for example, dropping EPA 608 and adopting EPA 608.3), whether laboratories are expected to submit Initial Demonstration of Capabilities (IDOC) to be certified in the newer version.
- Whether the above would be considered a new application or application amendment, or whether a laboratory would work under the certificate issued for the previous version.
- How ELAP will coordinate with its regulatory partners so that utilities are complying with permit requirements where previous version of the method is referenced.

BACWA recommends that these, and other questions, be addressed through supplemental fact sheets.

5. **On-Site Assessment, § 64802.25 (c)**

The On-Site Assessment section states that "The laboratory is responsible for scheduling an on-site assessment through ELAP or a third-party Assessment Agency". BACWA recommends that ELAP schedule the laboratory on-site assessment using either ELAP staff or a third party

assessor. A fact sheet clarifying what is meant by 'assessment agency' and what are the qualifications for an acceptable assessor needs to be explained. ELAP also must verify that there is an adequate pool of qualified assessors before the regulations are passed.

Hiring assessors does not represent a known, fixed cost to agencies; as the demand for assessors goes up, the cost of service will increase. BACWA requests that ELAP consider how to control costs to make required audits fair for all laboratories. Laboratories who must hire assessors should not pay more than those audited by ELAP staff. Also, laboratories should not be penalized because there are insufficient qualified assessors available, both within and outside of ELAP.

We appreciate your consideration of our comments.

Respectfully Submitted,

David R. Williams

David R. Williams
Executive Director

cc: BACWA Executive Board
Nirmela Arsem, BACWA Laboratory Committee Chair

Coalition of Accredited Laboratories

VIA EMAIL

February 8, 2019

Mr. Darrin Polhemus, Deputy Director
California State Water Resources Control Board
Division of Drinking Water

Via Email to: Darrin.polhemums@waterboards.ca.gov

RE: 3rd Draft of ELAP's Proposed Regulations

Dear Mr. Polhemus:

The Coalition of Accredited Laboratories (CAL) is an organization representing the community of laboratories accredited in the State of California for compliance testing as required by California environmental regulatory agencies. CAL is dedicated to safeguarding public health and the environment; bridging the gap between regulatory agencies and accredited laboratories; and providing education, training, and outreach to the community of accredited laboratories. CAL represents both large and small laboratories, those that are publicly owned as well as investor owned, and laboratories in all parts of the state.

ELTAC held a scheduled meeting on December 13, 2018. At this meeting, Amber Baylor, William Ray and Steven Jepsen gave a presentation on their TNI-lite rewrite of the ELAP regulations that would be ostensibly more cost-effective to ELAP-certified laboratories, compared to ELAP's 3rd Draft Proposed Regulations (DPR). ELTAC voted to form a sub-committee, which is subject to the Bagley-Keene Open Meeting Act, to develop a recommendation to ELAP regarding the proposal.

During this meeting, the DELAPO Christine Sotelo, stated that ELAP is 'not married' to TNI and is open to an acceptable alternative that has all the critical elements for a quality management system. ELAP would require an ELTAC consensus to present the alternative proposal to the State Water Resources Control Board. Ms. Sotelo stated that the proposal would have to be vetted by ELTAC and approved by the Board prior to the start of the rule-making process. Since then, the sub-committee has met and is working diligently to develop their recommendation to the proposal.

However, on December 18, 2018, the third draft regulations were released and the (extended) deadline to submit public comments from the public is February 8, 2019. It is concerning that ELAP went ahead and released the draft regulations without the input of the ELTAC sub-committee, which was voted upon just five days prior. Moreover, the third DPR does not include any of the recommendations from

the ELTAC sub-committee that was formed specifically to develop an alternative proposal to the draft regulations.

Mr. Polhemus, we sincerely request that you allow the time needed for the ELTAC sub-committee to submit their recommendations that they were requested to prepare. The DPR is simply not workable. With the ELTAC sub-committee working together, as directed by Ms. Sotelo and ELTAC, a truly workable and agreeable set of draft regulations can be brought forward, if given the time to do so. Ms. Sotelo has mentioned many times that the success of this effort relies heavily on stakeholder buy-in and support. The next ELTAC meeting is April 17, 2019. That would be an excellent opportunity for the sub-committee to present their work to the Division of Drinking Water and the broader laboratory community.

We thank you for your careful attention to the issues raised in this letter.

Respectfully submitted,

David Eugene Kimbrough, Ph.D. President, CAL

CALIFORNIA ASSOCIATION of SANITATION AGENCIES

1225 8th Street, Suite 595• Sacramento, CA 95814 • TEL: (916) 446-0388 • www.CASAweb.org

February 8, 2018

Sent via electronic mail to *elapca_comments@waterboards.ca.gov*

Environmental Laboratory Accreditation Program (ELAP)
Preliminary Draft Regulations Comments
P.O. Box 100
Sacramento, CA 95814

Subject: ELAP Preliminary Draft Regulations

Dear Ms. Sotelo:

The California Association of Sanitation Agencies (CASA) appreciates the opportunity to comment on the third preliminary draft Environmental Laboratory Accreditation Program (ELAP) regulations (Draft Regulations) prior to the initiation of the formal rulemaking process. CASA is an association dedicated to protecting public health and the environment through effective wastewater treatment. We promote sustainable practices including water recycling, biosolids management, and renewable energy production. We represent over 120 public agencies in California and focus on advocacy, education, and leadership.

Consistent with the letter dated January 29, 2019 from the Clean Water Summit Partners, we reiterate our request that the State Water Board pause the process for adoption of the current third draft regulations until April 15, 2019. This will provide enough time for the California Quality Management System (QMS) workgroup to review the CA QMS proposal, provide a recommendation to ELTAC, and for ELTAC to provide a recommendation of whether to support a parallel system at their late March or early April 2019 meeting. We also urge ELAP staff to continue working with stakeholders while the regulations are refined. We all share the same goal of an ELAP program and implementing regulations that makes the best use of scarce public resources to improve lab performance and protect public health and the environment.

The comments below include a short set of general comments pertaining to the economic impacts of the Draft Regulations as well as more specific comments and concerns relating to provisions in the Draft Regulations.

Compounding Economic Impacts and ELAP Fees

During the ELAP workshops in January, staff reported that the ELAP program intends for every lab in the state to be assessed. However, because the program does not have the financial resources to pay for the assessments, the proposal will require the ELAP fee structure to become the funding source for the assessments. CASA understands that in the past, the overall ELAP program has been relatively underfunded, and our members were willing to accept the marked fee increases that have been implemented in recent years. However, this new proposal to drastically increase fees for assessments on top of the general ELAP program fee increases is deeply concerning and controversial. This is particularly true as the regulations are being proposed in conjunction with a dramatic expansion in circumstances where a lab may be issued a citation accompanied by a monetary penalty.

Thus, as part of the ELAP revamp, labs will be hit with increased base fees, new fees charged specifically for assessments, and new penalty provisions which could result in substantial monetary costs for a plethora of even minor issues. Yet as far as we can tell, these sharp increases will not result in improved lab data quality, reliability of results, or positive environmental outcomes.

The concern with the increased program fees coincides with another concern related to the estimation of the overall economic cost and impact of the program under the Draft Regulations. While this issue will be discussed more fully by others, in brief, the Draft Regulations will result in environmental labs having to hire additional staff and incur burdensome administrative costs (in addition to the new fees). It is reasonable and probable that the rulemaking constitutes a "major regulation" under Senate Bill 617 due to the expected economic impact of the Draft Regulations exceeding the $50 million threshold. The major regulation status mandates heightened requirements for analysis and adoption, though it is not clear those requirements are currently being met. We emphasize the importance of ELAP including the full gamut of these costs in its economic and fiscal impact statement, and for the State Water Board members to consider whether this bevy of new fees, costs, and changes is the most efficient and effective way to improve lab oversight in California.

Specific Comments

In addition to the above economic concerns, we have the following detailed remarks on specific provisions of the Draft Regulations:

Article 1

Under the definition of "Sophisticated Technology" in § 64801.00(g), we recommend either moving this provision to a different section of the regulations or revising it. Specifically, if the purpose of this subsection is to establish the basis for accreditation fees, then this definition should be included in the rules and policies of the fee structure and not in the regulations themselves. Moreover, as written, there is inconsistency in the types of technology that are included in this subsection. For example, it appears that ion chromatography has been removed; however, atomic absorption spectrophotometry is included. These technologies are similar in terms of complexity. In the alternative, if this Section were to be removed, then Section (h) under § 64812.00 in Article 5 should be removed as well.

Article 2

Under § 64802.05(a)(5), an "approved corrective action report" is required as part of the application package for accreditation. However, clarification is needed on the approval authority for corrective actions. That is, if a third-party assessor (TPA) performed the assessment, would ELAP be the "approval" authority, or should the TPA be the "approval" authority for the on-site assessments conducted by them?

Similar to our prior comments on the initial draft regulations, regarding "Quality Systems" under § 64802.10, requiring laboratories to update the Quality Manual every time there are changes made to Standard Operating Procedures (SOPs) and laboratory equipment or instrumentation will generate a significant amount of of busy work for large and complex laboratories because such activities can happen on a weekly basis. Similarly, the requirement under § 64802.10 (b)(2), subparagraph (A) differs from and is not a requirement under the 2016 TNI Standard. Thus, CASA recommends that

subparagraphs (A) and (B) be removed from the list, as changes to SOPs and changes to laboratory equipment or instrumentation are common occurrences.

Additionally, regarding the notification requirement under § 64802.20(k)(2), CASA recommends that this requirement be removed because typically a laboratory must notify its clients whenever the status of its accreditation changes. This is different than the circumstances described here, where a laboratory would be in the process of performing corrective action for a proficiency testing failure. This corrective action is allowed by the regulations and does not have bearing on the status of its accreditation. Thus, notifying clients at this stage would be premature and could trigger over-reactions by clients.

Further clarity is needed in § 64802.20 (l) (1 – 3) regarding bioassay analyses. Specifically, subsections (2) and (3) are new items regarding proficiency testing. While laboratories have been submitting data related to (2) and (3) for onsite ELAP audits, it is generally not submitted together with the annual proficiency testing results. Thus, more clarification is needed on whether all of these need to be submitted annually as part of the annual proficiency testing submissions.

Finally, with regard to on-site assessments under § 64802.25, laboratories currently do not schedule on-site assessments with ELAP, ELAP schedules assessments with individual labs. ELAP has traditionally been the entity responsible for contacting laboratories to schedule assessments based on their schedule. While under some circumstance a lab-initiated assessment program can work, under the existing draft regulations such a program would not be advisable or implementable as it reduces ELAP's oversight ability. In addition, for labs utilizing third party assessment agencies, without a list of "approved" TPA Agencies or an established process to screen those TPA Agencies, it is not clear how labs will know who to contact and engage. Furthermore, subsection (c) places the responsibility of scheduling on-site assessments on laboratories, yet under subsection (i), ELAP is allowed to change/delay the schedule due to ELAP error or procedure. Additional clarification is also needed for when the delay is caused by the TPA Agency. Finally, subsection (j) states that when additional time is needed by ELAP to complete an on-site assessment, the laboratory shall be issued an interim certification. However, this subsection does not address situations when additional time is needed by the third-party Assessment Agency to complete an on-site assessment. All of these issues need to be addressed in the draft regulations.

<u>Article 3</u>

For renewal accreditation under § 64808.05, subsections (d), (e), and (f) should be condensed and consolidated into one as they are all related. In addition, for reciprocity accreditation under § 64808.05 (f), CASA recommends adding a requirement for the laboratory to notify its client of the change in status of its accreditation.

For amendment accreditation under § 64808.15 (c), currently laboratories are allowed to submit amendments during the renewal application process, which occurs every two years. Most labs prefer the current approach because the processing time is typically shortened, and labs can save money by not having to pay additional processing fees. With this change in the Draft Regulations, labs will have to pay processing fees twice: once for the biannual renewal application and another application fee for the amendment application. This is unnecessary and adds to the already high costs of the draft regulations described above.

Additionally, for amendment accreditation under § 64808.15 (e)(4)(A), CASA strongly recommends that ELAP provides a grace period during which the laboratory can report data at the new and old location for methods listed in the lab's current accreditation. The requirement above restricts the lab to choose from two possible scenarios: (1) if the lab wants to generate data during the move, it has to purchase a new set of equipment for the new location while maintaining its current operation at the old location, a costly proposition for all laboratories due to the high cost of instrumentation; or (2) the lab has to shut down, move all of its equipment to the new location, then wait for ELAP's approval prior to generating data which means either lost revenue for commercial labs or additional costs for public utilities who have to pay for an outside laboratory to analyze the compliance samples. Both options are extremely costly for any laboratory that wants to re-locate, and a grace period would help mitigate these costs.

Clarification is also needed under § 64808.15 (f)(3), related to whether the on-site assessment must be conducted at the satellite laboratory or at the main laboratory, or at both. Similarly, for satellite laboratories under § 64810.05, clarification is needed as the regulations are unclear whether these satellite laboratories need to submit proficiency testing results in addition to the results submitted by the Main laboratory for the same method, and whether on-site assessments need to be conducted for the Main laboratory or for the satellite laboratory, or both. These were issues raised in our initial comments that have still not been resolved by the revised draft regulations.

Article 5

For laboratory personnel under § 64812.00 (h) the requirements related to the principle analyst are confusing and needing clarification. If the goal is to establish a set of minimum qualifications for lab analysts, it is not clear why these requirements only apply to analysts operating sophisticated laboratory instruments and not all lab analysts. Moreover, section (i) allows the labs to by-pass these requirements altogether by allowing the Technical Manager to designate anyone in the laboratory to operate these sophisticated instruments. Additional language should be added to this section to ensure the intent and goals for these provisions are clear.

Article 7

Regarding the issuance of citations under § 64816.05, this section is new to the draft regulations and needs further development and clarification. This section will provide ELAP with the authority to issue citations (tied to monetary fines) to laboratories for not complying with ELAP statues and regulations. The economic consequences of this were discussed above, but this is also a dramatic departure and sweeping new authority being granted to the ELAP program at a such a late stage in the regulation development process. The current process of identifying issues at a lab and issuing a citation and assessment that allows for the lab to take corrective action makes sense. Adding monetary penalties onto that structure for a broad array of sometimes minor violations does not seem to benefit public health or the environment. The necessity for and planned application of these provisions needs to be more tightly defined so the opportunity to assess monetary penalties is not open-ended, and to ensure that the regulations are not open to multiple interpretations and are being enforced consistently.

Additionally, the identified reasons for issuing a citation in subsections (1) through (6) and (9) through (12) could have significant impact on data quality (particularly subsection (10)). To that point, to the extent that the regulations would allow the continued generation of data by a lab that merits a citation in these areas but simply pays a fine, CASA does not support such an approach. A laboratory must meet a certain quality standard specified by ELAP or a lab should not be accredited. Citation authority that

incudes monetary penalties is an appropriate approach or meet the fundamental purpose of improving lab data quality.

Conclusion

We appreciate the opportunity to comment on the Draft Regulations and look forward to discussing these issues with you in the coming months. If you have any questions or concerns, please do not hesitate to reach out to me directly at (916) 446-0388 or alink@casaweb.org.

Thank you,

Adam D. Link
Director of Operations

SCAP
SOUTHERN CALIFORNIA ALLIANCE OF PUBLICLY OWNED TREATMENT WORKS

REUSE
BRINGING WATER FULL CIRCLE
WASTE
TREATMENT

February 8, 2019

Sent via email to: elapca_comments@waterboards.ca.gov

Environmental Laboratory Accreditation Program (ELAP)
Preliminary Draft Regulations Comments
P.O. Box 100
Sacramento, CA 95814

Re: ELAP Preliminary Draft Regulations Comments

Dear Ms. Sotelo and the Environmental Laboratory Accreditation Program team:

The Southern California Alliance of Publicly Owned Treatment Works (SCAP) appreciates the opportunity to comment on the California Environmental Laboratory Accreditation Program's (ELAP) Third Preliminary Draft Regulations for Accreditation of Environmental Laboratories (Preliminary Draft Regulations).

SCAP represents 83 public water/wastewater agencies in southern California. SCAP members provide essential water supply and wastewater treatment for approximately 20 million people in Los Angeles, Orange, San Diego, Santa Barbara, Riverside, San Bernardino and Ventura counties. SCAP's wastewater members provide environmentally sound, cost-effective management of more than two billion gallons of wastewater each day and, in the process of protecting public health and the environment, convert wastewater into resources for beneficial uses such as recycled water and renewable energy.

We are appreciative of the extended comment deadline for the Preliminary Draft Regulations. The additional time provided SCAP, its partner agencies and the laboratory community the opportunity to better understand the Preliminary Draft Regulations and prepare comments that support a California water/wastewater utility focused approach to practical laboratory accreditation that will continue to protect public health and the environment.

California Quality Management System (CA QMS)

In an effort to be collaborative with the ELAP team and offer a practical accreditation program that will meet ELAP's goals, a small coalition (including SCAP) developed a California Quality Management System (CA QMS). The CA QMS is an administratively efficient system modeled

under elements of the TNI system with a focus on data quality. The coalition that developed this system included laboratory professionals with many decades of real world laboratory experience.

On December 13, 2018, Environmental Laboratory Technical Advisory Committee (ELTAC) convened a special meeting to consider the CA QMS as a viable accreditation system. SCAP membership and a prominent California laboratory consultant presented to the committee the draft CA QMS framework to fit within the Title 22 statute. ELTAC voted 9-4-1 (for-against-abstention) to support the review of the proposed CA QMS system for use in California as an alternative to the Proposed Draft Regulations TNI only standard. The TNI only system is administratively burdensome and would require additional staff without an increase in data quality.

Timing of Third Draft Regulation Release

The Clean Water Summit Partners which include the Bay Area Clean Water Association (BACWA), California Association of Sanitation Agencies (CASA), Central Valley Clean Water Association (CVCWA), California Water Environment Association (CWEA), and the Southern California Alliance of POTWs (SCAP) emailed a letter dated January 29, 2019 to the State Water Resources Control Board. The letter included information of the development of the CA QMS, information on the formation of a CA QMS subcommittee of ELTAC and a technical session schedule to update management level staff of the key elements the CA QMS. The letter requested that ELAP postpone the release of the third draft regulations to the Office of Administrative Law until April 15, 2019 to allow for review of the CA QMS by the ELTAC-CA QMS subcommittee, submittal of the CA QMS with recommendations to ELTAC, and for ELTAC recommendations on the inclusion of the CA QMS into the third draft regulations. We have recently learned that the next ELTAC meeting has been moved from late March to April 17, 2019. As such, SCAP requests a pause of the release of the Proposed Draft Regulations to the State Water Board and OAL until ELTAC can vote on inclusion of the proposed CA QMS.

The 2016 TNI Standard is not appropriate for Public Agencies

The TNI Standards are intended to provide a uniform quality management and documentation system for laboratories to easily conduct interstate business under a single national accreditation system. Interstate commerce is not a focus of California water/wastewater labs. There are elements in the 2016 TNI Standard that will conflict with state and county laws and codes as well as existing county, city or special district ordinances and resolutions. Some examples include Module 2 requirements related to purchasing, contracting, collective

bargaining, and hiring/firing of employees. SCAP incorporates by reference the comments from CVCWA on this issue.

Higher Costs without Corresponding Benefits

ELAP has indicated the Proposed Draft Regulation will require an increase in accreditation fees. Early adopters of the TNI standards have indicated that implementation and management of TNI requires labor efforts equivalent to 0.5 to 1.5 full time employees. Additionally, the Proposed Draft Regulations include provisions for citations with monetary penalties. When these costs are considered for over 600 accredited labs in California, the regulatory cost impacts will easily exceed $50 million, putting this into a 'major regulation' category under Senate Bill 617. Since laboratory experts, including TNI practitioners, agree that the TNI system focuses on enhanced laboratory practice documentation and does not improve laboratory test result quality the cost benefit analysis will definitely reflect a large increase in cost, but the benefit to public health and the environment will be challenging to justify. SCAP incorporates by reference the comments from CASA and CVCWA on this issue.

Furthermore, the costs and complexity associated with implementing the Proposed Draft Regulations would create substantial burdens for small non-profit municipal laboratories forcing them to close or forfeit their accreditation. Labs without accreditation will have a more difficult time retaining or acquiring qualified staff and justifying laboratory equipment upgrades or replacements, resulting in less water quality testing and longer hold/result times. This would adversely affect water/wastewater treatment plant optimization and pre-treatment/source control investigation/enforcement operations. This is especially true for laboratories serving disadvantaged communities in remote and rural areas of California and in direct conflict with the State Water Resources Control Board's Right to Water initiative. SCAP echoes the comments from ACWA and CMUA on this issue.

California Legislature Supports a Parallel Accreditation System

The California State Legislature supports a parallel-track accreditation system as a statewide policy for the accreditation of environmental laboratories in California. Assembly Bill 1317 added Health and Safety Code section 100829 to provide that the laboratory accrediting agency could offer both state accreditation and NELAP accreditation. The California Legislature passed and Governor Brown enacted Assembly Bill 1438. The law amended the Health and Safety Code section 100829 to provide that "the State Water Resources Control Board may… offer both state accreditation and TNI [The NELAC Institute] accreditation [and] adopt regulations to establish the accreditation procedures for both types of accreditation." (Health & Safety Code,

section 100829, subdivision (a), (b).) The inclusion of both a national and a state accreditation standard in the statute shows that the State Legislature intended ELAP to adopt a parallel-track system for California. SCAP incorporates by reference the comments from ACWA and CMUA on this issue.

Legality of Incorporation of the 2016 TNI Standard by Reference

The Preliminary Draft Regulations incorporate by reference the 2016 TNI Standard. SCAP and fellow industry partners have raised concerns that the standard has not been available to the public to review for free. While ELAP has worked with TNI to make a temporary exception to the cost for viewing the standards, this is ultimately insufficient to comply with California law governing incorporation by reference. The California Administrative Procedure Act (APA) requires that the contents of regulations, and evidence supporting them, be made available for public review and rebuttal, and that these materials ultimately be weighed and considered by the agency adopting the regulations. (Government Code, Sections 11346.2, 11346.8-11346.9.) Public disclosure and participation is a crucial ingredient to the promulgation and adoption of regulations in California. This requirement is not met when agency incorporates by reference a document that has not been made available for public discussion and review. SCAP incorporates by reference the comments from CVCWA on this issue.

Conclusion

In 2014 ELAP moved from the Department of Public Health to the State Water Resources Control Board. The State Water Resources Control Board, ELTAC and laboratories working under the ELAP accreditation program were concerned with the performance of ELAP. The State Water Resources Control Board contracted with the Southern California Coastal Water Research Program to form an Expert Review Panel (ERP) to conduct an evaluation of ELAP. The ERP indicated there were opportunities for improvement within ELAP and that the current regulations were out of date and should be updated. There was no indication of an issue with water/wastewater laboratory quality. Somehow during the ELAP regulation updates, there became a perception that the California laboratories needed to improve lab quality and the TNI standard accomplish this. We strongly disagree with the presumption that there is an issue with California water/wastewater labs and also disagree with the theory that the TNI standard would improve California laboratory water testing quality.

We agree that there is room for improvement within ELAP and that the ELAP regulations and accreditation program should be updated. We also commend the effort put forth by the ELAP team to date. As indicated several time previously, SCAP, its partner agencies and the

laboratory community stand ready to work with ELAP to craft workable regulations that will allow for California water/wastewater labs to continue providing high quality laboratory services to protect public health and the environment. We have clearly demonstrated this commitment by taking the initiative to draft the CA QMS. Our willingness to work together and compromise with the ELAP team is demonstrated by the fact that the CA QMS is partially based on selected practical TNI elements. We look forward to further collaboration with the ELAP team.

SCAP would like to thank you for the opportunity to comment on the third draft regulations and we wish to emphasize our request that that ELAP not move forward with the current draft regulations until the work can be completed with ELTAC related the CA QMS.

SCAP is always interested in opportunities for further discussion or clarification. If there are any questions please do not hesitate to call or email at 760.479.4112 or sjepsen@scap1.org.

Sincerely,

Steve Jepsen

Executive Director, SCAP

Central Valley Clean Water Association
Representing Over Fifty Wastewater Agencies

TERRIE MITCHELL – Chair, Sacramento Regional CSD **CASEY WICHERT – Vice-Chair, City of Brentwood**
JOSIE TELLERS – Secretary, City of Davis **KEN GLOTZBACH – Treasurer, City of Roseville**

February 8, 2019

Via Electronic Mail

Christine Sotelo
Chair – Environmental Laboratory Accreditation Program
State Water Resources Control Board
1001 I Street
Sacramento, CA 95814
Christine.Sotelo@waterboards.ca.gov
elapca_comments@waterboards.ca.gov

Re: ELAP Preliminary Draft Regulations Comments

Dear Ms. Sotelo and the Environmental Laboratory Accreditation Program:

The Central Valley Clean Water Association (CVCWA) appreciates the opportunity to comment on the California Environmental Laboratory Accreditation Program's (ELAP) Third Preliminary Draft Regulations for Accreditation of Environmental Laboratories (Preliminary Draft 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.

CVCWA appreciates that ELAP extended the comment deadline on the Preliminary Draft Regulations. The extension allowed us to provide much more detailed and constructive comments on the Preliminary Draft Regulations. Specifically, the additional time has allowed CVCWA and other members of the laboratory community to better conceptualize a parallel, California-centric approach to laboratory accreditation.

CVCWA and its members have actively participated in ELAP's development of the Preliminary Draft Regulations to date. As we have noted previously, many of our members operate their own environmental laboratories to provide compliance monitoring and ensure proper operation of their agency's wastewater treatment plants in a manner that is protective

of public health and the environment. Others rely on small local laboratories to perform basic chemistry testing. In this letter, we provide our comments on the Preliminary Draft Regulations and their potential impacts on publicly-owned treatment works (POTWs) in the Central Valley. Our comments focus on concerns related to the single standard based on an incorporated third-party standard; a lack of transparency and stability regarding the role of the State Agency partners and fields of accreditation; and enforcement. Additionally, we reiterate comments that we have made on previous versions of the Preliminary Draft Regulations that have not been adequately addressed. Attachment A includes a table of text-based suggestions to improve the Preliminary Draft Regulations.

In addition to the comments made below, and in the table in Attachment A, CVCWA supports comments on the Preliminary Draft Regulations submitted by the Association of California Water Agencies (ACWA) and California Municipal Utilities Association (CMUA), the California Association of Sanitation Agencies (CASA), the City of Vacaville, and Sacramento Regional County Sanitation District.

A. ELAP Should Consider a Parallel-Track State Laboratory Accreditation System

As CVCWA has commented in the past, ELAP should consider implementing a parallel state laboratory accreditation system alongside the 2016 The NELAC Institute (TNI) standard (2016 TNI Standard). Such an approach is within ELAP's authority to pursue, based on Health & Safety Code section 100829(a), and has the potential to resolve many of the areas of concern with a regulatory system based solely on the 2016 TNI Standard that has been raised in this comment letter and many others.

The Summit Partners' letter submitted to ELAP on January 29, 2019, and discussed at the December 13, 2018 Environmental Laboratory Technical Advisory Committee (ELTAC) meeting, refers to the newly-formed ELTAC Subcommittee on Developing Laboratory Standards for ELAP Regulations. This ELTAC subcommittee is tasked with evaluating and proposing a California-centric quality management system to use in lieu of, or in addition to, the 2016 TNI Standard in the proposed regulations. While the subcommittee is still developing its proposal, and will provide it to ELTAC at its next meeting, scheduled for April, CVCWA supports the subcommittee's effort. CVCWA urges ELAP to fully consider the subcommittee's proposal before ELAP produces a final draft of the Preliminary Draft Regulations for formal notice and comment rulemaking pursuant to Government Code sections 11346.2, et seq.

B. Incorporating the 2016 TNI Standard By Reference Violates California Law

The Preliminary Draft Regulations propose to simply refer to and incorporate by reference the 2016 TNI Standard. However, the development of the 2016 TNI Standard did not include an opportunity for public participation; specifically, California environmental laboratories were not afforded an opportunity to weigh in on the development of the 2016 TNI Standard, as required by the California Administrative Procedure Act (APA). In essence, the regulations would refer the regulated entities to a separate standard, not published alongside ELAP's regulations themselves or modified by ELAP, and require that regulated entities comply

with this outside standard. Furthermore, enforcement of the 2016 TNI Standard, as proposed to be incorporated by reference in the Preliminary Draft Regulations, would be contrary to express language in the APA prohibiting state agencies from enforcing standards not filed with the California Secretary of State. (Gov. Code, § 11340.5(a).)

CVCWA and its members have collectively and individually raised concerns about the Proposed Regulations' incorporation of the 2016 TNI Standard by reference. Specifically, we have raised concerns that the standard is not typically available to the public to review for free. While ELAP has worked with TNI to make a temporary exception to the cost for viewing the standards, this is ultimately insufficient to comply with California law governing incorporation by reference. The APA (Gov. Code, § 11340 et seq.) requires that the contents of regulations, and evidence supporting them, be made available for public review and objection, and that these materials ultimately be weighed and considered by the agency adopting the regulations. (Gov. Code, §§ 11346.2, 11346.8-11346.9.) Thus, public disclosure and participation is a crucial ingredient to the promulgation and adoption of regulations in California.[1] This goal is frustrated when an agency incorporates by reference a document that has not been made available for public discussion and review.[2]

The Preliminary Draft Regulations are simply a wholesale incorporation by reference of the 2016 TNI Standard, with few special provisions added to modify or replace those set forth in the 2016 TNI Standard. The 2016 TNI Standard is an environmental laboratory quality management standard developed by a consortium of member laboratories from across the nation. (See The NELAC Institute, *TNI Mission*, available at: https://www.nelac-institute.org/content/aboutus.php.) While some regulatory schemes, such as the Building Standards Code, are permitted to incorporate third-party standards by reference, ELAP's regulations for environmental laboratories are not part of such a narrow exception. (See Health & Saf. Code § 18928.1 [governing development of the California Building Standards Code].) The development of the 2016 TNI Standard did not include an opportunity for public participation, particularly by non-member laboratories, that approximated the requirements in the APA. In the past, the Third District Court of Appeal invalidated regulations governing Medi-Cal that incorporated by reference a California State Department of Finance schedule for rates.[3] The invalidation was based in part on the fact that the Department of Finance's schedule was produced by staff in the department and without public participation. (*Id.* at p. 814.) On the other hand, a regulation that incorporated water quality objectives by reference was held legally permissible because the water quality objectives to be incorporated had been promulgated by another state agency pursuant to the APA, which included the opportunity for public review of evidence supporting the objectives and participation in the rulemaking process.[4]

[1] See *California Association of Nursing Homes, Sanitariums, Rest Homes and Homes for the Aged, Inc. v. Williams* (1970) 4 Cal.App.3d 800, 813-814 (*Williams*).
[2] *Id.*; see also *California Association of Sanitation Agencies v. State Water Resources Control Bd.* (2012) 208 Cal.App.4th 1438, 1468 (*California Association of Sanitation Agencies*).
[3] *Williams*, *supra*, 4 Cal.App.3d at pp. 808-809.
[4] *California Association of Sanitation Agencies*, *supra*, 208 Cal.App.4th at p. 1468.

The promulgation of the 2016 TNI Standard is much more analogous to the Department of Finance rate schedule, because the public—in particular, most California environmental laboratories—was not afforded an opportunity to weigh in on the development of the 2016 TNI Standard.[5] Only TNI member laboratories were eligible to participate. Therefore, incorporating the 2016 TNI Standard by reference into the Proposed Regulations violates the APA. On this basis, the Preliminary Draft Regulations should not be adopted as currently proposed because they would be found invalid for violating the APA under *Williams* and *California Association of Sanitation Agencies*.

In addition to the procedural illegality surrounding incorporating the 2016 TNI Standard by reference into the Preliminary Draft Regulations, the incorporation also requires laboratories to comply with, and the State Water Resources Control Board (State Water Board) and ELAP to enforce, standards that are not freely available to the public. This lack of transparency should be avoided. Accordingly, CVCWA urges ELAP to recognize these legal and public policy concerns, and to revise the Preliminary Draft Regulations to bring them into compliance with the law. The parallel California-centric quality management system we recommend would likely resolve the issues we have identified with the proposed incorporation by reference of the 2016 TNI standard in the Preliminary Draft Regulations.

C. Role and Lack of Transparency With the State Agency Partners

The Preliminary Draft Regulations create, for the first time in regulation, the "State Agency Partners," and gives this amorphous group authority over fields of accreditation. (Article 2, § 64802.15(a).) Specifically, ELAP will only "accredit laboratories in Field(s) of Accreditation for use of environmental analyses *required by State Agency Partners* for regulatory purposes. . . ." (*Ibid.* [emphasis added].) This provision, together with ELAP's unilateral action making the State Agency Partners a so-called "advisory committee,"[6] gives the State Agency Partners authority over laboratory accreditation greater than that afforded to ELTAC (a creation of the California Legislature).[7] The advice that the State Agency Partners would provide falls under the purview of ELTAC, as described by the Legislature in Health and Safety Code section 100863. In fact, the State Agency Partners have representatives in ELTAC (the State Regulatory Agency Employee positions) currently, and thus are represented similarly to the laboratory community at large. ELTAC, then, can advise ELAP and incorporate input and expertise from the State Agency Partners, while fulfilling the intention of the Legislature and eliminating the need for another committee with veto power over ELTAC.

Additionally, the State Agency Partners are not, and have not been, subject to open meeting laws, such as the Brown Act (Gov. Code, § 54950 et seq.) or the Bagley-Keene Act (Gov.

[5] See *ibid*. ("[U]nlike the State Schedule of Maximum Allowances at issue in [*Williams*], the drinking water standards adopted by the [Department of Health Services] must be adopted pursuant to the APA, which provides for public participation.")

[6] See Handout Brochure, *State Water Resources Control Board Public Workshop on Environmental Laboratory Accreditation Program (ELAP) Regulations Development and Preliminary Recommendation for Laboratory Accreditation Standard* (Oct. 6, 2016) available at: <https://www.waterboards.ca.gov/drinking_water/certlic/labs/documents/trifold_oct6workshop.pdf>.

[7] Health & Saf. Code, § 100863.

Code, § 11120 et seq.), which obfuscate their processes and prevent laboratories from engaging and participating in the decision making that is done by the State Agency Partners. To the extent that ELAP insists on supplanting ELTAC with the State Agency Partners, CVCWA requests that the State Agency Partners be formally introduced as a committee and ensure that the committee is bound by open meeting laws.

Furthermore, it is unclear whether the State Agency Partners' own laboratories intend to become ELAP accredited under the regulations proposed in the Preliminary Draft Regulations. This, too, raises concerns about transparency and enforcement actions that these agencies may take with respect to accredited laboratories.

D. Fields of Accreditation Should Be Set Forth in Regulation

Related to our concerns about delegating ELAP authority to the State Agency Partners with regard to their ability to determine the available Fields of Accreditation, CVCWA understands that ELAP is required to adopt regulations governing the Fields of Accreditation offered in the state. Specifically, Health & Safety Code section 100830(a)(9) provides that ELAP "regulations shall include, but not be limited to, all of the following: . . . Units and fields of accreditation." Thus, the California Legislature requires ELAP to adopt regulations governing fields of accreditation. The Legislature did not authorize ELAP to post these fields on a website where they can be continuously updated without public notice and comment, which is required for rulemaking under the California APA. Accordingly, ELAP should develop proposed regulations, with ELTAC input, for Fields of Accreditation that comply with ELAP's statutory mandate.

E. Enforcement Actions Related to Accreditation

The Preliminary Draft Regulations set forth a variety of instances wherein citations may be issued to laboratories, or laboratories' accreditations may be suspended or revoked. CVCWA has two concerns related to these provisions in sections 64816.05 and 64816.10: (1) that the Preliminary Draft Regulations lack a reference to the due process procedures that must be exhausted before a laboratory's accreditation is suspended or revoked; and (2) that the circumstances listed for citation issuance and suspension or revocation are identical.

Health & Safety Code section 100910 requires that the State Water Board provide notice to the laboratory that its certification or accreditation is being suspended or revoked, and inform the laboratory owner that he or she may request a hearing on the matter. This due process procedure is an important protection for California laboratories. In an effort to provide additional clarity and information to environmental laboratories, CVCWA requests that a new subdivision be added to section 64816.10 that acknowledges the due process procedures in Health & Safety Code section 100910 and refers to this statute.

Next, both section 64816.05 (pertaining to citations) and section 64816.10 (pertaining to accreditation suspensions or revocations) contain a list of potential grounds for these ELAP enforcement actions. The lists for both sections are nearly identical, which raises questions

about why or when a laboratory might receive a citation, versus a suspension or revocation of its accreditation. Suspending or revoking a laboratory's accreditation is a serious action, as evidenced by the formalized due process procedures in Health & Safety Code section 100910. Accordingly, the Preliminary Draft Regulations should reflect that accreditation suspension or revocation may occur only where a laboratory's failure to comply with the statutes and regulations is material and consistent, or the laboratory owner acts in a criminal way (i.e., fraudulently). CVCWA requests that section 64816.10(a) be revised to read:

(a) **ELAP may suspend or revoke a laboratory's accreditation, subject to the due process procedures in Health & Safety Code section 100910, when there is evidence that the laboratory materially and consistently fails to comply with these regulations and/or Health & Safety Code section 100905. Examples of such violations are as follows** ~~Reasons for suspending or revoking accreditation shall include~~:

F. Remaining Issues with Specific Provisions of the Preliminary Draft Regulations

Many of the following comments are similar to comments CVCWA has raised on past versions of the Preliminary Draft Regulations. We provide them again here to update the section references, as applicable, and to reiterate the need for our requested revisions. Where specific reference is made to the 2016 TNI Standard, either below or in Attachment A, our comments should not be interpreted to endorse the 2016 TNI Standard as regulation. The proposed language would resolve concerns with implementation or confusion currently in the Preliminary Draft Regulations.

1. When in Conflict, Public Agency Law, Ordinance, and/or Resolution Should Supersede TNI Provisions Incorporated in the Preliminary Draft Regulations

In Article 2, section 64802.10(a)(1) of the Preliminary Draft Regulations, laboratories must comply with Volume 1, Module 2 of the 2016 TNI Standard,[8] with the exception of two sections governing technical manager qualifications and requirements. However, the quality management system specifications in the remainder of Module 2 contain several requirements that could or do conflict with established public agency law, ordinances, and resolutions. Specifically, these are provisions related to hiring and terminating laboratory employees, contracting, and collective bargaining. Publicly-owned laboratories must comply with the laws and ordinances governing their agency (e.g., city, special district, or county).

For example, municipal laboratories have limited control over subcontracting and purchasing requirements. The 2016 TNI Standard sets out very specific requirements that laboratories must meet in order to become accredited. However, municipal laboratories, as parts of a parent special district, city, or county, must follow the laws and procedures governing that parent agency. Additionally, municipal laboratories are limited by their parent agency in

[8] Section 64802.10(a)(2) would also require that laboratories comply with Volume 1, Modules 3-7 "where appropriate based on laboratory operations." However, the provisions of the 2016 TNI Standard that CVCWA is concerned with, and that are mentioned above, are all found in Module 2.

their ability to create new positions, or immediately terminate employees. As written, the 2016 TNI Standard may require that some small laboratories add positions in order to comply, and also makes certain infractions subject to "immediate termination." (2016 TNI Standard, section 5.2.7.) Public agency priorities, budget constraints, and laws may prevent municipal laboratories from meeting these detailed requirements.

While these requirements are likely included in the 2016 TNI Standard in an effort to ensure that TNI-accredited laboratories operate at a certain level of consistency, lack of consistency will not be a problem if municipal laboratories are exempted from these requirements. Municipal laboratories, as departments of public agencies, are already governed by standardized procedures for contracting and purchasing, as well as hiring and terminating personnel.

Along these lines, most municipal laboratories are primarily focused on analysis used for compliance with National Pollutant Discharge Elimination System (NPDES) or Waste Discharge Requirements (WDRs) permits. Where these permits specify laboratory methods and method validation, these provisions should prevail over any conflicting provisions in the 2016 TNI Standard.

Thus, to avoid these conflicts and to avoid putting these laboratories in jeopardy of non-compliance with ELAP's regulations, the Preliminary Draft Regulations should be revised to include a provision that resolves such potential conflicts. Accordingly, CVCWA requests that section 64802.10(a)(3) be added to the regulation as follows:

> **(3) To the extent that any provisions in 2016 TNI Standard, Revision 2.1, Volume 1, Module 2, as specified in subsection (a), conflict with California law governing a public agency or a public agency's adopted ordinances or resolutions, the law, ordinance, or resolution shall supersede the provision(s) in 2016 TNI Standard, Revision 2.1, Volume 1, Module 2.**

2. Preliminary Draft Regulations Lack a Transition to the New Accreditation Standard

The Preliminary Draft Regulations include certain provisions that provide an alternative to immediately complying with the 2016 TNI Standard, for a limited time. (See, e.g., art. 2, § 64802.10(b).) While CVCWA supports a phased approach to the Preliminary Draft Regulations, there remain concerns with the approach employed. Mainly, CVCWA is concerned that the timelines to comply with both the temporary alternative language to the 2016 TNI Standard and the 2016 TNI Standard itself are aggressive, particularly for small

municipal laboratories. Small municipal laboratories operate with significant personnel and resource constraints, which makes updating current laboratory Standard Operating Procedures to the specifications in the Preliminary Draft Regulations time consuming and resource intensive.

To address this problem, CVCWA reiterates its request for a truly phased implementation of the Preliminary Draft Regulations for small municipal laboratories. This will allow small municipal laboratories to benefit from lessons learned by other, larger laboratories with more resources. CVCWA proposes adding a new section to Article 1 that states the following:

Section 64801.X. Establishment of Accreditation Program

(a) The regulations set forth herein shall become effective one (1) year following the date these regulations are approved by the Office of Administrative Law (OAL).

(b) These regulations contain certain provisions that sunset three (3) years after the effective date of these regulations. Small municipal laboratories, as defined, shall have an additional one (1) year to comply with regulations requiring compliance with the TNI Standard.

As seen in the proposed language above, CVCWA recommends changing the "sunset" date of the alternative to the 2016 TNI Standard from the adoption date of the regulations to the effective date of the regulations. (See, e.g., art. 2, §§ 64802.05(a)(2)(C), 64802.10(c).) After the State Water Board adopts regulations of any kind, there is a delay before those regulations become effective, partially due to review by the Office of Administrative Law. Therefore, the pertinent date is not the adoption date, but the effective date. CVCWA requests that all references in the Preliminary Draft Regulations to the "adoption date" be revised to read the "effective date."

Next, the "sunset" language in sections 64802.05(a)(2)(C) and 64802.10(c), among others, states that the alternative provisions would "become invalid" three years after adoption. We are concerned that this language could cast doubt on whether past compliance with a now-invalidated section would still be considered compliance. CVCWA suggests alternative wording, such as: "Subsection (b), above, will be in effect for three (3) years following the date these regulations become effective, after which time laboratories must comply with subsection (a), above, when applying for accreditation." Similar language can be used throughout the Preliminary Draft Regulations, as seen in Attachment A. This will clarify that actions taken by a laboratory prior to the sunset date are grandfathered into compliance after the sunset date, until that laboratory needs to take the action again for future renewal accreditation.

As CVCWA has commented in the past, a transition period to the new accreditation standard, whether the TNI-based approach in Article 2, section 64802.10(a) or the "temporary" quality management system listed in subdivision (b), will assist laboratories as they begin to implement the regulations governing accreditation. The language proposed above in new section 64801.X, subdivision (a), which sets the effective date one year from the OAL approval date, gives laboratories sufficient time to bring their standards and practices into compliance with the new regulations as their certificates expire.

3. Technical Manager and Principal Analyst Qualifications Based on Trade Association Certifications

CVCWA appreciates that ELAP continues to include certifications for laboratory analysts issued by California Water Environment Association (CWEA) and the American Water Works Association (AWWA). However, the discussion of Technical Manager qualifications based on these certifications in the Preliminary Draft Regulations can be further clarified, similar to the manner in which the current ELAP regulations refer to the appropriate level of certification necessary to manage an accredited laboratory.

Specifically, CVCWA requests that ELAP add the following language and table in Article 5, section 64812.00, subdivision (b):

> An employee of a water or wastewater treatment facility, who holds a valid CWEA or CA-NV/AWWA laboratory analyst/water analyst certification, shall be deemed to meet the qualifications of Technical Manager if the level of certification has educational and**/or** experience requirements appropriate to the nature and size of the facility and the scope of analytical testing in the facility's regulatory permit. **The minimum grade of CWEA or CA-NV/AWWA certification needed to satisfy the qualifications for Technical Manager is illustrated in the conversion table below.**

Facility Scope of Analytical Testing	**CA-NV AWWA water quality analyst certificate**	**CWEA laboratory analyst certificate**
All microbiological methods/All technologies **All solids methods/all technologies**	I	I
All methods/titrimetric technologies **All methods/specific ion electrode technologies** **All methods/colorimetric technologies**	II	II
All methods/ion chromatography **All methods/flame atomic absorption** **All methods/graphite furnace atomic absorption**	III	III
All methods/all chromatography technologies including those using mass detectors **All methods/ICP** **All methods/ICPMS**	IV	IV

Relatedly, the current ELAP regulations provide specific qualifications for Principal Analysts at utility-owned water to wastewater treatment plants. (See Cal. Code Regs, tit. 22, § 64817(g).) The different qualifications are based on the same CWEA and AWWA certifications as listed above for Technical Managers. (*Ibid.*) Accordingly, CVCWA requests that this provision be carried over as a new subsection in the Preliminary Draft Regulations, following section 64812.00(h) or (i). Alternatively, the provision governing Principal Analysts can be removed completely, considering that proposed section 64812.00(h) would sunset three years after the effective date of the Preliminary Draft Regulations. (See section 64812.00(i).) If this alternative change is accepted, the reference to Principal Analysts in section 64812.00(j) can also be removed.

4. The 2016 TNI Standard Does Not Improve Data Quality

As CVCWA has commented in the past, improvements in data quality are not guaranteed or ensured by adopting regulations that incorporate the 2016 TNI Standard. Excessive documentation does not guarantee that laboratory data meets quality control guidelines. For instance, the 2016 TNI Standard includes over 500 requirements, translating into a significant number of written policies and procedures. However, these voluminous procedures do not yield any improvement in water quality or data quality commensurate with the burdens or costs of creating, documenting, and maintaining these procedures. This is especially true considering that all environmental laboratories already must follow certain discipline-specific standard methods that each include quality assurance and quality control procedures (QA/QC). For example, see Code of Federal Regulations, title 40, Part 136 governing wastewater laboratories, United States Environmental Protection Agency laboratory manuals, and ASTM International methods as a few examples of these discipline-specific standards. Thus, the addition of 2016 TNI Standard-based QA/QC is at best duplicative and at worst unnecessarily burdensome.

Other third-party organizations that develop model laboratory standards acknowledge that additional paperwork does not reflect increased data quality or laboratory function. For instance, the current 2017 revision of the ISO laboratory standard, number 17025, expressly focuses on improving processes rather than increasing paperwork.[9] ISO stated "[t]he process approach now matches that of newer standards such as ISO 9001 (quality management), ISO 15189 (quality of medical laboratories), and the ISO/IEC 17000 series (standards for conformity assessment activities), putting the emphasis on the *results* of a process instead of the detailed description of its tasks and steps."[10] The ISO also favors moving away from printed manuals and reports.

CVCWA disagrees with assertions that the Preliminary Draft Regulations, with their heavy reliance on the 2016 TNI Standard, would improve data quality from California laboratories. Furthermore, CVCWA has not seen any evidence that data quality is or has been

[9] Note that the 2016 TNI Standards are based on an older version of the ISO standard.
[10] International Organization of Standards, *ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories* (2017) p. 4, available at <https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf> (emphasis added).

inferior or otherwise inadequate under present regulations governing quality management systems. Without an identifiable benefit, ELAP should not impose unnecessary and overly burdensome procedural and recordkeeping requirements on California laboratories.

G. Conclusion

In closing, we request that ELAP not rush forward with formal notice and comment rulemaking based on the Proposed Draft Regulations, but dedicate sufficient time to the ELTAC Subcommittee on Developing Laboratory Standards for ELAP Regulations and ELAP's review of the proposal that comes from that subcommittee. A California-centric laboratory accreditation system has the potential to resolve many of CVCWA's members' concerns with the Preliminary Draft Regulations, and may provide a more efficient means for transitioning to an updated regulatory scheme.

As always, CVCWA appreciates the opportunity to provide comments on this matter. This is an issue we desire to work on further with ELAP staff. Please contact me for any further assistance you may need at (530) 268-1338 or eofficer@cvcwa.org.

Sincerely,

Debbie Webster

Debbie Webster,
Executive Officer

Encl.

CC: Summit Partners
ACWA

Attachment A

ATTACHMENT A
TO FEBRUARY 8, 2019 CVCWA COMMENT LETTER

Article No.	Section No.	Topic Name	ELAP 3rd Prelim Draft Regulatory Text (Redline Strikethrough/Version December 2018)	CVCWA Comments/Recommendations/Rationale
1	64801	Definition	Request to add definitions for the following terms used within the draft regulations, but lack definitions presently: * Environmental Samples * Interim certificate * Batch	Suggestion for definition for "batch" that is in addition to definition of "batch" in TNI, which is much larger. * Batch (Mini) - For laboratories that do not analyzed more than 7 samples for a given test and of the same sample matrix per week, a preparation or analytical batch may consist up to 7 samples, excluding quality control samples, processed during the course of no more than a week.
1	64801	Definition	For completeness, whenever applicable, in lieu of "*with ELAP statutes and regulation,*" cite the exact statutes or regulation that is applicable to the item being defined.	
2	64810.05(a)(1)(C)	Sunset Date	C) Subdivision (a)(2)(B), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption~~ **following the date ~~of~~** these regulations **become effective, after ~~at~~** which time ~~accredited~~ laboratories **must comply with** ~~will be required to meet the TNI Standard in~~ subdivision (a)(2)(A), above;	See Comment Letter, Section F.2
2	64810.05(c)	Sunset Date	(c) Subdivision (b), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption~~ **following the date ~~of~~** these regulations **become effective, after ~~at~~** which time laboratories **must comply with** ~~will be required to meet the TNI Standard in~~ subdivision (a), above;	See Comment Letter, Section F.2
2	64810.05(c)	Sunset Date	(c) Subdivisions (b)(2) and (b)(3), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption~~ **following the date ~~of~~** these regulations **become effective, after ~~at~~** which time ~~accredited~~ laboratories **must comply with** ~~will be required to meet the TNI Standard in~~ subdivision (b)(1), above;	See Comment Letter, Section F.2
2	64802.10(b)(1)	Term	(1) Develop and maintain a Quality Manual. The Quality Manual shall address ~~all~~ **the** quality assurance and quality control practices to be employed by the laboratory and shall include at a minimum:	The use of all is overly broad. Suggest using the word "the."

Article No.	Section No.	Topic Name	ELAP 3rd Prelim Draft Regulatory Text (Redline Strikethrough/Version December 2018)	CVCWA Comments/Recommendations/Rationale
2	64802.20(h)(4)	Repeat PT Testing	(h) If a laboratory does not achieve an acceptable score for a Field of Proficiency Testing, then within thirty (30) days of receipt of the "Not Acceptable" score from the Proficiency Testing provider, the laboratory shall: ... (4) **Within ninety (90) days, a**~~A~~chieve an acceptable score for that Field of Proficiency Testing in a subsequentProficiency Testing study; and ...	As currently written, this section requires (1) Notification to ELAP, (2) A root cause investigation, (3) Corrective action, and (4) Completion of a second PT study, and (5) notifying ELAP of the "Acceptable" score. Completion of all these within the first 30 days after the first score is not realistic.
2	64802.25(c)	On-Site Assessment Scheduling	(c) The laboratory is responsible for ~~**scheduling**~~ **requesting** an on-site assessment through ELAP or a third-party Assessment Agency **at least one year prior to the expiration date of the laboratory's accreditation**.	Laboratories should not be responsible for something they do not have control over. They can request an on-site assement through ELAP/Third Party, but ELAP/Third Party must agree to the proposed date and time. The suggested timeframe of one year is suggested so that both ELAP and laboratories will have sufficient time to find a mutually agreeable date for the assessment, and will avoid penalties associated with late submission of renewal applications.

Article No.	Section No.	Topic Name	ELAP 3rd Prelim Draft Regulatory Text (Redline Strikethrough/Version December 2018)	CVCWA Comments/Recommendations/Rationale
2	64802.25(j)	Interim Certificate or Accreditation	(j) If a laboratory has submitted a complete renewal or amendment application package in accordance with Section 64808.05 or 64808.15, respectively, and additional time is needed by ELAP to complete an on-site assessment, then the laboratory shall be issued an interim certificate **or accreditation**. (1) A laboratory that holds an interim certificate **or accreditation** is accredited for Field(s) of Accreditation listed on the laboratory scope of accreditation. (2) An interim certificate is non-renewable and shall be valid until one of the following occurs: (A) An on-site assessment has been completed and a certificate issued; (B) The laboratory fails to meet the requirements for accreditation in accordance with Section 64802.00; or (C) The expiration date on the interim certificate is reached.	This section is confusing. Per H&S Code Section 100850, interim provisions apply both to the certificates and accreditation. Additionally, this is essentially the only time in the regulations that the term "certificate" is used to refer to ELAP accreditation. if a definition for "interim certificate' is added as suggested above, this change is not necessary.
2	64802.25(f)	On-Site Assessment & Corrective Action	f) Within thirty (30) days of the on-site assessment, a laboratory will receive an on-site assessment report. If there are **written** findings in the on-site assessment report **listing items needing correction**, a laboratory shall: (1) Within thirty (30) days of receipt of the on-site assessment report, the laboratory shall submit a corrective action report that contains a root cause analysis of the finding(s); (2) If finding(s) are not correctable within thirty (30) days, a laboratory shall submit a corrective action plan, identifying the corrective actions that will take place and the date the finding(s) will be corrected; ~~**(3) Subsection (f)(1), above, will be invalid three (3) years from the adoption of these regulations, at which time laboratories will be required to submit, within thirty (30) days of receipt of the on-site assessment report, a corrective action report in accordance with 2016 TNI Standard – Rev 2.1, Volume 1, Module 2, Section 4.11.**~~	Regarding sunset provisions, see Comment Letter, Section D.2. 2016 TNI Volume 1, Module 2, Section 4.11 does not refer to a corrective action report, rather to the steps of correction action, including documentation. We recommend that it be removed because the laboratory's Quality Manual will comply with TNI and provide the basis for interal audits. Furthermore, the requirements in (f)(1) and (f)(2) appear to fit within the parameters set forth in TNI section 4.11.

Article No.	Section No.	Topic Name	ELAP 3rd Prelim Draft Regulatory Text (Redline Strikethrough/Version December 2018)	CVCWA Comments/Recommendations/Rationale
2	64802.25(f)(3)	Sunset Date/ Corrective Action Reports	**Preferred alternative: Remove the subsection 3 (see immediately above)** Other Alternative: (3) Subsection (f)(1), above, will **~~become invalid~~** **be in effect for** three (3) years **~~after adoption~~** **following the date** **~~of~~** these regulations **become effective, after** **~~at~~** which time laboratories will be required to submit, within thirty (30) days of receipt of the on-site assessment report, a corrective action report in accordance with 2016 TNI Standard – Rev 2.1, Volume 1, Module 2, Section 4.11.	Regarding sunset provisions, see Comment Letter, Section F.2. 2016 TNI Volume 1, Module 2, Section 4.11 does not refer to a corrective action report, rather to the steps of correction action, including documentation.
2	64802.20(f)(2)	2nd PT sample timing and late fee penalties	f) To maintain accreditation, a laboratory shall achieve acceptable scores in a minimum of one Field of Proficiency Testing at least once per year for each Field of Accreditation for which the laboratory holds accreditation. Acceptable scores in Field(s) of Proficiency Testing shall be achieved: 2) **~~Within~~** **No later than** ninety (90) days prior to the expiration date of accreditation in year two of the accredidation period	Complete applications, which requires PT samples in the year of accreditation, must be submitted prior to 90 days of the end of the accrediation period in order to avoid penalies per section 64808.05(c) - (e). This section contradicts the requirement to submit to avoid a penalty.

Article No.	Section No.	Topic Name	ELAP 3rd Prelim Draft Regulatory Text (Redline Strikethrough/Version December 2018)	CVCWA Comments/Recommendations/Rationale
2	64802.25(g)	Corrective Action	(g) If **ELAP, after reviewing the corrective actions taken and the results thereof as provided in the corrective action report, is not satisfied that the findings in the on-site assessment report have been corrected** ~~**a laboratory is notified that a corrective action report does not demonstrate the required corrections**~~, then **ELAP shall notify** the laboratory **of the identified shortcomings and shall provide** ~~**shall have**~~ an additional thirty (30) days from the receipt of the notification **for the laboratory** to submit a revised corrective action report. If the revised corrective action report does not demonstrate the required corrections, then accreditation shall be denied, suspended or revoked for the Field(s) of Accreditation affected by the failure to take **adequate or sufficient** corrective action. **Denial, suspension, or revocation shall be subject to notice procedures, as established in Health & Safety Code sections 100855 and 100910.**	The text makes it obvious that the laboratory is taking corrective action, if it says it will but doesn't, this is addressed in the paragraph below (h). However, this section does not provide any guidance as to how ELAP will determine whether corrective action is insufficient. Our suggestions provide this guidance and would ensure that laboratories are provided clear direction on why their corrective actions were not deemed sufficient, based upon the deficiencies noted in the on-site assessment report. Additionally, we suggest adding a reference to the notice procedures required by law for denial, suspension, and revocation of an ELAP accreditation
2	64802.25(i)	On Site Assessments	(i) Unless otherwise approved by ELAP, if a scheduled on-site assessment is not conducted within six (6) months from the scheduled assessment date and the delay is not a result of ELAP error or procedure, accreditation shall be denied, suspended or revoked. **(1) If ELAP needs additional time to schedule or complete an on-site assessment, ELAP shall provide an extension.**	What ELAP procedure is is very unclear. This section should be clear that any delay due to ELAP should not jeopardize a laboratory's accreditation status. This new subdivision will provide further clarity on such circumstances.

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3	64808.05(b)	Missing Application Elements	(b) If any of the elements in subdivision (a)(1), above, are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory **of the missing elements** and return the application **with instructions and deadlines for resubmittal for the renewal to be considered**. ELAP will not review whether Proficiency Testing reports have acceptable scores for the appropriate Field(s) of Proficiency Testing when reviewing the completeness of an application package, but will only ensure Proficiency Testing reports have been submitted with the application package.	These additions would incude requirements for notification anagulous to Health and Safety Code 100855.
4	64810.05(a)(1)	Satellite Laboratory	(1) The main laboratory and satellite laboratory operate under a single scope of accreditation that is **shared or** divided among each location;	Some satallite laboratories will perform the same test as the main laboratory (ex. pH, chlorine, etc.). This language is suggested to clarify this point.
4	64810.10(a)(3)	Mobile Laboratory	Request to add a new subdivision: (a)(3) The laboratory is stand alone, has the ability to conduct testing as a main laboratory and has the ability to generate final laboratory reports.	Provides additional clarity that a mobile laboratory can also be a main laboratory.
5	64812.00(h)(3)	Qualifications Required for Sophisticated Equipment	(h) A laboratory shall designate a Principal Analyst(s) to be a user of sophisticated laboratory instruments, defined in Section 64801.00 (q), or a supervisor of the users of sophisticated laboratory instruments. The Principal Analyst shall: (1) Possess at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, public health engineering, or natural and physical sciences; or (2) Possess a certificate of completion in a course taught by the manufacturer of the sophisticated instrument being used or supervised by the Principal Analyst; and ~~**(3) Have at least six months experience in the operation of sophisticated instrument in the analysis of environmental samples prior to obtaining the position of Principal Analyst.**~~	As written, subsection (c) may prohibit a laboratory from aquiring new equipment. Also see Comment Letter, Section F.3 for additional comments concerning this section, including removing the reference to Principal Analysts entirely.

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5	64802.25(e)	Sunset Date	(e) Subdivisions (d)(2), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption~~ **following the date** ~~of~~ these regulations **become effective, after** ~~at~~ which time ~~accredited~~ laboratories **must comply with** ~~will be required to meet the TNI Standard in~~ subdivision (d)(1), above;	See Comment Letter, Section F.2
5	64802.25(i)	Sunset Date	(i) Subdivisions (h), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption~~ **following the date** ~~of~~ these regulations **become effective.**	TNI does not specify a Principal Analyst position, and the referenced section of TNI refers generally to other laboratory employees. Also see Comment Letter Section F.2
5	64812.05(b)	Sunset Date	(b) Subdivision (a)(2), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption of~~ **following the date** these regulations **become effective**, ~~and~~ **after which** laboratories will be required to comply with subdivision (a)(1), above.	See Comment Letter, Section F.2
5	64812.00(g)	Quality Manager	(g) Three (3) years from the ~~adoption~~ **effective date** of these regulations, a laboratory shall designate a Quality Manager. The Quality Manager, and/or their designee, shall comply with 2016 TNI Standard – Rev 2.1, Volume 1, Module 2, Section 4.1.5(i), 4.1.7.1, ~~4.2.6~~, 4.2.8.2 and 4.14.1.	See Comment Letter, Section F.2 regarding effective date. Section 4.2.6 refers to a section that may not yet be incorporated into a Quality Manual within that three years.
5	64812.05(c)(d)	Handling, storage and disposal of hazardous chemical	Request to revise or delete (c) and (d) or revise and combine requirements into one, to read: "A laboratory shall have a chemical hygiene plan in place that includes procedures in handling, storing, and disposal of chemical and hazardous wastes."	Rationale: A chemical hygiene plan is required for laboratories generating chemical wastes, storing chemical, etc. under OSHA that has a separate regulatory requirements from another entity (not ELAP). Will require a different audit and inspection requirements by qualified assessors in this field.
6	64814.00(g)	Sunset Date	(g) Subsection (f)(2), above, will ~~become invalid~~ **be in effect for** three (3) years ~~after adoption~~ **following the date** ~~of~~ these regulations **become effective, after** ~~at~~ which time laboratories will be required to **comply with** ~~meet the TNI Standard in~~ subdivision (f)(1), above;	See Comment Letter, Section F.2

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6	64814.00(i)	Sunset Date	(i) Subsection (h)(2), above, will **~~become invalid~~** **be in effect for** three (3) years **~~after adoption~~** **following the date** **~~of~~** these regulations **become effective, after** **~~at~~** which time laboratories will be required to **comply with** **~~meet the TNI Standard in~~** subdivision (h)(1), above;	See Comment Letter, Section F.2
6	64814.00(o)	Sunset Date	(o) Subsection (n)(2), above, will **~~become invalid~~** **be in effect for** three (3) years **~~after adoption~~** **following the date** **~~of~~** these regulations **become effective, after** **~~at~~** which time laboratories will be required to **comply with** **~~meet the TNI Standard in~~** subdivision (n)(1), above;	See Comment Letter, Section F.2
7	64816.1(a)(7)	Suspending & Revoking Certification	**~~(7) If, during an on-site assessment, ELAP determines that suspension or revocation is necessary to protect public interest, safety or welfare;~~**	This provision exceeds ELAP's authority under Health and Safety Code Section 100905. This H&S Code section sets the parameters for suspending or revoking accreditation, and it does not include the ability for ELAP to arbitrarily decide that public health and saftey is threatened when there are not other violations of the regulations on which suspension/revocation may be based.