December 20, 2019

Sent via electronic-mail to: commentletters@waterboards.ca.gov

Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
1001 I Street, 24th Floor
Sacramento, CA 95814

Re: Comments – Proposed Environmental Laboratory Accreditation Program Regulations.

Dear Ms. Townsend:

On behalf of the California Association Sanitation Agencies (CASA), I write to provide comments on the October 11, 2019 draft of the ELAP regulations. CASA represents more than 125 public agencies and municipalities that engage wastewater collection, treatment, recycling, and resource recovery. Approximately 280 labs in the state are accredited for wastewater testing by ELAP, a number of which are operated by CASA member agencies, and will be impacted by these regulations.

We appreciate the opportunity to engage with staff over the past several years as ELAP has transitioned to the State Water Board. We recognize the challenges that face the program and the Board’s desire for improvement of the program. Unfortunately, CASA still has multiple concerns with this rulemaking package, including technical concerns with this draft of the regulatory text and with the adequacy of the supporting rationale, including the cost of compliance models and estimates. The staff report and supporting documentation do not adequately represent the extent of the impact of these regulations, particularly for small and very small labs. Due to the extensive costs associated with implementing the TNI standard across the state, the rulemaking package should also be classified as a major regulation.

As we have emphasized, there is a less costly, equally effective alternative available to the Board: the California Quality Management System (QMS). There is no question that California laboratories need an updated QMS. However, we disagree that it must be the 2016 TNI Standard. The purpose of the TNI standard is commercial, to enhance a lab’s ability to conduct business across state lines. However, California’s municipal labs do not generally need to engage in business or coordinate activities with labs in other states. In essence TNI is offering something that California’s municipal labs do not need to provide high quality reliable data, and at a cost that is prohibitive and will result in lab closures.

As was noted by several stakeholders at the recent workshop and as has been raised at ELTAC and throughout the regulation development process, TNI is not the only way to ensure in-state labs produce reliable, high-quality data. The need for California’s labs to produce legally defensible, high quality data has been cited repeatedly as the reason for ELAP’s pursuit of the TNI standard. However, this fails to take into account the inherent defensibility of data produced by using approved methods. Specifically, laboratory methods are designed such that the data collected is “defensible before sampling or testing even begins.” Moreover, the CA QMS incorporates all of the TNI requirements that actually go to the heart of data quality, without the additional administrative burdens that would impose costly compliance mandates.
The Supplemental Attachment does not provide a cost analysis for the alternatives and misunderstands the purpose of the CA QMS with regard to cost effectiveness.

The Supplemental Attachment states, “[t]otal statewide costs were not calculated for the alternative accreditation standards because the implementation and operational costs associated with each option would likely be similar to the estimated implementation and operational costs of the proposed regulations.” (D-2, p. 49.) CA QMS implementation costs may indeed be comparable to the draft regulations, in that the costs entail requirements for labs to install a Quality Management System. However, the operational costs for the CA QMS and the proposed regulations are markedly different. The CA QMS was designed specifically to relieve laboratories from having to hire additional staff to maintain and comply with the requirements of TNI, particularly those that are related to record keeping and administrative requirements.

In consideration of this, the regulatory package should contain a real analysis examining the difference in costs between the CA QMS and the draft regulations, and more specifically, how steep the trade-offs are for the cost savings of the CA QMS. Documents supporting the regulations contend that the CA QMS excluded enough elements of TNI to take away from the effectiveness of the TNI standard, but did not remove enough elements to eliminate the assumed need to hire new personnel or a consulting firm. (See Supplemental Attachment at p. 46 and p 49). We do not believe this is the case, and a straightforward cost analysis would provide the information needed to evaluate the cost-effectiveness of the proposals side-by-side.

Adopting the CA QMS as the “state accreditation” system would still allow labs to pursue TNI accreditation

Currently, approximately 35 labs in California are accredited by TNI. This figure represents only 5% of accredited labs, yet this draft of regulations requires 95% of the labs in the state to scale up to become TNI compliant. The rulemaking states that “all data [are] produced for the same broad regulatory purposes.” However, this does not account for the fact that the production of data under TNI adds significant costs to its generation, which are administrative by nature and for standardization purposes. These tasks have no bearing on the equivalent quality of the data and are not essential for data intended for in-state use. Bruce Godfrey confirmed at the Public Hearing that the TNI standard is specifically designed for conducting business across state lines, a function that many if not most California municipal labs have no need.

The proposed alternative CA QMS would allow for ELAP staff’s current proposal of “TNI-minus two” to be elevated to full TNI, and for the CA QMS to be adopted as the State Accreditation System. In this proposal, ELAP would not have to accredit the TNI labs, as that can be done through third-party assessors (TPAS) and TNI-accrediting bodies like Oregon or Utah. California could leave the minority of labs requiring accreditation by TNI to other professionals. Thus ELAP could administratively support a two-tiered accreditation system without increasing the burden on Water Board staff.

Given that the 2016 TNI standards and quality system requirements under it are the major cost drivers of the regulatory package (p.49), the CA QMS provides a viable alternative which should provide substantial cost savings.

We disagree with many of the reasons cited for ELAP’s reluctance to pursue the CA QMS

A number of considerations have been articulated by ELAP staff as to why they do not view the CA QMS alternative as viable. Each of these is addressed below.
“However, the major drawbacks to [state accreditation] are the difficulty, cost, and time associated with developing, writing, and keeping an updated original standard.”

We disagree with the premise that there would be increased difficulty and cost associated with the CA QMS. An Environmental Laboratory Technical Advisory (ELTAC) subcommittee developed alternative regulatory text which will be submitted “ready-made” by others in their written comments, and a majority of ELTAC voted to include this language in the regulatory package. The only staff time that would be associated with its inclusion in the regulations would be for updating the original standard, but this can be resolved simply by assigning ELTAC the responsibility to review the CA QMS and provide its recommendations for updating the standard based on identified deficiencies found in the assessment reports.

“Additionally, this option would require ELAP to develop state-specific training protocols for ELAP assessors and provide resources to communicate the new requirements to the laboratories.”

The CA QMS, like the TNI standard, includes a checklist for auditors. Given the CA QMS is heavily based on the substantive provisions within TNI, presumably any auditor who could perform a “TNI-minus two” assessment could perform one with fewer items to check, meaning there is an equivalency in costs – if not lower costs – associated with CA QMS. Also, ELAP would have a de minimis amount of work to develop state specific training protocols given that there are currently developed protocols. Moreover, the laboratory community has exhibited that it is a ready and able partner to communicate and train laboratories on new requirements, which would reduce the costs ELAP would have to bear directly.

“Furthermore, a state-created standard would significantly inhibit the State Water Board from relying on third-party assessment agencies to fulfill onsite assessment requirements for laboratories.”

As noted above, the CA QMS is based on TNI, and its checklist only eliminates, not adds, items from TNI, so the ability to rely on third-party assessors who can perform TNI assessments would not be hindered by the CA QMS, which only reduces what an auditor must examine.

“This option is analogous to the accreditations standards in the current regulations, which have been ineffective, and the time and costs constraints of this option are in opposition to the urgency the State Water Board has placed on selecting a new accreditation standard.”

The TNI-based CA QMS – which requires labs adopt a Quality Management System – is far different from the current 1994 draft of regulations. We are unclear as to what the time constraints and costs are, as the Supplemental Attachment includes no calculations or other information. See p. 49. D.2.

**The regulation imposes unnecessary reporting, recording keeping, and compliance requirements.**

Government Code § 11346.3(a) requires a state agency proposing to adopt, amend, or repeal any administrative regulation to assess the potential for adverse economic impact and avoid the imposition of unnecessary or unreasonable regulations, reporting, or record keeping. Critical here, the proposed regulations for accrediting labs impose significant administrative record keeping requirements, and by our calculations cost annually in excess of $50 million. Thus there must be a showing the regulations are necessary and reasonable.

The municipal lab community has attempted over the multi-year process to demonstrate the cost burdens of recordkeeping and compliance imposed by TNI, and urged ELAP to retain a state system, as the parties generally agree TNI is designed for commercial labs conducting business across state lines, not municipal labs. There is no
evidence of systemic issues with environmental labs nor the quality of the data they produce that would be solved by imposition of TNI. In fact, the ELAP chief noted in a December 4, 2019 letter that “the proposal to include the TNI quality management system standard in our draft regulations is not based on performance issues with accredited labs.”

The problems that U.S. EPA identified with ELAP — such as 45 laboratories having not received an onsite assessment in four to nine years, multiple labs having no onsite assessment in over three years but repeatedly issued new certificates for drinking water, and ELAP’s onsite assessment backlog growing 960% over three years — are not remedied by environmental labs in California adopting and complying with the TNI standard. Thus, there is a seeming disconnect between the actual challenges facing ELAP and the proposed solution.

**Pursuing TNI is not the most cost effective set of regulatory measures to achieve the purpose of accreditation**

The Administrative Procedures Act requires that the baseline for the regulatory analysis shall be the most cost-effective set of regulatory measures that are equally effective in achieving the purpose of the regulation. In this case, it would be difficult to meet such a requirement given that the Supplemental Attachment failed to provide an adequate economic analysis of the alternatives, undervalued the cost of compliance by understating the actual compensation for personnel to maintain the TNI system, and because the analysis provides no assessment on the impact on “Very Small Labs,” the very entities that stand to absorb the bulk of the costs of this regulatory package.

The economic analysis estimates the cost of compliance per agency at $47,280 (accounting for variations in the number of personnel needed across lab sizes). However, CASA’s annual member salary survey reveals that our members’ median salary for entry level lab techs is $77,783; for a Lab Analyst I, $92,889; for a Lab Analyst II — the likely staff to ensure compliance with TNI — $100,015. Moreover, the State Water Board’s Division of Drinking Water’s own costs for complying with the TNI standard is estimated to include $365,000 in salary for three additional employees. The $47,280 figure is markedly low, and thus the economic analysis should be recalibrated using an accurate number. A more accurate and comprehensive analysis is needed in order for board members, stakeholders, and the public to determine which regulations are the most cost effective set of measures for achieving the purpose of laboratory accreditation while ensuring full compliance with the Environmental Laboratory Accreditation Act.

**Conclusion**

CASA appreciates the opportunity to comment on the proposed regulations for ELAP. As explained above, we have multiple concerns with this rulemaking package, including technical issues with the regulatory text and concerns about the adequacy of the supporting materials, including its cost of compliance models and estimates. We look forward to the workshop in January 2020 to discuss these issues further in preparation for adoption of the rulemaking package later in the year.

If there any questions about these requested changes, please do not hesitate to reach out directly to (916) 446-0388 or jvoskuhl@casaweb.org.

Thank you,

Jared Voskuhl
Legislative & Regulatory Analyst
Attachment
Technical Comments

Article 1
§ 64801.00
(e) Citation – means monetary fine assessed to a laboratory due to non-compliance with ELAP statutes and regulations.

Comment: This is a new item. ELAP now wants to have the authority to issue citations to laboratories for not complying with ELAP statues and regulations (please see § 64816.05 Issuance of a Citation at the end of this summary for the list of reasons for issuing a citation). Some labs believe ELAP is looking for ways to generate revenue. If a laboratory fails to comply with ELAP statues and regulations, ELAP should suspend or revoke its certification instead of issuing a monetary fine. By allowing laboratories to pay a fine to continue to operate even when data quality is in question, ELAP is placing revenue ahead of data quality. I was told by ELAP’s legal counsel that ELAP is allowed to issue citation under the Environmental Laboratory Accreditation Act Section 100880. However, Section 100880 does not specify the criteria by which ELAP may issue these citations.

(r) “Sophisticated Technology” means ...

Comment: We recommend that subsection (g) “Sophisticated Technology” either be removed or revised. If the purpose of this subsection is to establish the basis for accreditation fees, then it should be included in the rules and policies of the fee structure and not in the regulations. As written, there is some inconsistency in the types of technology that are included in this subsection. For example, it appears that ion chromatography (IC) has been removed; however, atomic absorption spectrophotometry is included. These technologies are similar in terms of complexity, so we are unsure why one is removed but not the other.

Article 2
§ 64802.00 Application Package.
(a)(1)(B) Details on the laboratory’s type, location, ownership, contact, information, and the regulatory agencies that laboratory reports to;

Comment: information regarding the regulatory agencies that the laboratory reports its data to should not be a factor during the accreditation process. Data can be generated by laboratories for many purposes – some are not for regulatory compliance. In addition, commercial labs do not have information regarding the regulatory agencies that the data will be reported to. Similar language can also be found in (b)(1)(B).

(a)(5) A copy of the most recently completed on-site assessment report from an Assessment Agency in accordance with Section 64802.20, including all findings and approved corrective action report and/or corrective action plan; and

Comment: clarification is needed on the approval authority for corrective actions. Should ELAP be the approval authority? Or should the third-party Assessment Agency be the approval authority for the on-site assessments conducted by them? Similar language can also be found in (b)(5).

§ 64802.05 Quality Systems.
(b)(2) The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs:

(A) Changes to Standard Operating Procedures
(B) Changes to laboratory equipment or instrumentation
(C) Changes to laboratory structures or physical arrangements; or
(D) Changes in the laboratory organization

Comment: similar language was included in the first draft regulations and we commented on this. Requiring laboratories to update the Quality Manual every time there are changes made to SOPs and laboratory equipment or instrumentation will generate a lot of busy work for large and complex laboratories because these activities can happen on a weekly basis. In addition, (A) is not a requirement per the 2016 TNI Standard. We recommend that (A) and (B) be removed from the list.

§ 64802.20 On-site Assessment.
(d) The laboratory is responsible for requesting an on-site assessment through ELAP or a third-party Assessment Agency.

Comment: when will this requirement become effective? By the effective date of the regulations or the date by which laboratories are required to adopt the 2016 TNI Standard (3 years from the effective date of the regulations)? It is important for ELAP to clarify the effective date of this requirement because third-party Assessment Agencies typically assess labs based on TNI requirements. During the three-year implementation period, which Assessment Agencies are qualified to evaluate labs?

(f) When an on-site assessment is performed by a third-party Assessment Agency contracted by ELAP to perform on-site assessments, a laboratory shall pay the third-party Assessment Agency its market rate for onsite assessments.

Comment: the language in this clause is confusing. In previous sections, ELAP requires labs with sophisticated technologies to be assessed by third-party Assessment Agencies; and that it is the responsibility of these labs to make arrangement with third-party Assessment Agencies for this work. Here, it is stated that these third-party Assessment Agencies are contracted by ELAP.

§ 64802.25 Accreditation Fees.
(a) A laboratory located in California shall pay the following fees …
(b) A laboratory physically located outside of California shall pay the following fees …

Comment: these sections do not address a scenario in which a laboratory is in California but has accreditation issued by a TNI accreditation body outside of California. For example, some California labs might want to be accredited by either Utah or Oregon, both of which are TNI States. In these cases, do these labs pay fees based on (a) or (b)?

Article 3
§ 64808.10 Reciprocity Accreditation.
(g) If a laboratory, accredited through reciprocity, is notified of suspension or revocation of its certificate by its primary accreditation body, then the laboratory shall: …

Comment: One of the requirements should be that the laboratory must notify its client of the change in status of its accreditation.

Article 5
§ 64812.00 Laboratory Personnel.
(h) A laboratory shall designate a Principle Analyst(s) to be a user of sophisticated laboratory instruments, defined in Section 64801.00 (r), or a supervisor of the users of sophisticated laboratory instruments. The Principle Analyst shall:

   1. Possess at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, natural and physical sciences, or environmental, sanitary, or chemical engineering; or
   2. Possess a certificate of completion in a course taught by the manufacturer of the sophisticated instrument being used or supervised by the Principle Analyst; and
   3. Have at least six months experience in the operation of sophisticated technology in the analysis of environmental samples prior to obtaining the position of Principle Analyst.

(j) Sophisticated technology in the laboratory shall be operated by either the Technical Manager, Principle Analyst, or other personnel designated by the Technical Manager.

Comment: All of these are confusing, and it is unclear why this Section is needed in the first place. If the goal is to establish a set of minimum qualifications for lab analysts, why do these only apply to analysts operating sophisticated technology and not all lab analysts? Section (j) 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. We recommend that this Section be removed or at least revised.

Article 7
§ 64816.05 Issuance of a Citation.
(a) Reasons for issuing a citation shall include:

   1. A laboratory fails to maintain a quality system in accordance with Section 64802.05
   2. A laboratory fails to comply with the analytical method(s) listed on the Laboratory’s certificate of accreditation;
   3. A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;
   4. A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;
   5. A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.20;
   6. A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.20;
   7. A laboratory fails to pay fees in accordance with Section 64802.25;
   8. A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15 (d)(e) and (f);
   9. A laboratory fails to employee staff that meet the personnel qualifications in accordance with Section 64812.00;
   10. A laboratory makes consistent errors in analyses or erroneous reporting;
   11. A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;
   12. A laboratory knowingly makes any false statement or representation in an application, record, or other document;
   13. A laboratory fails to notify ELAP of a change in ownership; and/or
   14. A laboratory fails to comply with any other provision of the regulations.

Comment: As mentioned earlier, this is a new subsection. This subsection will provide ELAP with the authority to issue citations (tied to monetary fines) to laboratories for not complying with ELAP statues and regulations.
Reasons (1) through (6) and (9) through (12) could have significant impact on data quality (especially #10). It is inconsistent and not a good idea to allow labs with these deficiencies to continue to generate data by simply paying a fine. Either the laboratory meets a certain quality standard specified by ELAP or it should not be allowed to generate data at all. We recommend that this subsection be removed or revised.