CALIFORNIA ASSOCIATION of SANITATION AGENCIES

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September 6, 2017

Submitted via electronic mail *elapca_comments@waterboards.ca.gov*

Christine Sotelo
State Water Resources Control Board
P.O. Box 100
Sacramento, CA 95812-0100

RE: CASA Comments on ELAP Preliminary Draft Regulations

Dear Ms. Sotelo:

The California Association of Sanitation Agencies (CASA) appreciates the opportunity to comment on ELAP's Preliminary Draft Regulations. For 60 years, CASA has been the leading voice for public wastewater agencies on regulatory, legislative and legal issues. We are an association of local agencies, engaged in advancing the recycling of wastewater into usable water, generation of renewable energy, and other valuable resources. Through these efforts we help create a clean and sustainable environment for Californians.

CASA currently holds a seat on the Environmental Lab Technical Advisory Committee (ELTAC) and is actively participating in the ELAP process through our stakeholder representative, Huy Do from the Sanitation Districts of Los Angeles County. We also represent municipal wastewater laboratories both large and small throughout the state, and share members with a number of other associations that have been actively involved in ELAP activities over the past two years.

Detailed requests and recommendations on specific provisions within the proposed regulations are included in an attachment to these comments. However, CASA has more high-level concerns about the overall direction of the ELAP process that should be addressed before delving into the more detailed aspects of the proposed regulations. Most notably, we continue to have significant concerns regarding how the proposed regulations and adoption of the slightly modified TNI Standard will impact small wastewater laboratories in the state. There is a real risk of small lab closures, and even for those entities that could adjust to the new regime, it will require significant financial investment and resources to meet these new requirements. We are also concerned that the timeline and overall scope of the proposed changes to the ELAP program are overly-ambitious and infeasible given resource constraints. There has been no corresponding demonstration that this suite of changes will improve the quality of data coming out of our municipal labs.

Moreover, there is considerable confusion and ambiguity with regard to how the new program will tie into a new ELAP fee structure, and it appears the two processes are proceeding on somewhat independent tracks. Because decisions made in the regulatory process will have a direct and substantial impact on the validity of the fee structure being developed, it is important that these two processes be more closely coordinated, and that regulatory

decisions are made with fee implications in mind. Below are some of the more significant issues that CASA has identified with the proposed regulations.

1. ELAP's Approach to Processing Lab Certifications Appears (or is) Unworkable

CASA is concerned that ELAP does not have sufficient staff resources to achieve the ambitious schedule and approach that is being proposed, particularly as it relates to processing of certifications. There are currently more than 650 laboratories in the state of California, and ELAP anticipates processing certifications for all of these labs, simultaneously, each year. Specifically, the proposed regulations state that beginning September 1, 2020 all application packages shall be due 90 days prior to September 1, of each year. Setting one due date for all application packages for all laboratories in California will require a substantial amount of resources from ELAP to process them in a timely manner, which appears infeasible under current conditions. Thus, we suggest that ELAP continue to process laboratory certifications on a rolling or staggered basis, making it more practical and manageable.

In addition, there is no clear guidance or specific regulatory language covering what would occur if ELAP is unable to process the certifications in a timely matter. At a number of the workshops, staff has stated that some form of interim certification would be given, but this does not provide sufficient assurances for our municipal wastewater laboratories. This issue needs to be expressly dealt with in the proposed regulations. Finally, based on discussions at the recent workshops, it seems as though much of the certification process will be reliant on an online system that is not fully developed or implemented. It is not advisable to establish regulations for lab certification based on the assumption that an undeveloped technology system will be in place and functional sometime in the future.

2. ELAP's Approach to On-Site Assessments is Unclear, Could Treat Large and Small Labs Disparately, and is Not Adequately Reflected in the Fee Structure Development

It is not clear from the proposed regulations what the process will be for on-site assessments (OSAs), who will be responsible for the cost of the OSAs, how those costs will be assessed and distributed, and what role third-party auditors (TPAs) might play in the process. According to information gathered at the workshops, the proposed approach to OSAs appears impose the financial and perhaps contracting burden will be placed on the labs themselves. We have also heard that ELAP may pursue a hybrid approach, whereby smaller or more basic labs could be assessed and audited by ELAP staff (without additional fees) while larger, more complex labs could be audited and assessed by a TPA. This approach is preferable, though it may be beneficial for ELAP to be responsible for contracting with the TPAs instead of having each lab do so on an individual basis. Another option would be for ELAP to establish a list of "approved TPAs" and a fee structure that these TPAs will adhere to for auditing services. In either case, ELAP's approach to OSAs needs significantly more clarity moving forward.

Whatever approach is ultimately decided upon, it is clear that ELAP has not considered the cost and fee implications of these various approaches to OSAs and the role of TPAs. The financial burdens on both small and large labs could change dramatically depending on their level or responsibility for OSAs or the cost of procuring a TPA. That reality is not reflected in

the current fee proposals being circulated. All of these elements must come together at the same time or else the fee model will be dramatically skewed by the changes in approach embodied in the regulations.

3. ELAP's "Auxiliary" Lab Category is Confusing and Not Adequately Reflected in the Fee Structure Development

The proposed regulations contain three lab categories, one of which is the "auxiliary lab." While this designation could be appropriate and useful in some circumstances, as currently defined it is confusing and could be problematic without further clarification. More specifically, most public agencies have a lab on site at their treatment plant(s) for capacity and efficiency purposes where samples are collected and analyzed at the facility. The collection and analysis taking place at the auxiliary facility may not satisfy the definition found in section 64810.05, subsection (4), which requires that an auxiliary lab "[r]eceives samples only from, and reports raw analytical data only to, the primary laboratory for its generation of the final report." In order to satisfy this definition, a sample would need to travel to the main lab and then back to the auxiliary lab, negating the whole purpose of having that remote lab in the first place. This section requires modification in order to be workable.

The designation of a number of labs as "auxiliary" could have impacts on the proposed fee structure as well. The assumption is that auxiliary labs would not have an ELAP certificate and therefore would not have to pay fees as a satellite of the main lab. While this could make sense in some cases, it is not clear that ELAP determined how many labs might be considered auxiliary going forward, and therefore where those revenue impacts will be distributed among the other lab fee payers. Again, it is clear that ELAP has not considered the cost and fee implications of how its definition of an" auxiliary" lab could affect fees and revenues for the program. All of these elements must come together at the same time or the model built will be dramatically skewed by the changes in approach embodied in the regulations.

4. Additional Issues for Consideration

CASA has identified two additional issues for clarification. First, there is some confusion related to the use of the terms "technical manager" and "laboratory director" as part of the new proposed regulations. This may simply be an adjustment to nomenclature, but. currently every ELAP accredited laboratory in California has a "Laboratory Director." In this draft regulation, it appears that ELAP intends to replace the term "Laboratory Director" with "Technical Manager" but instead of using the definition listed in the 2016 TNI Standard, retain the definition of a "Laboratory Director" in place. We have received more questions about this item than any other item in the draft regulation; therefore, we would like to recommend that ELAP keeps the term "Laboratory Director" to avoid confusion.

Second, the proposed regulations require proficiency testing 180 days (6 months) in advance of the certification's expiration date. Essentially, ELAP is requiring laboratories to complete all of the proficiency testing requirements before March of each year. It is not clear why this is the case or what benefit is derived, particularly if as has been asserted the program will

continue to only require one proficiency testing sample per year. This poses a huge challenge for the laboratory community, especially for large laboratories that are accredited for hundreds of analytes. It is more reasonable if ELAP allows laboratories to complete all PT's prior to the application submittal deadline.

In addition to these broader issues, CASA appreciates your review of the more specific technical comments to the regulations attached hereto.

Finally, many of CASA's members are members of other wastewater associations, including the California Water Environment Association (CWEA), Bay Area Clean Water Agencies (BACWA) Southern California Alliance of POTWs (SCAP), and Central Valley Clean Water Association (CVCWA). CASA also supports the comments of our fellow associations, particularly on issues that may not have been raised in our own comments.

Thank you for your consideration of our comments and we look forward to working with you on future refinements to the proposed regulations and the ELAP program as a whole.

Sincerely,

Adam D. Link
Director of Government Affairs

Article 1

Page 4, (d) "California Analyte" means a substance, organism, physical parameter, property, or chemical constituent(s) regulated in California.

Comment: CASA recommends that this term be changed to "California-Specific Analyte." Also, since this definition is only limited to constituents that are being regulated in California, how will ELAP treat constituents that are not currently regulated, but for which agencies are required to monitor and report as per NPDES permit's requirements? Would the term "California Analyte" be applicable to these constituents as well? Clarification is needed on this point.

Page 6, (g) "TNI" means the National Environmental Laboratory Accreditation Conference Institute.

Comment: TNI means The NELAC Institute. "NELAC" is not an acronym in this case – it is a contrived word. Consider clarifying as part of definitions.

Article 2

Page 9, 64802.05 (d) If an application for renewal accreditation does not meet the requirements of (a), within 30 days of receipt by the State Board, the laboratory will be notified. Any noted deviation shall be corrected and the corrected application returned to the State Board within 15 days from the date of the State Board's notice or the application shall be considered null and void.

Comment: Depending on the severity of the deviation, 15 days might not be a sufficient amount of time for a laboratory to correct the deviation. For example, if a laboratory is notified that a Performance Testing (PT) sample needs to be repeated or correct, it will take more than 15 days to order a replacement PT, analyze it, receive notification from the PT provider that the result is acceptable, and re-submit the application package to ELAP. Since the State Board is allowed 30 days to notify laboratories of any noted deviation, CASA recommends that laboratories are also allowed 30 days to respond to the notification.

Page 9, 64802.05 (f) Beginning September 1, 2020 all application packages shall be due 90 days prior to September 1, of each year.

Comment: Setting one due date for all application packages for the approximately700 laboratories in California will require a substantial amount of resources from ELAP to process them in a timely manner. It is doubtful that ELAP will be able to achieve this. CASA recommends that ELAP instead process applications on a rolling or staggered basis, as is current practice.
Page 9, 64802.10 (a) To obtain accreditation, a laboratory shall comply with the management and technical requirements applicable to their operations in accordance with 2016 TNI Standard Volume 1, Module 2-7, with the following exceptions:

(1) Volume 1, Module 2, Section 4.1.7.2 (f) – Technical Manager Requirements.

(2) Volume 1, Module 2, Section 5.2.6 – Additional Personnel Requirements.

Comment: Volume 1, Module 2, Section 5.2.6.2- Technical Manager Qualification Exceptions should be included in Section 64812.00 – Laboratory Personnel. This Subsection provides exceptions for small wastewater treatment facilities that routinely conduct simple analyses to satisfy regulatory requirements.

Page 10, 64802.10 (d) A laboratory that has not implemented the management and technical requirements in (a) prior to January 1, 2022 shall:

(1) Develop and implement a quality assurance program to ensure the reliability and validity of the analytical data produced by the laboratory…."

(A) The quality manual shall address all quality assurance and quality control practices …

(B) The technical manager shall review, and amend if necessary, the quality assurance program and quality manual at least annually. The technical manager shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.

(2) Submit quarterly quality assurance reports to the State Board documenting compliance with subsection (1), including corrective actions for any noted deviations.

(3) This subsection will become inoperative January 1, 2022.

Comment: As written, a laboratory that has not implemented the management and technical requirements as specified in the 2016 TNI Standard prior to January 1, 2022 will have to comply with this Section. Although ELAP's intention has been to encourage laboratories to adopt the 2016 TNI Standard earlier than required, the concern from the laboratory community has been that the requirements specified in this Section go beyond "encouraging" and might have been overarching. We strongly recommend that ELAP re-evaluate the inclusion of this Section in the regulations. However, if ELAP determines that this Section must remain in the regulations, more clarification is needed, including:

- Specify what should be included in the quarterly report
- Since corrective actions for any noted deviation must be included in the quarterly report, specify how these noted deviation were discovered (e.g. internal audits, ELAP on-site audits, or audits by third-party assessors).
- Specify any applicable enforcement action, if available, for laboratories that do not submit these quarterly reports.
- Clarify whether and how these quarterly reports be reviewed and evaluated by ELAP. These reports might require substantial efforts by the laboratories to generate and these labs want to know that their work product is being evaluated.
- Subsection (d.1.B) stated that it is the responsibility of the Technical Manager to review and amend the quality manual at least annually. This contradicts with the requirement stated in 2016 TNI Volume 1, Module 2, Section 4.2.8.2. Should this instead be the responsibility of the Quality Manager? If the assumption is that a laboratory might not have a Quality Manager prior to January 1, 2022, clarifications should be included for

laboratories that do have a designated Quality Manager but are not in compliant with the 2016 TNI Standard prior to January 1, 2022.

- We recommend that an Ethics and Data Integrity program be included as a requirement in this Section.

Page 11, 64802.20 (c) (1) If a laboratory does not achieve acceptable scores for a Unit of Accreditation, within 7 calendar days upon receipt of the "Not Acceptable" results from the Proficiency Testing provider a laboratory shall:

(A) Determine the root cause of the failure and take corrective action.

(i) The laboratory shall provide the root cause investigation and corrective action documentation to the State Board within 30 calendar days of a request from the State Board;

(B) Achieve acceptable scores in a subsequent Proficiency Testing study for the Unit of Accreditation and submit a Proficiency Testing report(s) to the State Board with acceptable scores for that Unit of Accreditation.

Comment: Depending on the nature of the deficiency, it might not be possible for a laboratory to "determine the root cause of the failure" and to "achieve acceptable scores in a subsequent Proficiency Testing study" within 7 calendar days. A laboratory can begin an investigation into the root cause of the failure within 7 days but it is unlikely that a laboratory can finalize the investigation and successfully analyze a PT within one week. A more reasonable time frame would be 30 days. Laboratories can be required to begin an investigation into the failure within 7 days upon receipt of the "Not Acceptable" results from the PT provider, but should have 30 days to finalize the investigation and to implement appropriate corrective actions. Also, it is unclear whether laboratories are required to submit a report documenting the investigation into the root cause of the failure and associated corrective actions to the State Board within 30 calendar days, or this is only a requirement upon request by the State Board. The current practice is to send these documents to ELAP once the investigation is finalized. If ELAP would like for this practice to continue, please state so in the regulations.

Page 12, 64802.20 (c) (2) (B) Cease all analytical work for regulatory purposes for that Unit of Accreditation effective upon receipt to the second "Not Acceptable" results from Proficiency Testing provider;

Comment: Quite often, it is difficult for a commercial laboratory to determine whether or not a sample is submitted for regulatory purposes. Perhaps ELAP should require a laboratory to notify all of its clients when a Unit of Accreditation is suspended. This way, the laboratory and its clients can work together on determining the type of samples that should not be analyzed during the suspension. The same language can be found on page 12, 64802.20. (d)(2)(B).

Page 12, 64802.20 (d) For renewals, 90 days prior to the State Board's receipt of the laboratory's renewal application, a laboratory shall achieve acceptable scores in a minimum of one Proficiency Testing study for each Unit of Accreditation for which a Proficiency Testing study exits.

Comment: As stated on page 9, 64802.05. (f), the due date for all application packages is 90 days prior to the certification's expiration date. When combined with the requirement above, the

regulations would require a laboratory to complete all of its Proficiency Testing (PT) requirements at least 180 days (6 months) prior to the certification's expiration date. Essentially, ELAP is requiring laboratories to complete all of the PT requirements before March of each year. This poses a huge challenge for the laboratory community, especially for large laboratories that are accredited for hundreds of analytes. It is more reasonable if ELAP allows laboratories to complete all PT's prior to the application submittal deadline.

Page 13, 64802.20 (g) For a California analyte for which there is no commercial Proficiency Testing study available that meets the requirements in Subsection (a), the State Board may require an alternative demonstration of proficiency.

Comment: Please provide clarification on what would constitute an "alternative demonstration of proficiency." Will guidance be provided by ELAP on a case-by-case basis?

Page 14, 64802.25 (c) (1) Within 30 days of receipt of the On-Site Assessment Report, the laboratory shall submit a Corrective Action Report that details how each identified deviation has been investigated and corrections initiated and completed; the laboratory will be notified within 30 days whether the Corrective Action Report demonstrates the corrections.

Comment: Some corrective actions might take longer than 30 days to complete. In these cases, would a corrective action plan submitted to the State Board within 30 days satisfy this requirement? If this is an acceptable course of action, a clear statement should be included in this Section to allow for this.

Article 3

Page 21, 64808.10 (e) A laboratory applying to add a Field(s) of Testing and/or Unit(s) of Accreditation shall:

Comment: Field of Testing should be changed to Field of Accreditation. Similar correction should be made for the following Sections: Page 22, 64808.10 (f); page 30, 64812.05 (c); and page 34, 64814.00 (h).

Page 21, 64808.10 (e) (4) Provide the State Board with information necessary for the State Board to determine whether the laboratory has the capability to conduct the analysis …

Comment: Currently, it is an ELAP requirement to submit documentation related to the Initial Demonstration of Capability (IDOC) when a laboratory seeks accreditation for new methods; however, the preliminary draft regulation does not require laboratories to submit such documentation. We would like to recommend that the current requirement be included in the regulations.

Article 4

Page 25, 64810.05 (a) (4) Receives samples only from, and reports raw analytical data only to, the primary laboratory for its generation of the final report;

Comment: We would like to understand the rationale behind this requirement. In many instances, it is more convenient and efficient to ship samples directly to the auxiliary laboratory upon sample collection than routing these samples through the primary laboratory. Putting a restriction on the route by which samples are transported might not be the best approach in this case. More context for this clarification is provided in the CASA comment letter.

Page 25, 64810.05 (a) (5) Is located such that transport of samples to the auxiliary laboratory does not affect the quality of the analytical results;

Comment: It is not clear how a lab would determine whether the quality of the analytical result has been affected. If retained, this should be re-phrased to read: "Is located such that transport of samples to the auxiliary laboratory does not prevent the laboratory from meeting all quality control requirements associated with the method."

Article 5

Page 28, 64812.00 (a) A laboratory shall designate a technical manager …

Comment: The term "Technical Manager" creates a lot of confusion in the laboratory community as this term is also used in the 2016 TNI Standard but has a very different definition there. Currently, every ELAP accredited laboratory in California has a "Laboratory Director." In this draft regulation, it appears that ELAP would like to replace the term "Laboratory Director" with "Technical Manager" but instead of using the definition listed in the 2016 TNI Standard, ELAP wants to keep the definition of a "Laboratory Director" in place. We have received more questions about this item than any other item in the draft regulation; therefore, we would like to recommend that ELAP keeps the term "Laboratory Director" to avoid confusion.

Page 28, 64812.00 (b) In lieu of meeting the requirements specified in Subsection (a), a technical manager employed by a laboratory owned by a public drinking water or wastewater utility shall have …

Comment: We recommend that Section 5.2.5.2 of the 2016 TNI – Technical Manager Qualification Exceptions be incorporated into this Section. This will provide small wastewater treatment facilities with the needed flexibility to perform simple analyses for compliance purposes.

Page 30, 64812.05 (b) A laboratory shall notify the State Board when there is a change in major instrumentation in accordance with Section 64814.00 (d).

Comment: If this requirement is implemented, ELAP will be flooded with notifications. A typical commercial lab might add or remove 10-20 sophisticated instruments on an annual basis. A change in method would definitely require ELAP's attention but a change in instrumentation should not require as much scrutiny. Furthermore, most methods listed in CRF 40 Part 136 are performance-based methods so a change of instrumentation is allowed as long as the laboratory can meet all of the method's performance criteria. We recommend that this requirement be removed from the regulations.

Article 6

Page 34, 64814.00 (d) When there is a change of sophisticated instrumentation the laboratory shall:

(1) Submit notification on forms prescribed by the State Board that includes, but is not limited to: …

(5) Achieve acceptable scores in a Proficiency Testing study for any Unit(s) of Accreditation affected by the change of instrumentation, where Proficiency Testing studies exits; and …

Comment: Again, we recommend that the requirement to submit notification to the State Board whenever there is a change of sophisticated instrumentation be removed from the regulation. Also, Proficiency Testing (PT) is method-dependent and not instrument-dependent. Laboratories should not be required to participate in a PT study with every change of instrumentation.

Page 34, 64814.00 (f) A laboratory shall report to its clients in accordance with the request for analysis, the full and complete results of all detected contaminants and pollutants from the analyses of the sample or components thereof.

Comment: It is not clear why this requirement would be limited only to "all detected contaminants and pollutants." All results, whether detected or non-detected, should be reported to the client in accordance with the request of analysis.

Page 34, 64814.00 (h) When a laboratory subcontracts work, the subcontracting laboratory shall comply with 2016 TNI Standard, Volume 1, Module 2, Section 4.5 and the subcontractor shall be accredited by the State Board in the Field(s) of Testing and/or Unit(s) of Accreditation for the tests to be performed.

Comment: After January 1, 2022, all laboratories accredited by the State Board have to adhere to the 2016 TNI Standard so this requirement does not need to be spelled out. This can be simplified as follows: "When a laboratory subcontracts work, the subcontracting laboratory shall be accredited by the State Board in the Unit(s) of Accreditation for the tests to be performed."