Coalition of Accredited Laboratories

September 7, 2017

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California State Water Resources Control Board
Environmental Laboratory Accreditation Program
1001 I Street
Sacramento, CA 95814

Subject: ELAP Regulations Development and Fees

The Coalition of Accredited Laboratories ("CAL") is an organization representing environmental laboratories in the State of California which are accredited by the Environmental Laboratory Accreditation Program ("ELAP"). CAL represents a wide range of laboratories, large and small, publicly and privately owned. We are grateful for the opportunity to submit these comments and look forward to working with the Division of Drinking Water ("DDW") and ELAP to improve laboratory accreditation.

On July 24, 2017, ELAP released preliminary draft regulations and requested public comments before the regulations were submitted to the Office of Administrative Law ("OAL") to begin the formal rule making process. CAL has submitted comments on this topic in the past and believes that they are still relevant. In particular, the members of CAL believe that the provisions in the preliminary draft regulations referencing the thousands of supplemental requirements found in The NELAC Institute ("TNI") are counter-productive and will create an unnecessary burden upon laboratories. We also believe that requiring the use of these supplemental requirements are inconsistent with the Administrative Procedures Act ("APA") by creating record keeping and reporting requirements that do nothing to improve laboratory data quality. We further believe, as documented in our previous letters on this topic, that such an effort is contrary to the legislative intent of the Environmental Laboratory Accreditation Act. CAL is principally concerned about the sheer number of requirements, rather than with any particular requirement. Even the smaller laboratories would need to add over 1250 additional requirements and for larger laboratories, the numbers would be much higher. Based on the data from the States of Florida and New York have shown, this enormous number of additional requirements impelled laboratories out of the accreditation programs after adoption of the TNI requirements, especially smaller laboratories and those in more remote locations.

With the release of the preliminary draft regulations, concerns regarding three topics are listed below.

1. **The Letter and Spirit of the APA are compromised with Adoption of ELAP Regulations as Written.**

   One of the proposed changes in the definitions section, Title 22. Social Security, Division 4. Environmental Health, Chapter 19. Certification of Environmental Laboratories, Article 1. Definitions, which states:

"§ 64801. Definitions. The relevant definitions listed in the 2016 TNI Standard, Volume 1 apply throughout this regulation except as otherwise defined in this section."

This seems contrary to both the letter and spirit of the APA. Under the APA (Government Code, Title 2, Division 3, Part 1, Chapter 3.5, Article 5 Public Participation: Procedure for Adoption of Regulations, § 11346.3 (a) (1) it is written that *"The proposed adoption, amendment, or repeal of a regulation shall be based on adequate information concerning the need for, and consequences of, proposed governmental action."*

Additionally, in § 11346.3. (e) it is written that *"Analyses conducted pursuant to this section are intended to provide agencies and the public with tools to determine whether the regulatory proposal is an efficient and effective means of implementing the policy decisions enacted in statute or by other provisions of law in the least burdensome manner. Regulatory impact analyses shall inform the agencies and the public of the economic consequences of regulatory choices, not reassess statutory policy. 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 a manner that ensures full compliance with the authorizing statute or other law being implemented or made specific by the proposed regulation."*

As currently written, the regulation incorporates almost the entirety of The NELAC Institute's ("TNI") 2016 Standard documents, which constitute 180 pages, thus becoming the overwhelming majority of the text of this proposed regulation. However the TNI documents are not publicly available. They can only be reviewed by purchasing the documents from TNI. Licensing requirements of TNI preclude parties that have purchased these documents from sharing them, and they are not available in public libraries or other similar venues. This means that parties wishing to review the proposed regulations and assess the impact of those regulations on themselves and others have to buy a copy of the regulations from a third party. The goal of the APA is to achieve the best possible regulations through means of openness and transparency and the requirement to purchase a copy of the regulations seems contrary to that objective. CAL believes that if the entirety of the TNI Volume 1 is to be used for regulatory compliance, it should to be available in its entirety for public comment and review without having to purchase it.

2. **Application, Fees, and On-Site Assessments.**

Under current regulations, the certificate of accreditation is active for 24 months. During that period each laboratory must undergo an On-Site Assessment ("OSA") before accreditation is awarded. This clearly establishes a requirement that OSAs occur every 24 months. ELAP's fees are supposed to support a staff who can regularly visit the approximately 660 laboratories accredited by ELAP. Since December 2015 ELAP's fees have approximately doubled but to date they have been unable to keep to even a 24 month OSA cycle. In the preliminary draft regulations, it appears that ELAP is proposing that the OSA cycle

be increased to 36 months, although the language is rather unclear in part because the certificate life remains at 24 months. The confusion arises from the fact that the OSA provisions of the proposed regulations are scattered about in several different sections and seem to contradict each other. For example, §64802.00 (a) (4) says that an OSA needs to be completed *"when required"* but does not explain when that might be. In §64802.05 (a)(3) says that an OSA must occur within a *"three year interval"* but does not explain when that interval begins or ends or how it is associated with the issuance or termination of a certificate of accreditation. However, if the draft regulations mean the OSA cycle to be 36 months, this seems to be a problem for two reasons. First, it seems inequitable for ELAP to raise fees to support staff for a 24 month OSA cycle and then reduce their workload to a 36 month cycle. If ELAP wants to reduce the frequency of OSAs, the regulations need to state that clearly and their fees need to decrease accordingly. Second, the entire rationale for requiring TNI provisions was to improve laboratory performance. Reducing the frequency of OSAs seems to accomplish the opposite effect.

3. **Fields of Accreditation (FOA) and Units of Accreditation (UOA).**

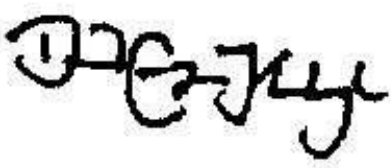
Preliminary draft ELAP regulations §64802.15 states that FOAs and UOA will not be defined in statute or regulation but only by listing them on their website. The stated goal is to keep the list of methods and analytes regulated current with the needs of the various regulatory agencies requiring accreditation. While that goal is certainly desirable, the method seems unsound. This allows ELAP to change FOAs and UOAs without any due process or following the APA. ELAP can add or subtract methods, analytes, and FOAs at any time. Fees are tied to the FOAs and UOAs so fees can change whenever webpage is changed. For example, inorganic tests for Safe Drinking Water Act compliance monitoring are grouped into FOA 2 / 102. Included in this FOA are methods for inorganic chemicals by Ion Chromatography ("IC") but there are many other methods as well. ELAP could, with a few keystrokes, remove IC from this FOA and create an entirely new FOA. Fees for laboratories with this FOA could increase significantly. FOAs and UOA can impact other parts of accreditation. It is a very bad idea for them to be changed on the fly without due process. It is also of questionable legal basis, it is hard to see how FOAs and UOAs found on webpage and nowhere else can be held up as legally defensible.

ELAP is currently struggling to do their job in a consistent and timely fashion as evidenced in the number of laboratories which have not had an OSA. We certainly agree that the current regulations are badly out of date and need to be overhauled but the current proposal only makes matters worse rather than better. It will require a great deal more work for ELAP staff, for the community of accredited laboratories, while providing less protection to public health, instead of more. Effective regulations can be developed which will not overly burden the laboratory community and will create a more efficient accreditation program.

We recommend that the State Board allow ELAP to take its existing program and budget, develop better regulations, and make that work before considering taking on vastly more complex efforts that will cost the laboratory community a great deal of money while providing no benefit to public

health, protection to the environment, or no sustained improvement to the quality of data being produced by accredited laboratories in California.

We thank you for your attention.



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Concurrences:

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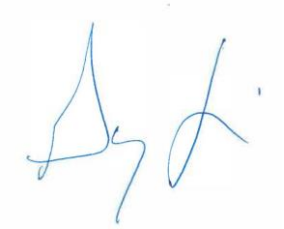

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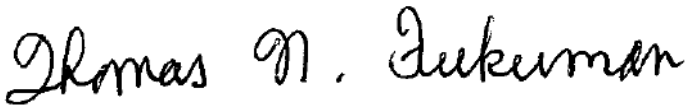

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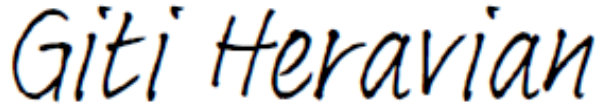

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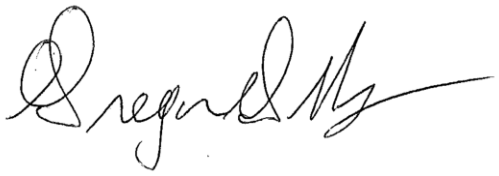

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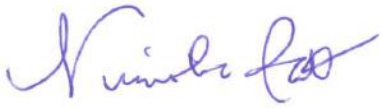

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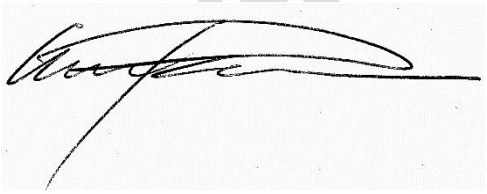

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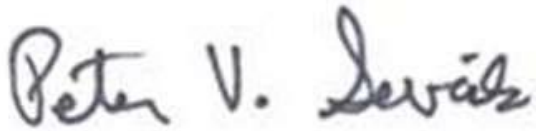

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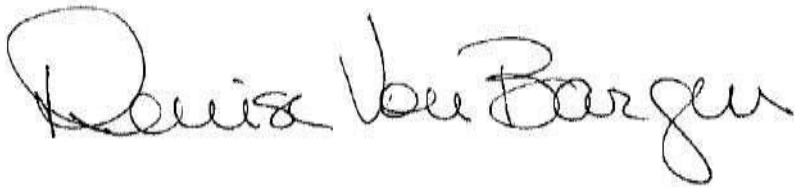

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