



PASADENA WATER AND POWER

October 19, 2016

Felicia Marcus, Chair Frances Spivy-Weber, Vice Chair Tam M. Doduc Steven Moore Dorene D'Adamo 10-17-16 SWRCB Clerk

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

Subject: ELAP Regulations Development/Laboratory Standard

On September 6, 2016 the State Board Water Resources Control Board (State Board) gave notice that they would be holding a Workshop on October 6, 2016 on the proposed changes to the laboratory accreditation regulations. The focus of the proposed changes is the Environmental Laboratory Accreditation Program's (ELAP) proposal to use Volume 1 of The NELAC Institute's (TNI) 2016 documents as requirement for laboratory accreditation. Pasadena Water & Power and the undersigned laboratories would like to submit the following comments on that proposal.

1) **General Policy**: California has more accredited environmental laboratories than any other state. This is a huge and important resource for the people of California for the protection of human health and the environment, which should be encouraged to grow. Laboratories accredited by ELAP with only one or two full time staff members are very common and most have five or fewer. This allows many smaller and more remote facilities to be able to have their own laboratory out on the front line. We believe that the State Board should, as a matter of policy, encourage the existence and expansion of environmental laboratories in general and those associated with utilities in smaller and more remote locations in particular.

The proposal to require all laboratories to comply with TNI has the effect discouraging the accreditation and even the existence of these laboratories.

2) Health & Safety Code Sections 100825-100920: When the State Legislature adopted the Environmental Laboratory Accreditation Act (ELAA) it created two options for accreditation, laboratories may be compliant with either the National Environmental Laboratory Accreditation Council (NELAC) or with California's own requirements. "100829. The State Water Resources Control Board **may** do all of the following related to accrediting environmental laboratories in the state:

- (a) Offer **both** state accreditation and NELAP accreditation, which shall be considered equivalent for regulatory activities covered by this article.
- (b) Adopt regulations to establish the accreditation procedures for **both** types of accreditation." (emphasis added).

The California legislature did not authorize ELAP to only offer one type of accreditation; it authorized ELAP to offer **both** types of accreditation. In proposing this regulation, ELAP is exceeding the authority granted it by the state legislature.

The proposed regulations are contrary to the legislative intent of the ELAA as well as the explicit language in the statute.

3) Administrative Procedures Act: The proposal to require the use of TNI as a condition of accreditation conflicts with the Administrative Procedures Act (APA).

"11346.3. (a) A state agency proposing to adopt, amend, or repeal any administrative regulation shall assess the potential for adverse economic impact on California business enterprises and individuals, avoiding the imposition of unnecessary or unreasonable regulations or reporting, recordkeeping, or compliance requirements. For purposes of this subdivision, assessing the potential for adverse economic impact shall require agencies, when proposing to adopt, amend, or repeal a regulation, to adhere to the following requirements, to the extent that these requirements do not conflict with other state or federal laws..."

TNI is nearly 100% "reporting, recordkeeping...requirements". The TNI requirements are not, for the most part, a set of technical requirements. It does not change how laboratories actually perform analytical tests on water or soil. The technical requirements are specified in regulation, 40 CFR 141 for compliance testing for the Safe Drinking Water Act, 40 CFR 136 for compliance testing for the Clean Water Act, and Title 22 of the California Code of Regulations for TSCA/RCRA/CERCLA. TNI is almost entirely a set of management requirements, not laboratory requirements. It creates requirements for writing of policies, establishment of procedures, and keeping of records of what a laboratory does.

The TNI requirements are entirely unnecessary because almost every state has some sort of environmental laboratory accreditation program, and the vast majority do not use the TNI requirements, and they run effective programs. Even among those states that use some variation of TNI (either the 2003 or 2009 versions, none currently uses the proposed 2016 version), in most cases not all laboratories are required to use it. In some states TNI is optional; it is up to the lab to decide if they want to use it. In some states only fee for service laboratories

are required to be TNI compliant, other laboratories are not. So clearly these TNI requirements are not necessary.

The TNI requirements are also clearly unreasonable. In the year 2000, the states of California, Florida, and New York all became TNI compliant. California made those requirements optional for laboratories, those that wanted to use it could, but 90% of laboratories did not. In Florida and New York all laboratories were required to be TNI compliant. In the intervening years a significant number of laboratories dropped their accreditation in those two states while in California the number of accredited laboratories increased (these changes are documented extensively in a whitepaper included as Attachment A). The net effect of implementing TNI in these states was to drive smaller laboratories, both public and private, out of the accreditation program.

The proposed regulatory approach of requiring TNI requirements is thus contrary to the letter and spirit of the APA.

4) Quantity of Requirements: The principal difficulty with the TNI requirements is not that any individual provision is too harsh or severe by itself. For example in Volume 1, Module 2, Section 4.6 covers "Purchasing Services and Supplies". Paragraph 4.6.1 requires that each laboratory have written policies and procedures for selecting and purchasing services and supplies. Sub-Paragraph 4.6.2 requires that requirements be established for services and supplies, and records that all services and supplies meet those requirements. Paragraph 4.6.3 requires that laboratories retain documents, and that they be reviewed for technical content before they are released. Paragraph 4.6.4 requires that laboratories evaluate suppliers of services and supplies, and keep records of those evaluations. There are perhaps eight different requirements in these four paragraphs. Ignoring whether any of these requirements serves the interests of the people of California to help protect human health and the environment they do require a significant amount of labor on the laboratory staff. By itself, this one section with these eight individual requirements in four paragraphs is certainly not an infeasible burden. However, Volume 1 of the TNI documents has seven Modules, 47 Sections, 130 Paragraphs (and numerous Sub-Paragraphs) with over 1,000 separate requirements. Of course not all laboratories will have to comply with each and every one of these requirements, but even the smallest laboratories will have to comply with a few hundred. Nearly half of all laboratories accredited by ELAP have no more than two employees and three quarters have five or fewer.

The cumulative effect of adding hundreds of requirements on to laboratories with only one or two staff members will be fatal to many laboratories' ability to remain accredited as it was in both Florida and New York.

5) Unnecessary Requirements: California has been accrediting drinking water and wastewater laboratories since 1952, most of that time it did so rather successfully. At no time in those more than 60 years did it require laboratories to document how, and from whom they purchased supplies. As noted above, the vast majority of laboratories accredited in the United States for drinking water and wastewater do not have to comply with these sorts of requirements to

document their purchasing practices, and they give every appearance of performing adequately. Aside from nearly three generations of experience accrediting laboratories without examining their shopping habits, it is intuitively obvious that the ability of laboratories to accurately and precisely analyze samples for regulatory compliance purposes is not dependent upon how many documents they retain from their purchases of supplies and services.

These requirements provide no benefit to the laboratory, the regulatory agencies receiving the laboratory results generated by the laboratory, nor ELAP itself, they are completely unnecessary.

6) Standardless Requirements: Part of the difficulty in implementing TNI is that most of the requirements do not have clear standards; they are "standardless" in a word. By way of analogy, if someone wants to ride the Matterhorn at Disneyland, there are two requirements, to have a ticket and to be 117 cm tall. Each requirement has a clear standard that can be applied, an individual has a ticket or they do not, an individual is 117 cm tall or is not. Next to the entrance to the queue for the Matterhorn there is a scale where a guest of the park can stand and determine if he or she is or is not 117 cm tall. Anyone can look and see if they meet this requirement; the standard is clear and objective. In contrast, the vast majority of requirements in the TNI documents do not have similar standards. To illustrate here is one requirement from Paragraph 4.6.2 which says:

"These services and supplies used shall comply with specified requirements."

The question that this raises is this; which specified requirements are the supplies and services to comply with? Nowhere in all of Section 4.6 are there any requirements described which might apply to the laboratory supplies and services. It would seem that each laboratory is free to set whatever "specific requirements" that they wish. How is an on-site assessor from ELAP to assess a laboratory for compliance with this requirement? How is a laboratory to implement such a requirement? What is an acceptable set of requirements for supplies and services and what is not? If one of ELAP's assessors has one opinion and a laboratory director has another, what is the basis for resolving the dispute? If any specific requirement is acceptable, what is the point of having the requirement at all?

One of the reasons that the requirement in the TNI document are unnecessary and provide no benefit is that they lack any clear and objective standards.

7) Vague, Ambiguous, and Subjective Requirements: ELAP has been the subject of considerable criticism for a very long time because of their on-site assessment practices. Different on-site assessors would apply different standards to different laboratories for the same test methods. The same on-site assessor might hold different laboratories to different standard for the same test methods. Different on-site assessors held the same laboratory to different standards for the same test methods. Inconsistency between on-site assessors has been a very serious problem for 20 years. This was a problem even though the technical standards relatively clear

and objective. The introduction of the TNI documents as an accreditation requirement simply multiply and magnify this historical problem. The wording of the TNI requirements is typically very vague and ambiguous. For example, Paragraph 4.6.3 has a sentence that says:

"These purchasing documents shall be reviewed and approved for technical content prior to release."

This is supposed to be a standard for laboratory accreditation. An on-site assessor is expected to determine if a laboratory is qualified to be accredited based on whether the laboratory staff is implementing this requirement. However, it is quite unclear what it is that the laboratory is supposed to be doing in this case, and how an assessor is to determine if they are doing it. Nowhere is it explained what "released" means in this context or what technical content of purchasing documents means. It is all very unclear, the language is vague and ambiguous which creates an environment where the subjectivity of assessors and laboratory staff are given maximum range to operate.

<u>Given ELAP's long history of difficulty with inconsistency between assessors and laboratories,</u> this sort of language will only offer greater opportunities for this sort of problem.

8) Costs: Requiring laboratories to be compliant with TNI Volume 1 will produce enormous labor costs upon the laboratory community, as it did in both Florida and New York. However, it is not just a drain upon the resources of laboratories, but also upon the resources of ELAP. At the June 2016 meeting of the Environmental Laboratory Technical Advisory Committee (ELTAC) two laboratories from other states, Illinois and Texas, gave presentations on how they became TNI compliant (this was voluntary as neither state requires wastewater laboratories to be accredited at all). Both laboratories had about five employees and both had on-site assessments by accreditation staff that lasted around four days [1]. ELAP sponsored two seminars in April of 2016 where a professional third party TNI on-site assessor gave a presentation on how Module 2 of the 2009 TNI documents would be applied. He stated that just for Module 2, one entire day was needed. Currently, in California, a laboratory with four staff members would have an on-site assessment lasting just one day.

So to implement TNI would require a great deal more labor time from both ELAP and the laboratories.

9) **Benefits**: In the Notice of Public Workshop of September 6, it is noted that "...ELAP's current regulations are inadequate..." which no one would disagree with. However, what has not been publically identified in any document or statement is what precisely is inadequate about the existing regulations. What has been missing to date is a "gap analysis" which identifies what ELAP needs in an accreditation standard to perform its duties and what the current standard lacks. No one has so far identified what in the current regulations needs to be added or changed. As a result, it is not at all clear how adopting regulations that require all laboratories to use TNI actually addresses whatever deficiencies may be present in existing regulations.

Indeed, a great many, if not all, of the requirements found in TNI are unnecessary and unreasonable, it seems that irrespective of what the exact failings of current regulations are, TNI does not appear to be the solution.

This being the case, adopting TNI requirements for all laboratories does not actually solve any inadequacies in existing regulation and as a result there are no identifiable benefits to adopting TNI Volume 1 as part of ELAP's accreditation standard.

10) **Alternative**: The APA requires any state agency writing regulations to consider alternatives. Section 11346.2(4)(A) states:

"(A) A description of reasonable alternatives to the regulation and the agency's reasons for rejecting those alternatives. Reasonable alternatives to be considered include, but are not limited to, alternatives that are proposed as less burdensome and equally effective in achieving the purposes 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. In the case of a regulation that would mandate the use of specific technologies or equipment or prescribe specific actions or procedures, the imposition of performance standards shall be considered as an alternative. (B) A description of reasonable alternatives to the regulation that would lessen any adverse impact on small business and the agency's reasons for rejecting those alternatives."

Twenty years ago the state legislature created the Environmental Laboratory Technical Advisory Committee (ELTAC) to provide advice to ELAP on accreditation matters. ELTAC met three times over the summer of 2016 to consider the problem of ELAP's deficiencies in regulatory authority. In the end, ELTAC voted not to support using TNI as the basis for an accreditation. Instead a majority of ELTAC members voted in favor of an alternative approach, which identified the failings of current regulations and simply filling in the gaps with new regulations designed specifically for California regulatory agencies and laboratories and ELAP (see Attachment B). This proposal is all of 33 pages long versus 176 pages and has requirements with clear, unambiguous language with standards. In this letter only one Section from TNI was assessed, in Attachment C other Sections are assessed in the same way.

The APA requires ELAP to consider alternatives and ELTAC has provided such an alternative, one that would have all of the benefits that ELAP needs to fill the gap in their regulations which TNI does not provide while producing only a tiny fraction of the costs of TNI.

<u>ELAP needs to at least consider this alternative which the majority of ELTAC has supported and give it an equitable review.</u>

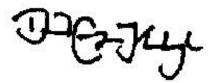
In conclusion, we believe it would be a very serious mistake to proceed with a regulation requiring all accredited laboratories to comply with the 2016 version of the TNI documents. Such a regulation would be contrary to the intent and letter of the Environmental Laboratory Accreditation Act, the

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Administrative Procedures Act, and would not provide ELAP with the regulatory support that it needs to perform its duties.

It would also place unneeded and unreasonable burdens upon laboratories and ELAP staff without providing any benefits. ELTAC's alternative is consistent with the ELAA, APA, and will provide ELAP with what it needs to do its job.

We thank you for your attention.



Raurahena

David Eugene Kimbrough, Ph.D. Water Quality Manager, Pasadena Water & Power

DEK/hs

Concurrences:

Shan Kwan, Assistant General Manager, Pasadena Water & Power (ELAP 3210)

Laura de Albidress, Water Quality Laboratory Supervisor, City of Fairfield, North Bay Regional Water Treatment Plant (ELAP# 1472)

Neal B. Allen, District Manager, Mt. View Sanitary District (ELAP# 2011)



Omar Arias-Montez, Operations Superintendent Sausalito – Marin City Sanitary District (ELAP #1110)



Dale Armstrong, Laboratory Supervisor, Goleta Water District (ELAP# 1374)



Samantha Bialorucki, Laboratory Manager, City of Palo Alto (ELAP # 1087).



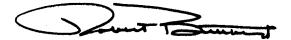
Steve Bigley, Director of Environmental Services, Coachella Valley Water District (ELAP# 2472)



Sara Burke, Plant Chemist, Oro Loma Sanitary District



Betty Burnett, General Manager, South Orange County Wastewater Authority (ELAP# 1280)



Robert Butterfield, President and Laboratory Director, A & L Western Agricultural Laboratories, Inc. (ELAP# 1657)

Cafeb B.

Mike Busse, CTPO / Utilities Superintendent, City of Grass Valley, (ELAP# 1762)

Brains

Bradley Davis, Laboratory Manager, Burbank Water Reclamation Plant (ELAP# 1819)

Mu Car

Allen Carlisle, CEO/General Manager Padre Dam MWD (ELAP# 1045)

LouisChion

Louis C. Chiourn, Laboratory Supervisor, City of Santa Barbara, PWD Water Resources Laboratories (ELAP# 1504)



Ron Coss, Environmental Laboratory and Ocean Monitoring Manager, Orange County Sanitation District (ELAP# 1601)

Lena Cox

Lena Cox, Laboratory Supervisor, Goleta Sanitary District (ELAP# 1374)

Stephen L. Clark, Vice President, Pacific EcoRisk (ELAP# 2085)

Erich Delmas, Laboratory Supervisor, City of Tracy, (ELAP # 1481)

Curtis B. Desilets

Curtis B. Desilets, Laboratory Director, Enviro-Chem, Inc

Gustavo A. Delgado, Ph.D., Chief Executive Officer, Forensic Analytical Laboratories, Inc. (ELAP# 1202)

Mary Erland

Mary Erland, Chemist, City of Lompoc, Water Division (ELAP# 1064)

Mary Lou Esparxa

Mary Lou Esparza, Laboratory Superintendent, Central Contra Costa Sanitary District (ELAP# 1397)

Anne Fairchild, Laboratory Manager, City of San Luis Obispo

Ane C Furchild

Jason Frink, Laboratory Supervisor, City of Vallejo, Water Department (ELAP# 1558)

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Donna Ferguson, Ph.D., Assistant Laboratory Director, Monterey County Health Department, Consolidated Chemistry Laboratory (ELAP# 1395)

Emilio Flores

Emilio Flores, Laboratory Supervisor, City of Yuba City Water/Wastewater Laboratory, ELAP# 1250

Scott MFrielland

Scott Fridlund, Laboratory Director, Dellavalle Laboratory, Inc.

Ikmas n. Zukuman

Thomas N. Fukuman, Manager of Analytical Services, Chem Pro Laboratory, Inc. (ELAP# 1265)

Scott Furnas

Scott Furnas, President, California Laboratory Services, (ELAP# 1233)

Rich Gossett

Rich Gossett, Director, Physis Laboratories (ELAP# 2769)



Heather Grove, Wastewater System Superintendent, City of Manteca WQCF (ELAP# 1098)

Stan No

Stan Gryczko, Assistant Public Works Director/Operations, City of Davis (ELAP# 2645)



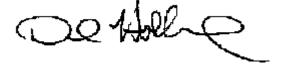
Richard Hansen, General Manager, Three Valleys Municipal Water District (ELAP# 1581)

Blair Hafner

Blair Hafner, Laboratory Director, Mammoth Community Water District (ELAP# 1453)

Giti Heravian

Giti Heravian, Laboratory Manager, Fairfield-Suisun Sewer District, (ELAP# 2067)



lorence B

David Holland, Laboratory Director, Monterey Bay Analytical Services (ELAP# 2385)

(ELAP# 1504)

Florence B. Jay, Laboratory Supervisor, Ventura Water (ELAP# 1193)

Daniel Jackson, Water Quality Supervisor, City of Benicia (ELAP# 1510, # 2655)

Julie Jeleti

Julie Jeleti, Laboratory Coordinator, South San Joaquin Irrigation District (ELAP# 2646)

Joan Kelly

Joan Kelly, Laboratory Director, City of Ukiah WWTP, (ELAP#)



Erin Kebbas, Water Quality Manager, City of Napa, (ELAP# 2413)



Bruce Keogh, Wastewater Division Manager, City of Morro Bay, (ELAP# 1530)



Jeff Koelewyn, Laboratory/Regulatory Affairs Supervisor, Castaic Lake Water Agency (ELAP# 2104)



Xiongbing Liang, Laboratory Supervisor, City of San Mateo WWTP (ELAP# 1151)

Hopken hinly

Stephen Linsley, Environmental Compliance Supervisor, West County Wastewater District



Justin Livesay, Laboratory Director, Antelope Valley-East Kern Water Agency (ELAP# 1460)

Istillend

Scott McClelland, Director of Water Quality, Sweetwater Authority (ELAP# 1412)

SM Mahn

Susan McMahon, Water Quality Supervisor, Casitas Municipal Water District, (ELAP# 1696)

Dregne My

Gregor G. Meyer, Public Works Director, City of Woodland, (ELAP# 2464)

Rod T. Miller

Rod Miller, Laboratory Director, Water Quality Division Laboratories, San Francisco Public Utilities Commission (ELAP # 1449, # 1721, # 1720, # 2207, # 2341, # 2335)



Jack Miyamoto, Chemist, City of Santa Monica (ELAP# 2975)



Dan Mount, Superintendent, Water Pollution Control, City of Millbrae (ELAP# 1219)



Tanya Mosier, former Wastewater Laboratory Coordinator, Nevada County Sanitation District (formerly ELAP# 2502)



Broderick Guy Moy, Laboratory Director, Union Sanitary Distrct (ELAP# 1324)



Guilda Neshvad, Laboratory Director, Positive Lab Service, (ELAP# 2534)



Nimisha Patel, Laboratory Director/Environmental Compliance Manager, Sewerage Agency of Southern Marin (ELAP# 1538)

Walter C Perse

Walter Pease, Director of Water Utilities, City of Pittsburg, (ELAP# 1479)

ange

Tony Pirondini, Water Quality Manager, City of Vacaville Utilities Department (ELAP# 1952)

Mary Powers

Terry Powers, Laboratory Director, South Tahoe Public Utility District (ELAP# 1569)

Janisty

Marc Oliver D. Quijano, Laboratory Manager, West Basin Water Quality Laboratory



Christina R. Ramirez, Laboratory Manager, UC Davis Waste Water Treatment Plant, (ELAP# 2343)



Pablo Ramudo, Laboratory Director/Water Quality Supervisor, North Marin Water District (ELAP# 1574)



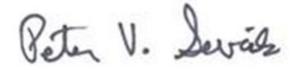
Cyrus Razmara Ph.D., CEO & Laboratory Director, American Environmental Testing Laboratory (ELAP# 1541)



Hector Ruiz, General Manager, Trabuco Canyon Water District



Mark W. Scandalis, Laboratory Director, City of Paso Robles



Peter V. Sevcik, PE, Director of Engineering and Operations, Nipomo Community Services District



Al Sexton, Laboratory Supervisor, City of Simi Valley WQCP (ELAP# 1337)

Men Simm

Ellen Simm, Water Agency Coordinator – Laboratory Services, Sonoma County Water Agency (ELAP# 2292 & 2293)

Anju Smizelsh.

Angie Smigelski, Environmental & Water Quality Lab Supervisor, City of Modesto (ELAP# 1362 and 2674)



Raji Subramanian, EU Compliance Administrator, City of Roseville (ELAP# 1709 and 2717)



Daniel T. Tafolla, Environmental Services Director, Vallejo Sanitation & Flood Control District (ELAP# 1957)



Tai Tseng, Operations Manager, Long Beach Water Department, (ELAP# 4206)



Miki Tsubota, Director of Public Works / City Engineer, City of Brentwood, (ELAP# 2577)



Tony Umphenour, Laboratory Director, Burbank Water and Power, (ELAP# 1464)



Pravani Vandeyar, Water Quality Superintendent, City of Sacramento Department of Utilities (ELAP#1508).



Marycarol Valenzuela, CEO, Performance Analytical Laboratories, Inc., (ELAP# 2960)

coon Val

Dan Verdon, Laboratory Director, EnviroMatrix Analytical, Inc. (ELAP# 2564)

Vasa Viplyt

Vasana Vipatapat, Laboratory Superintendent, City of Escondido, (ELAP# 1625)

Bob Wandw

Bob Wandro, Laboratory Director, Silicon Valley Clean Water (ELAP# 1688)

Von an W

Roger A. Westergard, Water Quality Laboratory Supervisor, City of Anaheim Public Utilities



Janet Williams-Harmon, Laboratory Director, Veolia - Rialto Water Services (ELAP# 1751)

Mott Chiller

Robert Wilson, Environmental Services Supervisor, City of Petaluma (ELAP# 1063)

Lejoung

Lee Yoo, Laboratory Director, Orange County Water District (ELAP# 1114)



Yanyang Xu, Laboratory Services Supervisor, Alameda County Water District (ELAP# 1524, 2768)

1. Zinti

Cindy Ziernicki, Senior Chemist, Helix Water District (ELAP# 1610)

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William Zolan, Supervising Chemist, Mel Leong Treatment Plant, San Francisco International Airport Commission

Attachments A, B, and C