

Coalition of Accredited Laboratories



May 1, 2017

Felicia Marcus, Chair
Steven Moore, Vice Chair
Tam Doduc
Dorene D'Adamo



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

Subject: ELAP Regulations Development and Fees

The Coalition of Accredited Laboratories (CAL) is an organization which represents environmental laboratories in the State of California which are accredited by the Environmental Laboratory Accreditation Program (ELAP). CAL represents laboratories of all sizes and types; from large commercial laboratories to small publically owned laboratories and every other type.

On September 6, 2016, the State 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 was ELAP's proposal to use Volume 1 of The NELAC Institute's (TNI) 2016 documents as requirement for laboratory accreditation. The TNI documents add an involved system of record keeping and reporting requirements but do very little to improve data quality – the fundamental basis for laboratory accreditation.

At that Workshop a very significant number of representatives from the community of laboratories accredited by ELAP were in attendance and overwhelmingly voiced their strong objections to this proposal. These representatives came both from individual laboratories as well as from trade organizations that represent agencies owning or using ELAP accredited laboratories. Additionally, a Coalition of Accredited Laboratories submitted joint comment letters identifying the basis for the very grave concerns that are shared by a great many in the ELAP accredited laboratory community. These concerns were both of a legal and practical nature. It was argued that the requirement for all laboratories to comply with the TNI record keeping and reporting requirements as a condition of accreditation was contrary to the intent of the legislature which left a clear written record (as documented in our letter of October 19, 2016, citing California Health & Safety Code sections 100825-100920) that it wanted two accreditation programs to be offered, only one of which would be TNI based. Further implementing such a requirement would produce an enormous and unnecessary economic burden upon the hundreds of laboratories, reducing the public health protection, while producing no benefits to the vast majority of parties.

While there were concerns about certain individual requirements, the principal concern was about the sheer number of requirements. Even the smallest laboratories would need to add over 1250 additional requirements and for larger laboratories, the numbers would be even higher. As the data from the States of Florida and New York showed, this enormous number of additional requirements drives laboratories out of the accreditation programs that adopt them. At the Workshop, Board Members indicated that ELAP staff would “whittle down” the TNI documents so as to make them more useful and less burdensome. The eventual product would be “TNI Lite”.

However, since that Workshop there have been a number of developments of considerable concern to many in the ELAP accredited laboratory community. The undersigned parties, while still believing firmly that the arguments offered at that October Workshop and in aforementioned letters remain valid, and this letter in no way alters that, however we feel the need to provide additional comments.

- 1) **TNI Plus:** Rather than whittling down the TNI documents as instructed to in the October workshop, ELAP has actually added on additional material. ELAP requested public comments on suggestions to reduce the size of the TNI requirements and in the very limited amount of time that was provided to do that, several hundred comments were submitted, including the recommended deletion of many requirements not pertaining to data quality. However, with the current proposal, ELAP is only recommending one deletion – a second set of PT analysis – and then just adding clarifying language to all the other requirements. Some proposed “modifications” were designed to be implemented later, while others had additional explanatory materials added. So effectively, ELAP actually added additional materials while removing very little.
- 2) **The Regulatory Status of Modifications to TNI:** Since October ELAP staff members have made confusing and contradictory statements about exactly how the TNI documents would be used. ELAP staff members have stated that they do not wish to alter the TNI documents in anyway yet simultaneously they wish to incorporate perhaps 58 modifications to the requirements. In public meetings and documents, they have suggested these modifications would be incorporated into a “guidance document” which ELAP could somehow attach to the TNI documents without actually adopting them as regulations. ELAP, of course, is a law enforcement body and can only enforce what is in law, i.e. statutes and regulations. Guidance documents are not law and not enforceable.
- 3) **The Regulatory Status of TNI documents:** The TNI documents are copyright protected and not publically available except through purchase. How would something like that be incorporated into the California Code of Regulation? For example, the Building Code is also developed by a third party (International Code Commission) just as the TNI documents are. California takes the ICC code and modifies it for its own purposes. It then incorporates the modified Building Code into Title 24 of the CCR through the normal rule making process. Anyone can then access and use Title 24. It does not seem that the TNI requirements can go through the same process. It is unclear how a copyright protected document which is not publically available can be used as a regulation. ELAP staff themselves seemed unclear based on public comments they have made.
- 4) **Fees:** Over the last 18 months ELAP has doubled its fees. At the December 2015 hearing, the

State Board adopted a resolution to increase ELAP's fees by 58%, the base/administrative fee increased from \$959 to \$1512 and the Field of Testing fee increased from \$432 to \$681. At the September 2016 hearing, the State Board adopted a resolution to increase ELAP's fee by an additional 25%. The base/administrative fee increased from \$1512 to \$1890 and the Field of Testing fee increased from \$681 to \$851. These fee increases were intended to make the current ELAP program entirely self-sustaining. That is a very substantial increase merely to maintain current operations.

- 5) **On-Site Assessments:** Under Title 22 of the California Code of Regulations a laboratory's certificate of accreditation expires after two years and ELAP cannot issue a new certificate until one of ELAP's laboratory assessors visits the laboratory and conducts an assessment. On-Site Assessments (OSA) have historically occurred approximately every two years. At two recent public events, ELAP staff have stated that they cannot conduct OSAs at all on a two year basis. The rationale was that they cannot hire, train, and retain a sufficient number of laboratory assessors. As a result, they are proposing to retain Third Part Assessors (TPAs). ELAP has proposed various models for doing this but the bottom line is this; ELAP, even after doubling the fees, cannot conduct even the minimum requirements of their current accreditation program. To retain TPAs would represent a very substantial increase in costs to laboratories. This could easily double the fees once more, again just to achieve the minimum operations of the current non-TNI based system. All of the recent fee increases have nothing to do with the implementation of TNI.

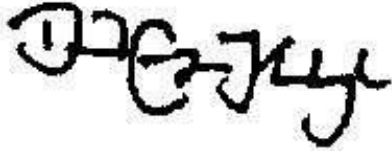
- 6) **Implementation of TNI:** The many hundreds, or even thousands in some cases, of additional TNI requirements that each laboratory must implement, represent extensive labor hours for the laboratory seeking accreditation. To adopt and implement TNI, a laboratory accreditation program must devote many extra labor hours. In April of 2016, ELAP organized two all day workshops on how TNI might be adopted. During these workshops, a full time professional TNI trained TPA described how much time he needed to conduct an on-site assessment using TNI criteria. He indicated that it would take at least eight (8) hours just to conduct an assessment of the Quality Management System (QMS - Volume 1, Module 2) which is the same for all laboratories, irrespective of size. This estimate of time was confirmed at the July meeting of the Environmental Laboratory Technical Advisory Committee (ELTAC). Two mid-sized waste water utility laboratories (four (4) to five (5) employees), one from Illinois and one from Texas, indicated their TNI OSAs were not less than three days in duration, which, of course, includes the QMS. Similar sized laboratories in California require less than eight hours for an entire OSA. Suffice it say, for ELAP to implement TNI, and accredit laboratories to TNI, it would require considerably more labor resources, which again would mean increased fees. That of course is on top of the fee increases already implemented and those required for TPAs independent of TNI.

Given the fact that ELAP is already struggling even now to maintain its statutory obligations and is unable to maintain their current accreditation program, it seems entirely unrealistic for ELAP to be able to implement a complex program of TPAs using TNI requirements. Furthermore, the excessive costs of such a system would drive up already elevated fees beyond what is reasonable or prudent.

SWRCB – ELAP Regulations Development and Fees May 1, 2017

We recommend that the State Board allow ELAP to take its existing program and budget and make that work before considering taking on vastly more complex efforts that will cost the laboratory community a great deal of money.

We thank you for your attention.

A handwritten signature in black ink, appearing to read "D. Kimbrough".

David Eugene Kimbrough, Ph.D. Chair, CAL

Concurrences:

A handwritten signature in blue ink, appearing to read "Laura de Albidress".

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

A handwritten signature in blue ink, appearing to read "Omar Arias-Montez".

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

A handwritten signature in blue ink, appearing to read "V. Astells".

Veronica Astells, Environmental Program Manager, Town of Windsor



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



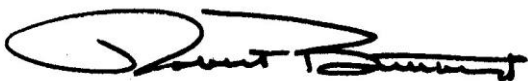
Samantha Bialorucki, Laboratory Manager, City of Palo Alto (ELAP # 1087).



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



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)

A handwritten signature in black ink, appearing to read "Mike Busse".

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

A handwritten signature in blue ink, appearing to read "Bradley Davis".

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

A handwritten signature in black ink, appearing to read "Sharon Campbell".

Sharon Campbell, Laboratory Director, WRF, City of Placerville,

A handwritten signature in blue ink, appearing to read "Allen Carlisle".

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

A handwritten signature in black ink, appearing to read "Sigourney Castel de Oro".

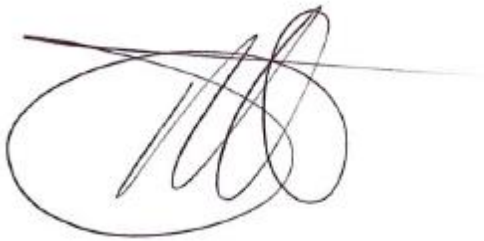
Sigourney Castel de Oro, Laboratory Director, American Water Services (ELAP# 2817)

A handwritten signature in blue ink that reads "Commodore Collins". The signature is written in a cursive style with a large initial 'C'.

Commodore Collins, Laboratory Supervisor, Valley Sanitary District, (ELAP# 1053)

A handwritten signature in black ink that reads "Ana Corti". The signature is written in a cursive style with a large initial 'A'.

Ana Corti, Water Quality Analyst/Laboratory Director, City of Pittsburg (ELAP# 1479)

A handwritten signature in black ink that reads "Martha Cordozo". The signature is written in a cursive style with a large initial 'M'.

Martha Cordozo, Water System Supervisor, City of Reedley, (ELAP# 1091)

A handwritten signature in black ink that reads "Ron Coss". The signature is written in a cursive style with a large initial 'R'.

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

A handwritten signature in black ink that reads "Lena Cox". The signature is written in a cursive style with a large initial 'L'.

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



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)



April Engen-Garza, Laboratory Technician, City of Hanford WWTP

Noel Enoki

Noel Enoki, ESD Laboratory Manager, City of San Jose (ELAP# 1313)

Mary Erland

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



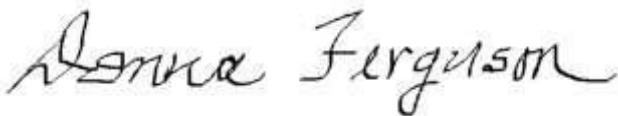
Gaylen Fair, Laboratory Supervisor, City of Santa Barbara, PWD Water Resources Laboratories (ELAP# 1504)



Anne Fairchild, Laboratory Manager, City of San Luis Obispo



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



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



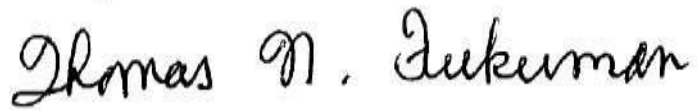
Emilio Flores, Laboratory Supervisor, City of Yuba City Water/Wastewater Laboratory, ELAP# 1250

Handwritten signature of Christopher Francis in blue ink.

Christopher Francis, Interim Regulatory Compliance Manager, Napa Sanitation District, ELAP# 2334

Handwritten signature of Scott M. Fridlund in black ink.

Scott Fridlund, Laboratory Director, Dellavalle Laboratory, Inc

Handwritten signature of Thomas N. Fukuman in black ink.

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

Handwritten signature of Scott Furnas in black ink.

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

Handwritten signature of Richard Gossett in black ink.

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

A handwritten signature in black ink, consisting of a large, stylized 'C' followed by a horizontal line.

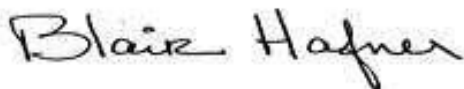
Charles Grace, General Manager, San Simeon Community Services District (ELAP#)

A handwritten signature in blue ink, reading 'Heather Grove' in a cursive style.

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

A handwritten signature in blue ink, reading 'Richard Hansen' in a cursive style.

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

A handwritten signature in black ink, reading 'Blair Hafner' in a cursive style.

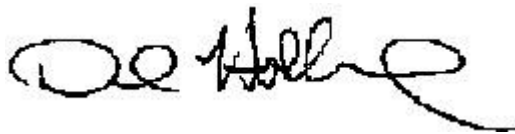
Blair Hafner, Laboratory Director, Mammoth Community Water District (ELAP# 1453)

A handwritten signature in black ink, appearing to read 'Jennifer', followed by a long horizontal flourish.

Jennifer Harrington, Environmental Services Director, Vallejo Sanitation and Flood Control District, (ELAP Cert #1957)

A handwritten signature in black ink that reads 'Giti Heravian'.

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

A handwritten signature in black ink that reads 'David Holland'.

David Holland, Laboratory Director, Monterey Bay Analytical Services (ELAP# 2385)
(ELAP# 1504)

A handwritten signature in blue ink that reads 'Florence B. Jay'.

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

A handwritten signature in black ink that reads 'Julie Jeleti'.

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



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



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



Erik Klinker, Assistant General Manager, Pasadena Water & Power (ELAP #1473)



Steve Jepsen, Executive Director, Southern California Alliance of Publically Owned Treatment Works



Jayne Joy, Director of Environmental and Regulatory Compliance, Eastern Municipal Water District, (ELAP# 1379)

A handwritten signature in cursive script that reads "Jeff Koelewyn".

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

A handwritten signature in cursive script that reads "Angie Koski".

Angie Koski, Laboratory Technician III, City of Healdsburg Water Reclamation Facility (ELAP# 2726)

A handwritten signature in cursive script that reads "Xiongbing Liang".

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

A handwritten signature in cursive script that reads "Stephen Linsley".

Stephen Linsley, Environmental Compliance Supervisor, West County Wastewater District

A handwritten signature in black ink, appearing to read "Justin Livesay". The signature is stylized with a large loop at the end.

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

A handwritten signature in black ink, appearing to read "Ty Maddux". The signature is written in a cursive style.

Ty Maddux, Water Quality Technician, Walnut Valley Water District (ELAP# 1460)

A handwritten signature in black ink, appearing to read "Susan McMahon". The signature is written in a cursive style.

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

A handwritten signature in black ink, appearing to read "Gregor G. Meyer". The signature is written in a cursive style.

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

A handwritten signature in blue ink, appearing to read "Rod T. Miller". The signature is written in a cursive style.

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)



Fanny Mui, Laboratory Analyst/Operator, South San Luis Obispo County Sanitation District (ELAP Cert # 1413)



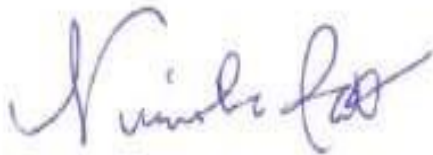
Guilda Neshvad, Laboratory Director, Positive Lab Service, (ELAP# 2534)



Salam Nael, Laboratory Supervisor, City of Redlands, (ELAP # 1513)



Ryan Peralta, Laboratory Coordinator. City of San Clemente, (ELAP# 1703)



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



Barbara Pierson, Laboratory Manger, City of Watsonville Utilities Department Laboratory, (ELAP Cert #1179)



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



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



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




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)

A handwritten signature in blue ink that reads "Victor Santa Cruz". The signature is written in a cursive style with a large, looping 'V'.

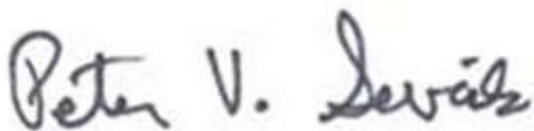
Victor Santa Cruz, Biologist, Inland Empire Utilities Agency (ELAP# 1808)

A handwritten signature in black ink that reads "Lori Sarti". The signature is written in a cursive style with a large, looping 'L'.

Lori Sarti, Water Quality Analyst, City of Antioch,

A handwritten signature in black ink that reads "Mark W. Scandalis". The signature is written in a cursive style with a large, looping 'M'.

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

A handwritten signature in black ink that reads "Peter V. Sevcik". The signature is written in a cursive style with a large, looping 'P'.

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

A handwritten signature in black ink that reads "Al Sexton". The signature is written in a cursive style with a large, looping 'A'.

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

A handwritten signature in blue ink that reads "Ellen Simm". The signature is fluid and cursive, with the first name being more prominent.

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

A handwritten signature in black ink that reads "Angie Smigelski". The signature is cursive and clearly legible.

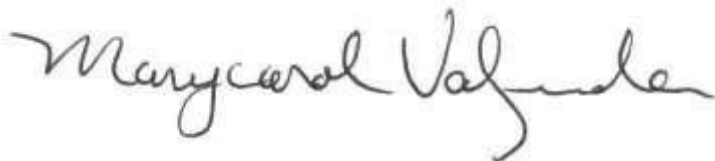
Angie Smigelski, Environmental & Water Quality Lab Supervisor, City of Modesto (ELAP# 1362 and 2674)

A handwritten signature in blue ink that reads "Tai Tseng". The signature is very stylized and cursive, with a large loop at the beginning.

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

A handwritten signature in blue ink that reads "Tony Umphenour". The signature is cursive and somewhat compact.

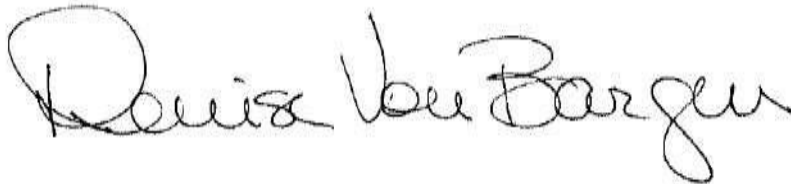
Tony Umphenour, Laboratory Director, Burbank Water and Power, (ELAP# 1464)

A handwritten signature in black ink that reads "Marycarol Valenzuela". The signature is cursive and clearly legible.

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

A handwritten signature in black ink, appearing to read "Dan Verdon".

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

A handwritten signature in black ink, appearing to read "Denise Von Barger".

Denise Von Barger, Laboratory Director, Ventura County Public Health Laboratory (ELAP# 1910)

A handwritten signature in black ink, appearing to read "Vasana Vipatapat".

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

A handwritten signature in blue ink, appearing to read "Bob Wandro".

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

A handwritten signature in black ink, appearing to read "Roger A. Westergard".

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

A handwritten signature in black ink, appearing to read 'J. Williams-Harmon', with a long horizontal flourish extending to the right.

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

A handwritten signature in black ink, appearing to read 'Robert Wilson', with a long horizontal flourish extending to the right.

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

A handwritten signature in black ink, appearing to read 'Lee Yoo', with a long horizontal flourish extending to the right.

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

A handwritten signature in blue ink, appearing to read 'C. Ziernicki', with a long horizontal flourish extending to the right.

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

A handwritten signature in black ink, appearing to read 'Bill Zolan', with a long horizontal flourish extending to the right.

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