

California Environmental Laboratory Accreditation Program

Environmental Laboratory
Technical Advisory Committee (ELTAC) Meeting

March 29, 2017



State Water Resources Control Board

Division of Drinking Water

NOTICE OF ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC) MEETING

March 29, 2017
10:00 a.m. – 4:00 p.m.
(or until completion of business)

Location 1	Location 2
California Environmental Protection Agency Building	Metropolitan Water District of Southern California – La Verne
1001 I Street, Conference Room 2540	700 Moreno Avenue, Weymouth Room
Sacramento, CA 95814	La Verne, CA 91750

The Environmental Laboratory Accreditation Program (ELAP) will host a meeting of its technical advisory committee, as noted above. The notice and agenda for this meeting and others can be found at www.waterboards.ca.gov/elap. For further information regarding this agenda, see below or contact ELAP at elapca@waterboards.ca.gov or (916) 323-3431.

This meeting is available via webcast at <https://video.calepa.ca.gov/>.

AGENDA

ITEM #1 - Call to Order/Roll Call

ITEM #2 - Public Comments on Items Not on Agenda

(The Committee will not take any action but will consider placing any item raised on the agenda at a future meeting.)

ITEM #3 – Summary of January 4, 2017 Meeting and Approval of Minutes

ITEM #4 – DELAPO Report

ITEM #5 – Unfinished Business - Fees

ITEM #6 – Informational Items

1. Changes in requirements for Drinking Water reporting
2. 2017 US EPA Method Update Rule

FELICIA MARCUS, CHAIR | THOMAS HOWARD, EXECUTIVE DIRECTOR

3. Follow up on Expert Review Panel meeting and draft report

ITEM #6 – Close – Review Action Items

Action may be taken on any item on the agenda. The time and order of agenda items are subject to change at the discretion of the ELTAC Chair and may be taken out of order. The meeting will be adjourned upon completion of the agenda, which may be at a time earlier or later than posted in this notice.

In accordance with the Bagley-Keene Open Meeting Act, all meetings of ELTAC are open to the public.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by ELTAC prior to ELTAC taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before ELTAC, but the ELTAC Chair may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before ELTAC to discuss items not on the agenda; however, ELTAC can neither discuss nor take official action on these items at the time of the same meeting [Government Code sections 11125 and 11125.7(a)].

The meeting locations are accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Katelyn McCarthy at (916) 322-7902 or emailing katelyn.mccarthy@waterboards.ca.gov. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Webcast Information

Webcast	https://video.calepa.ca.gov/
---------	---

State Water Resources Control Board

Division of Drinking Water

**NOTICE OF ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY
COMMITTEE (ELTAC) MEETING**

REVISED

March 29, 2017
10:00 a.m. – 4:00 p.m.
(or until completion of business)

Location 1	Location 2
California Environmental Protection Agency Building	Metropolitan Water District of Southern California – La Verne
1001 I Street, Conference Room 2540	700 Moreno Avenue, Weymouth Room
Sacramento, CA 95814	La Verne, CA 91750

The Environmental Laboratory Accreditation Program (ELAP) will host a meeting of its technical advisory committee, as noted above. The notice and agenda for this meeting and others can be found at www.waterboards.ca.gov/elap. For further information regarding this agenda, see below or contact ELAP at elapca@waterboards.ca.gov or (916) 323-3431.

This meeting is available via webcast at <https://video.calepa.ca.gov/>.

AGENDA

ITEM #1 - Call to Order/Roll Call

ITEM #2 - Public Comments on Items Not on Agenda
(The Committee will not take any action but will consider placing any item raised on the agenda at a future meeting.)

ITEM #3 – Summary of January 4, 2017 Meeting and Approval of Minutes

ITEM #4 – ~~DELAPO Report~~ **Follow up on Expert Review Panel Meeting and draft report**

ITEM #5 – DELAPO Report

ITEM #5 6– Unfinished Business - Fees

FELICIA MARCUS, CHAIR | THOMAS HOWARD, EXECUTIVE DIRECTOR

1001 I Street, Sacramento, CA 95814 | Mailing Address: P.O. Box 100, Sacramento, CA 95812-0100 | www.waterboards.ca.gov

ITEM #6 7 – Informational Items

1. Changes in requirements for Drinking Water reporting
2. 2017 US EPA Method Update Rule
3. ~~Follow up on Expert Review Panel meeting and draft report~~

ITEM #7 8 – Close – Review Action Items

Action may be taken on any item on the agenda. The time and order of agenda items are subject to change at the discretion of the ELTAC Chair and may be taken out of order. The meeting will be adjourned upon completion of the agenda, which may be at a time earlier or later than posted in this notice.

In accordance with the Bagley-Keene Open Meeting Act, all meetings of ELTAC are open to the public.

Government Code section 11125.7 provides the opportunity for the public to address each agenda item during discussion or consideration by ELTAC prior to ELTAC taking any action on said item. Members of the public will be provided appropriate opportunities to comment on any issue before ELTAC, but the ELTAC Chair may, at his or her discretion, apportion available time among those who wish to speak. Individuals may appear before ELTAC to discuss items not on the agenda; however, ELTAC can neither discuss nor take official action on these items at the time of the same meeting [Government Code sections 11125 and 11125.7(a)].

The meeting locations are accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Katelyn McCarthy at (916) 322-7902 or emailing katelyn.mccarthy@waterboards.ca.gov. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Webcast Information

Webcast	https://video.calepa.ca.gov/
---------	---



**ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
ELTAC MEETING**

Wednesday March 29, 2017 – 10:00 a.m.
1001 I Street, Conference Room 2540
Sacramento, CA 95814

And
Metropolitan Water District of Southern California
700 Moreno Avenue, Weymouth Room
La Verne, CA 91750

Meeting Agenda

TIME	AGENDA ITEM	PRESENTER(S)
10:00am	Call to Order <i>Objective: Roll call.</i>	Andy Eaton, <i>Chairperson</i>
10:05am	Public Comments on Items not on Agenda	Open
10:10am	Summary of January 4, 2017 Meeting & Approval of Minutes <i>Objective: Amend or approve minutes.</i>	Andy Eaton
10:15am	Follow up on Expert Review Panel (ERP) meeting and draft report <i>Objective: Dr. Weisberg will update members on stakeholder feedback received on the draft report and changes being made to the final draft.</i>	Dr. Stephen Weisberg, <i>Southern California Coastal Water Research Project</i>
10:45am	ELAP Perspective on the ERP draft report <i>Objective: Provide members with program perspective and discuss recommendations.</i>	Christine Sotelo, ELAP

12pm-1pm	Lunch	
1:00pm	DELAPO Report <i>Objective: Update members on recent developments and activities.</i>	Christine Sotelo, <i>ELAP</i>
1:15pm	Fees <i>Objective: Provide information to committee members.</i>	Christine Sotelo Ryan Wilson, <i>Division of Administrative Services</i> All Members
2:45pm	Informational Item – DDW’s Transition to SDWIS for Electronic Lab Reporting <i>Objective: Inform the committee of upcoming changes in drinking water reporting requirements.</i>	Jim Stites, <i>Division of Drinking Water</i>
3:15pm	Informational Item – 2017 US EPA Method Update Rule <i>Objective: Provide information to committee members.</i>	Maryam Khosravifard, <i>ELAP</i>
3:45pm	Close – Review Action Items <i>Objective: Review any assignments generated during the meeting.</i>	Andy Eaton
4:00 pm	Adjourn	

Welcome Environmental Laboratory Technical Advisory Committee

March 29, 2017

Accomplishments from Last Meeting

- You voted on **37** remaining proposals for modification of the TNI Standard
 - We used this feedback to form our presentation to the Expert Review Panel
- Also provided initial feedback on the fee structure model we should focus on developing options for

Today's Topics

- Follow up on Expert Review Panel Report
- Fees
- Informational Items
 - Changes in Division of Drinking Water reporting requirements
 - Method Update Rule

Call to Order/Roll Call



ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM ELTAC MEETING

Wednesday, March 29, 2017 – 10:00 a.m.
1001 I Street, Conference Room 2540
Sacramento, CA 95814
And
700 Moreno Avenue, Weymouth Room
La Verne, CA 91750

MEETING PACKET

Call to Order/Roll Call

Name	Affiliation	Type	Present
Christine Sotelo	ELAP	DELAPO	
Katelyn McCarthy	ELAP, Scribe	Scribe	
Mindy Boele	CWEA	Rep	
Jill Brodt	Brelje and Race Laboratories	Rep	
Bruce Burton	Division of Drinking Water	SRAE	
Gail Cho	CA Dept. of Fish and Wildlife	SRAE	
Stephen Clark	Pacific EcoRisk	Rep	
Ronald Coss	CWEA	Rep	
Huy Do	CASA	Rep	
Andy Eaton	Eurofins Eaton Analytical	Rep	
Miriam Ghabour	Metropolitan Water District of Southern California	Rep	
Bruce Godfrey	ACIL	Rep	
Anthony Gonzales	CAPHLD	Rep	
Rich Gossett	Physis Environmental	Rep	
David Kimbrough	Pasadena Water and Power	Rep	
Mark Koekemoer	Napa Sanitation District	Rep	
Bruce LaBelle	Dept. of Toxic Substances Control	SRAE	
Allison Mackenzie	Babcock Laboratories	Rep	
Renee Spears	State Water Resources Control Board	SRAE	

Abbreviation	Member Type
DELAPO	Designated ELAP Officer, nonvoting
Scribe	Minutes (non-member)
SRAE	State Regulatory Agency Employee, nonvoting
Rep	Representative Member, voting

Public Comments on Items Not on Agenda

Public Comments on Items Not on Agenda

Members of the public may address the Environmental Laboratory Technical Advisory Committee (ELTAC) regarding items that are not contained in the meeting agenda at this time.

However, ELTAC may not discuss or take action on any item raised during this public comment session, except to decide whether to place the matter on the agenda of a future meeting [Government Code sections 11125 and 11125.7(a)].

Summary of January 4th Meeting and Approval of Minutes

Approval of Minutes from January 4, 2017 Meeting

The Environmental Laboratory Technical Advisory Committee (ELTAC) is asked to review and approve the January 4, 2017 Meeting Minutes.

Attachment:

Draft Minutes

CALIFORNIA ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC)
COMMITTEE MEETING MINUTES
JANUARY 4, 2017

More information on the Environmental Laboratory Accreditation Program (ELAP) and previous ELTAC meetings can be found at <http://www.waterboards.ca.gov/elap>.

CALL TO ORDER

Chairperson Andy Eaton called the meeting to order on January 4, 2017 at 10:00 a.m. at the California Environmental Protection Agency Headquarters, 1001 I Street, Sierra Hearing Room, Sacramento, CA 95814 and the Metropolitan Water District of Southern California – La Verne, Weymouth Room, 700 Moreno Avenue, La Verne, CA 91750.

COMMITTEE MEMBERS PRESENT

DELAPO: Christine Sotelo

Representatives (voting):

Mindy Boele
Jill Brodt
Stephen Clark
Ronald Coss
Huy Do
Andy Eaton
Miriam Ghabour
Bruce Godfrey
Anthony Gonzalez
Rich Gossett
David Kimbrough
Mark Koekemoer
Allison Mackenzie
Guilda Neshvad

State Regulatory Agency Employees (non-voting):

Gail Cho
Bruce LaBelle
Renee Spears

Not Present:

Bruce Burton (non-voting State Regulatory Agency Employee)

OTHER STAFF PRESENT

Scribe: Katelyn McCarthy

ELAP: Maryam Khosravifard, Jacob Oaxaca

ANNOUNCEMENT

- *Evacuation information in case the fire alarm goes off during the meeting.*
- *The Committee meeting is being webcast and recorded.*

COMMITTEE MEETING

PUBLIC FORUM

Any member of the public may address and ask question of the Committee relating to any matter within ELTAC's scope provided the matter is not on the agenda, or pending before the Advisory Committee.

COMMITTEE BUSINESS

ITEM #1 - Call to Order/Roll Call

ITEM #2 - Public Comments on Items Not on Agenda

(The Committee will not take any action but will consider placing any item raised on the agenda at a future meeting.)

No Comments

ITEM #3 – Approval of Amended Minutes from November 2, 2016 Meeting

Motion: Member Kimbrough motioned to adopt the minutes.

Seconded by: Member Coss

MOTION CARRIED: January 4, 2017

Aye: Member Boele
Member Clark
Member Coss
Member Do
Member Eaton
Member Ghabour
Member Godfrey
Member Gonzales
Member Gossett
Member Kimbrough
Member Koekemoer
Member Mackenzie
Member Neshvad
Nay: None
Absent: Member Brodt
Abstain: None

ITEM #4 – DELAPO Report

- ***DELAPO Christine Sotelo updated committee members on the program's progress since last meeting:***
 - ***ELAP finalized its Quality Assurance Manual***
 - ***Two new staff hired in Sacramento Office***
 - ***Supervisor hired for Glendale Field Office – Maria Friedman***
 - ***ELAP's Assessor Training Contract is open for bids and expected to be awarded in February***
 - ***ELAP was audited by the US EPA November 16-18, 2016***
 - ***Still waiting on report, but verbal feedback was positive***
 - ***Three areas identified for improvement:***
 - ***Documentation***
 - ***Reciprocity***
 - ***Checklists***
 - ***ELAP is prepared to take corrective actions once the report is received***

ITEM #5 – Informational Item – 2017 Method Update Rule

Committee members discussed the timelines for the recently published Method Update Rule. Members indicated they would like to discuss in depth at a future meeting once more information was available. A summary of the changes was provided to the committee members in the meeting packet.

ITEM #6 – Unfinished Business

ASSESSOR CHECKLISTS

DELAPO Sotelo informed committee members that the Assessor Training Contract includes method checklists as a deliverable and requested tabling of this item until a later date.

Motion: Member Kimbrough motioned to table the item.

Seconded by: Member Gossett

MOTION CARRIED: January 4, 2017

Aye:

- Member Boele
- Member Brodt
- Member Clark
- Member Coss
- Member Do
- Member Eaton
- Member Ghabour
- Member Godfrey
- Member Gonzales
- Member Gossett
- Member Kimbrough
- Member Koekemoer
- Member Mackenzie
- Member Neshvad

Nay: None

Absent: None

Abstain: None

MODIFICATIONS TO THE TNI STANDARD

DELAPO Sotelo presented a summary of ELAP's preliminary determinations on 87 of modifications proposed by ELTAC members and requested ELTAC's vote on 37 proposed modifications still under consideration. This work product, including vote counts, is attached to this document as a table titled "ELTAC FEEDBACK REQUESTED".

Additionally, Sotelo informed committee members of next steps in the process of adopting a laboratory standard:

- Votes from this meeting will be presented to the State Agency Partners
- ELAP will make a preliminary determination on the remaining 37 modifications
- ELAP will present all preliminary determinations to the Expert Review Panel and consider changes based on their feedback

FEE STRUCTURE

DELAPO Sotelo presented committee members with three conceptual models and requested a preliminary count vote.

1. Model 1 – Everyone pays equally **(2 in favor)**
 2. Model 2 – Only a per Field of Testing Fee **(3 in favor)**
 3. Model 3 – Base + Per Field of Testing Fee **(14 in favor)**
-

ADJOURNMENT

The Committee adjourned at 4:30pm.

ELTAC FEEDBACK REQUESTED

Item	Module	Section	Page	Summary	ELTAC RECOMMENDATION	RATIONALE	ELTAC AGREEMENT		
							In Favor	Against	Abstain
A	4	1.5.2.1.1 (Notes)	96	MDL Procedures	Modify to say "Follow EPA's MDL procedure specified at 40 CFR Part 136 Appendix B." (submitted by Group 2)	May lead labs to use unapproved practices. Allows for possible reductions in data quality	4	9	1
B	4	1.7.1.1 (f)	103	Calibration Standards	Modify - only when the method does not specify then the section applies	Method already specifies the minimum number of calibration points	11	3	0
C	All	Notes	--	Notes provide clarification of the text	Revise - boldly state notes are not enforceable		10	4	0
D	1	5.2.1.1	12	PT Assessments	Revise - make Section 5.2.1.1 consistent with the requirement of one PT per year	cascading effect related to frequency of PT's that ELAP needs to clean up	13	1	0
E	2	3.1	24	Definition of MDL	Remove or Modify - to make more consistent with regulations in CA		3	8	3
F	2	3.1	27	Definition of Verification	Remove or Modify - to make more consistent with regulations in CA		2	9	3
G	2	4.1.5 (j)	29	Management Deputies	Delete	auditors will cite labs for not having deputies; not applicable to some labs	4	9	1
H	2	4.1.7.1 (c)	29	QA Officer Impartiality	Delete		3	9	2
					Modify or clarification	can not be impartial if there's only one person	11	3	0
I	2	5.1.1	43	Calibration and Test Items	Delete or Revise	eliminate dichotomy (see group 3 justification)	7	7	0
J	2	5.4.3	48	Lab Developed Methods	Remove	Doesn't ease concern that other labs can produce the same results Doesn't provide specific procedures	1	9	4
K	2	5.4.4	48	Lab Developed Methods					
L	2	5.4.5	49	Lab Developed Methods					

ELTAC FEEDBACK REQUESTED

Item	Module	Section	Page	Summary	ELTAC RECOMMENDATION	RATIONALE	ELTAC AGREEMENT		
							In Favor	Against	Abstain
	2	5.4.3, 5.4.4, 5.4.5		Lab Developed Methods	Modify - add to regs labs shall be able to generate data that is reproducible (by interlaboratory comparison) by other labs and process has to go to SAPC for method approval (see 1-page ELTAC recommendation)		11	0	3
M	2	5.5.1	51	Calibration and Test Items	Delete or Revise	eliminate dichotomy (see group 3 justification)	7	7	0
N	2	5.7	57	Sample Collection	Remove	outside purview of ELAP	4	7	1 absent 2 abstain
O	2	5.8	58	Calibration and Test Items	Delete or Revise	eliminate dichotomy (see group 3 justification)	7	7	0
P	2	5.10	62	Calibration and Test Items	Delete or Revise	eliminate dichotomy (see group 3 justification)	7	7	0
Q	2	5.10	62	Reporting the Results	Remove	outside purview of ELAP	4	5	1 absent 4 abstain
R	4	1.5.2.1	96	MDL	Remove or Modify	addressed under vote in item A and E			
S	4	1.5.2.1.1	96	MDL	Remove or Modify				
T	4	1.5.2.1.2	97	MDL	Remove or Modify				
U	4	1.5.2.1.2	97	Ongoing verification of MDL	Remove or Modify				
V	4	1.5.2.1.3	97	MDL	Remove or Modify				
W	4	1.5.2.2.1	97	Initial verification of LOQ	Remove	No need to develop an LOQ because no one in CA uses an LOQ	1	8	1 absent 4 abstain
X	4	1.5.2.2.2	98	Ongoing verification of LOQ	Remove				

ELTAC FEEDBACK REQUESTED

Item	Module	Section	Page	Summary	ELTAC RECOMMENDATION	RATIONALE	ELTAC AGREEMENT		
							In Favor	Against	Abstain
Y	4	1.5.2.3	99	Verification of MDL/LOQ	Remove				
W	4	1.5.2.2.1	97	Initial verification of LOQ	Modify - SAPC will identify specific requirements		4	8	2
X	4	1.5.2.2.2	98	Ongoing verification of LOQ	Modify - SAPC will identify specific requirements				
Y	4	1.5.2.3	99	Verification of MDL/LOQ	Modify - SAPC will identify specific requirements				
Z	4	1.7.1.1	102	Initial Calibration	Modify - add specific acceptance criteria	redundant, methods already have provisions. No additional value; stocking stuffer	4	8	2
AA	4	1.7.1.1 (n)	105	Initial calibration verification	Modify - add specific acceptance criteria				
AB	4	1.7.1.2	105	Continuing calibration verification	Modify - add specific acceptance criteria				
AC	4	1.7.2	108	Sample Specific Controls	Modify - add specific acceptance criteria (program by program) spike +/- 50%	Addressed in methods; simply adding add'l verbiage doesn't provide value	1	11	2
AD	4	1.7.2.3.1	108	Matrix Spike/Matrix Spike Duplicates (for Chemistry Methods)					
AE	4	1.7.2.3.2	109	Matrix Duplicates (for Chemistry Methods)					
AF	4	1.7.2.3.3	109	Surrogate Spikes					
AG	4	1.7.3	110	Data Acceptance/Rejection Criteria					
AH	4	1.7.3.1	110	Negative Controls					
AI	4	1.7.3.2 (a)	110	Positive Controls					
AJ	5	1.7.5.1	128	Sample Handling – Thermal Preservation	Delete	addressed in methods; add'l work	1	10	3

ELTAC FEEDBACK REQUESTED

Item	Module	Section	Page	Summary	ELTAC RECOMMENDATION	RATIONALE	ELTAC AGREEMENT		
							In Favor	Against	Abstain
AK	5	1.7.5.2	128	Sample Handling - Dechlorination	Delete	without benefits			

Follow Up on Expert Review Panel Meeting and Draft Report

Catching Up

- Expert Review Panel met Jan. 31st-Feb. 2nd to review the program's progress over the past year
- They released a draft report of findings and additional recommendations on March 17th
 - Stakeholders have been reviewing and submitting comments
- Dr. Stephen Weisberg, facilitator of the Expert Review Panel, is here to summarize the report and comments

ELAP's Perspective on the Draft Report

Tough, but Fair

- We think it accurately captures where we are now
 - We are proud of the progress we have made
 - But we recognize we have a ways to go
- We agree with their three major recommendations
- We have to make some decisions on how to move forward

Recommendations

- Invest in software
- Adopt the TNI Standard
 - Do so with only “essential modifications”
 - Address other modifications through clarifying comments
 - Develop an implementation strategy that helps the laboratories with adoption
- Accept third-party assessments to reduce our backlog

Adoption of the TNI Standard

- We agree with the Panel recommendation to adopt with only essential modifications
 - We want to stay close to the standard so that we can use as many TNI training tools as possible
- However, all 58 of your modifications will be addressed
- The Panel also recommended that we need a strong implementation plan for the laboratories
 - We agree, and are looking for ELTAC assistance in defining what this will be

Implementation Options

- They lay out options for phasing in new requirements:
 - Time-based
 - Documentation-based
 - Requirements-based
 - Combination of any or some of the above
- We'd like ELTAC's help in determining what option or combination works best for laboratories
- We see devoting a future meeting to this topic

Third-Party Assessors

- We see the acceptance of third-party assessments as a necessary step
 - ELAP cannot assess all laboratories on its own
- However, the Panel was vague on how to implement this recommendation
 - This is another area we would like ELTAC assistance

Third party assessor models

- The report outlines different models:
 - ELAP directly engages contractors
 - Laboratories employ contractors
- We want to explore the second option
 - The first would result in additional fee hikes to fund contracts
- Laboratories can employ a contractor to conduct their routine assessment
 - The contractor will submit a report to ELAP
 - ELAP will make the accreditation decision and issue a certificate
- But, the devil is in the details

Some Details to Discuss

- Is it optional, or are some laboratories required to use third-party assessors?
 - If so, which labs are required to?
- Which contractors should we accept?
- What implications does this have for our fee structure?

Our Vision

- Short-term: ELAP will continue to offer routine assessments for less complex FOTs
 - Require laboratories to obtain outside assessment services for more complex FOTs
- Long-term: Consider externalizing all routine assessments
 - ELAP staff would only do re-inspections
 - Depends on success associated with the short-term plan

Contractor Selection

- What criteria do we use to determine which firms can perform assessments?
- Should we use the Florida model?

Implications to Fee Structure

- Major
- Some laboratories would be paying a contractor for their assessment
 - We would need to adjust the fee they pay us
- We think this dovetails well with your recommendation from last meeting
 - You'll talk more about fees this afternoon

ELAP's Next Steps

- Explore options to address the non-essential modifications
- Create an implementation strategy for laboratories
 - With ELTAC assistance
 - With additional community assistance
- Lay the ground work for third-party assessments
- Restructure program fees (to be discussed this afternoon)



Questions

Agenda Items:

Follow up on the Expert Review Panel (ERP) meeting and draft report

ELAP's Perspective on the ERP draft report

Attachments:

Draft Year Two Report: Assessment of Progress and Final Recommendations by the Expert Review Panel for the State of California's Environmental Laboratory Accreditation Program, Lara Phelps, Jordan Adelson, Stephen Arms, David Spies

**Assessment of Progress and Final
Recommendations by the
Expert Review Panel for the State of
California's Environmental Laboratory
Accreditation Program**

Draft Year Two Final Report

Lara Phelps
Expert Review Panel Chair
U.S. Environmental Protection Agency

Jordan Adelson
U.S. Navy

Stephen Arms
Retired – State of Florida Department of Health

David Speis
Retired – Eurofins QC, Inc.

March 17, 2017

SCCWRP Technical Report xxx

TABLE OF CONTENTS

Foreword.....	1
Acknowledgements.....	1
Executive Summary	2
Chapter 1: Introduction.....	4
1.1 Background.....	4
1.2 Expert Review Panel	5
1.3 The Panel Charge	5
1.4 The Report	6
Chapter 2: Assessment.....	7
2.1 Infrastructure	7
2.1.1 Management System.....	7
2.1.2 Organizational Structure	7
2.1.3 Staff.....	10
2.1.4 Communication	10
2.2 Standards.....	11
2.3 Stakeholders	11
2.3.1 Agency Partners.....	11
2.3.2 Laboratories	12
2.3.3 Others	12
2.4 Resources.....	12
Chapter 3: Recommendations.....	14
3.1 Standard Selection	14
3.1.1 ELAP	16
3.1.2 Laboratories	16
3.1.3 Fields of Testing	16
3.2 Resources.....	16
3.2.1 Third-Party Assessments.....	17
3.2.2 ELTAC.....	18
3.2.3 Training	18
3.2.4 Software	18
3.2.5 Another Panel.....	Error! Bookmark not defined.
Chapter 4: Next Steps.....	19
Appendix A: Panel's Response to Charge Questions.....	20
Appendix B: Table from Tni on 58 Items from Tni Standard Identified by Stakeholders.....	22

Appendix C: Biographies of Panel Members	25
Appendix D: Stakeholder Advisory Committee (SAC) Membership	27
Appendix E: Meeting Agenda	28

FOREWORD

This report was produced under California State Water Resources Control Board contract to the Southern California Coastal Water Research Project Authority (Agreement Number 15-037-400) under the direction of Dr. Stephen Weisberg. The views and perspectives expressed in this report by the members of the Expert Review Panel are their own, and do not necessarily reflect the views of their employer or any other entity with which they are affiliated.

ACKNOWLEDGEMENTS

The Expert Review Panel wishes to thank Christine Sotelo, Program Chief for the California Environmental Laboratory Accreditation Program, in addition to the management and staff involved in the review panel process, for their openness and willingness to provide unfettered access to, and unfiltered information about, the program and its staff. The authors also wish to thank the members of the Environmental Laboratory Technical Advisory Committee (ELTAC), especially Chair Dr. Andy Eaton, for advice, counsel and support, and the speakers who offered invaluable perspectives and information essential to the Panel's deliberations. Finally, the authors wish to thank Dr. Stephen Weisberg and Scott Martindale of the Southern California Coastal Water Research Project Authority for their guidance and support.

EXECUTIVE SUMMARY

An Expert Review Panel (the Panel) was convened in 2015 to conduct an external examination of the State of California's Environmental Laboratory Accreditation Program (ELAP). During its initial review, the Panel identified a number of fundamental weaknesses that hindered the program's ability to achieve its mission of ensuring the State has high-quality data for use in environmental decision-making. The Panel made a series of recommendations to help ELAP reestablish itself as a respected accreditation program. Over the course of a year, the Panel followed ELAP's progress during quarterly public webinars, then reconvened in January 2017 to conduct a second year review of the program to assess whether the program had successfully implemented those recommendations and improved as a result.

During the follow-up review, the Panel found that ELAP made significant progress in implementing the majority of the Panel's recommendations. The Panel believes ELAP is regaining credibility with clients and the laboratory community; is working toward an accreditation process with State and stakeholders support; and has created proficiency testing and enforcement units to help ensure the competency of laboratories producing environmental data. With the extensive programmatic improvements ELAP implemented in the last year, the Panel has confidence ELAP's leadership understands its organizational charge and is well-positioned to accomplish the final Panel recommendations outlined in this report.

While the Panel applauds ELAP's progress during the past year, the program is still not meeting its programmatic goals. Specifically, the Panel notes that ELAP still lacks adequate staff to properly perform onsite assessments of applicant laboratories, which has resulted in a significant programmatic backlog, and an accreditation standard has not been adopted. The Panel has identified supplementary recommendations that should help resolve the remaining programmatic shortcomings:

- **Adopt an accreditation standard:** In its initial review, the Panel urged ELAP to immediately adopt an accreditation standard. While ELAP has worked well with its stakeholder communities over the last year to vet various options, this process has prevented ELAP from adopting a standard to move the program forward and is hindering investments the State Board has made for staff training. The Panel recommends that ELAP take immediate action to adopt a standard, yet disagrees with ELAP's suggestion to adopt The NELAC Institute (TNI) Standard with 58 modifications proposed by the stakeholder community. The Panel has reviewed those proposed modifications and feels that the TNI standard can be adopted without modification. Two items will need to be noted within the regulation, but the remainder of the concerns expressed by stakeholders can be satisfactorily addressed through clarifications and implementation guidance. Adopting a modified standard would isolate California from invaluable resources available from the national program.
- **Expand resources:** During its initial review, the Panel found that ELAP was not able to carry out its mission because the program lacked the proper tools, as well as the broad expertise needed among its assessor staff to conduct all required laboratory assessments.

The Panel recommended that ELAP consider using third-party, private-sector assessors to help clear a programmatic backlog. In actuality, ELAP instead pursued expansion and reorganization of in-house capabilities and resources, and did not attract or fully retain the in-house talent it needs. The Panel strongly urges ELAP to immediately begin accepting third-party assessments. The Panel also recommends that ELAP acquire software tools and external training resources to help meet workload demands and to ensure consistency when processing laboratory accreditation applications.

Support from the State Water Board is critical for ELAP to continue its journey to fully achieve its legislative mandates and regain credibility State- and nation-wide. The State Water Board should continue to hold ELAP accountable by requiring the program to establish additional reporting metrics, by bringing in an independent consultant to perform a gap analysis, and by creating another expert panel to keep ELAP on track to meet its present and future demands.

CHAPTER 1: INTRODUCTION

1.1 Background

Effective stewardship of the environment and protection of public health require generation of data to inform managers about effectiveness of regulatory actions. Such data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or toxicity of sediments. The field and laboratory methods employed to obtain these measurements are often complex, and the procedures and analytical instrumentation evolve as technology improves. Through the use of accreditation to oversee laboratories that provide these analytical services, the State is able to ensure that laboratories are competent to generate data of a known minimum quality, that data obtained from different laboratories are comparable, and that laboratories are performing to a common recognized standard of performance.

In January 1988, the California Environmental Laboratory Improvement Act (Assembly Bill 3729, Chapter 894, Statutes of 1988) established the State's Environmental Laboratory Accreditation Program (ELAP) to provide evaluation and accreditation of environmental testing laboratories. ELAP ensures the analytical data used for regulatory oversight of the State's drinking water, wastewater, shellfish, food, and hazardous waste programs meet State requirements. All environmental testing laboratories are required to receive accreditation prior to providing analytical data used for State regulatory purposes.

ELAP was one of the eleven original state accreditation programs to become a recognized accreditation body by the National Environmental Laboratory Accreditation Program (NELAP), which was formed in 1999. The goal of NELAP is to foster cooperation among accreditation activities of different states and other governmental agencies, and to unify state and federal agency standards. Each state-level accreditation body agreed to implement standards written by the National Environmental Laboratory Accreditation Conference (NELAC), and accept the accreditation of laboratories accredited by other NELAP accreditation bodies. In 2006, The NELAC Institute (TNI) was established for the long-term management of NELAP and development of standards.

ELAP withdrew from TNI NELAP in 2014 following the identification of programmatic deficiencies during a TNI programmatic evaluation. The evaluation affirmed the concerns expressed by local California laboratories regarding ELAP's effectiveness as an accreditation body. Shortly after ELAP's withdrawal from TNI, ELAP transitioned from the California Department of Public Health to the California State Water Resources Control Board (herein referred to as the State Water Board). With new ELAP management in place under the State Water Board's Division of Drinking Water, ELAP asked for an external, independent programmatic review to help the program frame its future directions. This review was intended to cover internal management procedures, staffing, finances, the laboratory assessment process, and communication strategies, with an overarching goal of improving ELAP's effectiveness.

1.2 Expert Review Panel

In 2014, ELAP's newly installed management team asked for an external, independent programmatic review to improve ELAP's effectiveness. The State Water Board turned to the Southern California Coastal Water Research Project Authority (SCCWRP) to establish an Expert Review Panel (the Panel) to develop recommendations for improving ELAP.

An 11-member Stakeholder Advisory Committee (SAC) was formed to vet the nomination and selection process for Panel members. SAC members (listed in Appendix D) represented municipal and private environmental laboratories operating in California, as well as State agency users of data from ELAP-accredited laboratories. Candidates for the Panel were nominated based on nationally recognized expertise and a requirement they not be part of an organization regulated by or having official interactions with ELAP. To ensure the Panel was well-rounded, candidates were grouped according to their categories of expertise, such as laboratory operation, operation of accreditation bodies, and on-site assessment. The SAC then ranked the nominated panelists within each category and was given the opportunity to eliminate any of the candidates from consideration. This vetting process ensured the Panel members were both highly qualified and free from bias regarding the issues on which they would deliberate.

The five-member Panel, established in early 2015, consisted of:

- Dr. Jordan Adelson, U.S. Navy
- Stephen Arms, State of Florida (now retired)
- Mitzi Miller, Dade Moeller & Associates (resigned from Panel)
- Lara Phelps (*Panel Chair*), U.S. Environmental Protection Agency
- David Speis, Eurofins QC, Inc. (now retired)

Following a decision by her company to pursue work with ELAP, Mitzi Miller resigned from the Panel in January 2017. Brief biographies of the Panel members are provided in Appendix C.

The Panel's initial report, "Findings and Recommendations by the Expert Review Panel for the State of California's Environmental Laboratory Accreditation Program: Year One Final Report" was released in October 2015. After monitoring the progress of ELAP through public, quarterly webinars, the Panel reconvened for a face-to-face public meeting in January/February 2017. The meeting agenda (provided in Appendix E) was developed by SCCWRP, with assistance on topic development and identification of speakers from the Stakeholder Advisory Committee and the Environmental Laboratory Technical Advisory Committee (ELTAC), to provide the Panel with a comprehensive range of information and perspectives. Members of the Panel, participants, and public were given time to ask questions of the speakers. The meeting agenda, background materials provided to the Panel, presentation slides, and written public comments are posted to a public website (<http://www.sccwrp.org/ELAP>).

1.3 The Panel Charge

Panel charge questions were developed by ELAP with the assistance of the Stakeholder Advisory Committee. The Panel has addressed these seven questions throughout the document, and Appendix A provides direct answers to these charge questions.

1. Has California ELAP been responsive to the recommendations provided by the Panel in their initial review?
 - a. Did ELAP provide appropriate rationale for any deviations from the Panel suggestions?
2. Has the program become more effective as a result of those changes?
3. Do you have any modifications to the advice you provided in October 2015 as a result of lessons learned by the program in the last year?
4. What are the biggest challenges remaining for the program?
5. Is the timeline outlined by ELAP for meeting these remaining challenges appropriate?
6. The Panel recommendations from the first review focused on activities needed to address to meet minimum program acceptability. What new activities does the Panel suggest the program engage in next to take it beyond minimum acceptability?
7. This is the last meeting of the Review Panel. What metrics should the program use in the future to self-assess how well it is progressing toward its goal of becoming one of the best laboratory accreditation programs in the nation?

1.4 The Report

This report provides the Panel's assessment of the program's progress and its final recommendations based on the original evaluation, recommendations, and implementation timetable provided in the Panel's year one report. This is the second of the two reports that the Panel will produce.

CHAPTER 2: ASSESSMENT

The Panel completed a one-year follow-up review of ELAP during a three-day public meeting in January/February 2017. The Panel concluded that ELAP has made significant progress in implementing the majority of the Panel's recommendation. Specifically, the Panel found that ELAP is regaining credibility with clients and the laboratory community, working toward an accreditation process the State and stakeholders support, working to ensure environmental and public health data used are of known, consistent and documented quality, and working toward long-term sustainability.

While the Panel commends ELAP on these accomplishments made over the past year and is encouraged to see that ELAP has been working tirelessly on the arduous task of rebuilding, there is still a great deal of work ahead for ELAP to achieve its objective to ensure laboratories are competent to generate data of known, consistent, and documented quality for use by the State of California in its environmental and public health decision making. This section is broken down into four main categories to capture the Panel's evaluation of ELAP's progress in the areas of concern raised in this report.

2.1 Infrastructure

During its year one assessment, the Panel concluded that ELAP management inherited a program with fundamental deficiencies. Notably, ELAP did not have a process in place for verifying whether laboratory assessments or proficiency testing (PT) evaluations were being performed to a recognized standard, had historically shown indifference to known operational problems, and had a reputation for being unresponsive to client complaints and the stakeholder community at large. Over the past year, with the adoption of a management system, establishment of three key structural units, and vastly improved communication efforts, ELAP is on the right path to overcome many of the shortcomings that existed in the work environment. ELAP has developed a framework for success, yet more remains to be done.

2.1.1 Management System

By choosing to adopt *General Requirements for Accreditation Bodies Accrediting Environmental Laboratories* (EL-V2-2009 published by The NELAC Institute [TNI]), ELAP made a giant leap towards establishing a structured environment under which management and staff can operate effectively. Extensive effort has gone into the development of a Quality Assurance Manual (QAM) that maps out ELAP's operational policies and procedures. Moreover, it is clear that the necessary internal structural and cultural adjustments have been made to begin implementing the processes described in these documents. However, more time and additional team efforts will be required to evolve the system to maturity. To ensure growth under this new system, it will be critical to hold everyone involved in implementation accountable, to evaluate progress critically and equitably, and to take corrective and preventive actions as needed.

2.1.2 Organizational Structure

As a result of acquiring personnel with the skillsets needed to begin addressing client concerns and to conceive and write the QAM, management has made organizational decisions for staff

assignments and performance expectations. Three functional units have been established that give emphasis and a sense of mission to the related areas of responsibility.

2.1.2.1 Program Development, Research, and Enforcement Unit

ELAP has lead a concerted outreach plan that includes establishing a State Agency Partners Committee to facilitate cooperation with the State agencies that use the environmental data generated by the laboratories accredited by ELAP. These clients have recognized that ELAP is a valuable resource capable of supporting their respective missions. The importance of these renewed relationships to ELAP's long-term success cannot be overemphasized. Restoring confidence has resulted in clients coming to ELAP to address concerns about laboratory issues that have potentially compromised the quality of data being presented to them. This is evidenced by ELAP having received more than 30 referrals since reform efforts were initiated.

ELAP has established an enforcement unit, led by an energetic and capable manager, to meet these expressed client needs and expectations. In its first year, this unit has conducted more than 25 investigations that resulted in 18 enforcement actions. It also has been leading the internal reforms of the program, and will be responsible for writing the new rule draft. Although these activities are commendable and necessary to engender confidence in ELAP's ability to carry out its obligation to set and enforce the regulations imposed upon laboratories, it has resulted in an unintended consequence. Because this was not a previous activity performed by ELAP and was not a task that was planned, ELAP staff had to be assigned to this unit, leaving even fewer qualified individuals available to perform onsite assessments. The Panel appreciates the reliance of stakeholders on ELAP to meet their needs, but is concerned with the added responsibility – in the absence of any new resources – to meet the demands of the evaluation and accreditation of laboratories. If the creation of this unit ultimately results in a continued inability by ELAP to evaluate the competency of all laboratories that perform the methods and produce the data the clients need, the newly gained confidence will no doubt begin to erode.

2.1.2.2 Proficiency Testing (PT) Unit

ELAP has not historically used the PTs received in the primary evaluation of in-state laboratories or reciprocal recognition of out-of-state laboratories during the accreditation process. With the establishment of a PT unit overseen by a talented manager to provide guidance and set expectations for staff within the unit, a positive step has been taken to meet this requirement in the accreditation process. More must be done, however, to effectively use PT data and make efficient use of staff time.

Currently, the PT unit evaluates the PT results it receives for laboratories manually using PDF files. (Note: It appears ELAP accepts PT reports directly from laboratories as well as from the approved PT providers. All nationally recognized programs receive results directly from the PT provider. This is a potential vulnerability that could call into question the validity of some PT results). Manual entry is a labor-intensive and time-consuming task with a significant potential for error. A sizeable backlog persists that is growing every day. The lack of automation also renders it nearly impossible to track whether laboratories are participating at the mandated

frequency. Although there are now written procedures available to staff, these procedures are general and do not provide clear guidance on the rules to be applied to determine compliance. Frequently, staff must contact laboratories to provide or receive clarifications. This is due, at least in part, to ambiguities in the requirements and the resulting misunderstandings among laboratories as to their obligations regarding PTs.

Even though ELAP now has a group of staff dedicated to PT review, as well as a manager for this group who shows a strong commitment to success, and performance measures to hold staff accountable, the program continues to face a nearly insurmountable task. Indeed, ELAP has recognized its former neglect of PT review and has taken steps to rectify the situation, but the lack of automation and a large backlog combine to make significant progress by the PT unit challenging.

2.1.2.3 Onsite Assessment Unit

Onsite assessment is the core activity of any laboratory accreditation program. It constitutes the “eyes and ears” of ELAP by allowing first-hand observation of a laboratory’s capabilities. It is also the most outwardly visible activity and the one most open to criticism. As previously identified, ELAP has lacked adequate staff with the requisite expertise to properly and timely perform onsite assessments of accredited and applicant laboratories. While ELAP appears to be moving in the right direction, it is not meeting its obligations in this area.

The Panel hopes that the onsite assessment unit created during ELAP’s restructuring process will serve to advance the effectiveness of this crucial accreditation activity. This unit now has seasoned leadership and staff, seemingly with strong technical and educational backgrounds. ELAP lists eight assessors in its workforce. However, many of the assessors listed are being used in other areas of the program, leaving only four positions to conduct assessments, with one of these currently vacant. Because of this, there is a large backlog of laboratories that are awaiting onsite assessments (see Table 1). Under current conditions, the prospects for eliminating the backlog are dim. ELAP has, out of necessity, turned its focus only to drinking water testing laboratories, which means it is largely neglecting laboratories accredited in wastewater and other matrices.

Table 1. Laboratory Assessment Backlog (data provided: January 31, 2017)

<u>Drinking Water Laboratories</u>	<u>Non-Drinking Water Laboratories</u>
313 are current	147 are current
41 are not current:	144 are not current:
9 are over 5 years	21 are over 5 years
14 are over 4 years	35 are over 4 years
18 are over 3 years	88 are over 3 years

During the assessments that are taking place, there also appears to be a heavy reliance on checklists, inadequate reviews of the laboratory's accredited Fields of Testing (FOTs) (including the inflexibility to address new FOTs requested by the laboratory), and cursory PT reviews. This reflects ongoing training and experience challenges that result in misunderstandings of technical requirements, assessment procedures, and PT requirements, respectively.

2.1.3 Staff

Under ELAP Chief Christine Sotelo's leadership and contagious enthusiasm, one of the brightest areas of improvement evident at ELAP is that of the work environment. Even under adverse circumstances that include historically low poor staff morale and rigid hiring practices, she has managed to pull together a promising team. Each employee the Panel interviewed demonstrated pride in his or her position, an eagerness to see ELAP succeed, a clear understanding of the program's mission, and a willingness to do the hard work ahead. Staff appear to be functioning as a real team with an esprit de corps the Panel did not observe a year ago.

2.1.4 Communication

Prior to improvements made over the past year, it was common for stakeholders to receive little or no response when they contacted ELAP to get information or ask a question. This was an area of constant frustration among the laboratory community. Now, ELAP staff are repeatedly complimented on the fact that they return phone calls and respond to emails. The professionalism with which that feedback is being given has not gone unnoticed; indeed, this simple advancement in customer service has gone a long way towards reestablishing the trust that had been lost between ELAP and the public.

ELAP also is making progress on its website, a list serve and a newsletter. The website has evolved a great deal, and work is being done to keep the newsletter on track as a regular feature. The newsletter will be an excellent resource to keep stakeholders up-to-date. ELAP also now communicates with accredited laboratories through ELTAC, although ELTAC has expressed concerns that the communications with laboratories needs to take place more directly.

Finally, a staff member has been assigned to manage customer service and to facilitate communications. This shows ELAP's firm commitment to being responsive to its customers' needs. ELAP should continue its resolute efforts toward improving communications.

2.2 Standards

ELAP is bound by inadequate laboratory accreditation standards codified in California's regulations. This challenge has prevented ELAP from fully regaining control of the assessment and accreditation process, even though the adoption of a management system, organizational restructuring decisions, and development of standard operating procedures have all had a positive impact.

The Panel compliments ELAP for thoroughly engaging its entire stakeholder community in the process to identify a standard that would meet everyone's needs. While it was prudent to do this, it has created a significant delay in moving ahead with the selection, adoption, and implementation of a more structured program. Thus, ELAP has not yet achieved one of the key recommendations in the Panel's initial report. The Panel remains hopeful and confident that the mutual understandings gained by actively involving data users and regulated laboratories in the process of identifying a standard will help the community at large move forward together in a positive way to complete the rebuilding process. The Panel still feels strongly that establishing a robust accreditation standard is a crucial element of that rebuilding process, without which the progress to date could be lost.

2.3 Stakeholders

The perception of ELAP was extremely low in the stakeholder community during the Panel's initial review of the program. ELAP lacked credibility or trust from any part of the stakeholder community. Although there is more work to be done, a long and high bridge has already been crossed in the establishment of new relationships. Seeds have been planted that need further growth.

2.3.1 Agency Partners

During the Panel's initial review, ELAP was uncertain who its clients were. Today, ELAP has a State Agency Partners committee composed of its clients and which meets regularly to help guide the program towards meeting their needs. Moreover, ELAP has created a new enforcement unit to investigate concerns from clients regarding the quality of data from particular laboratories. Trust is being established as a result of ELAP's actions to investigate and mitigate these matters. Work, however, still needs to be done to meet the oversight and accreditation needs of all State programs that rely on laboratory data for their decision-making. Current ELAP staffing levels and expertise are not adequate for all sample media areas required. As stated above, the current focus is on drinking water testing laboratories, due in part to inadequate staffing levels and in part to a lack of expertise in other areas. While the public health protection aspect of providing safe drinking water is obvious, the agency partners have expressed data needs that go beyond drinking water.

ELAP also faces numerous competing pressures. Although ELAP still has much to do just to gain a firm understanding in the basics of accreditation, clients and laboratories have already voiced needs for ELAP to expand to consider emerging contaminants and “real-world” PT samples. ELAP will eventually have to become responsive to those needs.

2.3.2 Laboratories

ELTAC historically has been the primary conduit for ELAP’s relationship with the laboratory community. In spite of the outward willingness of both parties, the relationship had grown to be dysfunctional. ELTAC’s members felt that their work often went unnoticed and unused, and the laboratories they represent were extremely frustrated by never knowing whether someone with any competence would come to assess their performance. With ELTAC dismantled and reconstituted over the past year, it has been invigorated as never before, and ELAP’s dialogue with the laboratory community has experienced an about-face. Individual laboratories are even complimenting ELAP staff on their communication and transparency. However, concerns still loom about assessments and expertise, as well as with an over-reliance on ELTAC for communication with the laboratory community.

ELAP management has to date not been using ELTAC as the advisory arm it is intended to be, but rather is relying on ELTAC for detailed technical support – possibly a consequence of ELAP still lacking adequate technical depth. This has resulted in an over-full ELTAC agenda and deliberations that often get caught in the weeds. There also is a perception among ELTAC members that they are being asked to do much of ELAP’s work, which in the long run could jeopardize the healthy new relationship between ELAP and ELTAC. It must be clear to all concerned that ELTAC is an advisory body, and that ELAP is the decision-maker regarding policy. On the other hand, ELAP cannot neglect to include the laboratory perspective in ELAP policy decisions.

2.3.3 Others

State accreditation programs across the nation, as well as members of the public and private sector, watched with concern the unexpected collapse of the California program a few years ago. ELAP management and staff have responded by very publicly acknowledging their challenges and sharing their journey to regain their national stature. Via ELAP’s participation in national meetings and events, the progress is not unnoticed, and the hope of renewal remains alive and well. ELAP has a unique opportunity to show itself as an example of how to turn inferiority into excellence. It should remain engaged in the national environmental testing community.

2.4 Resources

As discussed above, staff resources have been inadequate to meet the minimum accreditation requirements or the timeliness required by the program. While staff members are being more effectively utilized for their abilities and expertise, this has still left openings in the overall needs of the program. Instituting new units of responsibility, while necessary, has put a further strain on the number of staff needed to meet accreditation demands for the number and diversity of

laboratories in California. Conversely, borrowing from these new units to alleviate assessment demands could adversely affect other internal operations.

The support of the State Water Board to fund an assessor training program for ELAP staff is highly commendable. The activities outlined in this training contract should prepare current staff to properly meet expectations in their roles as assessors, and hopefully prepare them to train future staff. It should also serve to temporarily provide some relief to the onsite assessment workload through the assessments that will be performed under the contract. However, the contract only addresses the immediate technical training needed to give assessors the minimum skills for current FOTs for drinking water. Additional expertise is called for if ELAP is to ever have the flexibility to address new FOTs and other programs as demanded by agency and laboratory clients.

Over the past year, it has become apparent to the Panel that ELAP still lacks the resources it will need to accomplish everything laid out before it. A combination of a fully trained and complete staff, automation of internal processes, and the use of contractors will be necessary to put ELAP on a path to reaching its goals.

CHAPTER 3: RECOMMENDATIONS

ELAP faces a number of unresolved challenges as they continue rebuilding California's laboratory accreditation program, many of which are identified in Chapter 2 of this report. Nonetheless, the Panel sees solid evidence that the program is heading in the right direction. In particular, the breadth and quality of the ELAP reforms implemented to date have given the Panel confidence that ELAP leadership understands its organizational charge and is well-positioned to execute the final Panel recommendations outlined in this report. Success in completing the rebuilding effort is dependent upon maintaining a focus on the primary Panel recommendations and taking prompt action to implement the supplementary recommendations that follow.

The Panel's supplementary recommendations fall into two broad categories: standard selection and resources. Specific tasks are identified that build on the progress ELAP has made to date, and that will ultimately lead to achievement of ELAP's mission objectives and fulfillment of its vision.

3.1 Standard Selection

In its initial review of ELAP, the Panel found that the laboratory accreditation standards being used by the program were insufficient, and urged the program to immediately adopt an accreditation standard.

A remarkable partnership has been established between ELAP and its stakeholders that has taken into consideration the recommendations offered by the Panel regarding adoption of a laboratory accreditation standard for the program. The initial selection of the TNI Standard, however, was caveated by perceived implementation barriers expressed by the laboratory community. A detailed review of the standard by stakeholders identified a list of 58 requirements, detailed in Appendix B, that appeared to pose implementation difficulties for laboratories. These concerns led ELAP to lean toward developing a modified version of the TNI standard, which is unnecessary.

ELAP should adopt the TNI Standard with only essential modifications. A review of the proposed modifications indicates that the majority of these items do not warrant the creation of a modified standard. Instead, they can be satisfactorily addressed through clarifying comments and implementation guidance that provides examples of compliance techniques. Following this approach creates a win-win situation for ELAP and their stakeholders. From an accreditation perspective, adopting a modified standard would isolate the State of California from other States and the training/implementation resources available from the national program.

Of the 58 proposed modifications, the Panel sees only two that will require modification of the TNI Standard for implementation in California: (1) The TNI Standard requires that laboratories analyze two proficiency test (PT) samples per year, whereas California ELAP regulations only require one PT per year, and (2) the TNI Standard contains education and experience criteria for laboratory supervisors that exceed those for laboratory supervisors currently contained in

California regulations. These two requirements can and should be modified in the short term to facilitate implementation in California. Although these modifications will cause some divergence from the TNI Standard, California ELAP will not be seeking NELAP recognition in the immediate future, so these issues are not of immediate concern. These two issues, however, will require resolution if/when California chooses to rejoin the national program.

In planning for adoption of the TNI Standard, ELAP should take a strong leadership role in defining the implementation path and timeline for the laboratory community. Clearly communicating specific milestones to organizations unfamiliar with the development and implementation of the TNI Standard will be key to a successful transition.

ELAP's implementation schedule for the TNI Standard should be aggressive yet reasonable, and should feature several steps, including: (1) modification of the laboratory accreditation regulations and training on multiple levels to further meet assessor, laboratory, and client needs beyond the initial laboratory assessor training contract currently being finalized, (2) phased implementation of the standard to facilitate a smooth community integration process.

There are several models ELAP can employ during the phase-in process. These include time-based phasing, documentation processes phasing, requirements phasing, or any combination of the three. Time-based phasing provides a long lead-in time for the entire standard to be in place before statewide accreditation is required. Documentation phasing employs time-based milestones for requiring specific documentation processes to be in place, while recognizing accredited laboratories prior to the occurrence of those milestones. Requirements phasing employs a process similar to documentation phasing, but substitutes specific requirements instead of documents at fixed milestones. Using a combination of all three would enable ELAP to accredit laboratories on a faster schedule, while also providing milestones at later dates for documentation and other specific requirements to be in place.

An example of the phased approach is to institute milestones for completing the specific elements of the quality system that are defined in the standard. Development milestones can be established for completion of the quality system, quality system SOPs and analytical SOPs, which can be evaluated for compliance during on-site assessments. Once developed, milestones for executing the specifications of the SOPs can be put in place. Additional milestones can be established for initiating the documentation processes specified in the standard.

The phase-in period should be supplemented with formal external training, integrated throughout the phase-in process to assist laboratories in developing their quality systems. Training can either be through ELAP staff or external contractors. The panel recommends that ELTAC take the lead in establishing laboratory self-support groups to assist with implementation. There is a sufficient number of California NELAP-accredited laboratories that have program implementation experience that can provide user group leadership.

3.1.1 ELAP

Selecting an established national standard offers ELAP the opportunity to become a true leader in laboratory accreditation. Participating as an accreditation body within the TNI community is a realistic goal, which becomes more attainable as key program elements are put in place and the program gains operational stability.

3.1.2 Laboratories

Laboratories that perceive the TNI Standard as potentially imposing onerous, rigid requirements will instead have the flexibility to develop a quality system within the TNI framework that complements their size and operational style. In becoming part of a large community of accredited laboratories, there will be ready access to user groups, training, free support, and operational tools, which would not be available to these laboratories if California created a modified standard. Stakeholders will be able to participate in the standards development process and obtain formal interpretations on standard requirements, regardless of whether they are TNI members, benefiting the standards development process nationwide.

3.1.3 Fields of Testing

ELAP's field of testing array focuses on traditional methods and parameters used for environmental measurement, but it requires modification to meet client needs. Client needs can effectively be met by using programmatic needs and regulatory requirements as the driver, rather than hard-wired links to established environmental testing methodology. Accreditation mechanics should be overhauled for greater flexibility and to enable a quicker ELAP response to specific changes or needs when requested by clients, dictated by regulatory changes, or requested by laboratories as the need arises.

3.2 Resources

ELAP remains unable to meet many of its programmatic obligations because of several factors, including a lack of adequate resources and the use of manual processes for labor-intensive tasks. This shortcoming is exacerbated by the need to continue operations while the program is being overhauled, and is further complicated by the addition of new program responsibilities. The Panel has identified several recommendations to provide relief for the resource shortfall. As these recommendations are implemented, ELAP should be continually evaluated and modified as the program evolves.

Additional staffing resources will be needed to assess new fields of testing when they are requested by laboratories. Maximum use of staff resources from other ELAP sub-program elements should be employed to conduct assessments, relieving the pressure on the assessment unit to conduct the additional assessments without additional staffing. However, borrowing resources from other program elements will certainly affect the performance of the units lending resources.

3.2.1 Third-Party Assessments

Although during its initial review, the Panel at the time recommended use of third-party, private-sector assessors as an option to help clear a programmatic backlog, ELAP instead pursued expansion and reorganization of in-house capabilities and resources. Because these efforts did not result in ELAP being able to attract and retain the in-house talent it needs, the Panel strongly urges ELAP to immediately begin accepting third-party assessments.

Eliminating the accreditation backlog, especially for non-drinking water programs, is a critical component of ELAP's charge and must be maintained from an operational perspective, even as program rebuilding activities are occurring. ELAP does not have the diversity of expertise on its staff needed to conduct all the required accreditation activities, nor to conduct accreditation for needs that go beyond the mainstream regulatory fields of testing.

Non-governmental accreditation bodies and assessor bodies (i.e., third-parties) have the expertise to evaluate a laboratory's quality system implementation to an ELAP-specified standard, as well as the ability to conduct technical assessments of all laboratory methodologies commonly used by environmental laboratories. This is especially relevant for laboratory programs not currently accredited by ELAP, such as ambient air and soil gas analysis for which a need exists. Through the use of third-parties for assessment and evaluation of laboratories conducting wastewater, solid and hazardous waste analysis and other non-drinking water programs, ELAP will be able to focus its existing resources on accreditation recognition and drinking water laboratory accreditation.

There are several models that can be employed for the engagement of third-parties. These include direct engagement as contractors, and self-engagement by individual laboratories to conduct accreditation activities to a specific standard. When employed as a contractor, the third-party assessor would evaluate the laboratory's information submittal, conduct the assessment and produce a report for ELAP, which would then render the accreditation decision. When employed as an accrediting body, the laboratory would engage the third-party directly to evaluate the laboratory's information submittal, conduct the assessment, write the assessment report, and render an accreditation decision. This accreditation would be submitted by the laboratory to ELAP, which would then issue a California-specific accreditation or license to the laboratory. In either model, ELAP retains their regulatory authority for oversight, enforcement, and accreditation.

Regardless of which model is used, provisions for continued operation during the transition must be in place to ensure that accreditations can continue until third-parties are engaged and operational. The reciprocity system currently being used can be employed by ELAP to ensure continuity of operation until third-party resources can be secured. Essential to the use of reciprocity for laboratory accreditation is the development of a formal reciprocity procedure. The procedure must detail who and how reciprocity will be conducted.

Not using a third party would necessitate an internalization of accreditation activities for non-drinking water programs, which would require additional staff and an accompanying fee increase to maintain cost neutrality of the program. This would be unpopular among the laboratory stakeholders.

3.2.2 ELTAC

The Panel recommends that ELAP continue to use ELTAC as a technical resource, employing them to perform tasks that could not be performed by ELAP in a timely manner because of resource issues. In addition to fostering a stronger symbiotic relationship with the laboratory community, this relationship would provide the ELTAC community and the laboratory community in general an opportunity to have a greater voice in the laboratory accreditation process and possibly the regulatory process as it applies to ELAP's clients.

3.2.3 Training

The absence of a strong technical training program should be addressed to ensure that methods are clearly understood by the staff conducting assessments. Outside training resources can be used to buoy internal resources.

3.2.4 Software

The majority of the processes being conducted by ELAP staff for laboratory accreditation are being performed manually. This exacerbates the shortage of staff resources and lengthens the time to complete the accreditation of any individual laboratory.

Use of software to improve the processing efficiency of information being evaluated for laboratory accreditation should be initiated as soon as possible. Automated processes will enhance management of the overall accreditation process. This includes a significant labor reduction for management of the PT program, which is a significant consumer of labor resources. Software investment will facilitate the efficient use of the currently available labor resources.

CHAPTER 4: NEXT STEPS

The number one priority for ELAP, the State Water Board and stakeholders remains getting the fundamental accreditation program established and properly functional. Without an adopted standard and new resources, there will not be a future to explore. California's program must firmly reestablish itself before looking to expand beyond this critical role.

To evaluate achievement of ELAP's core foundation, plus prioritize the journey beyond, the State Water Board should require ELAP to establish additional reportable metrics, to have a gap analysis performed, and to create another expert panel.

Metrics must demonstrate ELAP is meeting all programmatic requirements, which includes expectations outlined in the programmatic Standard Operating Procedures (SOPs), expectations outlined in the TNI Standards, and expectations inherent in all client requests. Making use of a formal complaint process is another important metric for evaluating improvements over time. While a reduction of complaints is desirable, ELAP should view complaints as evidence that the community is invested in ELAP and wants to make the program stronger.

Once ELAP has been operational under its new quality management system for a year, ELAP should hire an independent consultant to perform a gap analysis. The resulting report will offer the State Water Board a critical evaluation of the core program's status, provide an immediate spring board for engaging another expert panel, and inform the program's readiness to establish goals beyond ELAP's base functions.

ELAP should commission a new panel to conduct a follow-up review of the Panel's supplemental recommendations in approximately two years. This panel should be charged with the mission of evaluating the ELAP program from an internal and external perspective. The proposed panel's objectives would include an assessment of program development progress, recommendations for mid-course corrections, and suggestions for future improvements oriented toward the completion of ELAP's overhaul. In the interim, it is recommended that ELAP continue to brief the existing Panel on their progress through webinars every six months.

ELAP is not presently achieving its mission, but there is a path to get there. The Panel believes ELAP is regaining credibility; working toward an accreditation process the State and stakeholders support; working to reliably ensure environmental and public health data used are of known, consistent, and documented quality; and working on sustainability. State support is critical for ELAP to fully achieve its mission, and the State should continue to hold the program accountable.

APPENDIX A: PANEL'S RESPONSE TO CHARGE QUESTIONS

1. Has California ELAP been responsive to the recommendations provided by the Panel in their initial review?

Yes. The program has been responsive and made significant improvements in many areas covered by the recommendations provided by the Panel. ELAP has worked tirelessly to begin the arduous task of rebuilding. However, there is still a great deal of work ahead for ELAP to achieve its objective to ensure laboratories are competent to generate data of known, consistent, and documented quality for use by the State of California in its environmental and public health decision making. (Chapter 2)

a. Did ELAP provide appropriate rationale for any deviations from the Panel suggestions?

The only deviations from the Panel's suggestions were related to adjustments in the timeline for completing the suggested actions. This was most evident in the effort associated with selecting the standard used for assessing laboratories. This delay was a result of ELAP thoroughly engaging its entire stakeholder community in the process of identifying a standard that would meet everyone's needs. While it was prudent to do this, it has created a significant delay in moving ahead with the selection, adoption, and implementation of a more structured program. (Section 2.2)

2. Has the program become more effective as a result of those changes?

In some areas, ELAP has become more effective as a result of the changes it has made. Chapter 2 details the effectiveness of these changes and identifies where some of these changes have yet to be fully implemented, limiting the improvements to the program.

3. Do you have any modifications to the advice you provided in October 2015 as a result of lessons learned by the program in the last year?

No. The Panel feels that the advice provided in the October 2015 report are still valid and will result in the desired improvements to the program.

4. What are the biggest challenges remaining for the program?

ELAP faces a number of remaining challenges as it continues rebuilding California's laboratory accreditation program. Chapter 2 of this document addresses these concerns by looking at infrastructure, standards, stakeholders and resources.

5. Is the timeline outlined by ELAP for meeting these remaining challenges appropriate?

Yes. Key to meeting the timeline is the ability to quickly achieve consensus on issues where extended debate is delaying progress.

6. The Panel recommendations from the first review focused on activities needed to address to meet minimum program acceptability. What new activities does the Panel suggest the program engage in next to take it beyond minimum acceptability?

The Panel's supplementary recommendations fall into two broad categories: standard selection and resources. Specific tasks are identified that build on the progress that ELAP has made to date, and will ultimately lead to the accomplishment of ELAP's mission objectives and fulfillment of its vision to become one of the best laboratory accreditation programs in the nation. (Chapter 3)

7. This is the last meeting of the Review Panel. What metrics should the program use in the future to self-assess how well it is progressing toward its goal of becoming one of the best laboratory accreditation programs in the nation?

To continue to assess the progress of the program, ELAP should conduct a third-party assessment of its program once the quality management system is implemented to identify any areas that are not meeting the specifications of the quality system and the TNI Standard. ELAP should also look to establish a new review panel to assist the program in the establishment of ongoing metrics to evaluate progress (Chapter 4). One item the next review panel should explore is whether ELAP should apply for ISO 17011 accreditation (Conformity assessment – general requirements for accreditation bodies accrediting conformity assessment bodies).

APPENDIX B: PANEL COMMENTS ON THE 58 ITEMS IDENTIFIED BY STAKEHOLDERS AS NEEDING MODIFICATION OF THE TNI STANDARD

This table is a simplified copy of the one produced by ELAP to highlight the 58 items identified by stakeholders for modification to the TNI Standard. The first three items highlighted in yellow were noted as ‘ELAP Deleted’. The remaining items were marked by the Panel as ‘implementation’ or ‘clarification’. Implementation means the item should be addressed by ELAP in a timetable or schedule provided for implementation or addressed during rulemaking, which is highlighted by an * and discussed in section 3.1. Clarification means the item should have supplemental information provided in guidance or through training.

ITEM #	MODULE	SECTION	SUMMARY	PANEL RECOMMENDATION
A	2	4.1.5 (k)	Relevance of Activities	ELAP DELETED
B	2	5.6.4.1	Reference standards and reference materials. Delete sentence that precedes subsection (a)	ELAP DELETED
C	5	1.7.3.7 (b) (ii) (a)	Autoclaves	ELAP DELETED
D	2	4.1.7.1 (d)	QA Manager training/experience	IMPLEMENTATION
E	2	4.3	Document Control	IMPLEMENTATION
F	2	4.8	Complaints	IMPLEMENTATION
G	2	4.11	Corrective action (documentation requirements)	IMPLEMENTATION
H	2	4.12	Preventive action (documentation requirements)	IMPLEMENTATION
I	2	4.13	Control of Records (documentation requirements)	IMPLEMENTATION
J	2	4.15	Management reviews (documentation requirements)	IMPLEMENTATION
K	All	Notes	Notes provide clarification of the text. Revise - boldly state notes are not enforceable.	CLARIFICATION
L	1	4.2.4	LOQ Requirements. Remove any reference to LOQ and replace with something more specific to CA regulatory agency needs (for example DLR for DW). ELTAC will work with SAPC	CLARIFICATION
M	1	4.3.5	LOQ Requirements.	CLARIFICATION
N	1	4.3.7	LOQ Requirements.	CLARIFICATION
O	1	5.0	PT Frequency. Revise	IMPLEMENTATION*
P	1	5.2.1.1	PT Assessments. Revise - make Section 5.2.1.1 consistent with the requirement of one PT per year	IMPLEMENTATION*
Q	2	2.0	Normative References	CLARIFICATION
R	2	3.1	MDL Verification. Remove any reference to MDL as currently specified; work with SAPC to come up with solution that more adequately meets their needs	CLARIFICATION
S	2	4.1.2	Reference to "International Standard"	CLARIFICATION
T	2	4.1.6	Staff Communication. Recommend ELAP provide training/clarity on how this provision will be audited against.	CLARIFICATION

ITEM #	MODULE	SECTION	SUMMARY	PANEL RECOMMENDATION
U	2	4.1.7.1 (c)	QA Officer Impartiality. Modify to say something like: "without influence from others within or outside the lab."	CLARIFICATION
V	2	4.1.7.2 (e)	Requirements when Tech. Mgr. is absent > 15 days. Delete timeframe for notification, require an alternate when on leave; or delete and replace with current ELAP language	IMPLEMENTATION
W	2	4.2.2.3	Reference to "International Standard"	CLARIFICATION
X	2	4.2.4	Staff Communication	CLARIFICATION
Y	2	4.2.6	Reference to "International Standard"	CLARIFICATION
Z	2	4.4	Review of Requests, Tenders and Contracts	CLARIFICATION
AA	2	4.5	Subcontracting	CLARIFICATION
AB	2	4.5.1	Reference to "International Standard"	CLARIFICATION
AC	2	4.5.4	Reference to "International Standard"	CLARIFICATION
AD	2	4.11.5	Reference to "International Standard"	CLARIFICATION
AE	2	4.14.1	Reference to "International Standard"	CLARIFICATION
AF	2	4.14.5 (c)	Internal Audits. Modify - require internal audits during years ELAP is not performing assessment	CLARIFICATION
AG	2	5.2.6 (all)	Technical Manager Qualifications. Add a sentence saying if the technical manager does not meet qualifications in TNI Standard, the lab should describe how they will ensure this does not adversely affect the quality of the work.	IMPLEMENTATION*
AH	2	5.2.6.1 (f)	Technical Manager Qualifications (for labs analyzing radon in air). Remove. Not Applicable	IMPLEMENTATION*
AI	2	5.4	Use of Non-Standard Methods. Add a sentence saying that the State regulatory agency can approve methods.	CLARIFICATION
AJ	2	5.4	Requirements for calibration labs. Be careful not to delete references to calibration of equipment such as balances and pipets to traceable standards.	CLARIFICATION
AK	2	5.4.1	Use of Non-Standard Methods. Add a sentence saying that the State regulatory agency can approve methods.	CLARIFICATION
AL	2	5.4.3	Lab Developed Methods. Modify - add to regs labs shall be able to generate data that is reproducible (by inter-laboratory comparison) by other labs and process has to go to SAPC for method approval (see 1-page ELTAC recommendation)	CLARIFICATION
AM	2	5.4.4	Lab Developed Methods. Add to regulations: Comparability of non-standard methods should be demonstrated by inter-laboratory study or analysis of split samples by an independent laboratory. ELTAC propose comparability language for non-chemical methods.	CLARIFICATION
AN	2	5.4.5	Lab Developed Methods.	CLARIFICATION
AO	2	5.4.6.1	Requirements for calibration labs	CLARIFICATION
AP	2	5.5	Requirements for calibration labs	CLARIFICATION

ITEM #	MODULE	SECTION	SUMMARY	PANEL RECOMMENDATION
AQ	2	5.5.1	Reference to "International Standard"	CLARIFICATION
AR	2	5.6.2.1.1	Requirements for calibration labs	CLARIFICATION
AS	2	5.6.2.2.2	Requirements for calibration labs	CLARIFICATION
AT	2	5.8	Handling Samples. ELTAC: Remove and simplify and make more specific. SAPC: Do not delete; consider adding the DoD clarifications and additions.	CLARIFICATION
AU	2	5.9	Requirements for calibration labs	CLARIFICATION
AV	2	5.9.3	LOQ Requirements.	CLARIFICATION
AW	2	5.10	Requirements for calibration labs	CLARIFICATION
AX	2	5.10.7	Reference to "International Standard"	CLARIFICATION
AY	4	1.5.2.1	LOQ Requirements.	CLARIFICATION
AZ	4	1.5.2.1.2	MDL Verification.	CLARIFICATION
BA	4	1.5.2.2	LOQ Requirements	CLARIFICATION
BB	4	1.5.2.2.2	MDL Verification.	CLARIFICATION
BC	4	1.7.1	Calibration Requirements (for Chemistry Methods). Delete last sentence of first paragraph 1.7.1	CLARIFICATION
BD	4	1.7.1.1 (f)	Calibration Standards. Modify - only when the method does not specify then the section applies	CLARIFICATION
BE	4	1.7.1.2	MDL Verification.	CLARIFICATION
BF	4	1.7.2.4	Data Reduction. Modify - strike "such as use of linear regression"	CLARIFICATION

APPENDIX C: BIOGRAPHIES OF PANEL MEMBERS

Jordan Adelson



Dr. Jordan Adelson has a Ph.D. in environmental analytical chemistry, and currently serves as the Director of the Navy's Laboratory Quality and Accreditation Office (LQAO) and as the Chair of the DoD Environmental Data Quality Workgroup (EDQW). As Director of the LQAO, Dr. Adelson manages the accreditation programs for the Naval Shipyard Material Testing Laboratories and implements quality system requirements on all NAVSEA testing laboratories. As the Chair of the EDQW, Dr. Adelson oversees the DoD Environmental Laboratory Accreditation Program (DoD ELAP) and develops and recommends DoD policy with respect to environmental sampling and

Stephen Arms



Stephen Arms is the former Administrator of the Florida Department of Health's Environmental Laboratory Certification Program. He was responsible for oversight of the program's quality system and day-to-day operations, and was the central point of contact for information, interpretations, and decision-making in all areas of certification for the State. He retired from state service in February 2016 but remains active in the environmental laboratory community. He now does part-time consulting and training with a small environmental quality assurance firm in Florida and also serves in leadership roles for The NELAC Institute and the Florida Society of Environmental Analysts.

Lara Phelps



Lara Phelps (Panel Chair) is the Senior Advisor for Measurement, Modeling, Monitoring, and Laboratory Science Issues with the U.S. Environmental Protection Agency (EPA) in the Office of the Science Advisor (OSA). Over her years of government service, she has gained expertise in a wide range of areas including budgeting and program planning, quality systems, laboratory accreditation, monitoring and testing issues, proficiency testing, regulatory issues, modeling, statistical design and analysis, and innovative strategies and technologies. At present, she is not only an advisor for science issues, but is serving as the Director of the Forum on Environmental Measurements, Director for the Environmental Modeling Community of Practice, Designated Federal Official for the Environmental Laboratory Advisory Board, and Quality Assurance Manager for OSA. She has received numerous honors including the Association of Public Health Laboratories 'On the Front Line' award, four bronze medals, and service recognition in support of the Nation's response to the Deepwater Horizon Oil Spill. Lara is also involved in several professional organizations.

David Speis



David Speis is the retired President of Eurofins QC, Inc. in Southampton, Pennsylvania. He has extensive senior staff and management experience in commercial environmental laboratories including technical operations, quality assurance, business development, and facility general management. Mr. Speis has served on the USEPA's Environmental Laboratory Advisory Board as a member and Past Chair. He also serves as a Board member and Treasurer of The NELAC Institute (TNI) and had also served as past chair. He is a past member of the Executive Committee of ACIL's Environmental Sciences Section. He served on the board of the International Association of Environmental Testing Laboratories (IAETL), and during this time assisted in development of the initial framework for National Environmental Laboratory

APPENDIX D: STAKEHOLDER ADVISORY COMMITTEE (SAC) MEMBERSHIP

The members of the Stakeholder Advisory Committee are:

- Socorro Baldonado, Metropolitan Water District
- Cindy Ziernicki, Helix Water District
- Andy Eaton (Chair), Eurofins Eaton Analytical, Inc.
- Bruce Godfrey, Curtis & Tompkins Labs
- Calvin Liu, Contra Costa Water District
- Terry Powers, South Tahoe Public Utility District
- Pamela Schemmer, Test America, Inc.
- Josie Tellers, City of Davis
- Anthony Gonzalez, Sacramento County Public Health Laboratory
- Allison Mackenzie, Babcock Laboratories
- Pete Ode, California Department of Fish and Wildlife

APPENDIX E: MEETING AGENDA

STATE OF CALIFORNIA ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

**Jan 31-Feb 2, 2017
Draft meeting agenda**

To be held at:
Southern California Coastal Water Research Project
3535 Harbor Blvd. Costa Mesa, CA 92626
Meeting will be webcast via gotomeeting

Day 1 – Tuesday, January 31 (open to public)

8:00	Coffee & pastries	
8:30	Welcome and introductions	Steve Weisberg SCCWRP
8:40	Purpose of the review	Tam Doduc Board Member - State Water Resources Control Board
8:50	Panel charge questions	Steve Weisberg SCCWRP
9:00	Overview of actions taken by ELAP since the Panel report	Christine Sotelo SWRCB
9:45	Have these actions led to program improvements?	Christine Sotelo SWRCB
10:10	Break	
10:25	Implementation of ELAP management systems	Jacob Oaxaca SWRCB

10:50	Staff training	Katelyn McCarthy SWRCB
11:15	Laboratory standards and regulation	Christine Sotelo SWRCB
11:40	Remaining tasks and vision for the future	Christine Sotelo SWRCB
12:00	Lunch (provided on site for \$10)	
Stakeholder Perspectives		
1:00	ELTAC and SAC perspectives	Andy Eaton Eurofins Eaton Analytical
1:30	State agency partner committee perspective	Bruce LaBelle Department of Toxic Substances Control
2:00	Results of US EPA Program Audit	Andy Lincoff EPA – Region IX
2:30	US EPA Perspective	Dan Hautman EPA – Cincinnati
2:50	Break	
3:10	Perspective of labs that have recently undergone inspections	Patrick Jones Jones Environmental
		Jill Brodt Brelje and Race Laboratories
		Mindy Boele City of Vacaville
4:10	Challenges facing small laboratories	Daniel Jackson City of Benecia
4:30	Public comments	

5:30 Adjourn for the day

6:00 Dinner (Panel members & ELAP management team only)

Day 2 – Wednesday, February 1

8:00 Panel deliberations (panel members only)

9:00 Interviews with ELAP support staff (panel members only)

10:00 Panel deliberations (panel members only)

12:00 Lunch on-site (panel members only)

1:00 Panel deliberations (panel members only)

5:00 Adjourn for the day

6:00 Dinner (panel members only)

Day 3 – Thursday, February 2

8:00 Panel deliberations (panel members only)

Panel Report Out (open to public)

10:30 The Panel's initial findings

Panel Chair

11:00 Public comment and questions for the Panel

11:45 Timeline for completing Panel reporting

Steve Weisberg
SCCWRP

12:00 Adjourn

DELAPO Report

Christine Sotelo, CA ELAP

ELAP Progress

- Training contract has been awarded
 - The winning firm is Dade Moeller
 - Several subcontractors have signed on: Steven Arciaga Inspection Services, A2LA, EM2 Management Solutions
- We expect training assessments to begin this summer

ELTAC Vacancy

- Committee Member Guilda Neshvad has resigned
- We will call for nominations to fill her seat
 - New member will represent hazardous waste laboratories
 - Selection process will follow the same process as your appointments
 - Appointee will be selected by Division of Drinking Water's Deputy Director
- We want to take this opportunity to recognize the extraordinary commitment that you all have made since you were appointed

Thank You, ELTAC Members



Fees

Department of Administrative Services (DAS)

- DAS will be taking over this topic
 - Ryan Wilson is the contact person:
ryan.wilson@waterboards.ca.gov
- They are proposing to form a stakeholder workgroup and will be looking for volunteers

Flexibility

- Senate Bill 839 (2016) made changes to the fee language
- It required that the State Water Resources Control Board adopt fees by emergency regulations
 - This is consistent with other fee-supported Water Board programs
- It also removed the outdated Field of Testing list
 - Specifics were replaced with general language
 - This will provide for maximum flexibility in the creation of new ELAP fee schedule

ELTAC's Role

- ELTAC will provide initial direction
 - Your preliminary vote and today's discussion will serve as a jumping-off point
- You will have the opportunity to give feedback on the models the workgroup develops
- We'll ask for a formal recommendation when options are finalized

Andy will kick off the discussion

- Ryan Wilson is here to answer questions as needed

Potential Fee Models

Andy Eaton

ELTAC Chair

We have a spreadsheet to allow us to do modeling

- Based on current stats for certs for every certified lab.
- Does not include the type of lab (muni vs commercial vs captive).
- We can work live with the spreadsheet during the ELTAC meeting.

Basic Stats on ELAP Labs (as of March 1)

- 709 certified labs
- 2968 FOTs
- 18,457 methods

Former Total Fees

- $\$1512 \text{ base fee} \times 709 = \$1,072,088$
- $\$681/\text{FOT} \times 2968 = \$2,021,208$

Total \$3.1M (vs budget of \$3.4M)

There is also about \$120K of fee waivers, so..

Total ~\$3M

New Total Fees based on new emergency regs effective now

- $\$1890 \text{ base fee} \times 709 = \$1,340,010$
- $\$851/\text{FOT} \times 2968 = \$2,525,768$

Total ~\$3.9M (vs budget of \$3.4M)

There is also about \$120K of fee waivers, so..

Total ~\$3.8M (budget plus 10% contingency plus 3% annual increase)

A Question to Ponder

- Current fees generates **\$3.8M**, but that includes 10% to reserves, so if we keep fees at that level we would be adding to the reserves each year.
- Current approved budget is \$3.34M, so should the goal going forward be to generate that plus 3% increase per year?
- If one assumes \$120K of waivers, that equates to **\$3.56M** as target revenue in 2018-19.

Credits for External Assessments

- A typical external assessment for a large lab would be anywhere from \$6K (surveillance) to \$15K (full assessment).
- For ISO, every other year is a full assessment and in between years are surveillance.
- But also, CA would not be doing annual on site assessments in any event, and is generally looking at tri-annual, so the assessment cost is not as large a portion of the overall fee as one might think.
- So a credit of \$5,000 for labs using external assessors would be a reasonable starting number.

One Approach

- Keep base fee where it is under the new regs (\$1890)
- Split FOTs into L, M, H complexity (use the old CA NELAC categories)
 - Low (115, 120, 121)
 - Medium (101, 102, 103, 106, 107, 108, 109, 112, 114, 118)
(NB: Should radchem really only be Medium)
 - High (104, 105, 110, 111, 113, 116, 117, 119)
- Use FOT fees of \$350 (L), \$700 (M), and \$1050 (H), which averages out to \$789 (midway between \$681 and \$851)
- Credit labs that use an external assessor \$5,000

Lets do some modeling

- Under the proposal ($\$1890 + 350/700/1050$) we generate total fees of \$3.7M
- We then need to subtract \$0.12M (waivers) and
- Assume 66 labs (all those with calculated fees of \$10K or more) use an external assessor and receive a credit of \$5,000 each. (-\$330K)
- The total fees are: \$3.2M, so not quite enough. Range for labs would be \$2.24K-\$14K (assuming all labs with fees > \$10K use an external assessor).

Version 2: increase base fee

- Under the proposal ($\$2250 + 350/700/1050$) we generate total fees of \$3.9M
- We then need to subtract \$0.12M (waivers) and
- Assume 66 labs use an external assessor and receive a credit of \$5,000
- The total fees are: $\$3.5M$, so in the right range. Range for labs would be \$2.6K-\$14K (assuming all labs with fees > \$10K use an external assessor). If some of the >\$10K labs DON'T use an external assessor, the revenue would be higher, and per lab cost could go as high as \$19K.
- Range of per lab fees is comparable to current range with new fees

Version 3: increase FOT fees

- Under the proposal ($\$1890 + 400/800/1200$) we generate total fees of \$4.02M
- We then need to subtract \$0.12M (waivers) and
- Assume 66 labs use an external assessor and receive a credit of \$5,000
- The total fees are: $\$3.6M$, so again in the right range. Range for labs would be \$2.3K-\$16K (assuming all labs with fees > \$10K use an external assessor). If some of the >\$10K labs DON'T use an external assessor, the revenue would be higher, and per lab cost could go as high as \$21K.
- Note that with this model there is a much greater range of fees (smaller labs are about 10% lower and larger labs are about 10% higher)

What if we use method instead of FOT?

- Too much incentive for labs to drop methods, which limits availability for permits, etc. and could also lead to limited competition.
- In general, fees for larger labs go WAY up (\$30K) if we make the per method fees enough to cover the \$3.9M, and the credit for external assessments should probably be a lot higher.

So What Are The Questions We Need to Resolve (or at least weigh in on)?

- What's an appropriate base fee?
- What is the relative amount of resources that CA will need to expend on different size labs?
- What should the magnitude of credit be for labs that use external assessors?
- How wide a spread should there be among CA certified labs as far as fees? (our version of "income inequality")

Agenda Item:

Fees

Electronic Attachment:

Fee Model spreadsheet – by Laboratory, Fields of Testing, and Number of Certified Methods

DDW's Transition to SDWIS for Electronic Water Quality Data Reporting

Jim Stites, Division of Drinking Water

DDW's Transition to SDWIS for Electronic Water Quality Data Reporting

Jim Stites, PE

DDW SDWIS Unit Manager

SDWIS Transition Goals

- Electronic Data must meet Quality Control and Quality Assurance criteria
- Electronic Data must be legally defensible with adequate signatory authority.
- Transition to SDWIS-Prime & Compliance Monitoring Data Portal (CMDP) and move completely away from Write-On/WQIR.

Where We Are Now

- WQIR is our current database of record for water quality data
- Schema based on Electronic Deliverable Format [EDF] Version 1.2i Data Dictionary
- Write-On & LIMS use this schema for electronic data files

Where We Need To Be

- SDWIS-Prime (Safe Drinking Water Information System for Primacy Agencies)
 - Compliance Management System developed by EPA
 - Tracks and reports compliance with SDWA rules
- Compliance Monitoring Data Portal (CMDP)
 - CROMERR Compliant portal
 - Shared CROMERR Services
 - Electronically submit compliance sampling results

SDWIS Transition

- Short Term - SDWIS 3.33
 - Current process
 - Last stand alone version that is supported by EPA
 - Costly for EPA to support across all Primacy Agencies
 - Includes Lab-To-State application for electronic water quality data files
- Long Term – SDWIS Prime
 - Cloud based architecture supported by EPA
 - Includes CMDP
 - CROMERR Compliant Portal
 - SDWIS Prime full release expected 2018

SDWIS 3.33 Transition

- Track and report individual Pb & Cu results for LCR
- Will require updated processes for lab submittal of water quality data
- Files must follow eDWR v3.0 schema
 - csv or XML format
- We will stand up new portal (Lab-To-State) that supports this format

WQIR and EDF vs LTS and eDWR

- EDF files do not match SDWIS requirements (eDWR)
 - Storets vs. Analytes
 - Missing Lab Sample ID
 - Laboratory Analytical Method Association
 - Associating repeat samples to routine positive samples
- WQIR is not able to track compliance with Distribution System Monitoring
 - RTCR (TCR)
 - LCR
 - DBPR (except LRAA)
- Migrating data from WQIR to SDWIS is not efficient and can result in data errors

Phased Approach for Transitioning Lab Data to SDWIS

- Rule-base approach
- LCR – Not currently reported electronically
- RTCR – Not currently reported electronically
- GWR – Not currently reported electronically
- DBPR – Reported electronically
- Source Water Data – Reported electronically
- SWTR – Not currently reported electronically
- Operational Data and Sample Data

Immediate Goals (2017)

- Get individual LCR results into SDWIS
 - Lead in drinking water is a national Issue
 - Not currently tracked in WQIR
 - Gain familiarity with migration process and implementing SDWIS business rules
 - Will require a new portal (Lab-To-State) and reporting format

Lab-To-State

- Developed by EPA's contractor.
- Generates XML files for migration to SDWIS
- XML schema based on eDWR v3.0 standard
- Portal only and not a replacement for Write-On
- Accepts csv or XML files
- LTS is also available to labs as a stand-alone application
- LIMS should be capable of producing formatted files

Lab To State Issues

- Includes validations to ensure proper schema formatting
- Does not include validations for Inventory or PS-Codes components
- Additional validations needed for
 - PWS ID
 - PS Codes
 - Collection Address
 - Lab and Method Certification
- These validations will be handled outside of LTS
- Does not meet CROMERR compliance by itself

Electronic Data Files

- We will continue to use WQIR for compliance tracking while we phase in SDWIS
- Labs will need to be able to submit EDF files for WQIR as well as eDWR files for LTS/SDWIS
- Labs will only need to submit files in one format, depending on whether data are going into WQIR or SDWIS
- Write-On will continue to be functional for WQIR data
- LIMS will need to be updated to generate EDF or eDWR formatted files
 - Expect that larger national labs are already familiar with SDWIS format

Long Term Goals

- Transition to SDWIS Prime
 - Expect to be in full production in 2018
 - May be a couple of years before we adopt
- Compliance Monitoring Data Portal (CMDP)
 - Hosted by EPA
 - CROMERR Compliant
 - Portal where all water quality data will be submitted
 - Lab accesses directly
 - Implement CMDP within next 2 to 5 years(?)

CMDP

- Pulls inventory from SDWIS
- Allows Labs and water systems to request updates to their own profiles
- Up-to-date profiles allows CMDP to properly validate samples at the time of data submittal
- Federal reporting validations – works with SDWIS Prime
- Uses proprietary XML schema. Does not support eDWR XML schema

CMDP – Electronic Reporting Methods

- Web Services
 - Connecting submitter data management systems to CMDP
 - One way services
- Upload XML files generated by CMDP Excel templates
- Direct data entry using webforms

Data Validations

- Built into SDWIS/St and SDWIS-Prime
- Valid Lab ID
 - Lab Name and administrative contact
- Standard Method names and codes
- Analyte method pairing
- Lab–Analyte Method Association
- Dates of certification
- State-specific validations
 - May need to be developed outside of CMDP or LTS

CROMERR

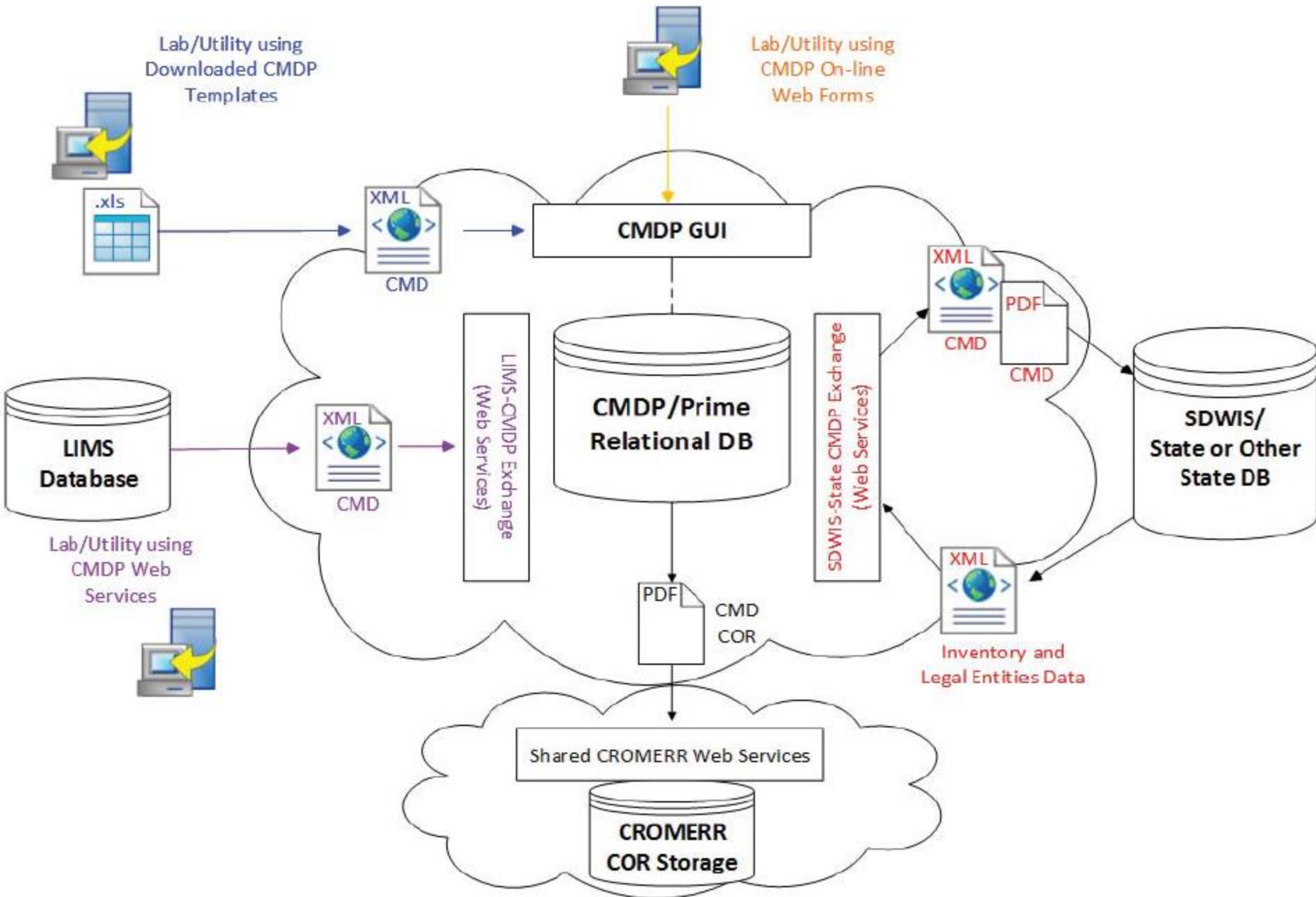
- CMDP Is CROMERR-Compliant
- Shared CROMERR Services
- All Labs must register
- Registration includes a third-party verification process and any e-signature requirements between user and organization

EPA CMDP Helpdesk

- <https://cmdp.zendesk.com/hc/en-us>

CMDP Reporting Process Flow Diagram

States *not* using SDWIS Prime



Questions?



Status of the 2016 Clean Water Act Analytical Methods Update Rule (MUR)

Maryam Khosravifard, CA ELAP

Status

- **Not in effect**
 - Because it has not been published in the Federal Register
- MUR was signed December 2016, before new US administration took office
 - All new regulations are on hold by the new USEPA Administrator
- Future uncertain

When (if) Published, What Next?

- ELAP will not immediately update FOTs
- Before we offer the updates several things have to happen
 1. Agencies need to update policies, permits, regulations
 2. Agencies need to request that we accredit laboratories for the updated methods
 3. ELAP builds internal capacity to assess
 4. Update FOTs and notify community
- These tasks take time

What will the MUR Change?

- Alternate Test Procedure (ATP) process
- Method Detection Limit (MDL) procedures
- Updates various methods

Clarifying the ATP Process

- The rule clarifies that the US EPA is the only authority for approving limited use ATPs
 - Currently, language suggests States or permitting authorities can approve
- Regional ATP Coordinators will be able to authorize regional ATPs
- Language is added that instructs laboratories to contact the EPA Regional ATP Coordinator with questions

Revised MDL Procedures

- Will require quarterly analysis of samples
 - Current requirement is once-per-year
- This will satisfy the TNI standard requirement for MDL procedures



Questions

Close