California Environmental Laboratory Accreditation Program

Environmental Laboratory

Technical Advisory Committee (ELTAC) Meeting

July 13, 2017

CALIFORNIA
Water Boards
STATE WATER RESOURCES CONTROL BOARD
REGIONAL WATER QUALITY CONTROL BOARDS

Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

State Water Resources Control Board
Division of Drinking Water

NOTICE OF ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC) MEETING

July 13, 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
1001 I Street, Conference Room 2540	700 North Alameda Street, Room 2-145
Sacramento, CA 95814	Los Angeles, CA 90012

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 March 29, 2017 Meeting and Approval of Minutes

ITEM #4 – DELAPO Report

ITEM # 5 – Workgroup Updates

ITEM # 6 – Enforcement Implementation Discussion

ITEM # 7 – Draft Regulations Outline

ITEM # 8 – Close

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

Thursday, July 13, 2017 – 10:00 a.m.
1001 I Street, Conference Room 2540
Sacramento, CA 95814
And
Metropolitan Water District of Southern California
700 North Alameda Street, Room 2-145
Los Angeles, CA 90012

Meeting Agenda

TIME	AGENDA ITEM	PRESENTER(S)
10:00am	**Call to Order** *Objective: Roll call.*	Andy Eaton, *Chairperson*
10:05am	**Public Comments on Items not on Agenda**	Open
10:10am	**Summary of March 29, 2017 Meeting & Approval of Minutes** *Objective: Amend or approve minutes.*	Andy Eaton
10:30am	**DELAPO Report** *Objective: Update members on recent developments and activities.*	Christine Sotelo, *DELAPO*
11:00am	**Fees Stakeholder Workgroup Update** *Objective: Update members on recent developments and activities.*	Andy Eaton
11:15am	**Proficiency Testing Workgroup Update** *Objective: Update members on recent developments and activities.*	Dr. Christopher Ryan, ELAP

11:30am	**Enforcement Implementation Discussion** *Objective: Discuss administrative and PT requirements.*	David Kimbrough, all members
12pm-1pm	Lunch	
1:00pm	**ELAP Draft Regulations Outline** *Objective: Discuss preliminary draft regulations concepts.*	Maryam Khosravifard, ELAP
3:45pm	**Close – Review Action Items** *Objective: Review any assignments generated during the meeting.*	Andy Eaton
4:00 pm	**Adjourn**	

Welcome Environmental Laboratory Technical Advisory Committee

July 13, 2017

Today's Topics

- ELAP Progress
- Workgroup Updates
- Draft regulations concepts

Call to Order/Roll Call

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
ELTAC MEETING
Thursday, July 13 2017 – 10:00 a.m.
1001 I Street, Conference Room 2540
Sacramento, CA 95814
And
700 North Alameda Street, Room 2-145
Los Angeles, CA 90012

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 March 29th Meeting and Approval of Minutes

CALIFORNIA ENVIRONMENTAL LABORATORY TECHNICAL ADVISORY COMMITTEE (ELTAC)
COMMITTEE MEETING MINUTES
MARCH 29, 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 March 29, 2017 at 10:00 a.m. at the California Environmental Protection Agency Headquarters, 1001 I Street, Conference Room 2540, 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 (Chairperson)
Miriam Ghabour
Bruce Godfrey
Anthony Gonzalez
Rich Gossett
David Kimbrough
Mark Koekemoer
Allison Mackenzie

State Regulatory Agency Employees (non-voting):

Gail Cho
Renee Spears

Not Present:

Bruce Burton (non-voting State Regulatory Agency Employee)
Bruce LaBelle (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 Minutes from January 4, 2017 Meeting

Motion: Member Gossett motioned to adopt the minutes.
Seconded by: Member Mackenzie
MOTION CARRIED: March 29, 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
Nay:	None
Absent:	None
Abstain:	None

ITEM #4 – Follow up on Expert Review Panel Meeting and draft report

- Expert Review Panel facilitator, Dr. Stephen Weisberg, Ph.D, gave an update to committee members on the nature of the public comments he had received on the draft Final Expert Review Panel Report.

- DELAPO Christine Sotelo updated committee members on ELAP's perspective on the report:
  - Tough, but fair
  - Agree with three main recommendations:
    - Invest in new software
    - Only adopt essential modifications to the TNI Standard in regulation and develop an implementation plan to assist laboratories
    - Accept third-party assessments to reduce backlog
  - ELAP requests ELTAC guidance on details of implementation and third-party

- Committee members discussed the Expert Review Panel's recommendations but **no formal action was taken**.

ITEM #5 – DELAPO Report

- DELAPO Christine Sotelo updated committee members on the program's progress since last meeting:
  - 2nd edition of ELAP newsletter, The Lab Report, was released
  - Training contract was awarded to Dade Moeller & Associates
    - Expect training to begin this summer

- ELTAC vacancy was announced – ELAP will call for nominees to fill empty seat representing hazardous waste laboratories

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ITEM #6 – Fees

- The Water Board's Department of Administrative Services Fee Branch will form a fees stakeholder workgroup to consider revising the ELAP fee structure.

- Senate Bill 839 made changes to the fee language in the California Health and Safety Code
  - Requires the Water Board adopt ELAP fees by emergency regulation, which is consistent with all other Water Board programs
  - Removed outdated Fields of Testing list and replaces it with general language
    - This was done to provide maximum flexibility in the creation of a new ELAP fee schedule

- Chairperson Andy Eaton presented a new fee model.

- Committee members discussed ELAP fees but **no formal action was taken**.

ITEM #7 – Informational Items –

- Jim Stites, Division of Drinking Water, presented Division of Drinking Water's (DDW) Transition to Safe Drinking Water Information System (SDWIS) for Electronic Water Quality Data Reporting. He explained DDW's plan to transition to SDWIS and steps they anticipate taking to accomplish that goal.

- Maryam Khosravifard, ELAP, gave an overview of the 2016 Method Update Rule and confirmed that it was not in effect until published in the Federal Register.

ITEM #8 – Close

Motion: Member Clark motioned to cancel the committee's tentatively scheduled May meeting in favor of meeting in July.
Seconded by: Member Boele
MOTION CARRIED: March 29, 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
Nay:	None
Absent:	None
Abstain:	None

ADJOURNMENT

The Committee adjourned at 4:30pm.

DELAPO Report

Christine Sotelo, CA ELAP

ELAP Progress Since May 3rd

- Training contract
- Regulations
- TNI training for laboratories
- Third-party assessments

Update on Training Contract

- Classroom training begins in August
- Training assessments begin in September
  - All laboratories performing drinking water analyses will be assessed over three years
- Assessments will be scheduled based on geographic location
  - This may not coincide with renewal application
  - ELAP is considering performing assessments this way in the future

Aug 1st Board Item

- ELAP will propose a resolution asking the Board to fund a contract to train small laboratories on the 2016 TNI Standard

- If approved
  - We then begin the contracting process
  - Anticipate 7-9 months until a contract is in place

- We envision 30-ish small, single-day workshops held throughout the state
  - Templates will be provided and adapted with the assistance of the instructor
  - Goal is to leave with critical documentation of the TNI quality management system in hand

Regulations

- We’re nearing completion of a preliminary draft
- Your comments from today’s discussion will be taken into consideration
  - May result in potential revisions
- Expect preliminary draft text to be released next week

Third-Party Assessments

- The Board supported our proposal to accept third-party assessments to reduce our backlog
- We are working on a contract to identify minimum qualifications
- In interim we may be able to accept assessments from TNI accrediting bodies and TNI AB approved assessment firms

Informational Items

- Beach Monitoring Workgroup
- Radiochemistry announcement from US EPA
- Perchlorate MCL

Beach Water Quality Monitoring Workgroup

- Agency Partners want us to be capable of accrediting new and developing methods
- We reached out the to Beach Water Quality Monitoring Workgroup
  - They are a coalition of entities that meet quarterly to address beach quality issues
  - A number of them use the QPCR method
- Outcome was that they are satisfied with the current services received from ELAP
  - They believe it is premature to build capability to accredit QPCR because the method is still changing

Radiochemistry Announcement

- We have clarifying information on detection limits for radionuclides from US EPA

- The draft announcement is in the meeting packet
  - Please send comments to maryam.khosravifard@waterboards.ca.gov

- We will send the announcement to accredited radiochemistry laboratories and post online when finalized

Perchlorate DLR

- On July 5th the State Water Board approved a resolution directing staff to revise perchlorate regulations by lowering the detection limit for purposes of reporting (DLR)

- Division of Drinking Water is here to give an update

DELAPO Report

Attachments:

- Draft Announcement – “ANNOUNCEMENT REGARDING DETECTION LIMITS FOR RADIONUCLIDES”
- Document – Procedure for Safe Drinking Water Act Program Detection Limits for Radionuclides, United States Environmental Protection Agency

ANNOUNCEMENT REGARDING DETECTION LIMITS FOR RADIONUCLIDES

A new document titled "Procedure for SDWA Program Detection Limits for Radionuclides" has been posted to the EPA website: (https://www.epa.gov/dwlabcert/procedure-safe-drinking-water-act-program-detection-limits-radionuclides). This publication grew out of observations made repeatedly while auditing laboratories for radiochemistry. Almost universally, commercial laboratories were not performing the calculation correctly.

Drinking water detection limits (DL) need to be reported with the data. Radiochemistry DL's have posed an ongoing problem for laboratories because the calculations provided in the Alternative Test Procedure (ATP) protocol for radionuclides contain other requirements that may cause confusion. There is also a mistake in the current version of the Certification Manual that adds to the confusion. It cites the method detection limit (MDL) procedure from Appendix B to Part 136, which does not apply to the typically low levels.

Many laboratories report the minimum detectable activity (MDA), but MDA is not defined the same as the regulatory drinking water DL which is what they should be reporting and is detailed in the document. Additionally, the document pulls out the section from the ATP protocol that details the calculations starting from the definition to the final equation. If a laboratory has done an MDL study based on the procedure in Part 136 appendix B, they already have the data they need to calculate the drinking water DL. This requirement will be included in the next edition of the Certification Manual.

United States Environmental Protection Agency

Procedure for Safe Drinking Water Act Program Detection Limits for Radionuclides

Office of Water (MS-140) EPA 815-B-17-003 April 2017

Questions concerning this document should be addressed to:

Glynda A. Smith, Ph.D.

U.S. EPA, Office of Ground Water and Drinking Water, Standards and Risk Management Division, Technical Support Center, 26 W. Martin Luther King Dr., Cincinnati, OH 45268

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Acknowledgements

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1.0 Introduction

1.1 Background and Objectives

When analyzing radionuclides for the drinking water program, it is important to carefully evaluate method performance at the lowest concentrations attainable for the method. Critical water testing and treatment requirements impacting public health are made based on results that are often near the limits of method detection capability.

The Code of Federal Regulations (CFR) specifies Required Detection Limits (RDLs) for radionuclides. Laboratories must demonstrate their performance at those levels. Many radiochemistry laboratories are accustomed to using a Minimum Detectable Activity (MDA) to achieve this requirement. The MDA is a calculation that is based on counting precision that is scaled by multipliers to account for such factors as sample volumes, chemical yields, and counting times, which may vary. It is therefore a useful, sample-specific tool. However, MDA equations vary and may or may not account for the variability of the whole system (including, for example, the sample separation steps, which often precede instrument counting). Consequently, the Office of Ground Water and Drinking Water (OGWDW), in administering the National Drinking Water Program, emphasizes the need for laboratories to capably and reproducibly demonstrate system performance through detection limit studies. These experimental studies seek to confirm that the system does, in fact, meet the method performance that can be derived mathematically.

Because most radiochemistry methods are based on Poisson distributions rather than Gaussian distributions (as in other chemistry fields), the mechanism of calculating the detection limit for radionuclides differs from that described in 40 CFR 136 Appendix B, which is applied for inorganic and organic analytes. This document provides the derivation of the Safe Drinking Water Act (SDWA) program's radionuclide Detection Limit (herein after referred to as the "SDWA DL"), as well as practical steps for executing the experimental DL study.

1.2 Scope and Application

The procedure provided in this document describes the basis for the SDWA DL for radionuclides and provides an example calculation (see Appendix A) intended to assist laboratories conducting the DL determination for the first time. This procedure describes in detail the calculations associated with the radionuclide detection limit that is defined in 40 CFR 141.25(c). The DL procedure is one part of demonstrating method capability. The evaluation and monitoring of laboratory reagent blanks (LRBs) are also required to verify low system background, and method accuracy and precision are demonstrated through the evaluation of laboratory fortified blanks (LFBs).

2.0 Overview

As an initial estimate, laboratories should calculate their theoretical ability to meet the DL requirement of 40 CFR 141.25(c). Subsequently, they experimentally verify that their analytical system does actually perform consistently with what has been demonstrated in theory. The experimental verification consists of the analysis of at least seven standards spiked at or near the concentration of the RDL. These standards are taken through the entire analytical process, and the results are evaluated against a Chi-

square (χ^2) distribution to determine if the experimental results compare favorably with the expected values.

3.0 Calculating Detection Limits for Radiochemical Measurements

3.1 Definition of the Detection Limit for SDWA Radiochemical Measurements

The detection capability of radiochemical measurements used for SDWA drinking water compliance monitoring is defined at 40 CFR part 141.25(c) as a detection limit with the following conditions:

"The detection limit shall be that concentration which can be counted with a precision of plus or minus 100 percent at the 95 percent confidence level (1.96σ, where σ is the standard deviation of the net counting rate of the sample)."

The SDWA Detection Limit according to this definition differs from other "detection limits," such as the method detection limit or MDL (defined in 40 CFR part 136, Appendix B), and the Minimum Detectable Activity (MDA), which is commonly used by radiochemists. The RDLs for SDWA drinking water compliance monitoring of radionuclides are expressed in terms of the definition given in 40 CFR 141.25(c).

For measurements involving simple nuclear counting with Poisson counting statistics, the procedure given in Section 3.2 below is used to obtain a preliminary estimate of the SDWA DL.

3.2 Derivation of the SDWA Detection Limit Calculation

The **definition of the SDWA DL** may be expressed mathematically as follows:

$$R_{DL} = 1.96 \times \sigma_{DL} \qquad \textbf{(1)}$$

Where:
R_{DL} is the mean net count rate for a sample with concentration at the detection limit
σ_{DL} is the standard deviation of the net count rate

The relationship for the standard deviation of a radiochemical measurement is centered around the fact the gross rate has a background rate subtracted from it to derive a net count rate:

$$R_{DL} = R_G - R_B \qquad \textbf{(2)}$$

Where:
R_G is the mean gross count rate for a sample (with concentration at the DL)
R_B is the mean background count rate for a sample measurement

However, each count rate is a calculated quantity as specified below:

$$R_G = \frac{C_G}{t_G} \quad \text{and} \quad R_B = \frac{C_B}{t_B} \qquad \textbf{(3)}$$

Where:
R_G is the mean gross count rate for a sample (with concentration at the detection limit)
R_B is the mean background count rate for a sample measurement
C_G is the mean total (gross) sample count
C_B is the mean total background count

t_G is the time of the measurement used to accumulate the sample count
t_B is the time of the measurement used to accumulate the background count

The standard deviation of a count rate is proportional to the square root of the mean of a measurement. Assuming Poisson counting statistics, the standard deviations of the measured values of R_G and R_B are given by:

$$\sigma_G = \frac{\sqrt{C_G}}{t_G} = \sqrt{\frac{R_G}{t_G}} \qquad \text{and} \qquad \sigma_B = \frac{\sqrt{C_B}}{t_B} = \sqrt{\frac{R_B}{t_B}} \qquad \textbf{(4)}$$

Where:
σ_G is the standard deviation of the measured gross count rate
σ_B is the standard deviation of the measured background count rate

Since the net count rate, R_{DL}, is the difference between R_G and R_B, its standard deviation is given by:

$$\sigma_{DL} = \sqrt{(\sigma_G^2 + \sigma_B^2)} \qquad \textbf{(5)}$$

Where:
σ_{DL} is the standard deviation of the net count rate

Combining equations **(4)** and **(5)**, one arrives at:

$$\sigma_{DL} = \sqrt{\left(\frac{R_G}{t_G} + \frac{R_B}{t_B}\right)} \qquad \textbf{(6)}$$

Substituting equation **(6)** into equation **(1)**, one arrives at:

$$R_{DL} = 1.96 \times \sqrt{\left(\frac{R_G}{t_G} + \frac{R_B}{t_B}\right)} \qquad \textbf{(7)}$$

Equation **(2)** may now be used to eliminate the variable, R_G, from the equation. Since $R_G = R_{DL} + R_B$, equation **(7)** may be rewritten as:

$$R_{DL} = 1.96 \times \sqrt{\left(\frac{R_{DL}+R_B}{t_G} + \frac{R_B}{t_B}\right)} \qquad \textbf{(8)}$$

Equation **(8)** is then solved algebraically for the value of R_{DL}. First, rewrite the radicand:

$$R_{DL} = 1.96 \times \sqrt{\left(\frac{R_{DL}}{t_G} + R_B \times \left(\frac{1}{t_G} + \frac{1}{t_B}\right)\right)} \qquad \textbf{(9)}$$

Squaring each side of the equation, one arrives at:

$$R_{DL}^2 = \frac{1.96^2}{t_G} \times R_{DL} + 1.96^2 R_B \times \left(\frac{1}{t_G} + \frac{1}{t_B}\right) \qquad \textbf{(10)}$$

Collecting all items on the left-hand side to put the equation in standard quadratic form, one arrives at:

$$R_{DL}^2 - \frac{1.96^2}{2t_G} \times R_{DL} - 1.96^2 R_B \times \left(\frac{1}{t_G} + \frac{1}{t_B}\right) = 0 \qquad \textbf{(11)}$$

The quadratic formula gives two solutions to equation **(11)**, one of which is positive and one of which is negative. The positive solution is required and it is given by the following equation:

$$R_{DL} = \frac{1.96^2}{2t_G} \times \left[1 + \sqrt{1 + \frac{4t_G^2}{1.96^2} \times R_B \times \left(\frac{1}{t_G} + \frac{1}{t_B}\right)}\right] \qquad \textbf{(12)}$$

Equation **(12)** provides a reasonable estimate of the count rate at the DL for the net activity that is based on counting statistics alone. This count rate is then divided by the product of the experimental factors, *H*, which can include the following items: the method of detection's counting efficiency, the sample volume, chemical recoveries (measured by gravimetric or tracer techniques), conversion factors to picocuries, etc. The result is used to derive a specific DL of the radioanalyte of interest for a radiochemical method of analysis that is used for SDWA compliance monitoring:

$$SDWA\ DL = \frac{R_{DL}}{H} \qquad \textbf{(13)}$$

Where:

H is the product of the experimental factors (see example calculations in Appendix A)
$SDWA\ DL$ is the SDWA Detection Limit

This SDWA DL is mathematically equivalent to the detection limit specified in 40 CFR part 141.25(c). It is expected that the experimental factors will vary with specific method and sample conditions.

If an estimate of the SDWA DL described in equation **(13)** does not exceed the required DL, a DL study is performed as described below to verify that laboratory performance in practice can be demonstrated prior to analyzing drinking water samples for compliance. However, if the estimate of the DL exceeds the required DL, the performance will be considered inadequate and there will be little value in completing the experimental DL study. Conditions would need to be adjusted to meet the required DL before proceeding to confirm the DL experimentally. This may entail using a larger sample volume or longer sample counting time.
NOTE: Typical drinking water compliance samples will have very low activity levels and compliance samples should be run under the same conditions as those used to confirm the DL.

4.0 Performing Experimental Confirmation of SDWA Detection Limits for Radiochemical Measurements

4.1 Experimental SDWA Detection Limit Studies

The experimental SDWA DL study will verify that the method is capable of routinely achieving the required detection capability.

The experimental SDWA DL study consists of seven replicate samples. Each sample is prepared with ASTM II grade reagent water, or other blank matrix as appropriate for the method, and using the sample volume described in the method. For example, gross alpha analyses are highly dependent on the total dissolved solids content in the sample matrix. Reagent water can yield artificially low DLs due to higher detector efficiencies. Thus, more realistic gross alpha DLs will be obtained using either laboratory tap water or a synthetic water solids matrix to prepare the DL study samples. Each DL study sample is spiked with NIST traceable source(s) of the method target radionuclide(s) to an activity concentration at or near their RDL. The sample is mixed and then processed through sample preparation, processing and analysis per the test method. The measurements of the DL study samples are then assessed by calculating a precision statistic.

4.2 Statistical Evaluation of Detection Limit Studies

The assessment of the replicate results for each radionuclide uses a chi-square statistic to test whether the relative standard deviation of the results exceeds the maximum value allowed at the RDL.

Calculate the mean, $\bar{X}$, and a chi-square statistic, χ^2, as follows:

$$\bar{X} = \frac{1}{n}\sum_{j=1}^{n} X_j$$

$$\chi^2 = \frac{1.96^2}{\mu^2}\sum_{j=1}^{n}\left(X_j - \bar{X}\right)^2$$

Where:
n is the number of replicate measurements ($\geq$ 7)
μ is the spike concentration (at or near the RDL)
X_j is the result of the j^{th} replicate measurement (j = 1,2,…, n)

To be deemed acceptable, the value of χ^2 must be less than or equal to the 99th percentile of the χ^2 distribution with (n-1) degrees of freedom. When n = 7, the value of this percentile is 16.812.
NOTE: Refer to Appendix A – Example Calculations. Refer to Appendix B for a table of Chi-square values.

5.0 References

1. 40 CFR 141: National Primary Drinking Water Regulations
2. ASTM D1193-99[E01]: Standard Specifications for Reagent Water. American Society for Testing and Materials. March 1999, with editorial change made in October 2001.
3. MARLAP 2004. *Multi-Agency Radiological Laboratory Analytical Protocols Manual*. NUREG-1576, EPA 402-B-04-001C.
4. Chapter VI, Critical Elements for Radiochemistry. *The Manual for the Certification of Laboratories Analyzing Drinking Water*. (EPA/815-R-05-004).

Appendix A: Example Calculations

The following section provides example calculations for the estimation and experimental confirmation of the SDWA Detection Limit for radionuclide activity. The example uses gross alpha results obtained using EPA Method 900.0. The data was generated by the New Jersey Department of Health (NJDOH) Radioanalytical Services Laboratory, and is used with their permission[1].

1.0 Example Detection Limit Calculation

Equations (12) and (13) in Section 3.2 state:

$$R_{DL} = \frac{1.96^2}{2t_G} \times \left[1 + \sqrt{1 + \frac{4t_G^2}{1.96^2} \times R_B \times \left(\frac{1}{t_G} + \frac{1}{t_B}\right)}\right]$$

And

$$SDWA\ DL = \frac{R_{DL}}{H}$$

Combining these equations and considering the experimental factors relevant for gross alpha determination, the following equation is obtained:

$$DL(^{pCi}/_{L}) = \frac{1.96^2}{2t_G} \times \frac{\left[1 + \sqrt{1 + \frac{4t_G^2}{1.96^2} \times R_B \times \left(\frac{1}{t_G} + \frac{1}{t_B}\right)}\right]}{(Efficiency)(Volume)(Chemical\ Recovery)(2.22)}$$

Where:
R_B is the mean background count rate for a sample measurement
t_G is the time of the measurement used to accumulate the sample count
t_B is the time of the measurement used to accumulate the background count
2.22 is the conversion factor from dpm to pCi

For this DL study, gross alpha recovery is assumed to be 100%. R_B = 0.03 cpm, Volume = 1.0 L, and t_G = t_B = 200 minutes. The detection efficiency was 0.177 cpm/dpm. Substituting these values into the equation produces the following:

$$DL\ (^{pCi}/_{L}) = \frac{1.96^2}{(2 \times 200)} \times \frac{\left[1 + \sqrt{1 + \frac{4(200)^2}{1.96^2} \times 0.03 \times \left(\frac{1}{200} + \frac{1}{200}\right)}\right]}{(0.177)(1)(1)(2.22)}$$

$$= 9.6x10^{-3} \times \frac{1+\sqrt{1+12.5}}{0.393}$$

$$= 2.44x10^{-2} \times 4.7$$

$$= \textbf{0.11 pCi/L}$$

The Required Detection Limit (RDL) for gross alpha is **3 pCi/L**. Because 0.11 pCi/L is a smaller quantity than 3 pCi/L, it is theoretically true that the counting times, volumes, and efficiencies assumed for this example would lead to acceptable precision at the RDL concentration.

2.0 Example Experimental SDWA Detection Limit Study

The instructions for performing an experimental SDWA DL study are given in Sections 4.1 and 4.2. The following example illustrates how the evaluation criteria are applied.

Table 1. Experimental Values for Seven Spiked Replicates

Replicates	**Measured Gross Alpha (Th-230) Activity (pCi/L)**	**Spike Amount (pCi/L)**
BS 1	2.89 ± 0.30	3.0
BS 2	5.51 ± 0.45	3.2
BS 3	2.88 ± 0.31	3.3
BS 4	3.72 ± 0.36	3.2
BS 5	3.42 ± 0.34	3.0
BS 6	3.11 ± 0.32	3.1
BS 7	3.17 ± 0.32	3.1
Average:	3.53	3.13

The mean gross alpha activity is calculated using the equation:

$$\bar{X} = \frac{1}{n}\sum_{j=1}^{n} X_j$$

Substituting the data, this produces:

$\bar{X}$ = $\frac{1}{7}$(2.89 + 5.51 + 2.88 + 3.72 + 3.42 + 3.11 + 3.17) = 3.53 pCi/L

The Chi-square statistic is calculated using the equation:

$$\chi^2 = \frac{1.96^2}{\mu^2}\sum_{j=1}^{n}\left(X_j - \bar{X}\right)^2$$

Where:
n is the number of replicate measurements (7)
μ is the spike concentration (at or near the RDL; in this case 3.13 pCi/L)
X_j is the result of the j^{th} replicate measurement

Substituting the data, this produces:

$$\chi^2 = \frac{1.96^2}{3.13^2} \times [(2.89 - 3.53)^2 + (5.51 - 3.53)^2 + (2.88 - 3.53)^2 + (3.72 - 3.53)^2 + (3.42 - 3.53)^2 + (3.11 - 3.53)^2 + (3.17 - 3.53)^2]$$

= $\frac{3.84}{9.8} \times (5.1)$

= 2.0

This data set has seven replicates and thus, six degrees of freedom. So, the critical value for the statistic is the 99th percentile of the χ^2 distribution with six degrees of freedom, which equals

16.812. (see Chi-Square Table provided in Appendix B). Since the calculated χ^2 value of 2.0 does not exceed 16.812, the method passes the experimental DL study.

1. Detection Limit Study, Gross Alpha, Evaporation, EPA Method 900.0. Dr. Bahman Parsa, NJDOH Laboratory, 3 Schwarzkopf Drive, West Trenton, NJ 08628. June 14, 2011.

Appendix B: Chi-Square Values at the 99th Percentile

Table 2. Chi-Square Values (99th Percentile)

Degrees of Freedom	χ^2
1	6.635
2	9.210
3	11.345
4	13.277
5	15.086
6	16.812
7	18.475
8	20.090
9	21.666
10	23.209
11	24.725
12	26.217
13	27.688
14	29.141
15	30.578
16	32.000
17	33.409
18	34.805
19	36.191
20	37.566

Appendix C: Abbreviations and Acronyms

ASTM	ASTM International
CFR	*Code of Federal Regulations*
DL	Detection Limit
EPA	U.S. Environmental Protection Agency
MARLAP	*Multi-Agency Radiological Laboratory Analytical Protocols Manual*
MDA	Minimum Detectable Activity
NJDOH	New Jersey Department of Health
NIST	National Institute of Standards and Technology
OGWDW	Office of Groundwater and Drinking Water
RB	Reagent Blank
RDL	Required Detection Limit
SDWA	Safe Drinking Water Act

Fee Workgroup Update

Andy Eaton

Members

- **Mindy Boele** – City of Vacaville
- **Adam Borchard** – Association of California Water Agencies
- **Ron Coss** – Orange County Sanitation District
- **Andy Eaton** – Eurofins Eaton Analytical
- **Anthony Gonzalez** – California Association of Public Health Laboratory Directors
- **Nick Haring** – City of San Diego
- **Katya Ledin** – Napa-Solano-Yolo-Marin County
- **Adam Link** – California Association of Sanitation Agencies
- **Allison Mackenzie** – Babcock Laboratories, Inc.
- **Lars Oldewage** – Irvine Ranch Water District
- **Josie Tellers** – City of Davis
- **Debbie Webster** – Central Valley Clean Water Association
- **Jonathan Young** – California Municipal Utilities Association

Workgroup has met twice

- May 30th – Kickoff Meeting
  - Informational
  - Members were charged with developing options to present at the next meeting
- June 29th – Presentation of options
  - 9 concepts were presented

ELAP FEE Structure Options

Goal is to make a Fee Structure Sustainable and Scalable

- Budget numbers for ELAP vary from $3.5M to $4.1M, depending upon which costs get absorbed.

- Members have received a spreadsheet that includes:
  - All current certified labs (not by name) – 670
  - Breakdown of accreditation for each lab by:
    - In state/out of state
    - # of methods
    - # of UOAs (analytes) by complexity
    - Whether lab requires 3rd Party assessment based on ELAP capabilities

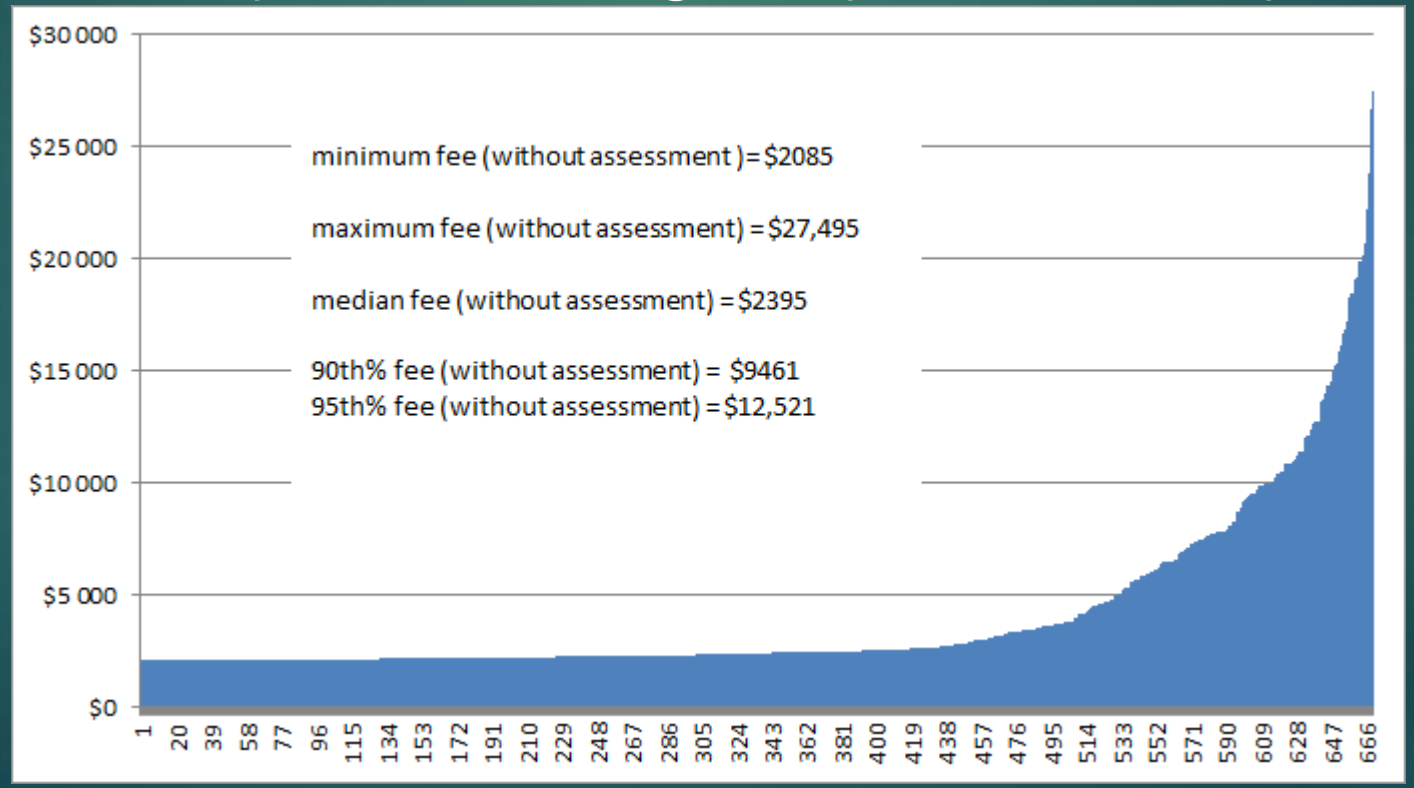
Lab	Out of State	UOAs that require third party assessment	Count Total Current FOTs	Count Total Methods	Count Total UOAs	Count Low UOAs	Count Med UOAs	Count High UOAs

There were 9 Different Options Presented/Discussed at the 29 June workgroup meeting

- All options included a base fee (but fee varied substantially)
- Additional costs
  - Some based on FOTs (current FOTs or revised FOTs)
  - Some based on method complexity
  - Some based on analytes (FOAs)
  - Some included a credit for external assessments
  - Some included assessments as an additional fee
  - Some included different charges for out of state labs

Each Person/Group That Had an Approach is being asked to model it

- Look at range of fees among labs
- Look at the slope of the range as per the example here.



The 9 Options Will then be Narrowed Down to 3 or 4

- These will be fleshed out by the group as used as the basis for workshops in the fall.
- Several of the initial proposals had similarities to each other.
- There were some significant differences in proposals as far as both the lowest fee and the highest.

Proficiency Testing Workgroup Update

Chris Ryan
Supervisor, Proficiency Testing Unit, ELAP

Origin of the workgroup

- During ELTAC meeting the need arose to have an advisory group for PT issues

Purpose of the workgroup

- Formed to identify recommendations for ELAP in addressing issued related to PT compliance

Workgroup Members

- Marshall Chaffee – Jones Environmental, Supervisor Organics section
- Maria Friedman – ELAP, Supervisor Assessment Unit
- Rich Gossett – Physis (owner), ELTAC member
- Maryam Khosravifard – ELAP, Supervisor Program Development and Research Unit
- Chris Ryan – ELAP, Supervisor Proficiency Testing Unit
- Christine Sotelo – ELAP, Chief

Workgroup Goals

- Resolve a specific *complaint* about a proficiency testing review from an ELAP accredited lab
- Make recommendations on interpretation of the *current regulations* that deal with proficiency testing
- Provide guidance on proficiency testing sections of *new regulations*

Kick-Off Meeting

- April 14, 2017

- Topics discussed:
  - Member introductions
  - Charge of the workgroup – recommendations related to PT compliance
  - Deliverables – provide recommendations to ELAP
  - Operating logisitics – how to conduct our meetings (when, where, frequency)
  - Discussion of key issues – complaint, interpretation of current regulations, and input on new regulations
  - Future meetings

Second Meeting

- June 1, 2017

- Some Topics Discussed:
  - Should ELAP require a different PT for both a WS and WP FOT w/same analyte/method?
  - Should there be a WP PT requirement for FOT 126 Microbiology of Recreational Water?
  - Should there be a PT requirement for FOT 115 Extraction Test of Hazardous Waste?
  - Feedback on our PT Web page

Thanks for your attention!

Questions?

Enforcement Implementation Discussion

David Kimbrough, Pasadena Water and Power

PASADENA

Pasadena Water and Power

Enforcement Issues with ELAP

Presented by
David Kimbrough, Ph.D., Water Quality Manager
Presented to
Environmental Laboratory Technical Advisory Committee

July 13, 2017

Enforcement Problems

Pasadena Water and Power

Approved Methods

ELAP's job is to ensure that all accredited laboratories are using approved methods with the necessary quality control and assurance procedures in a documented and consistent fashion.

a) Methods Approved by the United States Environmental Protection Agency and the State of California.
b) Including USEPA Methods, Standard Methods, ASTM Methods, and others.

Regulations

Pasadena Water and Power

Article 12. Subgroups for Fields of Testing

§64823. Fields of Testing.

(a) Field of Testing 1 consists of those methods whose purpose is to detect the presence of microorganisms in the determination of drinking water or wastewater quality and encompasses the following Subgroups: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Multiple Tube Fermentation techniques; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Membrane Filter techniques; Heterotrophic Plate Count techniques; detection of both total coliforms and Escherichia coli (E. coli) organisms by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside - 4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) techniques; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by use of Clark's Presence/Absence medium; Fecal streptococci and Enterococci by Multiple Tube Fermentation techniques, Fecal streptococci and Enterococci by Membrane Filter techniques; detection of total coliforms and fecal coliforms other than for drinking water or wastewater quality.

(b) Field of Testing 2 consists of those analytes or methods whose purpose is to detect the presence of inorganic substances in the determination of drinking water quality and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technique; and encompasses the following Subgroups: alkalinity; calcium (titrimetric techniques); chloride; corrosivity; fluoride; hardness (direct determination); magnesium (titrimetric techniques); methylene blue active substances (MBAS); nitrate; nitrite; sodium (flame emission techniques); sulfate; total filterable residue and conductivity; iron; manganese; orthophosphate; silica; cyanide; potassium (flame emission techniques).

(c) Field of Testing 3 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of drinking water quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: arsenic; barium; cadmium; total chromium; copper; iron; lead; manganese; mercury; selenium; silver; zinc; aluminum; asbestos; antimony; beryllium; nickel; thallium; calcium; magnesium; sodium; potassium.

Regulations

Pasadena Water and Power

Article 6. Required Test Methods

§64811. Test Methods.

(a) Laboratories certified for any Subgroup within Fields of Testing 1 through 6, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 141 as amended July 17, 1992, 57 Federal Register 31776.
(b) Laboratories certified for any Subgroup within Fields of Testing 9 through 14, as identified in Section 64823, shall employ those methods found in Article 5, Section 66260.11, Title 22, California Code of Regulations.
(c) Laboratories certified for any Subgroup within Fields of Testing 8 or 16 through 19, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 136, amended September 11, 1992, 57 Federal Register 41830, or methods stated in any permit issued by a California Regional Water Quality Control Board. If no method is stated in the permit and there is no method cited for the substance in Part 136, the laboratory is to seek approval for the use of the method from the Regional Board issuing the permit.

Article 5. Performance Evaluation Testing Process

22 CCR § 64809

§ 64809. Performance Evaluation Testing.

(a) No laboratory shall be certified to perform analyses in any Subgroup of any Field(s) of Testing as identified in Section 64823 unless the laboratory has submitted results for the analysis of performance evaluation sample study set(s) (where performance evaluation sample study set(s) exist) in each Subgroup within each Field of Testing for which certification is requested, and the results for the testing of the study set are in agreement with the criteria established below:

(1) within the 99% confidence limit of the mean computed by the Department for the collection of results received for the performance evaluation sample set for the following Subgroups: detection of total coliform or fecal coliform organisms in wastewater by Multiple Tube Fermentation technics; detection of total coliform or fecal coliform organisms in wastewater by Membrane Filter technics; Heterotrophic Plate Count technics; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics; Fecal streptococci and Enterococci by Membrane Filter technics of Field of Testing 1; all Subgroups in Fields of Testing 6, 9, 10, 12, 13, 16, 17, 18, and 19;

(2) positive/negative, present/absent, above/below, or other similar discrete response when the only result possible from a test is a discrete response for the following Subgroups in Field of Testing 1: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Membrane Filter technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by use of Clark's Presence/Absence medium; detection of both total coliforms and Escherichia coli (E. coli) organisms in drinking water by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside - 4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics;

(3) for all Subgroups in Field of Testing 8: within the 99% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set, or within the 95th percentile of a distribution of non-normal values. The choice determined by the Department through the application of standard tests that determine the normalcy of data;

(4) within the 95% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set for the following Subgroups: alkalinity, calcium, chloride, corrosivity, hardness, magnesium, MBAS, sodium, sulfate, total filterable residue and conductivity, iron (colorimetric methods only), manganese (colorimetric methods only), and ortho phosphate in Field of Testing 2; asbestos in Field of Testing 3;

Regulations Article 5 § 64809.

- (d) If a laboratory fails to submit results for the analysis of performance evaluation sample study sets, which meet the above requirements, **the laboratory may, within 30 days, request that it be given a second, successive attempt to submit such results.** Failure of a laboratory to submit results for the analysis of performance evaluation sample study sets meeting the requirements of (a) or (c) within 6 months from the date of receipt by the Department of the laboratory's application for certification, or of its request for the addition of one or more Subgroups within a Field(s) of Testing shall result in the denial of the application or request.

Regulations Article 5 § 64809.

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(e) With the exception of Field of Testing 6, a certified laboratory shall, within 12 months from the date of certification, participate in at least one performance evaluation sample study set (where performance evaluation sample study set(s) exist) for each Subgroup within each Field of Testing as identified in Section 64823 for which certification is held. **If the results from the study do not meet the requirements of (a) or (c), the laboratory shall be provided a second, successive attempt to submit such results.** Irrespective of whether a second, successive attempt is provided, results meeting the requirements of (a) or (c) must be submitted by a certified laboratory to the Department at least 90 days prior to the expiration of its certificate or the laboratory's certificate may be restricted under Health and Safety Code, Section 1015(c).

Regulations Article 3 § 64805

- (c) All applications filed with the Department shall be considered complete unless within 30 days of receipt, the Department mails to the laboratory's mailing address a notice that the application is not complete. Any noted deficiencies in a submitted application must be corrected and the corrected application returned to the Department within ninety days from the date of the Department's notice of deficiencies or the application shall be considered null and void.

Statute

Pasadena Water and Power

California Code, Health and Safety Code - HSC § 100875

Whenever the department determines that any person has violated or is violating this article or any certificate, regulation, or standard issued or adopted pursuant to this article, the director may issue an order directing compliance forthwith or directing compliance in accordance with a time schedule set by the department.

California Code, Health and Safety Code - HSC § 100855

Upon the denial of any application for ELAP certification or NELAP accreditation, or the revocation or suspension of ELAP certification or NELAP accreditation, the department shall immediately notify the applicant or organization by certified mail, return receipt requested, of the action and the reasons for the action. Within 20 calendar days of receipt, the applicant or organization may present the department with a written petition for a hearing. Upon receipt in proper form by the department, the petition shall be set for hearing. The proceedings shall be conducted in accordance with Section 100171 and the department has all the powers granted in that section.

Statute

Pasadena Water and Power

STATE WATER RESOURCES CONTROL BOARD
RESOLUTION NO. 2017-

DIRECTING STAFF TO PROCEED WITH A REGULATORY REVISION OF THE DETECTION LIMIT FOR PURPOSES OF REPORTING (DLR) FOR PERCHLORATE AND REVIEW OF THE PERCHLORATE MAXIMUM CONTAMINANT LEVEL (MCL)

WHEREAS:

1. All public water systems (PWS), as defined in Health & Safety Code (HSC) Section 116275, are subject to regulations adopted by the U.S. Environmental Protection Agency (U.S. EPA) under the Safe Drinking Water Act of 1974, as amended (42 U.S.C. 300f et seq.), as well as by the State Water Resources Control Board (State Water Board) under the California Safe Drinking Water Act (HSC, div. 104, pt. 12, ch. 4, § 116270 et seq.)

2. California has been granted primary enforcement responsibility ("primacy") by U.S. EPA for PWS in California;

3. California has no authority to enforce federal regulations, and federal laws and regulations require that California, in order to receive and maintain primacy, promulgate regulations for California that are no less stringent than the federal regulations;

Guidance

Pasadena Water and Power

Field of Testing 101 : Microbiology of Drinking Water

Lab Name:	City of Pasadena Water Quality Laboratory
Certificate No.:	1473

Subgroup Code	Analyte Code	Method	Analyte	Enter Y for Selection	Technology/ Medium
101.010	001	SM9215B	Heterotrophic Bacteria	Y	Pour plate
101.011	001	SimPlate	Heterotrophic Bacteria		SimPlate
101.020	001	SM9221A,B	Total Coliform		MTF/LTB
101.021	001	SM9221E (MTF/EC)	Fecal Coliform		MTF/EC
101.022	001	(MTF/EC+MUG)	E. coli		MTF/EC+MUG
101.030	001	SM9221D	Total Coliform		P-A broth [1]
101.031	001	SM9221E (P-A/EC)	Fecal Coliform		P-A/EC [1]
101.032	001	CFR 141.21(f)(6)(i) (P-A/EC+MUG)	E. coli		P-A/EC+MUG [1]
101.050	001	SM9222A,B,C	Total Coliform		MF/m-Endo [2]
101.051	001	SM9221E (MF/EC)	Fecal Coliform		MF/EC
101.052	001	CFR 141.21(f)(6)(i) (MF/EC+MUG)	E. coli		MF/EC+MUG
101.053	001	CFR 141.21(f)(6)(ii)	E. coli		NA + MUG
101.060	002	SM9223	Total Coliform	Y	Colilert [3]
101.060	003	SM9223	E. coli	Y	Colilert [3]

Guidance

Pasadena Water and Power

[1] P-A (Presence-Absence) broth is also referred to as Clark's.

[2] m-Endo represents both m-Endo and m-Endo LES media.

[3] Colilert represents both Colilert and Colilert 18 media.

[4] A-1 is a single step multiple tube fermentation test for Fecal Coliforms only.

[5] Surface Water Treatment Rule

[6] Long Term 2 Enhanced Surface Water Treatment Rule

Webpage

Pasadena Water and Power

Microbiology

- FOT 101 - Microbiology of Drinking Water - *revised April 2016*
- FOT 107 - Microbiology of Wastewater - *revised May 2015*
- FOT 126 - Microbiology of Recreational Water - *revised June 2014*

Colilert 18 Hour vs 24 Hour

Laboratories have had their accreditation revoked or denied for not doing two separate PT samples.

a) No one was advised of this change in guidance
b) The 18 Hour version of this test was not an approved method in 1992 (Article 6 & 12)
c) The regulations do not identify any requirement along these lines (Article 5)
d) These labs were not notified that they had failed
e) They were not given an opportunity to participate in a 2nd PT
f) They were not given an opportunity to correct

Enumeration of Bacteria in Recreational Waters

Pasadena Water and Power

Field of Testing 101: Microbiology of Drinking Water

Safe Drinking Water Act 40 CFR 141

Lab Name:
Certificate #:

Subgroup Code	Analyte Code	Method	Analyte	Technology	Enter Y for selection	Comments
101.080	001	ReadyCult	Total Coliform, P/A	Enzyme Substrate		
101.080	002	ReadyCult	E. Coli, P/A	Enzyme Substrate		
101.090	001	Chromocult	Total Coliform, P/A	Enzyme Substrate		
101.090	002	Chromocult	E. Coli, P/A	Enzyme Substrate		
101.100	001	Colitag	Total Coliform, P/A	Enzyme Substrate		
101.100	002	Colitag	E. Coli, P/A	Enzyme Substrate		
101.120	001	EPA 1603	E. Coli, Enumeration	Membrane Filter		
101.130	001	EPA 1604	Total Coliform, P/A	Membrane Filter		
101.130	002	EPA 1604	E. Coli, P/A	Membrane Filter		
101.130	003	EPA 1604	Total Coliform, Enumeration *	Membrane Filter		
101.130	004	EPA 1604	E. Coli, Enumeration	Membrane Filter		
101.140	001	SM 9230 B	Enterococci	Multiple Tube Fermentation		
101.150	001	SM 9230 C	Enterococci	Membrane Filter		
101.160	001	EPA 1600	Enterococci	Membrane Filter		
101.170	001	Enterolert	Enterococci	Enzyme Substrate		
101.180	001	Tecta EC/TC	Total Coliform, P/A	Enzyme Substrate		
101.180	002	Tecta EC/TC	E. Coli, P/A	Enzyme Substrate		
101.190	001	EPA 1601	Coliphage, P/A	Membrane Filter		
101.200	001	EPA 1602	Coliphage, P/A	Membrane Filter		
101.210	001	Fast Phage	Coliphage, P/A	Enzyme Substrate		

Enumeration of Bacteria in Recreational Waters

Laboratories have had their accreditation for using Water Pollution (WP) PT samples even though they had been doing this for years and there are no Water Sanitation (WS) PTs for Enterococci.

a) ELAP's regulations do require the use of WS samples for FOT 1 (Article 5)
b) These tests are not listed in Articles 6 or 12
c) These labs were not given an opportunity to participate in a 2nd PT
d) They were not given an opportunity to correct
e) No one was advised of a change in guidance.

Denial of Accreditation

- Laboratories are being told, weeks or days before their accreditation is to expire that there is a problem with their application, sometimes including the PT samples.
  - > They then lose their accreditation, temporarily or not, in part or not.

ESTABLISHING ~~POOR~~ CREDIBILITY

- Credibility – The quality of being trusted and believed in
- California ELAP ~~lacks~~ developing credibility with:
  - Clients,
  - Laboratories, and
  - Other states

Eliminating the 'Gotcha' mentality

Draft Regulations

Maryam Khosravifard, CA ELAP

Current Status

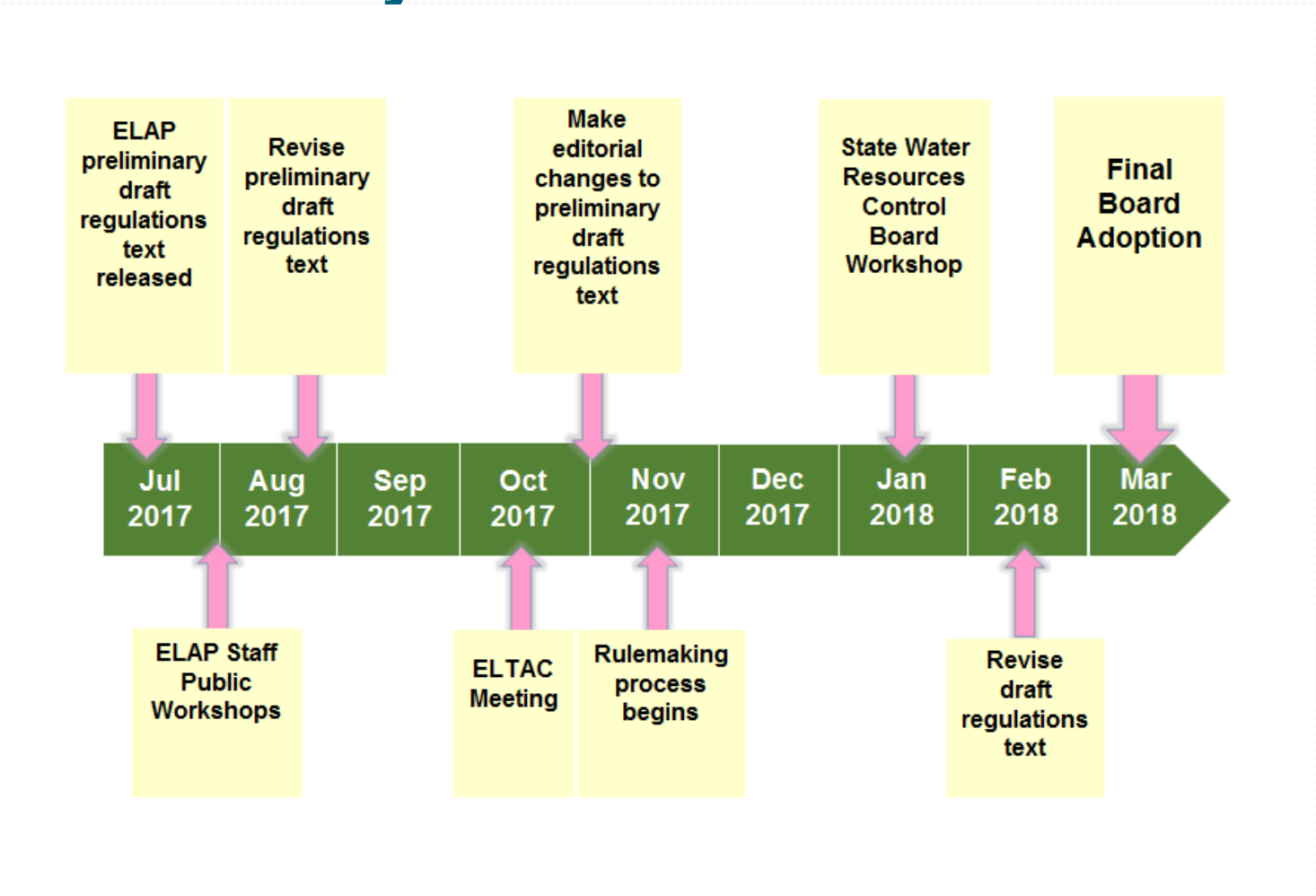
- We anticipate releasing a preliminary draft next week
- Encompasses a complete overhaul of administrative and assessment processes
- Text was developed based on two previous drafts:
  - 2005 ELTAC
  - 2014 Division of Drinking Water
- 2016 TNI Standard is incorporated by reference

TNI 2016 Revisions

Volume 1, Module 4 (Quality Systems for Chemical Testing)
Section 1.5.2

- Detection Limit (DL)
  - Revision to the procedures for initial determination of the DL
  - Revisions to criteria for ongoing verification of the DL
- Limit of Quantitation (LOQ)
  - Revisions to selecting an LOQ value
  - Clarification on criteria for initial verification of the LOQ
  - Revisions to criteria for ongoing verification of the LOQ

Projected Timeline



Workshops

- The purpose is to present and review Preliminary Draft Regulation text for clarity and completeness, solicit comments, and answer questions.

- Six locations throughout California:
  - Fresno – July 25, 2017
  - Sacramento – July 26, 2017
  - Redding – July 28, 2017
  - Los Angeles – August 1, 2017
  - San Diego – August 2, 2017
  - San Francisco – August 3, 2017

Outline of Major Changes

- Article 1 – Definitions
- Article 2 – Accreditation Requirements
- Article 3 – Types of Accreditation
- Article 4 – Types of Laboratories
- Article 5 – Quality Systems
- Article 6 – Notification/Sale of Ownership
- Article 7 – Denial, Suspension, or Revocation

Article 2 - Accreditation Requirements

- Streamlines administrative processes and adds monetary fines for late submittal of applications
- Incorporates quality management into assessment standards
- Removes references to Fields of Testing and specific methods
- Makes Proficiency Testing requirements consistent with 2016 TNI Standard
  - Except for frequency

Article 2 - Laboratory Standard

- Only 2 modifications to the TNI Standard:
  - Personnel Qualifications
  - Proficiency Testing (PT) frequency
- Three year delayed compliance upon adoption of regulations
- Early TNI adopters will be given priority status and reduced accreditation process time

Article 3 - Types of Accreditation

- Defines five types of accreditation:
  - Initial
  - Renewal
  - Amendment
  - Interim
  - Reciprocity
- Addresses variances in requirements for each type of accreditation

Article 4 - Types of Laboratories

- Classifies three types of laboratories:
  - Stationary
  - Auxiliary
  - Mobile
- Allows cost accounting due to variance in assessment requirements for each type of laboratory
- Adds one criteria to definition of auxiliary laboratory
  - Must be included in Quality Manual
- Mobile laboratories are regulated as an independent entity and not as an extension of a stationary laboratory

Article 5 - Quality Systems

- Incorporates 2016 TNI Standard into the existing required elements of the quality manual

- Adds language for:
  - Standard Operating Procedures
  - Demonstration of Capability
  - Data Integrity

Article 6 - Notifications/Reporting/Record Retention

- Adds and/or modifies notification requirements for DDW
- Updates electronic reporting requirements for DDW
- Standardizes reporting requirements in accordance with 2016 TNI Standard

Article 6 - Sale or Transfer of Ownership

- Extends notification time frame from 15 to 30 days
- Requires record retention for the previous 5 years to continue operation under original certificate
- Removes mandatory site visit and PTs for use of certificate to its expiration date

Article 7 - Reasons for Denial, Suspension, or Revocation

- Establishes criteria for denial, suspension, or revocation of accreditation

- Establishes measures to allow data users to assess data quality from revoked laboratories:
  - Removal of reference to ELAP accreditation
  - Return certificate
  - Cease all testing for regulatory purposes
  - Notify all regulatory clients
  - Provide a list of regulatory clients affected
  - Discontinue subcontracting agreements with accredited laboratories after 7 days

Next Steps

- Release preliminary draft text
- Hold stakeholder workshops
- Finalize text based on stakeholder input and prepare Draft Regulation package
- Begin formal rulemaking process

Draft Regulations Item

Attachments:

- Notice of Intent to Establish or Modify a TNI Standard
- Proposed Modification of V1M4 (Quality Systems for Chemical Testing), Section 1.5.2
- White Paper – David Kimbrough, Pasadena Water and Power – “Why Laboratories Relinquished Their Accreditation in Florida”
- Rulemaking Process Graphic

NOTICE OF INTENT TO ESTABLISH OR MODIFY A TNI STANDARD

Expert Committee or group requesting the establishment or change to the Standard	Chemistry Expert Committee

Proposal Date	3/7/2017

CSDEC Approval	3/9/2017

TNI Volume	Module	Sections(s)
ELS Volume 1	4	1.5.2.1.1; 1.5.2.1.3; 1.5.2.2; 1.5.2.2.1; 1.5.2.2.2

Nature of the standard to be established or the change to the existing standard proposed:

Pursuant to The NELAC Institute's SOP 2-100 on consensus standard development, notice is hereby given that the Chemistry Expert Committee seeks to review and modify Module 4 of the Environmental Sector (ES) standard.

Any person objecting and believing there is not a compelling need for the proposed modifications should contact the NELAC Institute Consensus Standards Development Program Administrator, ken.jackson@nelac-institute.org, within 30 days of this notice.

Justification or need for the standard or the change in the standard:

ELS Volume 1 Module 4 was recently modified from its 2009 version, was approved through the NELAC Institute consensus standards development process, and was approved by ANSI as an American National Standard. Subsequently, the NELAC Institute Accreditation Council raised objections that would prevent its National Environmental Laboratory Accreditation Program (NELAP) from adopting and implementing the standard. It is the intent of the Chemistry Expert Committee to modify the standard to meet the needs of NELAP.

How is the proposal an improvement over the existing standard:

1. Section 1.5.2.1.1 b) will be re-worded for consistency with EPA 40CFR Part 136, Appendix B.
2. The requirement that the Limit of Quantitation must be at least 3 times the Detection Limit will be modified in Sections 1.5.2.1.3, 1.5.2.2.1, and 1.5.2.2.
3. Clarification of the intent of the standard will be added to Section 1.5.2.2 d).
4. Section 1.5.2.2.2 a) will be modified to include a quantitative requirement for verification of the on-going Limit of Quantitation.

Items 1 through 4 above will make the standard acceptable for adoption and implementation.

Any potential conflicts developed upon development of the standard or the proposed change to the standard?	No

Any potential obstacles to implementation by ABs?	No

Kenneth W. Jackson	3/7/2017
Signature of proposal representative	Date

Proposed Modification of V1M4 (Quality Systems for Chemical Testing), Section 1.5.2

The TNI Chemistry Committee has received input towards its further development of the 2016 Standard, resulting in the proposed modifications provided below. The rationale/justification for each proposed amendment is provided in the text boxes in BLUE font.

Stakeholders are invited to provide further input NO LATER THAN JULY 26. The committee will meet with the commenters if necessary, and further amendments may then be made to produce a Voting Draft Standard.

Input should be provided to the Chemistry Chair, Valerie Slaven at Valerie.Slaven@gmail.com, and should be limited to those sections highlighted through tracking.

1.5.2 Limit of Detection and Limit of Quantitation (however named)

Procedures used for determining limits of detection and quantitation shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained.

1.5.2.1 Detection Limit (DL)

If a mandated test method or applicable regulation includes protocols for determining detection limits, they shall be followed. The laboratory shall document the procedure used for determining the DL. If the method or regulation does not contain specific directions for determination of the detection limit, the following requirements shall apply. DL determinations are not required for methods/analytes for which a detection limit is not applicable such as pH, color, odor, temperature, titrimetric, or dissolved oxygen. DL determinations based on spikes are not required for analytes for which no spiking solutions are available. If results are not reported below the limit of quantitation (LOQ), an initial DL determination is required, but ongoing verification is not.

1.5.2.1.1 Initial determination of the DL

The laboratory DL procedure, unless following a mandated test method or procedure, at a minimum, shall incorporate language addressing the following requirements:

a) the DL shall reflect current operating conditions;

b) the DL determination shall incorporate the entire analytical process~~, including sample preservations~~;

Removal of "including sample preservations" makes the section consistent with both the current version of 40 CFR Part 136 Appendix B and the pending updated version.

c) the DL determination shall include data from low level spikes and routine method blanks prepared and analyzed over multiple days; at least one spike~~d sample~~ and routine method blank~~s~~ must be analyzed on each applicable instrument; a minimum of seven replicates is required for both low level spikes and routine method blanks;

It was already a requirement for 7 replicates, but was not stated explicitly. This assures the wording of the standard is consistent with the referenced EPA MDL procedure that does explicitly require at least 7 replicates.

d) results from spiked samples used in the DL determination shall meet qualitative identification criteria in the method, and shall be above zero;

e) the DL procedure shall include criteria for and evaluation of false positive rates in routine method blanks;

f) the DL shall be determined for the analytes of interest in each test method in the quality system matrix of interest in which there are neither target analytes nor interferences at a concentration that would impact the results, or the DL shall be performed in the sample matrix of interest.

NOTE: One option is to follow the procedure found in R2014-MDL, a regulatory comment developed by the TNI Chemistry Expert Committee and published on the Committee's pages on the TNI website. This is identical to the MDL procedure published by the US Environmental Protection Agency in December 2016.

1.5.2.1.2 Ongoing verification of the DL

At a minimum, ongoing verification of the DL shall include assessments of spikes at or below the LOQ and of method blanks. A minimum of one (1) verification spike and one (1) blank shall be analyzed on each instrument during each quarter in which samples are being analyzed and results are being reported below the LOQ. The criteria listed in Section 1.5.2.1.1 shall be met for ongoing verification over the course of a year.

If the method is altered in a way other than routine maintenance and the change can be expected to elevate the detection limit, then a spike at or below the LOQ concentration and a blank shall be prepared and analyzed. If the spike at the LOQ concentration gives a result meeting qualitative identification criteria above zero, and the blank gives a result below the DL, then the DL is verified. If not, the DL shall be re-determined.

In the event that verification fails, the laboratory shall perform a new DL study within thirty (30) calendar days.

1.5.2.1.3 When a new DL is determined, the laboratory shall verify that the LOQ value is ~~at least three (3) times~~greater than the DL. If it is not, the laboratory shall raise the LOQ value to ~~at least three (3) times~~greater than the DL.

Although it is technically defensible for the LOQ to be at least 3 times the DL, this would cause problems with some methods (particularly drinking water), preventing laboratories getting a low enough reporting limit for some analytes. Just requiring the LOQ to be greater than the detection limit would be consistent with the 2009 standard. Additionally, the new 2016 standard, of which this will be a modification, has more rigorous LOQ verification requirements. Laboratories must set their LOQ at a level at which they could reliably analyze the sample. They must do it every quarter on every instrument, collect data spiked at that level, and demonstrate what their precision and accuracy are. There is also the additional requirement of measuring Relative Error in the calibration, so there will be additional controls.

1.5.2.2 Limit of Quantitation (LOQ)

If a mandated test method or applicable regulation includes protocols for determining quantitation limits, they shall be followed. The procedure used for determining the LOQ shall be documented by the laboratory. The laboratory shall select an LOQ for each analyte, consistent with the needs of its clients, and ~~at least three (3) times~~greater than the DL. An LOQ is required for each quality system matrix of interest, technology, method, and analyte, except for any component or property for which

See 1.5.2.1.3 comment above

spiking solutions are not available or a quantitation limit is not appropriate, such as pH, color, odor, temperature, dissolved oxygen, or turbidity.

a) Each selected LOQ shall be verified through analysis of initial verification samples. An initial verification sample consists of a spiked matrix blank at or below the selected LOQ.

b) All sample preservation, processing and analysis steps performed for routine sample analysis shall be included in the LOQ verification testing.

c) The LOQ must be at or above the lowest corresponding calibration standard concentration with the exception of methods using a single point calibration.

d) The laboratory shall establish acceptance criteria for accuracy for the LOQ verification spikes.

1.5.2.2.1 Initial verification of the LOQ

When first establishing an LOQ, or when an LOQ concentration has been selected that is lower than the concentration of the LOQ verification spikes previously performed, an initial verification shall be performed as follows:

a) A minimum of seven (7) blanks spiked at or below the LOQ concentration shall be processed through all steps of the method, including any required sample preservation. Both preparation and analysis of these samples shall include at least three (3) batches on three (3) separate days.

NOTE 1: Spiking slightly below the LOQ may help ensure that the results are also suitable for DL determination.

NOTE 2: If spiked blanks have been analyzed in order to generate a DL, the results may be used to perform the initial verification of the LOQ.

i. If there are multiple instruments that will be assigned the same LOQ, then these spiked blanks shall be distributed across all of the instruments.

ii. A minimum of two (2) spiked blanks prepared and analyzed on different days shall be tested on each instrument.

b) Existing data may be used if compliant with the requirements for at least three (3) batches, generated within the last two (2) years and representative of current operations.

c) The LOQ is verified if the following criteria are met:

i. All results are quantitative (above zero and meet the qualitative identification criteria of the method (e.g., recognizable spectra, signal to noise requirements, and presence of qualifier ions).

If a result from an LOQ verification sample is not above zero and/or does not meet the qualitative identification criteria in the method, the problem shall be corrected and the verification repeated, or the LOQ verification shall be repeated at a higher concentration.

ii. ~~Recovery~~ The mean recovery of each analyte is within the laboratory established accuracy acceptance criteria.

This is considered an editorial change for clarification purposes, since it was implicit that the initial LOQ have recoveries calculated based on the mean.

iii. The LOQ is ~~at least three (3) times~~greater than the established DL and at or above the spiking concentration.

If the LOQ is less than ~~three (3) times~~or equal to the DL, the LOQ shall be raised to ~~at least three (3) times~~greater than the DL.

NOTE: It is **not** necessary to repeat the LOQ verification at a higher concentration when it is necessary to raise the LOQ to ~~three (3) times~~greater than the DL.

See 1.5.2.1.3 comment above

d) The laboratory shall document the results of the initial LOQ verification as described in Section 1.5.2.4.

1.5.2.2.2 Ongoing verification of the LOQ

The laboratory shall prepare and analyze a minimum of one (1) LOQ verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are being analyzed for each quality system matrix, method, and analyte.

~~a)~~ Results of each LOQ verification sample analysis shall be evaluated at the time of the testing and shall meet the qualitative identification criteria in the method and laboratory Standard Operating Procedure (SOP) and the quantitated result shall be greater than ~~zero~~the DL and meet the laboratory established accuracy criteria. If a continuing LOQ verification test does not meet this requirement, the laboratory shall take corrective action and document a technically valid reason for the corrective action~~.~~ Corrective action shall be either (i) correcting method or instrument performance and repeating the verification test, (ii) evaluating the laboratory established control limits to ensure they reflect current performance, or (iii) raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study within thirty (30) calendar days of the initial failure. Any samples analyzed in a batch associated with a failing LOQ verification shall be reanalyzed or reported with qualifiers. ~~, or (ii) correcting method or instrument performance and repeating the verification test one time. In the event of second failure of a quarterly verification sample, the quantitation limit shall be raised and the initial study repeated within thirty (30) calendar days.~~

Concerns had been raised about the lack of a quantitative requirement in the on-going LOQ verification. There are insufficient data to specify accuracy limits in the standard, so it is now made incumbent on the laboratory to provide its own accuracy limits. The corrective action requirement is strengthened by requiring the laboratory to document its reason for corrective action. It is no longer stated that the quantitation limit shall be raised, because only one of several instruments may have failed.

White Paper #4: Why Laboratories Relinquished Their Accreditation in Florida

By David Kimbrough, Pasadena Water & Power

Florida adopted the NELAP / TNI requirements in 2000 and required all accredited laboratories to be compliant. As accreditation certificates expired, the new requirements were applied. In the subsequent 16 years, a significant number of laboratories dropped their accreditation. This paper assesses how that happened.

1. Background

In October of 2016, the State Water Resources Control Board ("The Board") held a hearing to receive public comment on a proposal from the Environmental Laboratory Accreditation Program ("ELAP") to supplement their accreditation standard with requirements found in documents prepared by The NELAC Institute (TNI). ELAP was authorized under the Health & Safety Code to offer TNI accreditation on a voluntary basis, but they were proposing to now make it a mandatory condition for all laboratories. At that hearing, data was presented which showed that where TNI had been applied in a mandatory fashion, i.e., Florida and New York, significant numbers of laboratories withdrew from the accreditation program. Where it was offered on a voluntary basis, i.e., California, the number of accredited laboratories increased over the same period. A summary of these changes was presented to the Board during oral presentations and a written White Paper (listed as #3) documenting these changes was also submitted during the public comment period. In the comments provided, it was argued that the TNI documents added hundreds or thousands of additional requirements upon the existing requirements and that the huge number of additional requirements made laboratory accreditation cost-prohibitive to many laboratories.

In May of 2017, a second Workshop by the Board was held on TNI. The topic of what had happened in Florida was again discussed. Some presenters reiterated their concern that what had happened in Florida and New York would happen in California if TNI were made mandatory for all laboratories. The vast majority of states do not use TNI at all but a number recognize TNI or offer it on a voluntary basis but only five require that all laboratories be TNI compliant. California has long made TNI available on voluntary basis and provided recognition to out of state laboratories with TNI accreditation. Florida and New York are among that very short list of states that require all laboratories to be TNI compliant. Since the year 2000 a very significant number of laboratories dropped out of the

accreditation programs of these two states. It was the addition of these supplemental TNI requirements to the accreditation standards of these two states that caused so many laboratories to drop their accreditation in Florida and New York.

Other speakers suggested that the major reason that laboratories relinquished their accreditation in Florida and New York was the initial accreditation process. TNI was very difficult to achieve but easy to maintain once obtained. These speakers believed that If ELAP simply allowed enough time for the initial accreditation process and provided sufficient numbers of templates and training, the problem of laboratories dropping out would be minimized, if not eliminated.

2. Inactive Laboratories

However the data from Florida does not support this interpretation. In 2000, the State of Florida began requiring all laboratories to be TNI (NELAP) compliant. As each laboratory's certificate of accreditation expired, the Florida Department of Health ("FDOH") would require it to become TNI compliant. In March of 2002, the Florida Department of Environmental Protection ("FDEP") began tracking the accreditation status of laboratories in its databases. There were two databases, one for Active Laboratories (those with current accreditation) and one for Inactive Laboratories (those that were once accredited, but are no longer accredited). The two databases have the same design, there is a field for "Programs" and there are three possible entries; "None", "State" and "NELAP". A second field is "Status" and there are several possible entries: "No Certification", "Accredited", "Relinquished", "Applied", "Withdrawn" "Suspended" or "Inactive".

There were 376 laboratories listed in the Inactive Laboratory Database, 202 were physically located in Florida. 89 of these inactive laboratories were government owned, 11 of which were found in the Active Laboratory Database under different names and 78 of which were no longer accredited at all and were not found in the Active Laboratory Database.

Some the 78 inactive government owned laboratories did not attempt to become TNI compliant and simply relinquished their certificates. In some cases, the laboratory became inactive before March 2002 so there is no record of their change in status and they are presumed to have never applied for TNI. Other laboratories had records in the Inactive Database which showed that they never obtained TNI accreditation. Table 1 lists those laboratories.

It appears that 17 laboratories in all never made the attempt to become TNI compliant. It is worth noting that these laboratories were being assessed using

the 1998 version of the TNI documents which is significantly less complex than the 2003 or 2009 documents. They were given a period of time to prepare for accreditation with the new TNI supplements. Nonetheless they declined to make the effort.

Table 1. Inactive Labs in Florida that never had TNI Certification

Inactive Lab Name	Date became Inactive
Brevard County Utilities	Pre 2002
Mims Water Treatment Plant	Pre 2002
City of Atlantic Beach Wastewater Treatment Plant	Pre 2002
City of Fort Meade	Pre 2002
Florida DACS Central Dairy Laboratory	Pre 2002
Florida Government Utility Authority	Pre 2002
Gulf Gate Laboratory	Pre 2002
City of North Lauderdale Water Plant	2004
City of Lauderhill	2004
City of Wachula	2004
City of Seabring, Plant	2004
Plant City	2004
Bonita Springs	2004
Niceville-Valparaiso-Okaloosa	2004
Florida Department of Health – Bureau of Radiation Control	2004
City of Saint Cloud	2004
City of Clearwater	2004

The remaining 51 government laboratories made the attempt to become TNI compliant and were successful, but then later relinquished their accreditation. For example, the City of Belle Glade had State Accreditation and then obtained TNI accreditation in 2001, but relinquished it in 2003 (see Appendix 1). The City Tamarac never had State Accreditation and obtained TNI accreditation in 2005, but relinquished their accreditation in 2015. The complete list of all of these laboratories are listed White Paper #3 mentioned above.

Table 2 lists the number of labs that relinquished accreditation and became inactive per year. As can be seen the process of laboratories becoming inactive was drawn out over many years, long after the initial accreditation.

Table 2. Summary of Years in which Laboratories Relinquished Accreditation in Florida

Year Relinquished Accreditation	Number of Laboratories
2001	6
2002	6
2003	10
2004	5
2005	12
2006	5
2007	4
2008	5
2009	1
2010	2
2011	5
2012	6
2013	3
2014	4
2015	4
2016	1

3. Active Laboratories

Among the Active Laboratories, there is additional information on this topic. There are 368 in the Active database, of which 233 were physically located in Florida. Many laboratories that are currently accredited successfully made the transition from either prior State accreditation but eventually narrowed the scope of their accreditation. For example, the City of Hollywood had been accredited prior to 2002 for over 40 analytes in close to 100 Fields of Accreditation (FOA) under the State program for both Potable Water and Non-Potable Water. In 2002, this laboratory successfully obtained TNI accreditation for all of those FOAs. However, in subsequent years the laboratory relinquished accreditation for most of these FOAs. Appendix II lists both the total list of all analytes for which the City of Hollywood had at one time or another been accredited and the current list. As can be seen, the current list is considerably shorter than the full list. Additionally, this laboratory applied for accreditation for the Total nitrate-nitrate test (Systea Easy (1-Reagent) Nitrate Method/UV-VIS) and Un-ionized Ammonia (DEP SOP 10/03/83) in 2014 and obtained accreditation successfully for both. This laboratory was able to make the transition from State accreditation to TNI successfully in 2002. It was also able to at a later date, add accreditation de novo. So at least in this case, initial accreditation was not a barrier to a laboratory achieving TNI accreditation.

However once that occurred, the laboratory ultimately relinquished the majority of the FOAs.

Conclusions

A great many laboratories in the Florida accreditation program, indeed the majority, successfully gained TNI accreditation from either having no accreditation at all, or from the pre-TNI accreditation program. Only a handful made no attempt to make that transition. The majority of laboratories that ultimately left the program did so only after that successful transition. In many cases, the laboratory completely withdrew from the program, but in many other cases, the laboratories simply narrowed the scope of their accreditation. In the vast majority of cases where laboratories were negatively impacted by the transition to TNI, the loss of accreditation, either in part or entirely, occurred after successful accreditation under the TNI requirements. This would strongly suggest that the principal difficulty was increased labor and other costs associated with the ongoing day-to-day requirements of TNI, not the initial accreditation.

Appendix 1

City of North Lauderdale Water Plant

NELAP-Certified Laboratories

Laboratories no longer certfied Under NELAP by the Florida Department of Health

Transaction History Query Results

Database Version: 05/14/2016 08:30:00

Organization:	**City of North Lauderdale Water Plant**
DOH ID:	**E56721**

Program	Method	Analyte	Date Effective	Status	Accreditation Type	Primary AA	Date Entered
Drinking Water	SM 9223 B	Total coliforms ~and~ E. coli	3/24/2004	**From:** Accredited **To:** Relinquished	STATE STATE		3/25/2004

City of Belle Glade's Wastewater Treatment Plant

NELAP-Certified Laboratories

Laboratories no longer certfied Under NELAP by the Florida Department of Health

Transaction History Query Results

Database Version: 01/23/2016 8:18:22 AM

Organization:	**City of Belle Glade Wastewater Treatment Plant**
DOH ID:	**E56034**

Program	Method	Analyte	Date Effective	Status	Accreditation Type	Primary AA	Date Entered
Non-Potable Water	EPA 350.2	Ammonia as N	7/24/2001	**From:** Accredited **To:** Accredited	STATE NELAP	FL	2/18/2003
Non-Potable Water	EPA 350.2	Ammonia as N	4/5/2003	**From:** Accredited **To:** Relinquished	NELAP NELAP	FL FL	4/4/2003

top

Last updated: April 23, 2015

NELAP-Certified Laboratories

Laboratories no longer certfied Under NELAP by the Florida Department of Health

Transaction History Query Results

Database Version: 05/14/2016 08:30:00

Organization:	**City of Tamarac Utilities Laboratory**
DOH ID:	**E56725**

Program	Method	Analyte	Date Effective	Status	Accreditation Type	Primary AA	Date Entered
Drinking Water	NA + MUG	Escherichia coli	12/29/2004	**From:** No Certification **To:** Accredited	None NELAP	FL	1/7/2005
Drinking Water	NA + MUG	Escherichia coli	6/16/2009	**From:** Accredited **To:** Relinquished	NELAP NELAP	FL FL	6/23/2009
Drinking Water	SM 9223 B	Escherichia coli	3/13/2002	**From:** No Certification **To:** Accredited	None NELAP	FL	5/19/2008
Drinking Water	SM 9223 B	Escherichia coli	6/1/2010	**From:** Accredited **To:** Suspended	NELAP NELAP	FL FL	6/1/2010
Drinking Water	SM 9223 B	Escherichia coli	6/7/2010	**From:** Suspended **To:** Accredited	NELAP NELAP	FL FL	6/7/2010
Drinking Water	SM 9223 B	Escherichia coli	7/1/2015	**From:** Accredited **To:** Inactive	NELAP NELAP	FL FL	7/10/2015

Appendix II

List of All Analytes the City of Hollywood had been Accredited for and the Current List

Alkalinity as CaCO3
Aluminum
Ammonia as N
Antimony
Arsenic
Barium
Beryllium
Biochemical oxygen demand
Boron
Cadmium
Carbonaceous BOD (CBOD)
Chloride
Chromium
Cobalt
Conductivity
Copper
Enterococci
Escherichia coli
Fecal coliforms
Fluoride
Heterotrophic plate count
Iron
Kjeldahl nitrogen - total
Lead
Magnesium
Manganese
Mercury
Molybdenum
Nickel
Nitrate
Nitrite
Orthophosphate as P
Oxygen, dissolved
Phosphorus, total
Potassium
Residual free chlorine
Residue-filterable (TDS)
Residue-nonfilterable (TSS)
Selenium
Silver
Sodium
Thallium
Total coliforms
Total nitrate-nitrite
Turbidity
Un-ionized Ammonia
Zinc
pH

NELAP-Certified Laboratories

Laboratories Certified Under NELAP by the Florida Department of Health

Listing of Organization FOAs Query Results

Database Version: 05/27/2017 08:30:00
Laboratory Name: City of Hollywood Utilities Laboratory
DOH ID: E56407

Matrix	Category	Analyte	Method	Certification Date
Drinking Water	Microbiology	Enterococci	EPA 1600	7/8/2010
Drinking Water	Microbiology	Heterotrophic plate count	SM 9215 B	7/8/2010
Drinking Water	Microbiology	Total coliforms	SM 9222 B	9/25/2002
Drinking Water	Microbiology	Escherichia coli	SM 9223 B	7/8/2010
Drinking Water	Microbiology	Total coliforms	SM 9223 B	9/25/2002
Drinking Water	Primary Inorganic Contaminants	Fluoride	SM 4500 F-C	9/25/2002
Drinking Water	Secondary Inorganic Contaminants	Chloride	SM 4500 Cl- B	11/2/2012
Non-Potable Water	General Chemistry	Un-ionized Ammonia	DEP SOP 10/03/83	2/6/2015
Non-Potable Water	General Chemistry	Alkalinity as CaCO3	SM 2320 B	9/25/2002
Non-Potable Water	General Chemistry	Conductivity	SM 2510 B	9/11/2007
Non-Potable Water	General Chemistry	Residue-filterable (TDS)	SM 2540 C	9/25/2002
Non-Potable Water	General Chemistry	Residue-nonfilterable (TSS)	SM 2540 D	9/25/2002
Non-Potable Water	General Chemistry	Chloride	SM 4500 Cl- B	11/2/2012
Non-Potable Water	General Chemistry	Ammonia as N	SM 4500-NH3 D (19th, 20th, 21st Ed.)/ISE	9/11/2007
Non-Potable Water	General Chemistry	Phosphorus, total	SM 4500-P E	9/25/2002
Non-Potable Water	General Chemistry	Carbonaceous BOD (CBOD)	SM 5210 B	9/25/2002
Non-Potable Water	General Chemistry	Nitrate	Systea Easy (1-Reagent) Nitrate Method/UV-VIS	2/6/2015
Non-Potable Water	General Chemistry	Total nitrate-nitrite	Systea Easy (1-Reagent) Nitrate Method/UV-VIS	2/6/2015
Non-Potable Water	Microbiology	Enterococci	ENTEROLERT	2/6/2015
Non-Potable Water	Microbiology	Enterococci	EPA 1600	11/2/2012
Non-Potable Water	Microbiology	Total coliforms	SM 9222 B	9/25/2002
Non-Potable Water	Microbiology	Fecal coliforms	SM 9222 D	9/25/2002

FOAs: 22

The Rulemaking Process & ELAP's Regulations

Legislature Grants Authority to Adopt Regulations to State Agency

State Agency State Water Resources Control Board

California Water Boards

ELAP Environmental Laboratory Accreditation Program STATE WATER RESOURCES CONTROL BOARD

ELAP's Preliminary Activities

1. Research Accreditation Standard Options
2. Assess Feasibility Through Stakeholder Outreach
3. Evaluate Recommendations from Advisory Bodies
4. Select Accreditation Standard
5. Develop Draft Regulation Text
6. Hold Stakeholder Workshops

WE ARE HERE

NOTICE of Publication By OAL Begins Rulemaking Process

State Water Board Meeting To Receive Comments

45 Day Public Comment Period

Water Board Considers Comments

Non Substantial or No Changes?

Major Changes?

Substantial and Sufficiently Related Changes?

New 45 Day Notice

15 Day Comment Period; SWRCB publishes notice and text of proposed changes

ELAP Submits Draft Regulation Package for Water Board Consideration

State Water Board Meeting to Consider Adoption of Proposed Regulations

Adoption

ELAP Submits to **OAL** for Final Review 30 Day Administrative Review

Regulation Published by Secretary of State Rulemaking Process Completed

Training and Implementation

www.waterboards.ca.gov/drinking_water/certlic/labs/index.shtml

Close

TENTATIVE ELTAC CALENDAR

Key

Meeting Date	
Event	

January 2017

S	M	T	W	Th	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	**31**				

4 ELTAC Meeting
Lab Accreditation Standard
Fee Structure
Jan 31 – Feb 2 Expert Review Panel Meeting

FEBURARY

S	M	T	W	Th	F	S
			1	**2**	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28				

Jan 31 – Feb 2 Expert Review Panel Meeting

MARCH

S	M	T	W	Th	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	**29**	30	31	

29 ELTAC Meeting
Fee Structure

APRIL

S	M	T	W	Th	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

5 Listening Session – Northern California
6 Listening Session – Southern California
11 AWWA Conference – Speaking Engagement
27 CWEA Conference – Speaking Engagement

MAY

S	M	T	W	Th	F	S
30	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	**18**	19	20
21	22	23	24	25	26	27
28	29	30	31			

3 State Water Board Workshop – Expert Review Panel Year 2 Report

JUNE

S	M	T	W	Th	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

JULY

S	M	T	W	Th	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	**13**	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

13 ELTAC Meeting
Regulations
25 Regulations Workshop – Fresno
26 Regulations Workshop – Sacramento
27 Regulations Workshop - Redding

AUGUST

S	M	T	W	Th	F	S
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

1 State Water Board Meeting
1 Regulations Workshop – Los Angeles
2 Regulations Workshop – Sand Diego
3 Regulations Workshop – San Francisvo
7-11 National Environmental Monitoring Conference

SEPTEMBER

S	M	T	W	Th	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

OCTOBER

S	M	T	W	Th	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Annual ELTAC October Meeting – DATE TBD