

Laboratory Accreditation Standards Webinar

May 5, 2016



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



Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

Background

- Expert Review Panel Report – October 2015
- Recommendation: Adopt a new laboratory accreditation standard
 - We agree
- Presently working with ELTAC to evaluate options

Today's Goal

- Communicate the direction we're headed
- Empower you to communicate with your ELTAC representative
 - ELTAC will play a major role in the final decision
- Ensure we are considering all the options
- NOT A GOAL – make any decisions

Decisions ELAP needs to make

- **Decision #1** - Should we update our technical standard?
 - **1a.** If yes, what should we use?
- **Decision #2** - Should we add a quality management system?
 - **2a.** If yes, which one?
 - **2b.** What are our options for implementation?
- **Decision #3** - How frequently should we require proficiency testing?

Structure for the Presentation

1. Tell you what other states do
 2. Use research to create a list of available options
 3. Pros and cons of all of the options
- ✓ Do this separately for each decision
 - ✓ Allocating 30 minutes for discussion at the end of each decision
 - ✓ Extra half hour at the end to discuss whole presentation

Decision #1

1. Should we update our laboratory technical standard?

1a. If yes, what should we use?

What other states do

Technical Standard	Number of States
U.S. EPA Drinking Water Certification Manual	21
ISO 17025	2
NELAC 2003	2
The NELAC Institute (TNI) 2009	13
State-created	11

US EPA Drinking Water Manual

Alabama

Alaska

California

Colorado

Delaware

Hawaii

Idaho

Indiana

Iowa

Maine

Maryland

Massachusetts

Michigan

Mississippi

Missouri

Montana

Nebraska

Nevada

North Dakota

South Dakota

Tennessee

ISO 17025

- Georgia
- New Mexico

NELAC 2003

Florida

New York

2009 TNI

Illinois

Kansas

Louisiana

Minnesota

New Hampshire

New Jersey

Oregon

Pennsylvania

Texas

Utah

Vermont

Virginia

Oklahoma

State-Created

Arizona

Arkansas

Connecticut

Kentucky

North Carolina

Ohio

Rhode Island

South Carolina

Washington

West Virginia

Wisconsin

No program

- Wyoming

More detail on State-created standards

- 8 States
 - Only slightly deviate from EPA DW Cert Manual
- 1 State (Kentucky)
 - Used EPA DW Cert Manual/ISO 17025/40CFR Part 136 to create their standard
- 1 State (Wisconsin)
 - Used TNI technical requirements as the framework for their standard
- 1 State (Arizona)
 - Took a whole different approach

Options for ELAP's Technical Standards

- U.S. EPA Drinking Water Certification Manual/Federal regulation
- ISO 17025
- NELAC 2003
- 2009 TNI
- Create-our-own

U.S. EPA Drinking Water Manual

- Pro
 - Everybody is already using it
 - Implement immediately
 - Already in regulation
- Cons
 - Not specific enough
 - Our auditors are interpreting differently
 - CA more than just drinking water matrix

ISO 17025

- Pro
 - International recognition
- Cons
 - Designed for testing/calibration laboratories
 - Not many states use it unmodified
 - We'd have to pay for it
 - Not CA specific

NELAC 2003

- Pro
 - Free
 - Everybody can use it
 - Could begin implementation period immediately
 - Some compliance resources available
- Con
 - Outdated
 - Less flexible than updated version

TNI 2009

- Pro
 - More flexible technical requirements than NELAC 2003
 - Resources available
- Con
 - We'd have to pay for it
 - Lab perspective: more specific than U.S. EPA DW Certification Manual

Create Our Own

- Pros
 - Tailor to California technical needs
- Con
 - Long process
 - Resource intensive process
 - We'd have to create our own outreach, education, and training tools for labs and assessors
 - Island effect

Discussion

Decision #2

2. Should we add quality management system?
 - 2a. If yes, what should we use?
 - 2b. What are our implementation options?

What do other states do

- DW Cert Manual States (21 states) - None require QMS
- State-created (11 states) -
 - 7 states have QMS elements
 - 4 states have no QMS
- ISO 17025 (2 states) - all require QMS
- NELAC 2003 (2 states)- all require QMS
- TNI States (13 states) - all require QMS

More detail on State-created QMS

- 1 State (Kentucky)
 - Use ISO as foundation for QMS
- 1 State (Wisconsin)
 - Use NELAC/TNI as foundation for QMS
- 5 States (CT, NC, RI, SC, WA)
 - Created their own

Inclusion of a Laboratory Quality Management System

Pros

- Allows us to evaluate more than the one day we are there
- More consistent audits
 - More specificity in requirements = less subjectivity during assessment
- Enhances consistency for laboratories during times of turn-over
- Allows ELAP to verify capability for non–standard methods
 - Emerging contaminants
- State Agency Partner group has expressed higher data confidence
- We had a strong recommendation from the Expert Review Panel

Inclusion of a Laboratory Quality Management System

- Cons
 - Change
 - Additional staff time and resources
 - Some evidence that it leads to laboratory closure
 - Increased ELAP resources
 - Longer audits, more details
 - Additional training of staff to standard

Florida Case Study

- Review Panel characterized FL as success
 - Many labs did not agree
- Records show a number of laboratories surrendered certification following the implementation of TNI requirement
 - Approximately 90 govt. labs on inactive list
- Was this because of the requirement?

Decision #2a

If we include QMS, which one

- Options
 - ISO 17025
 - NELAC 2003
 - 2009 TNI
 - Create our own

ISO 17025

- Pros
 - Internationally recognized
- Cons
 - Designed for testing/calibration laboratories
 - Not many states use it unmodified
 - We'd have to pay for it
 - Not CA specific
 - Resources intensive (Labs and ELAP)

NELAC 2003

- Pros
 - Free
 - Everybody can use it
 - Could begin planning implementation period immediately
 - Some compliance resources available
- Cons
 - Outdated
 - Less flexible than updated version
 - Resource intensive (ELAP and Labs)

TNI 2009

- Pros
 - More flexible technical requirements than NELAC 2003
 - Resources available
- Con
 - We'd have to pay for it
 - Resource intensive (Labs and ELAP)

Create our own

- Pros
 - Tailor to our state
- Cons
 - Long process
 - Resource intensive process
 - We'd have to create our own outreach, education, and training tools for labs and assessors
 - Island effect

Decision #2b What are our options for implementation?

- Options
 - Immediate implementation
 - Staggered implementation
 - Delayed compliance date

Immediate implementation

- Pros
 - State Agency Partners get what they want
 - expressed higher data confidence
- Cons
 - Not sustainable, effective

Staggered Implementation

- Pros
 - More time for us to provide training
 - Allows time for meaningful development of lab processes
 - Less burdensome on operations
- Cons
 - State Agency Partners may oppose

Delayed Compliance

- Pros
 - Even more:
 - time for us to provide training
 - time for meaningful development of lab processes
 - Less burdensome on operations
- Cons
 - State Agency Partners may oppose

Our Commitment

- Not overnight
- Implementation assistance
- Researching financial assistance

Discussion

Decision #3

3. How frequent do we require Proficiency Testing?

What do other states do

- 17 states – 2 per year
- All the rest – 1 per year
- Historically – some states have required 4 per year
- Opportunity to monitor labs

PT Frequency - 1 time per year

- Pros
 - Do this already
 - No change
- Con
 - Less opportunity to monitor

PT Frequency – 2 times per year

- Pros
 - More opportunity to monitor labs
- Con
 - Additional cost to laboratories
 - More time and money for PT samples
 - Disruption of day-to-day lab process
 - Resource intensive
 - to administer 2 PT

PT Frequency – 3+ times per year

- Pros
 - Even more opportunity for monitoring
- Con
 - No ELAP resources to administer 3+ PTs
 - More cost to laboratories

Discussion

Next Steps

- We are going to use ELTAC to help guide our decisions
 - Planning multiple ELTAC meetings
 - Next meeting - May 11th
- Also getting input from our State Agency Partner group
- Recommendation to Board in September 2016
- Anticipate Board decision by December 2016

Do you have adequate information?

- We originally discussed having 3 webinars at 2 hours each
 - Time and resource constraints
 - We found by condensing it would be more cohesive
 - Did we achieve this?
 - Do we need additional webinars?