

# Countdown to Method Approval

Meeting Regulator Needs



CA ELAP at NEMC, August 2021



# Speaker

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# Goals of this Presentation



Provide a perspective on California's regulatory landscape



ELAP's approach to accrediting emerging methodologies



Preview what's next for California

# California ELAP

- Accredit over 650 laboratories that generate data for regulatory purposes
- Stakeholders include:



# ELAP Accredited Laboratories Help Environmental Stakeholders

## Protect

- 1.6 million acres of lakes
- 1.3 million acres of bays and estuaries
- 211,000 miles of rivers and streams
- 1,100 miles of coastline
- 7,500 public water systems

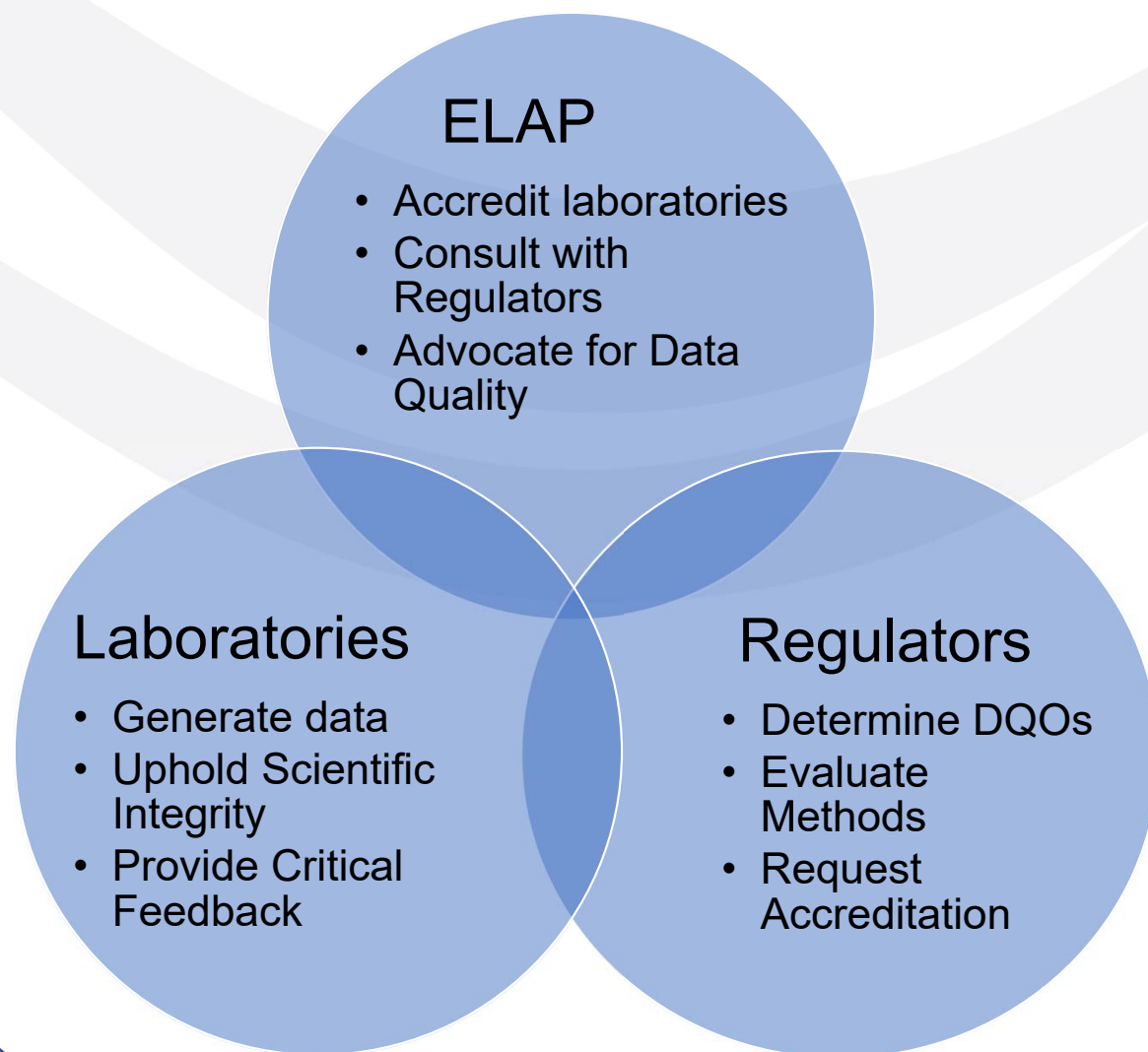
## Comply With:

- Federal regulations
  - Clean Water Act
  - Safe Drinking Water Act
- Statewide regulations, policies, and orders

# Separation of Functions

- ELAP is not the regulatory body that writes permits or regulations that specify monitoring or required methods
- Method selection is dictated by the agency who receives the regulatory data
- ELAP only offers methods that State Agencies request

# Shared Purpose



# Two Levels of Regulatory Authority

## Federally Regulated Parameters

- Federal regulations identify approved methods
- Alternate test procedures (ATP)



Clean Water Act (40 CFR 136)

## State Regulated Parameters

- State agencies decide on approved methods
- Fit for use



CA Code of Regulations (CCR)



# The Evolving Process



New contaminants and chemicals are being discovered

Ex. 6PPD-quinone



Regulators want the certainty and comparability accreditation provides



Decisions impacting public health and the environment should use defensible scientific data

## California is Uniquely Primed

- CA regulatory agencies and their Dischargers are monitoring for emerging contaminants NOW
- New laboratory methods are being developed all the time and state regulators are always exploring experimental methods or optimizing methods
- Many of our CA regulators want them to be available for use with confidence and defensibility

# California's Method Approval

- No centralized agency grants method approval
  - Some directives are issued by Legislature
    - Ex: Microplastics in Drinking Water
  - Agency needs determine method selection
    - Ex. Regional based permits
- ELAP does not approve methods, advocates for data quality and provides recommendations

## ELAP as a Consultant

- ELAP is often approached by our state agencies inquiring about robust methods for new contaminants
- CA state agencies are not built like US EPA
  - Most don't have a dedicated laboratory
  - Some have little laboratory experience
- ELAP's old regulations hindered our ability to provide accreditation for their needs

## CA ELAP Programmatic Changes

- New regulations for CA ELAP, effective January 2021
  - Include the 2016 TNI Standard, with 2 exceptions and a three-year transition period
- Regulations afford some new flexibilities
  - Allows laboratories to schedule their own assessment dates, using either ELAP, TNI State ABs, or NGABs for

# Effects of the New Regulations

1

Improve services to California regulatory agencies

- Better data defensibility
- More confidence in the data

2

Gives ELAP a clear framework to accredit for new methods

- CA regulatory agencies want to use new methods for emerging contaminants

# Partnerships are Key

## California Regulatory Agencies

- Consult with ELAP
- Make a formal request

## Environmental Laboratory Technical Advisory Committee (ELTAC)

- Helps to build laboratory capacity

## Third Party Assessment Firms

- Retain technical expertise
- Conduct assessments

# The “Language” Barrier

Laboratory  
Vocabulary  
does not easily  
translate to  
Regulatory  
Language

CA specific  
contaminants  
may not have  
developed or  
published  
methods

Technical  
expertise  
needed to  
review new  
analytical  
methods

Suggestions  
from  
laboratories do  
not always align  
with agency  
needs

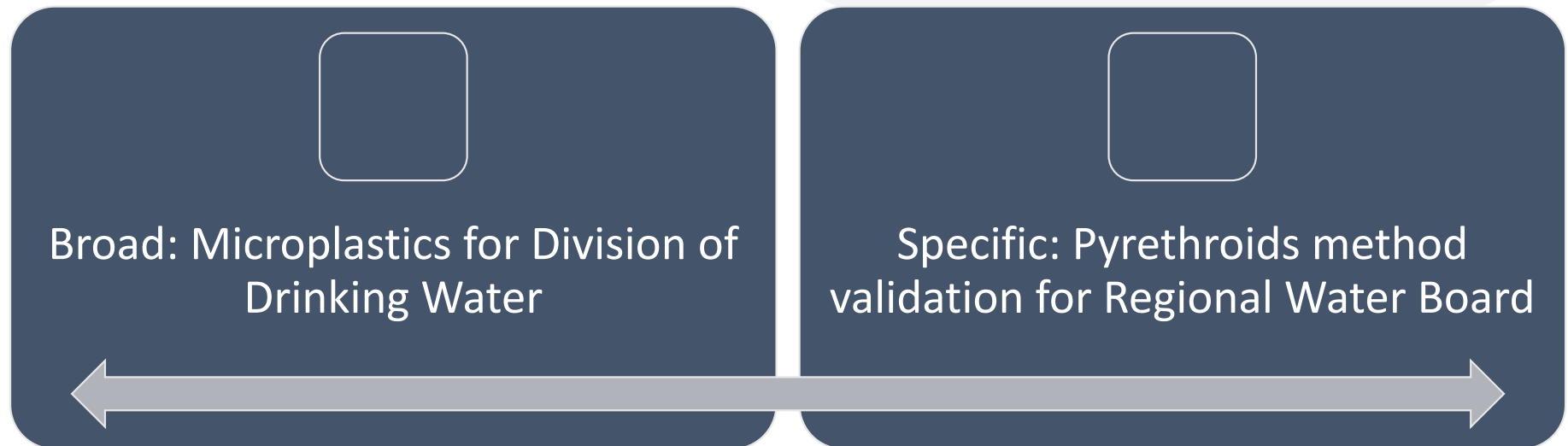


# What's Next?

- Build active participation between Regulators and the laboratories providing data
- ELTAC to provide a guidance document for both CA agencies and our laboratory community
  - Capture and reference existing guidance for method development and validation
  - Provide an easier way for agencies to review potential methods

# Navigating Complex Requirements

- A lot of regulators need help, and ELAP's small program does not have the capacity
- ELAP doesn't know the specific needs of each program



# Guidance Document – In Development

- We asked ELTAC for help
  - Identify existing guidance for method development
  - Explain the core method building blocks
- Document looks to:
  - Be general enough to capture main themes
  - Have broad appeal for use, minimal laboratory jargon
  - Need minimal revisions
- Assist agencies to determine which method(s) they select

# Thank You

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