

# California Environmental Laboratory Accreditation Program

*The Path from Worst to First*



# The Expert Review Panel is Correct

- **The process was thorough**
  - Intense information gathering process
  - Self examination on our part
- **Year 1 Report was critical and in-depth**
  - Much more than a simple summary
  - Detailed analysis of ELAP
- **Findings are accurate and precise**
  - We agree with their assessment

# How do you fix a program with so many flaws?

## On the To-Do List:

1. **Select and implement an internal management system**
2. Update the methods we offer for certification
3. Improve the quality of our staff
4. Improve communications with clients and laboratories
5. Adopt new laboratory accreditation standards
  - Foundation for our program

# Select and Implement an Internal Management System

- **The choice was easy**
  - TNI Volume 2
- **Implementation is difficult**
  - We need to develop and implement 50+ Standard Operating Procedures
    - We've written 20
    - Currently test driving

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# Update our methods

- **Cleaning up our certification offerings list with the most up-to-date methods**
- **Verifying the list with our California regulatory agencies / end users to meet their needs**

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# Improve the Quality of Staff

- **Personnel Management**
- **Training our Staff**



# Personnel Management

- **This has been a difficult task**
  - We encountered bureaucratic hurdles
  - There has been emotional resistance to cultural change
- **TNI Volume 2 process is a great road map**
  - Clear, concise
  - Establishes a standard for ELAP

# The Results

- **Major changes in last year**
  - 35% staff turnover
  - 6 staff left the program
  - Opportunity for new staff
- **Comprehensive Assessor Training Program**
  - Foundation for training right people for the right job
  - Truly improve quality of our staff

# Assessor Training Program

- **We are investing in creating the top assessor training program in the country**
- **Three-year contract with multiple elements**
  - Classroom training on assessment skills and analytical methods
  - Compliance Assessments for Drinking Water Laboratories
    - ELAP staff will shadow experienced assessors
- **Train the trainer model**
  - ELAP staff will be trained to maintain the program after the contract ends

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# Communications

- **Expert Review Panel accurately assessed that ELAP was siloed**
  - No communication existed with regulatory agency clients
  - Strained communication existed with ELTAC
  - Very little communication existed with the laboratory community at large
- **We developed and are implementing a communications plan to address this deficiency**

# State Agency Partners Committee

- **We created a solid partnership**
  - The relationship between ELAP and the agencies had never existed
- **Made up of representatives from California regulatory agencies**
  - Members are decision-makers

# State Agency Partners Committee

- CA Department of Toxic Substances Control



- CA State Water Resources Control Board



- CA Department of Public Health



- CA Department of Pesticide Regulation



- CA Department of Fish and Wildlife



- CA Regional Water Quality Control Boards



# State Agency Partners Committee

- **Committee is meeting regularly**
  - Considering key issues in the Expert Review Panel report
  - Responding to ELTAC requests
- **Serve as an advisory body to ELAP**
  - Their first task was to define their collective regulatory needs
  - Their needs are the driving force behind ELAP accreditation services



# State Agency Partner Needs

- **Accurate Data**
- **Consistency of results**
- **Robust quality assurance program**
- **Legally defensible documentation**

# Environmental Laboratory Technical Advisory Committee

- **We rebuilt ELTAC**
- **We took steps to ensure the committee would be representative**
  - Worked with the lab community to rewrite their By-Laws
  - Instituted a formal interview process for candidates
  - We've defined a clear set of charges
  - We are committed to providing a written response if we do not take ELTAC's advice

# The Result

- **We have 14 well-qualified, diverse members representing the laboratory community:**
  - Municipal, Commercial, Academia
  - Large, Medium, Small
  - Northern and Southern
  - Organizational
  - Specialty laboratories
  - State Agency Partners

# ELTAC Members

- **Mindy Boele** - CWEA
- **Jill Brodt** - small, Northern commercial
- **Stephen Clark** – Bioassay, Aquatic toxicity
- **Ronald Coss** - CWEA
- **Huy Do** - CASA
- **Andy Eaton** – Chairperson, Large, interstate commercial
- **Miriam Ghabour** - Large municipal
- **Bruce Godfrey** - ACIL
- **Anthony Gonzalez**- Public health labs
- **Rich Gossett** - Commercial and academia
- **David Kimbrough** - small, Southern municipal
- **Mark Koekemoer** - small, Northern municipal
- **Allison Mackenzie** – California commercial
- **Gilda Neshvad** – Hazardous Waste
- Four non-voting, regulatory agency representatives

# ELTAC Current Tasks

- **Fee Structure**
- **Fields of Testing lists**
- **Proficiency Testing scoring system**
- **Laboratory Accreditation Standard**

# ELTAC Accomplishments

- **Created a process for agency and laboratory coordination when new regulatory needs emerge**
  - Accepted by the CA Division of Drinking Water
- **Created a new Field of Testing list structure**
  - Changed accreditation from method to analyte based
  - We have accepted their recommendation

# Communication with Laboratory Community

- **We developed a communications plan**
  - Aimed at transparency, consistency, and creating access for the community
  
- **We are implementing that plan**
  - Electronic communication, Email, Redesigned Web Site, Electronic newsletter, Web meetings, ELTAC meetings

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# Elements of an Accreditation Standard

- **We tasked both of our advisory committees with recommending a standard**
- **Separated laboratory accreditation standards into three elements**
  1. Technical Standards
  2. Monitoring Requirements
  3. Quality Management Systems
- **They have been deliberating on these three elements**
  - We have some resolution

# Technical Standard

- **State Agency Partners Committee recognize the analytical method as the technical standard for laboratories**
- **ELTAC agrees**
- **We have accepted this recommendation**

# Monitoring Requirements

- **State Agency Partners Committee recommend one Proficiency Testing sample per year**
- **ELTAC recommends one sample per year**
- **We have accepted this recommendation**

# State Agency Partner Concerns

## **Why it's a bad system**

- Simple matrix, unrepresentative matrix
- Samples not truly blind
- Laboratories already know the answer
- Everyone games the system
  - Best analyst
  - Reruns analysis until they get the right answer

## **Not about the frequency of PT samples**

- Low opinion

# Quality Management System

- **State Agency Partners Committee recommends including a quality management system as a condition for accreditation**
- **ELTAC agrees**
- **ELAP agrees**

# Which one?

- **State Agency Partners Committee recommends using The NELAC Institute (TNI) Quality Management System**
  - Dissention expressed by 1 agency partner

# Why Agency Partners want TNI

- **Ready for adoption**
- **Sustainable**
- **Consensus-based**
- **Clear, consistent standard for ELAP assessment staff**
- **Training and implementation resources are available for ELAP and for laboratories**

# Why Agency Partners want TNI

- **State Agency Partners Committee recognize this may be a big change for some laboratories**
  - Open to a phased Implementation
- **Would like to work with ELTAC to prioritize elements and create an implementation schedule**
- **Not recommending laboratories be TNI-Accredited, only meet TNI requirements**



# ELTAC is Deliberating

- **Difficult decision to make**
  - They represent a large diverse community
- **Some members are hesitant about TNI**
  - Concerned about the effects of adoption into regulations

# Diverse Laboratory Community

- **Accredit 700+ laboratories**
  - Largest in the nation
- **80% are small laboratories**
- **Approximately 350 are municipal laboratories**

# Why is ELTAC hesitant?

- **Unnecessary paperwork**
  - Documentation of non-critical elements
- **Doesn't equate to improved data quality**
  - No evidence, anecdotal
- **Not relevant to two-person laboratories**
- **Time is money**
  - Additional resources/staff to comply

# Process to New Laboratory Accreditation Standards

- **Anticipate ELTAC's recommendation end of August**
- **Decision in September 2016**
- **State Water Board Members workshop with the community October 2016**
- **Formal rulemaking process early 2017**

# Worst to First: Harnessing the Challenges

- **Comprehensive Assessor Training**
- **Improve monitoring of laboratories**
- **Expanding certification offerings**

# Improve Monitoring of Laboratories

- **Make samples truly blind**
- **Increase complexity of sample matrix**
- **Conduct laboratory intercalibration exercises**

# Expanding Certification Offerings for State Agency Partners

- **California is uniquely primed**
- **Harness how to accredit new methods/method developers**
  1. Emerging contaminants - State Water Board dischargers are monitoring
    - Close to requiring bio-analytical screen techniques – cell line assays
  2. qPCR - 14 labs routinely use it, USEPA approved for beach monitoring
- **We have good communications: Partners & ELTAC**

# Questions

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