

# REGULATORY AGENCY NEEDS

Bruce LaBelle, Ph.D.

California Environmental Protection Agency
Department of Toxic Substances Control
Environmental Chemistry Laboratory



- Department of Public Health
- Department of Toxic Substances Control
- Department of Pesticides Regulation
- Department of Fish and Wildlife
- State Water Resources Control Board
- Federal Food and Drug Administration



## **QUESTIONS**

- 1. What is important to Regulatory Agency Partners?
- 2. What are our laboratory needs for data quality?
- 3. How can ELAP meet regulatory or data user needs?



### WHAT WE NEED

- 1) Accurate Data
- 2) Consistency
- 3) Quality Assurance Program
- 4) Legally Defensible



## 1) ACCURATE DATA

- a) Believable Reporting Limits
- b) Standard Curves
- c) Repeatability Among Replicates
- d) Acceptable Spike Recovery
- e) Acceptable Proficiency Evaluation Sample Results



- a) Consistency of Results Across Staff and Time
  - Control Charts to document quality
  - Training and Continuing Education
  - Internal Auditing
- b) Consistency of Results Across Other Laboratories (State and National)
- c) Consistency of Data Reporting Formats and Language in Reports
- d) Understanding Comparability among Methods
  - Non-Standard and Modified Methods

## 3) ROBUST QUALITY ASSURANCE PROGRAM

- a) Corrective Action Process
  - Client Notification
  - Documentation of Variations in Procedures
- b) Preventative Measures to Ensure Quality
  - Documentation to Ensure Procedures are Followed
  - Traceable Standards



## 4) LEGALLY DEFENSIBLE

#### a) Documentation

- Chain of Custody
- Sample Receipt and Storage
- Records for Analysts who Prepare or Analyze Samples
- Training Records
- Records Retention



#### **SUMMARY**

- 1) Accurate Data
- 2) Consistency
- 3) Robust Quality Assurance Program
- 4) Legally Defensible



## THANK YOU