

# Inspection Program Overview

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# Outline

- ▶ Scope of the Inspection Program
- ▶ General Inspection Program Process
- ▶ Typical Problems/Types of deficiencies
- ▶ Metrics
- ▶ Recommendations for the future

# Scope of Inspection Program

- About 700 laboratories
- Certify 25 FOTs
- Triaging inspections
  - Based on risk to public and environmental health
  - Flow charts for different scenarios
    - New laboratory
    - New FOT/method/technology
    - Out of State laboratory
    - Drinking water Labs

# Inspection Process

- **Pre Site inspection**
  - Application, QA manual, FOT list, PT sample results
- **On Site inspection**
  - Instrumentation & Chemicals
  - Method details
  - Monitoring & Training records
  - Data review
  - Laboratory Facility

# Inspection Process

- **After On Site inspection**
  - Within 30 Days ELAP drafts report (OSAR)
  - Within 45 Days Laboratory responds (CAR)
  - Field Office Supervisor Responsibilities
    - Assigns Labs to auditor
    - Reviews OSAR
    - Guide Auditors
    - Reviews completed work
    - Generate Certificate documents for signature
    - Arranges trainings for auditors

# Time to complete inspection

- Title 22 – Ideal
  - The median time is 6 months
  - The minimum time is 3 months
  - The maximum time is 12 months
- Reality
  - Average 1–6 Months
  - Not enough staff
  - Staff accountability

# Typical types of deficiencies

- QA manual not updated annually
- PT sample results not acceptable
- Qualifications of Laboratory personnel
- Quality controls not acceptable for method
- Monitoring Records for Instruments & Equipment
- Expired calibration standards, Quality Control samples & reagents
- ▶ Laboratory facilities not acceptable
  - Housekeeping – not clean, adequate temperature, humidity control and lighting

# Metrics

- ▶ There are no official ELAP metrics
- ▶ Anecdotally
  - Denied certification for unacceptable FOT/method/technique during inspection
  - Denied certification based on PT sample results & On site inspection
  - 90% labs need OSAR
  - 90% Lab send CAR in time
  - Add/Delete FOTs on request
  - Add/Delete FOTs based on inspection



# Recommendations for the Future

- Strong Leadership
  - Goals/Vision
- Triaging makes sense – can't inspect all labs every two years
- Adequate Resources
  - Cross-train staff
    - Shellfish, Crypto, Radiochemistry (currently 1 per discipline)

# Recommendations for the Future

- Streamline processes
  - Electronic documents
  - Utilize Reciprocity to streamline out of state certifications
- Accountability
  - Supervisors and Auditors
- ▶ Consistent standards
  - Possibly TNI / ISO

Questions?