Tips for Successful ELAP Inspection

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Outline

• Inspection Process

• Timeline to Complete Inspection

• Typical Types of Deficiencies
Inspection Process

• Pre Site inspection
  • Application, QA manual, FOT list, PT sample results

• On Site inspection
  • Instrumentation & Chemicals
  • Method details & SOPs
  • Monitoring, Training, maintenance records
  • Data review
  • Laboratory Facility
Inspection Process

- After On Site inspection
  - Within 30 Days Auditor sends (OSAR)
  - Contact lab with E mails & phone calls
  - Within 45 Days Corrective Action Report due Labs
Timeline to complete inspection

- Median time is 6 months
- Minimum time is 3 months
- Short on Certified Auditors
- Specialty audits with the help of other ELAP offices (Radiochemistry, Bioassay & Cryptosporidium)
- Help other ELAP offices with audits
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
- Preservation & Holding time
- Laboratory facilities not acceptable
Stay Abreast

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• Timeline to Complete Inspection

• Typical Types of Deficiencies
Questions?