

Tips for Successful ELAP Inspection

By

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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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- Typical Types of Deficiencies

Questions?