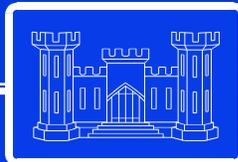


Lab Auditing Overview

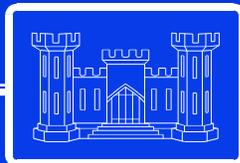


Richard Kissinger
US Army Corps of Engineers
4 March 2002



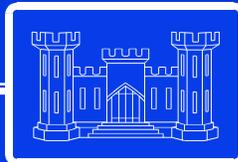
Elements in Laboratory Validation

- Identify the lab.
- Review documents.
- Evaluate Performance Testing sample results
- Conduct an on-site inspection.
- Resolve any deficiencies found



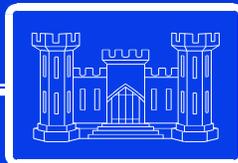
Characteristics of a Good Auditor

- Strong personality
- Thick skinned
- Strong backbone
- Able to focus
- Curious
- Sense of order (Organization)



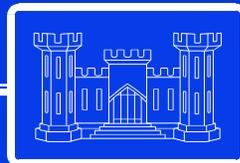
Characteristics of a Good Auditor

- Authoritative.
- Understand system approach.
- Have interviewing skills.
- Knowledge of appropriate practices.
- Detail oriented - good documentation.
- Integrity.



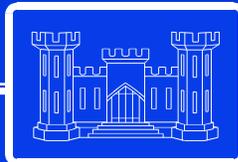
Audit Technique

- No specific checklist.
- Must be knowledgeable.
- Must have fundamental understanding of the “science”.
- Must differentiate between systems and data audits.
- Must have knowledge of the methods.
- Must be able to explain “why” to the labs.



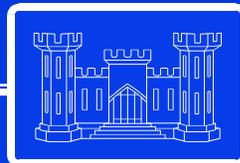
Audit Technique

- This may be a type of training for the lab.
- Must recognize inappropriate practices.
- Review instrument data.
- Make sure quality system is implemented.
- Explain why the lab should follow the method.
- Have new auditor audit an expert and get feedback.
- Computer/Instrument is not always correct



Audit Technique

- Have a new auditor audit an expert and get feedback.
- The instrument/computer is not always right.
- Manual integration may be needed.



Audit Technique

- What to do if inappropriate practices are found.
 - Document the finding by obtaining copies.
 - Sign and return a copy to the lab.
 - Call CX with the information and send a copy.

