



ANAB 2015 Update

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Overview



- Transfer policy
- Most common assessment findings
- Policy on scope expansions



Transfer Policy



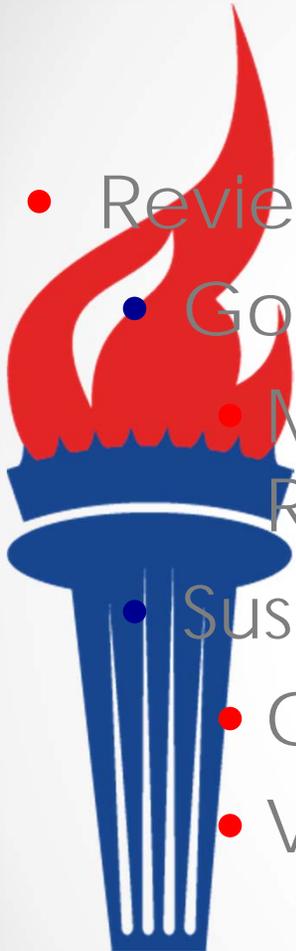
Transfer policy

- Laboratories may transfer at any time
 - Review standing of laboratory
 - Review cycle of accreditation
 - Expiration Date



Transfer policy

- Review standing of laboratory
 - Good Standing
 - May be offsite Document and Records Review
 - Suspended within last year
 - Onsite Review of System
 - Verification of implementation of CA



Transfer policy

- Review cycle of accreditation
 - Surveillance
 - Review Evidence of
 - C/A to previous NCRs
 - Complaints & resolution
 - Internal Audit
 - Management Review
 - PT Participation
 - Reassessment
 - Full Management System Review



Common Assessment Findings



Common Assessment Findings

- Management System
 - Document Control
 - External Documents not in Master List
 - Complaints
 - Incomplete tracking
 - Corrective Actions
 - No system for tracking or trend analysis



Common Assessment Findings

- Management System
 - Records
 - Incomplete
 - Sufficient information to establish **Audit Trail**
- Cross-outs



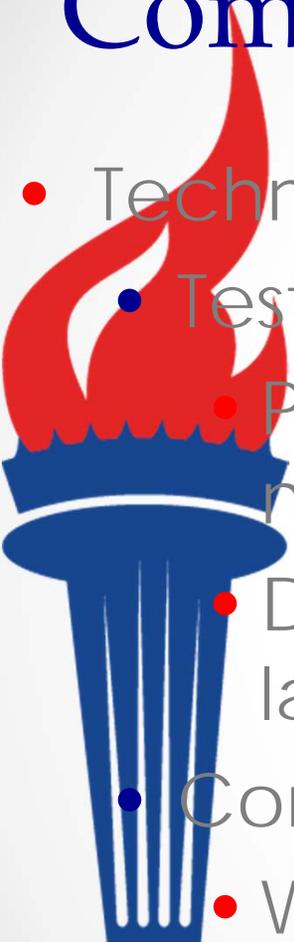
Common Assessment Findings



- Internal Audit
 - Missing Evidence of Review of some Management System elements
 - Technical Elements
 - Strictly Data Review
 - Electronic files
 - Initials observed are not the analyst



Common Assessment Findings

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- Technical Requirements
 - Test Methods
 - Practices observed in laboratory does not reflect SOP
 - Do not reflect reference method +/- laboratory SOPs
 - Control of Data
 - Worksheet Validations



Common Assessment Findings

- Modules and Tables
- Control Charts are not utilized for trend analysis
- Table QC are not always utilized
 - DoD ELAP accredited labs which do little or no DoD ELAP work



Common Assessment Findings

- Computer security requirements
 - Password changes
 - Training
 - System event monitoring
- Log in failures
- Break in attempts

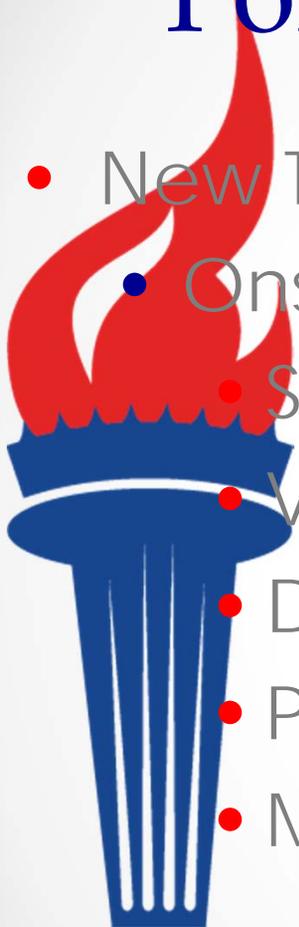


Scope Expansions



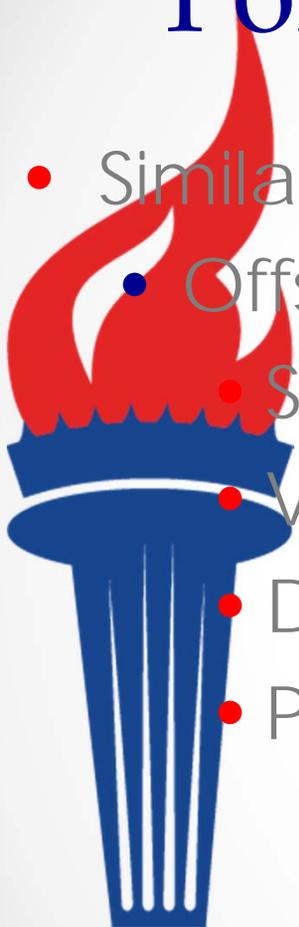
Policy on scope expansions

- New Technology for scope
 - Onsite Review
 - SOP
 - Validations (DL, LOD, LOQ, P&A)
 - DOCs
 - PTs, when applicable
 - Methods witnessing



Policy on scope expansions

- Similar Technology on scope
 - Offsite Review
 - SOP
 - Validations (DL, LOD, LOQ, P&A)
 - DOCs
 - PTs



Scope Expansion

- Not NELAC State interpretation
- Order of Events
 - Valid Effective SOP
 - Validations Study
 - DOC (at least PT analyst)
 - PT Participation, when applicable

