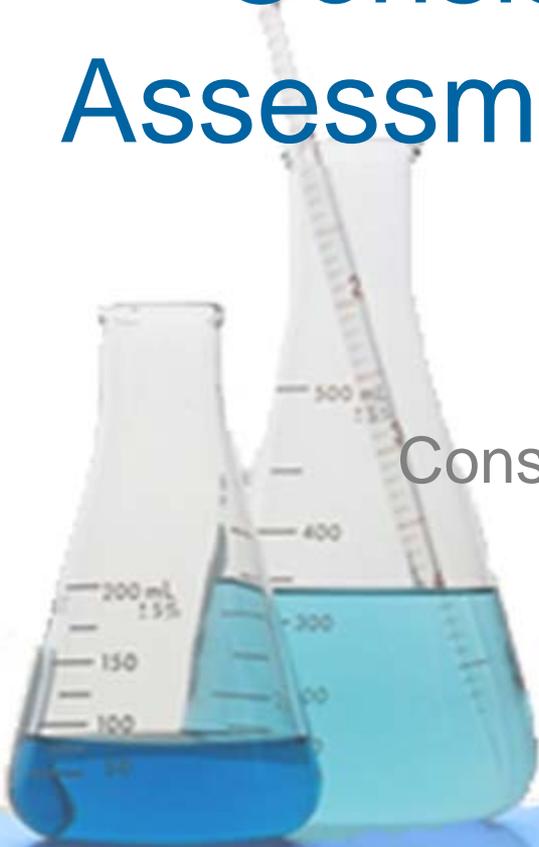




Consistency of On-Site Assessments of Laboratories

Consistency Improvement Task Force (CITF)





Group Members

- Tom McAninch, Lead – LCS (Consultant)
- Barbara Escobar – AzDHS (Non-TNI AB)
- Victoria Pretti – NYDOH (TNI AB)
- Keith Chapman – SLAG (Lab)
- Mitzi Miller – Moeller (Consultant)
- Jack Farrell – AEX (Consultant)
- John Gumpper – Chemval (Consultant)
- Ed Hartzog – DOD (Non-TNI AB)
- Bob DiReinzo – ALS (Lab)





Task Force Goals for On-Site Group

- CI Task Force Assigned Group Five Goals
 - Explore how assessor training can be used to improve the consistency of laboratory assessments (John/Mitzi)
 - Develop a blueprint for conducting assessments (Tom/Ed)





Task Force Goals, cont.

- Establish expectations for the communication of assessors within and between ABs (Barbara/Victoria)
- Investigate opportunities for having assessors observe other assessors performing laboratory assessments (Barbara/Bob)
- Focus on the corrective action cycle of laboratory findings as an area in need of improved consistency (Mitzi/Keith)





Assessment Blueprint Development

- Step 1 - Identify all steps of the assessment process
- Step 2 - Identify steps with potential significant inconsistencies
- Step 3 – Collect input
- Step 4 - Develop recommendations/BMPs to minimize inconsistency





Seven Major Steps of Assessment Process

- 1. Pre-assessment activities
 - Establish Laboratory Assessment Plan***
 - Send Assessment Plan to Laboratory
 - Request Documents from laboratory
 - Pre-assessment preparation by assessor

*Major potential for inconsistency





Steps of Assessment, cont.

- 2. Conduct of On-site Assessment
 - Opening Meeting
 - Management, Technical, Testing Requirements Review*
 - Lab Staff Interviews***
 - Resolution of Disagreements*
 - Closing Meeting*





Steps of Assessment, cont.

- 3. Review of Draft Report by AB
 - Review of report for consistency of standard interpretation by assessor*
 - Identify and resolve interpretation issues within AB*
 - Finalize Report





Steps of Assessment, cont.

- 4. Submission of Report to Laboratory
 - Report Format
 - Timeliness of Report to Laboratory
 - Instructions for Response to Assessment Report





Steps of Assessment, cont.

- 5. Laboratory Response to Assessment Report
 - AB response to questions for developing corrective action
 - Documentation to Provide to AB for Corrective Action*
 - Time Limits for Submitting Report and Addressing/Implementing Actions
 - Report Format





Steps of Assessment, cont.

- 6. Laboratory Corrective Action
 - Application of Finding to all areas of lab operation*
 - Determination of Root Cause
 - Documentation of Implementation of Corrective Action for All Areas*





Steps of Assessment, cont.

- 7. Issuing of Accreditation Certificate
 - When to Issue Certificate
 - Follow-up Assessments*





Potential Major Inconsistencies

- 1. Pre-assessment Activities (3 Identified)
 - Selections of test methods to be reviewed (#1)
 - Identification of Lead Assessor and Assessment Team (#2)
 - Determination of the number of assessor-days required (#3)





Potential Major Inconsistencies, cont.

- Conduct of On-site Assessment (6 Identified)
 - Depth of Review (#4)
 - Amount of Time/Data Required for Interview (#5)
 - Findings Citation (#6)
 - Identification of Repeat (Critical?) Findings (#7)
 - Resolution of Disagreements (Consultancy?) (#7A)
 - Draft Report Left With Laboratory? (#8)





Potential Major Inconsistencies, cont.

- Review of Draft Report Within AB (2 Identified)
 - Inadequate Review within AB for Consistency of Requirement Interpretation (#9)
 - Reluctance to Over-rule On-site Assessor by AB Reviewer (#10)





Potential Major Inconsistencies, cont.

- Laboratory Response to Assessment Report (1 Identified)
 - Amount of Documentation to Provide to AB as Evidence of Corrective Action (#11)





Potential Major Inconsistencies, cont.

- Laboratory Corrective Action (2 Identified)
 - Laboratory Application of Action to All Applicable areas of Laboratory Operation (#12)
 - Documentation to AB of Implementation of Corrective Action to All Applicable Areas (#13)





Potential Major Inconsistencies, cont.

- Issuing of Accreditation Certificates (1 Identified)
 - Follow-up Assessment Required? (#14)





Path Forward

- Finalize input collection

- Analyze input for:
 - BMPs/procedures that appear to work well
 - Predominance of input
 - Compliance with standard

- Develop guidance/recommendations for each assigned goal

- Incorporate into final Task Force product for review by TNI Board





- Questions?
- Input?

➤ Send comments to:

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