



Consistency Improvement Task Force (CITF)

Consistency: A Laboratory Perspective



Objective - Consistency

Provide support document for laboratories that focuses on identified areas of most inconsistency.



- Not a compliance document
- Targets areas that may not be readily recognized by labs
- “Bill of Rights”



Objective - Simplicity

Don't over-think the implementation of the standard

Inconsistency - Labs may implement requirements using different levels of complexity



Approach to Develop

Identify areas of inconsistency

- reach out to labs
- poll SLAG
- CITF
- 2009 TNI Standard

Identify areas of frequent misunderstanding

- review 2003 NELAC & 2009 TNI standards

Provide TNI reference to support consistent approach



- ▶ Not a compliance document
- ▶ Targets areas that may not be readily recognized by labs



Major Areas Identified

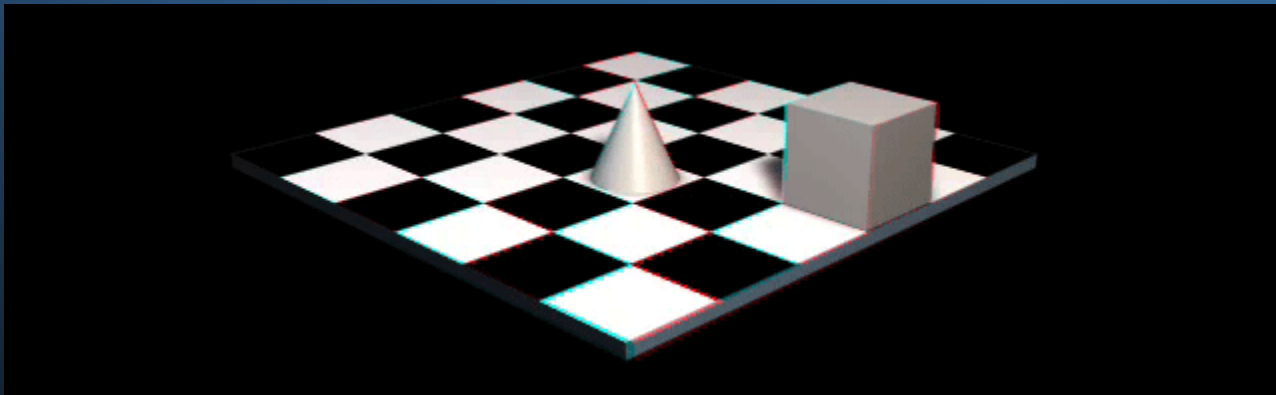
Inconsistencies fell into 4 categories

- Standard Interpretation
- Proficiency Testing
- Assessment
- Lab Management



1) Standard Interpretation

- A) The laboratory has the right to a uniform interpretation of the TNI standard.
- Pivotal inconsistency
 - Also noted by CITF On-Site Assessment workgroup
 - How do we get there?



1) Standard Interpretation

B) The laboratory has the right to request interpretations of standard requirements from TNI. Requests to TNI are separate from individual assessment processes.



- TNI can not be arbitrator between labs and ABs
- Process for requesting interpretation is >30 day audit response time-frame



1) Standard Interpretation

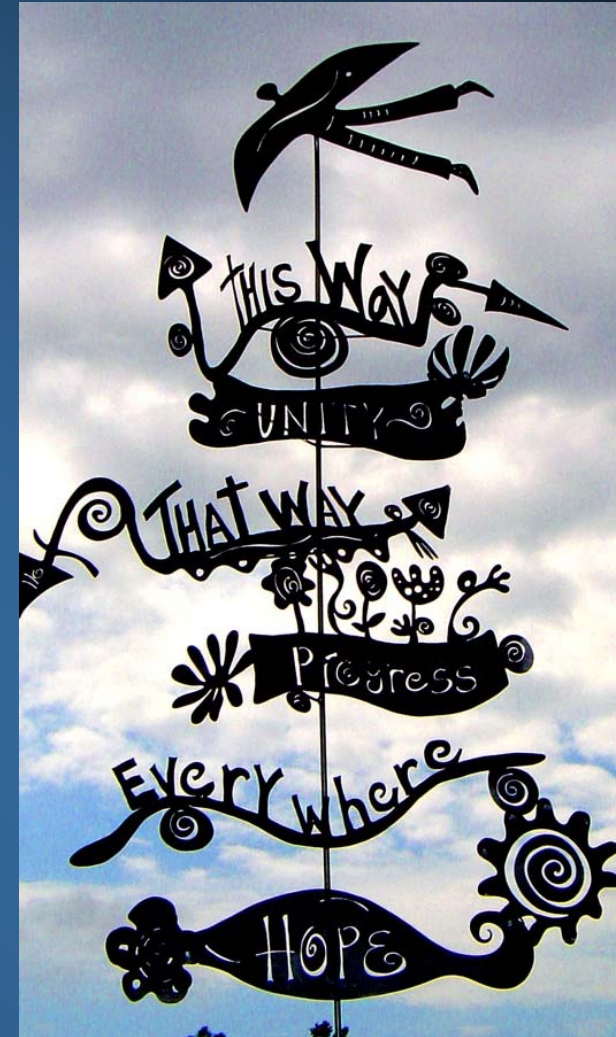
C) The laboratory has the right to receive referenced citations for **written or verbal requirements** and/or findings stated by the assessor **during the assessment** or in the written report.

- Inconsistencies due to assessor opinion or interpretation
- Labs have been known to proceed with CA for issues not cited in final report



1) Standard Interpretation

- D) The laboratory may contest assessment findings or interpretations.
- Potential inconsistencies due to assessor opinion or interpretation
 - Possible support products
 - Guide for preparing informal requests for interpretations
 - Guide for deciding what constitutes an appropriate dispute



2) Proficiency Testing

- A) The laboratory may analyze the same PT sample for any accreditation or experimental field of proficiency testing by multiple methods as long as those test methods are within the same field of accreditation matrix.
- Not required to analyze a PT sample for each test method within the same technology, except for fields of accreditation for the drinking water matrix.
 - An acceptable performance score for one test method will be acceptable for all test methods that use that same technology within that field of accreditation



2) Proficiency Testing

A) (continued)

- Inconsistent approach used by labs in analyzing & reporting PTs
- Inconsistent approach used by ABs in evaluating scores for continued accreditation



2) Proficiency Testing

B) The laboratory may submit questions about PT samples or performance evaluations made by the PT provider to the PT provider

- Inconsistent recognition of PT provider as technical support



So many questions!!



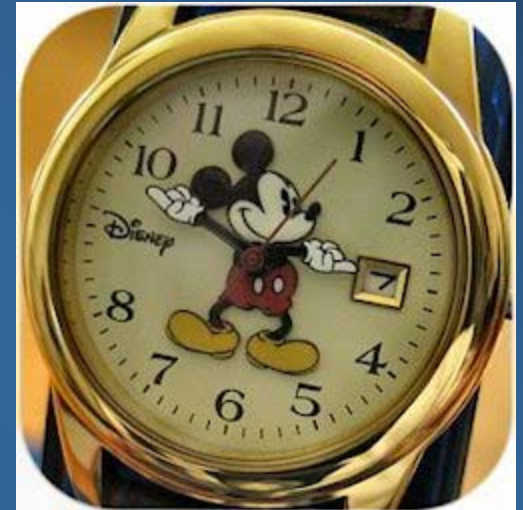
3) Assessment

- A) The laboratory may expect trained, competent and qualified assessors that are free of conflicts of interest.
- B) The laboratory may object to the appointment of any particular assessor or expert.
 - Former lab employees
 - Third party may be client or competitor



3) Assessment

- C) The laboratory has the right to negotiate the schedule of the audit to meet agreeable timeframes.
- Appropriate personnel present
 - Normal hours of operation
 - Unannounced audits – accommodate without adversely affecting operations



3) Assessment

- D) The laboratory has the right to privacy for areas of the facility not related to the audit scope.



- Confidentiality: The laboratory has the right to privacy for areas of the facility not related to the audit scope. They need to provide written consent for the audit to proceed.



3) Assessment

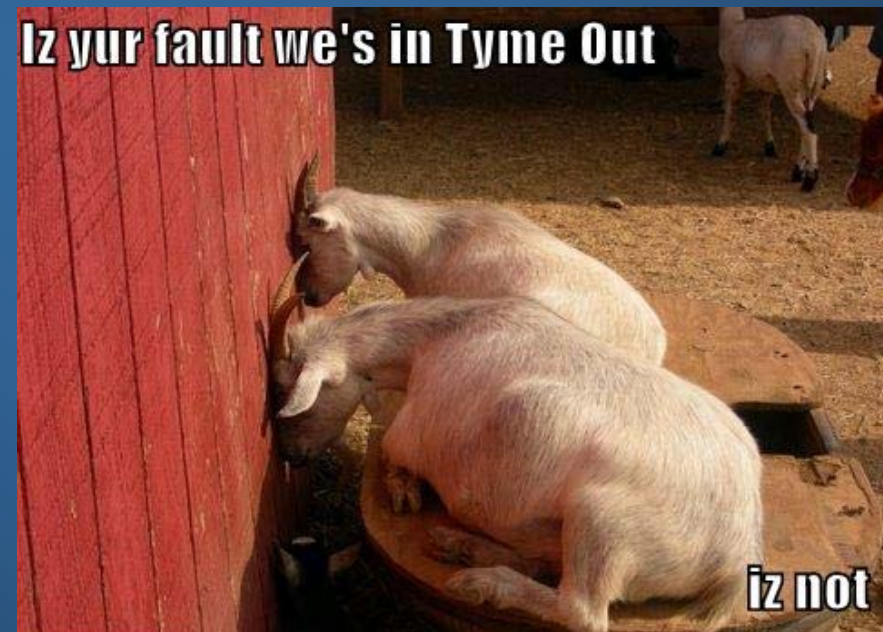
- E) The laboratory has the right to receive any standard forms or checklists that will be used by an assessment team in advance of an announced assessment.
- Inconsistent checklists used by ABs
 - Inconsistent in how checklists are used
 - Lab completes in advance
 - AB completes during audit



3) Assessment

F) Where audit team members decline to follow laboratory procedures, the laboratory has the right to call a 'time-out' to an assessment for the purpose of obtaining resolution from audit team managers or state AB office.

- EH&S PPE
- Access to restricted areas
- Contamination control
- Confidential business information



3) Assessment

G) At the close of an assessment, the laboratory shall have the opportunity to receive a preliminary report (written or verbal) of findings and to ask questions about the findings and their basis.

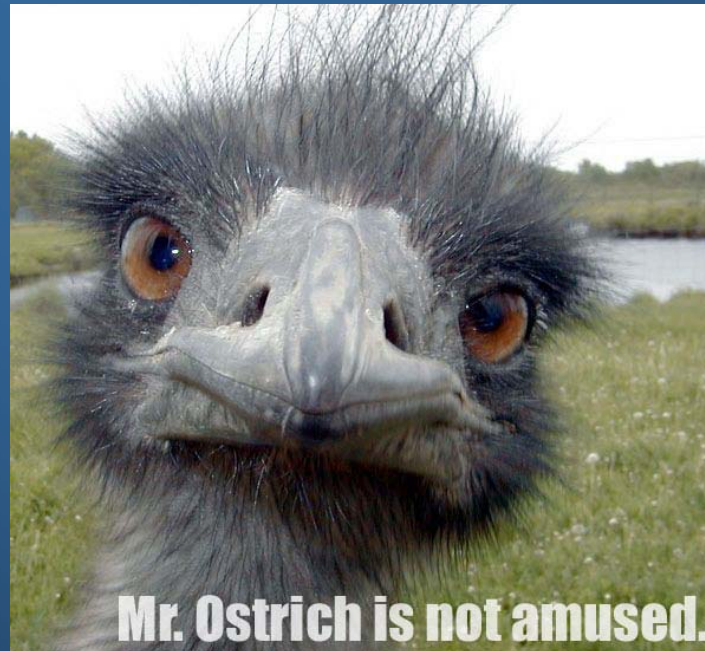


- Reduces misunderstandings
- Allows opportunity for discussion of possible corrective actions



3) Assessment

H) The laboratory has the right to provide an evaluation of the audit and audit team without fear of retaliation.



- Inconsistency – Labs do not submit evaluation forms which drive the audit improvement process.



3) Assessment

- 1) The laboratory has the right to receipt of notice of audit closure or acceptance of corrective actions.



- Inconsiste
- Provides r
repeat def

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3) Assessment

- J) The laboratory may expect re-assessments at a minimum interval of 2.5 years.



- Labs not only expect but welcome the return of the assessment team



3) Assessment

K) The laboratory may appeal for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status.

Adverse decisions include:

- Refusal to accept an application
- Refusal to proceed with an assessment
- Decisions to deny, suspend or withdraw accreditation
- Appeal process specific to state regulations and laws



3) Assessment

L) The laboratory has the right to be reinstated for accreditation after suspension or revocation.

- Meet appropriate requirements
- Labs not always aware that reinstatement can be obtained



4) Lab Management

- A) Individuals of laboratory staff may serve more than one management function.
- Limited staff – Technical Manager & QA Manager may be same
 - Should be balanced approach



4) Lab Management

B) For internal customers laboratories may have a simplified approach to review of requests, tenders and contracts.

- Define and document



4) Lab Management

C) For external customers, the laboratory has the right to inquire as to the end-use of data to determine applicability of the standards.



- TNI standard requirements do not necessarily apply to all work that a lab performs.



...hard working team...

Verl Preston

Robin Cook

Silky Labie

Donna Ruukonen



Are we on the right path?

- Suggestions?
- Comments?
- Unaddressed Areas of Inconsistency?



Martin Liebermann

