

State Agency Partner Committee Perspective

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State Agency Partners

- Perspectives of Regulators
- ELAP's ultimate customers
- Rely on ELAP lab data:
 - Used for decision-making
 - Used by those they regulate;
 - Used in legal proceedings;
- Staff in regulatory programs not experts at requesting or assessing data quality

State Agency Partners Committee

- Discussion and input to ELAP
- ELTAC important to SAPs and to ELAP
- Value recommendations & concerns of ELTAC and its members
- My comments are my own
 - Neither SAPC nor ELTAC are consensus bodies for Standard-setting or input

ELTAC

- **Perspectives of labs regulated by ELAP**
- **Critical for ELAP**
 - Points of view of those it regulates
- **Critical for SAP**
 - Points of view of those who generate data for their regulatory programs
- **Extremely diverse**
- **Wide range of real-world expertise**
- **Same needs and concerns as labs nation-wide**

How I Reviewed ELTAC Comments and Recommendations

- **TNI = Integrated System of Quality Requirements**
- **I considered questions about:**
 - **The Section**
 - **Related Sections**
 - **History**
 - **Best Practices**
 - **Level of Effort**
 - **“Straight-Face Test”**

The Section

- What does the section require?
- How does it contribute to quality, consistency, auditability, enforceability, etc.?
- How would modifying/deleting this section affect quality, etc.?

Related Sections

Impacts of the changes on the overall system...

- With other sections does it interrelate?**
- What do those other sections require?**
- How do those other sections contribute to quality...?**
- How would modifying/deleting this section affect those other sections?**

History

- **What is the section's history & what Quality Needs does it address?**
- **Why was it created and how did it evolve...**
 - **NELAC's History and TNI subcommittee meeting information and notes;**
 - **EPA Inspector General Reports**
 - **EPA, DoD, and other lab quality reviews, investigations & recommendations**
 - **Cal/EPA documents and recommendations**

Best Practices

- **Do other organizations provide clarifications or additional requirements related to the section?**
 - **DoD/DoE Quality Systems Manual for Environmental Laboratories (DoD QSM)**
 - **Recommendations in Standard Methods**
 - **Recommendations in EPA, DoD, and other reports**

Level of Effort

- What level of effort is needed to comply with the section?
 - To Implement
 - To Sustain
 - Time, cost, resources, administrative, bureaucratic, etc.
- Would it be logical to phase it in later?
 - ELTAC members' real-world perspectives
- Unique challenges of small labs (public, private)

“Straight-Face” Test

When I state the opposite, does it pass the “straight-face” test?

“If a lab does not do X it will not adversely affect quality...”

“When purchasing supplies, reagents, and consumable items that affect the quality of the test, it is acceptable if the lab does not inspect or otherwise verify that the items meet the requirements of the Method and Customer before they are used” [M1V2, 4.6.2]

[Most ELTAC members voted to delete M1V2 4.6 – Purchasing Services and Supplies]

Why Robust System Needed?

Inappropriate or Fraudulent Activities - EPA OIG Reports:

- **“EPA Has Not Implemented Adequate Management Procedures to Address Potential Fraudulent Environmental Data,”** Report No. 14-P-0270 May 29, 2014
- **“Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks,”** Report No. 2006-P-00036 September 21, 2006. [Especially Appendices A, C, D, E]

Data quality problems can have serious consequences

Figure 1.1 - Widespread Potential Impact of an OIG Laboratory Fraud Case

City and County Residents	1.8 million people
School Districts and Individual Schools Served	129
Hospitals Served	12
Bottled Water Companies Served	104

Source: EPA OIG Office of Investigations analysis

NELAC/TNI Framework

- Cal/EPA's Environmental Data Quality Team recommended NELAC/TNI standard (1997)
- Comprehensive
 - Addresses all aspects of management and technical activities that may affect the quality of the results
- Customer focus
- Continuous improvement mindset!

Continuous Improvement Mindset

- **Phased implementation**

- Give labs sufficient time
- Not about following a checklist
- Audits are to help you improve
- Great if different auditors look at different things!
- If a serious deficiency is found... be glad they found it so you can correct it

**Auditors' Mindset: Continuous improvement,
not “gotcha” enforcement**

Should California be Less Than the Best?

I hope you will guide California to set a clear path to being the best

- Quality takes time and money
- How can ERP, SAP, ELAP, ELTAC actively help labs be the best?
 - Small, municipal labs

California as the Leader: Is TNI the Ceiling or the Floor?

“Straight-Face” Test: Try stating the opposite....

“Have quality system requirements that are less robust than those which other states and federal agencies require of their laboratories”

“Be less stringent than other agencies who have determined that certain best practices beyond TNI are critical to ensure data are of the quality needed for decision-making”

“Only hold laboratories to the minimum required by US EPA Methods, even when the Methods themselves recommend additional steps be undertaken”

TNI-Minus?

TNI?

TNI-Plus?

Help Labs Systematically Improve TNI-Minus → TNI → TNI-Plus

- **Phased Approach**

- Time to implement initial elements of TNI
- Time to improve those aspects
- Time to implement additional elements
- Input from ELTAC Members

- **Information & Training**

- Templates, Forms, Checklists, Examples

- **Audits as Assistance**

Performance Testing Samples

- I support one PT sample per year for the current time
 - ELAP's PT program is not yet functional at a quality system level
 - ELAP not ready to make use of two PT/year
 - Start with TNI-Minus with path to TNI-Plus
- ELAP should review history of Performance Testing
 - Frequency
 - Truly blind samples
 - Relevant matrices
 - Structure of programs
 - Evaluation of data

Standard Methods

- Many Standard Methods are “Guidance”
 - Allow deviations and omissions of steps
 - How do you assess what the lab is doing?
- Often say “should” and “may”
 - Recommendations are not requirements
 - How do you ensure the quality of the results?
- Should California’s Standard be for labs to do less than what EPA recommends?
 - If EPA recommends something, require labs to do it or explain why not doing it won’t adversely affect quality

My Recommendations

- Do not attempt to implement all sections of TNI right away
- Give labs plenty of time and support, especially small, municipal labs
- Phase-in over time several of the sections ELTAC members identified to be “deleted” or “modified”
- Consider the “Questions” when prioritizing delays and phase-ins – Get ELTAC input

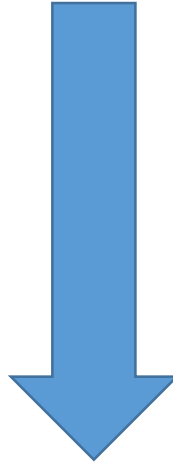
My Recommendations (cont.)

- Goal is TNI-Plus, not TNI-Minus: ELAP must have specific plan for how it will establish and require best practices, not just minimum allowed by federal law.
- If EPA recommends something as best practice, require labs to do it or explain why not doing it will not adversely affect quality
- Include clear path to TNI-Plus in Regulations
 - Easy to justify consensus standards; difficult to justify changes
 - If TNI-minus now, how will ELAP explain need for TNI-Plus later?

Additional Recommendations

- Specify standard “Flag” definitions, unless otherwise specified in a Method, in federal or State law, or in customer-specific requirements [cf. DoD QSM Ver. 5, 2013, 5.10.3.1.1]
- Specify default “Format” for reports, unless the format is otherwise specified in federal or State law, or in customer-specific requirements [cf. DoD QSM, Appendix A]
- Specify minimum information to include in report narratives
- Specify what is to be included at a minimum in Level/Stage I, II, III, IV, V Data Packages

Thank You



Some General Comments From ELTAC Members

- **It's too expensive**
- **Our District makes us go with low-bid purchases**
- **Some requirements are vague, impossibly broad, and unenforceable**
- **The assessment is entirely subjective**
- **The checklist is too long**
- **Different auditors check different things**
- **It's a "one size fits all" Standard**
- **The Standard requires more than what is required in the Method**
- **Some of the requirements are just busy-work**
- **The Quality Manager cannot be independent of outside influence if they do other work**
- **Many of the sections and requirements are redundant**
- **Two PT samples is too onerous**
- **Labs should only be required to meet what is in the federal requirements (drinking water, wastewater, etc.)**

Are TNI Requirements Impossibly Broad and Unenforceable?

California Vehicle Code section 22350: “No person shall drive a vehicle upon a highway at a speed greater than is reasonable or prudent having due regard for weather, visibility, the traffic on, and the surface and width of, the highway, and in no event at a speed which endangers the safety of persons or property.”