

TNI STANDARD & WORK PLAN TIMELINE Presented by Allison Mackenzie

RECAP OF NEED FOR TNI STANDARD

Comprehensive

- > Widely recognized: employs ISO17025, reciprocity in 23 States, 12 State AB's, recognized in 35 out of 50 States.
- Consensus Based: Culmination of more than 20 years of work by laboratory & regulatory professionals
- ➤ Addresses PTs & ABs
- Scalable for small labs & Applicable to specialty labs and multiple regulatory programs

Practical

- Well established & continuously improved
- Resources available, including training & templates

➤Economical

- ➤ Ready to use now
- > Recreating the wheel = Years + \$\$\$\$\$\$\$

RECOMMENDED VERSION OF TNI: 2016

- ➤ 2003 Standard
 - Not a viable option; outdated
- ➤ 2009 Standard
 - > Problems with language and some modules
- > 2016 Standard Recommendation
 - ELTAC members in attendance at NEMC meeting agreed 2016 Standard is best of all TNI revisions available for adoption
 - > Provides some key clarifications, easier to implement in smaller labs
 - > 2016 Standard has been approved and published; Does not require TNI adoption for use
 - Copies of the 2016 Standard have been provided to ELTAC members for their review, at no cost
 - TNI's Jerry Parr will provide ELTAC with summary of changes between 2009 and 2016 Standards

PROPOSED TIMELINE FOR IMPLEMENTATION

- > Proposed timeline for implementation of the Standard will involve several different but interrelated timelines:
 - SWRCB decision regarding Standard selection
 - Legal rule making process
 - Training for ELAP personnel
 - Training for labs
 - Lab implementation

PROPOSED TIMELINE FOR IMPLEMENTATION

ELTAC RECOMMENDATIONS to ELAP:

- TNI training & conformity assessments for labs implemented over 3 year period
 - Starts January 2017 (training)



- Includes training and orientation for labs on a need/want basis
- Progresses to a first round of TNI Standard lab assessments in 2018-2020
 - ➤ Full implementation no later than Dec. 31, 2020
- Implementation should include provisions for interim accreditation of nonconforming labs during initial 3 year period

PROPOSED TIMELINE FOR IMPLEMENTATION

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ELTAC RECOMMENDATIONS:

- ELAP attitude toward initial assessments should be cooperative and educational, i.e. compliance assistance
 - Primary mission should be training labs on how to comply with the Standard
- After first round(s) of TNI Standard assessments, labs will be expected to:
 - Create corrective actions with time frames
 - Schedule for resolution
- Solution of the second seco

PROPOSED IMPLEMENTATION STRATEGIES

TNI Standard 2016 should be adopted by California ELAP





QUESTIONS?