

BACWA Laboratory Committee: New ELAP Regulations

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Overview

- ELAP Background
- Proposed regulations
- TNI Background
- Change to Accreditation Process
- Enforcement Provisions
- Regulatory Timeline

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

ELAP was established in the Environmental Laboratory Accreditation Act, 1988

ELAP accreditation required to perform analyses for regulatory programs in California

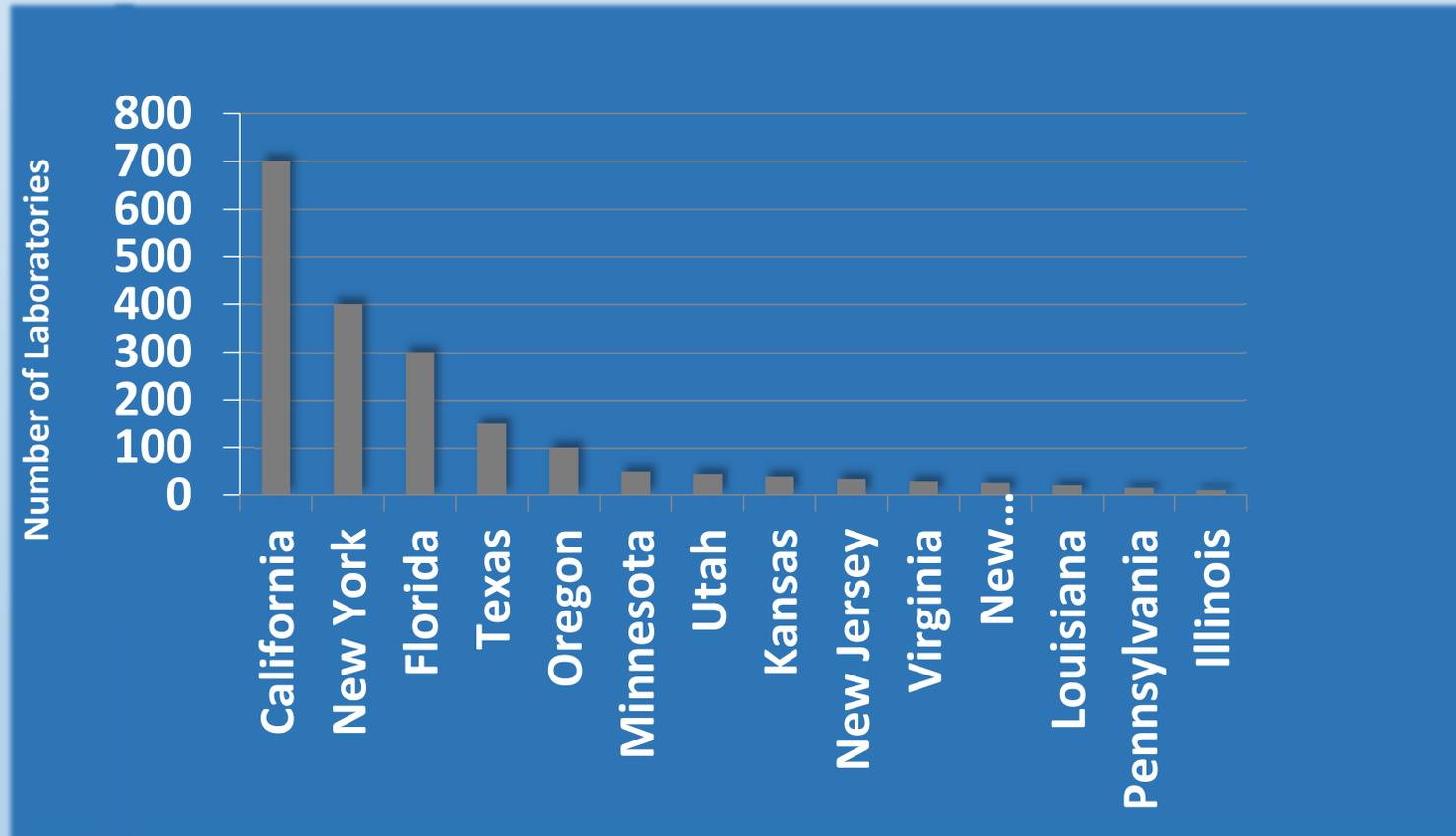
685 Environmental Laboratories are accredited by ELAP

AREAS OF TESTING

- **ELAP offers accreditation in methods approved for use in California Regulatory Programs**



SIZE AND SCOPE



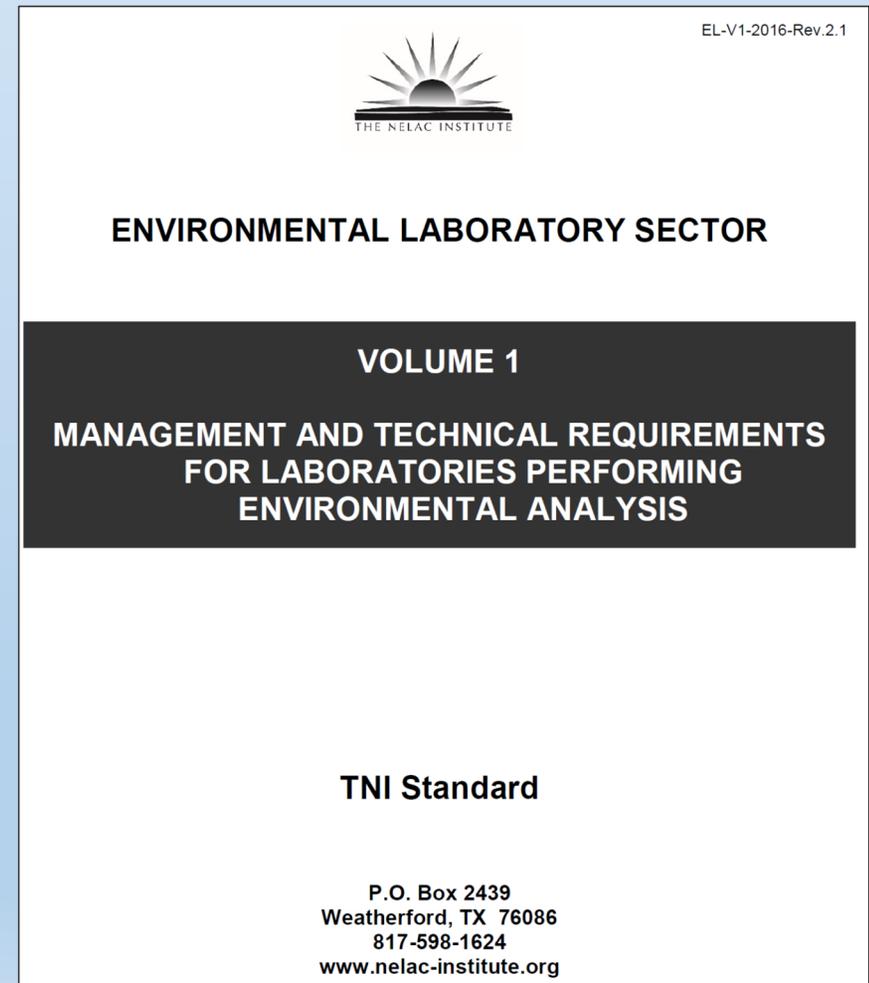
Slide Courtesy of ELAP

New proposed ELAP Regulations

- 4th Draft
- Accreditation Standard: TNI 2016
- Accreditation process: include On-Site Assessment (OSA) report with corrective actions as part of renewal application
- Third Party Assessors
- Enforcement Provisions

TNI 2016 Standard

- TNI = “The NELAC Institute”
- NGO supported by EPA
- TNI Standard structure:
 - Module 1 – PT Testing
 - Module 2 – Quality System
 - Modules 4, 5, 7 - Chemistry, Micro, Toxicity specific QC requirements
- ELAP wants TNI with two changes



TNI 2016 vs. CA ELAP

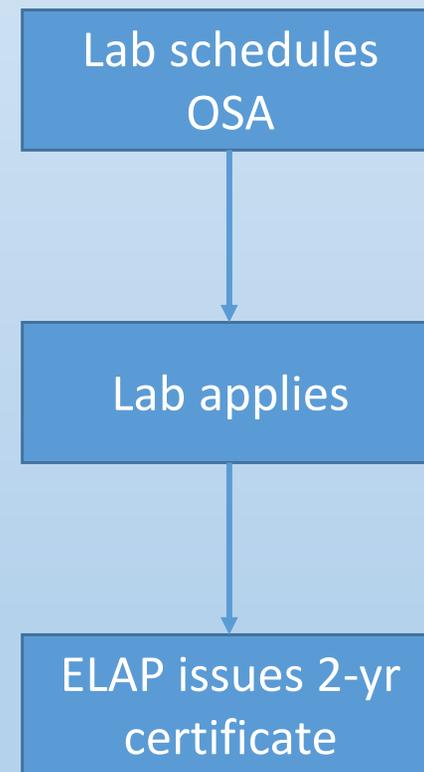
- Both require use of standard methods approved by regulation.
- TNI requires Quality System; current CA regs are vague.
- About 587 requirements in TNI vs. 180 in current CA regs.
- TNI contains many administrative and record-keeping requirements.
- Current ELAP audit practice is to stretch current regs as far as possible; especially for traceability and equipment.

Change to Accreditation Process

Current Process



New Process



Third-Party Assessors

- ELAP will require Third-Party Assessors for labs with sophisticated technologies.
- ELAP will maintain list.
- Labs pay TPAs directly.
- Labs pay ELAP an assessment fee if ELAP performs OSA
- Lab is responsible to schedule OSA. Leave time for Corrective Actions!



Enforcement Provisions



- Draft regs allow ELAP to take enforcement actions:
- “Denial” – reject application for renewal
- “Citation” – ELAP can fine laboratories
 - First-ever fine was \$137,000 against private lab
- “Suspend/Revoke” – ELAP can suspend or revoke certification between renewal cycles
- BACWA comments – all penalties triggered by the same list of offenses; suggested more clarity.

Regulatory Timeline

- Dec 18, 2019 – State Board Hearing
- Mar 7, 2020 – Tentative State Board Adoption
- July 1, 2020 – Regulations go into effect
- July 1, 2023 – TNI standard required for all labs