California's Withdrawal From NELAP
Causes, Effect and Solution

Dr. C. Bruce Godfrey

Agenda

- **California's exit as NELAP AB**
  - **You can't fire me, I quit!**
  - **Effect on Labs, TNI, and NELAP**
- **CA AB developments/foreword look**
- **Non-Government Accreditation**
  - **Solution for CA, and NELAP problems**
  - **Why TNI should recognize NG AB's**

Accreditation Goals

- Ensure conformance to program requirements & standards
- Detect and correct substandard practices
- Ensure protections for end users of measurement data

NELAP Components

Accrediting Authority-States

- *Exercise regulatory authority through licensing*

Accrediting Body (AB)

- *Provide accreditation services to laboratories*

AB Recognition Authorities

- ILAC, NACLA, TNI: Recognize/certify ABs

Standards Generation & Maintenance Organization

- ISO, TNI

Standards of Practice

- Consensus Laboratory Standards
  - ISO 17025, TNI NELAC Standard 2009
- Customer Laboratory Standards
  - DoD/DoE QSM v 5.0
- Accrediting Body Standards
  - ISO 17011
- State standards?
- Labs assessments are about conformity to defined standards of practice

Licensing, Accreditation, NELAP Access

- Accrediting Laboratories
  - On Site Skilled/Trained NELAP Assessors 30-90+ hrs
- Licensing Laboratories
  - Desk review of conformity assessment report: 1-4hrs
- States recognize ABs **Reciprocity**
- ABs perform standards based conformity assessments
  - Substandard ABs perform substandard laboratory assessments

CA ELAP

- A Troubled Program
  - To long without any leadership or management
- Lacking basic accountability & systems
- Ignored & neglected by DPH
- Switch from DPH to Water Board
  - Will new “ownership” bring needed change?

ACIL Survey Results 2012

- Timeliness
  - Routine extraordinary service delays, lapsed lab inspection intervals
- Assessors are unprofessional/unaccountable
  - Unethical behaviour, timewasting, irrelevant assessor opinions
  - Inaccessible & unaccountable to their lab customers
- Competency
  - Assessors insufficiently trained in standards & methods
- Costs to Labs
  - Very expensive fees for inadequate/incompetent/inconsistent service
- Effectiveness
  - Lacking adequate organization systems, poor customer service

TNI ELAP Assessment 2012

- 13 findings 2 observations
  - Recommendation not to renew NELAP AB status
- Lack of appropriate management & oversight
  - No Director, QA Systems nonexistent and/or unimplemented
- Competency
  - Assessors lacked adequate knowledge of standards & methods
- No systems for evaluating organizational performance
- Internal audits: long term problems, no corrective action(s)

Root Causes

- No State standard of practice
  - Allows assessor opinions range & relevance
- ELAP & State lab staffed separately
  - Inexperienced/unqualified assessors
- History of neglect, mismanagement
  - Poor systems, training, accountability

ELAP Ownership Change

- 4 of 6 DWEM groups moved to Water Board
- Environmental Management and DW/Rad Lab to stay with DPH
  - (what) are they thinking?
- Is the new "owner" like the old one?
- How will they deal with NELAP?
  - Reciprocity?
  - Will CA-ELAP get back in the NELAP game?

NELAP Today

- Underlies interstate provision of lab services
- *Inadequate for federal agency buyers*
- Uneven state participation/commitment
- *Exclusive province of Gov ABs (?)*
- CA-ELAP problems are not unique
- *Lab customers support the program*
  - *Concerns related to nonstandard ABs*

NELAP Value Proposition

Commercial labs value NELAP highly as an alternative to multiple redundant accreditations….NELAP can be more.

1) Reciprocity agreements save effort, reduce costs

- Established separable licensing & conformity assessment services
- CA extends reciprocity to NELAP ABs for out of state labs

2) An evolving, defined consensus standard of practice

3) Ensure AB performance/accountability

- *AB standards (ISO 17011) are required for credibility going foreword*
- *TNI must be seen as capable of "disciplining" governmental AB's*

CA's Effect on NELAP

- Large state AB "fails" the program
  - TNI can discipline governmental ABs & survive(?)
- CA labs access thru OR, UT: & save fees
- CA extends reciprocity for out of state NELAP labs: They save fees too!
- CA labs must endure an ELAP onsite assessment in addition to OR/UT NELAP assessments: Step backward

"The Big Idea"

Bring private ISO17011 ILAC/NACLA Recognized ABs into NELAP as primary accreditors of laboratories

Why?

•One organization to address a lab's conformity assessment needs

•Governmental ABs may likely require several years to get programs to conformance with ISO 17011

• ISO Conforming ABs improve lab conformity assessments

What's in it for TNI-NELAP?

Government agency signatories, ISO/ILAC recognition

Legitimacy, Relevance, Recognition

The ACIL Approach

- Separate licensing and accreditation services at states
- Labs choose primary state AB or alternative ISO 17011 conforming nongovernment AB
- Fees charged are appropriate to the level of effort
- Accommodate unique state requirements
- Loss of accreditation means loss of license(s)
- Working examples: WA, FL

Benefits

- Improve assessment consistency
- *Likely to reduce state's costs*
- Probably reduce lab accreditation costs
- *National and international NELAP relevance/recognition*
- Probably save data users & taxpayers $
- *Improve lab access to NELAP*
- Accommodation of unique state requirements
- *Likely to increase states participating in NELAP*

Concerns

- Shift state AB support cost to smaller municipal/utility labs
- *Reduced state regulatory "control"*
- Outsourcing state government function
- *Minutiae of implementation*
- Loss of state expertise/capability

The "Take Away"

- Recognized ISO17011 compliant Nongovernmental ABs are the highest value providers of laboratory accreditation services
- *All stakeholders benefit from ISO conforming ABs*
- Its time for ISO 17011 conforming ABs in the program
- *Verified conformance to international standards for **both** Labs and ABs improves NELAP*