



**Curtis & Tompkins Laboratories**

FULL SERVICE ENVIRONMENTAL ANALYTICAL TESTING

Reinventing California's ELAP  
An ACIL Perspective

Dr. C. Bruce Godfrey  
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## ACIL

The American Council of Independent Laboratories is the national trade association representing independent, commercial scientific and engineering firms

Accreditation is a key concern for ACIL laboratories that provide the majority of tests and measurements for environmental regulatory purposes in CA and the rest of the USA

ACIL member lab representatives are actively working with ELAP leadership, staff, and stakeholders to improve services offered by California's Environmental Lab Accreditation Program (ELAP)

Following are ACIL views and positions on the best path forward for ELAP

## Agenda

Review ELAP's Progress Since Ownership Change

Discuss ELAP Reform Process

Review Victories and Learning Opportunities

Discuss why ACIL thinks ELAP "reinvention" needs "rethinking"

## Laboratory Accreditation Goals

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

## Standards Based Systems & Conformity Assessment

The best, if not only path for laboratory accreditation is based on written consensus standards of practices, transparent processes, and mutual obligations agreeable to all involved parties

Written standard of laboratory practices generated by consensus of data users, laboratories, other stakeholders (TNI-NELAP, ISO 17025)

Accrediting Body (ABs) credibility/legitimacy is derived from conformity to standards of AB practice (TNI, ISO17011)

Transparency: everyone understands their roles obligations and requirements through the process

## Standards Based Laboratory Accreditation System Components

### Accrediting Authority (States)

- *Regulatory authority granted by law, maintained through licensing*  
*Provision of AB services is optional*

### Accrediting Bodies (AB, ABs)

- *Provide standard(s) based conformity assessment services to laboratories*

### AB Recognition Authorities

- *Provide standard(s) based conformity assessment services to ABs;*  
**ILAC, NACLA, TNI**

### Standards Generation & Maintenance Organizations

- *Create and maintain the standards for labs and ABs; ISO, TNI*

## ELAP Overview & Progress Report – ACIL View

Under DHS, ELAP suffered long term leadership neglect ELAP failed to adopt or develop standards of practice and maintain a credible laboratory assessment capability

Dedicated and hardworking Waterboard ELAP leadership & staff are developing capabilities toward a (as yet, unconfirmed) goal of providing an effective standards based conformity assessment program

Expert Review Panel (ERP) process: 2+ years of program evaluation and stakeholder feedback delaying meaningful, seemingly inevitable program corrective action(s)

ERP process is training ELAP leadership & staff on issues of operating an AB.

Decision on a standard of practice limits most if not all significant progress. Stakeholders appear fragmented, portending further delay

**The best model for reconfiguring ELAP was never seriously considered, ensuring substandard ELAP AB service provision into the future**

## What's Changed on the Ranch Since We Bought It?

This is government folks; deliberate, time consuming process

ERP conceived, convened, and ongoing: "360" program review

ERP identified "heavy lifting" for ELAP staff: Staff & Leadership effort is commendable, appreciated, and recognized by ACIL members

New Hires and staff changes at ELAP....."start up" work environment

ELTAC reconstituted under new bylaws & with broader representation

Participation is impressive, ELAP success requires an active ELTAC

Significant communication improvement: all stakeholders are identified, defined, & involved; Issues identified, positions, roles materializing



## Is ELAP “Reinventing” the Program?...or Restructuring on an Ineffective & Outdated Business Model?

We’re working through constraints imposed by existing law and stakeholders’ views & thought processes

We are rebuilding ELAP on a outdated & inadequate business model

Better, faster, and cheaper service model based on 3<sup>rd</sup> party assessments successfully implemented in other states was either quashed, or never seriously considered

The ERP process & stakeholder involvement mitigates constraints to implementing a better, more sustainable ELAP “business model”

Bring 3<sup>rd</sup> party ABs into the program

## How Much Longer until ELAP is “Fixed”?

Years.... How many, nobody can really predict

Significant corrective actions identified by ERP involve potentially contentious stakeholder disagreements

Standard decision: Critical & rate limiting, What to do in the interim?

Legislative action likely required

ELAP needs: experienced leadership, recruiting, staff training, management & QA systems

*We have to say it....* State workplace rules present impediments

ILAC/NACLA conformity assessment to the ISO 17011 standard for ABs, the defining mark of ELAP AB service legitimacy is a long way off

## ACIL's California Solution

- Adopt the TNI standard for all CA Labs: Stakeholders hold disparate views, there is no alternative standard
- Separate ELAP fees for licensing and conformity assessment services. Set fees based on level of effort and program support costs
- Recognize ISO 17011 conforming nongovernmental third party ABs to provide TNI standard conformity assessment services to labs
- Allow labs to choose AB conformity assessment providers, ELAP is an option, not the sole AB services provider for the program
- Recognize NELAP reciprocity agreements for AB services provided to out of state labs

## CA & ELAP Need 3<sup>rd</sup> Party ABs

- To support ELAP assessment effectiveness in the interim between now and credibility/legitimacy, next 2-5 years
- ELAP is self supporting, labs experiencing ~50% user fee increases without any ELAP capability or service improvement
- ELAP needs real, existential incentives to improve efficiency, effectiveness, and service quality
- ELAP needs more resources invested for systems, personnel, & infrastructure; resulting in years of costs w/o any lab user benefits
- 3<sup>rd</sup> party ABs can contain/control ELAP fees, Hugely important issue to all laboratory stakeholders

## Nongovernmental AB - ELAP "Partnership"

### It's the best system for all stakeholders

- Shortest interval between now and "program fixed"
- Licensing services: lower cost, faster, easier implementation
- It's a Successful Model: FL implemented 3<sup>rd</sup> party solution. NJ adopting; WA, MN recognize 3<sup>rd</sup> parties
- If AB services are desired: ELAP is free to focus on the DW/WW AB services their small muni & metro laboratory customers want
- Rare FoTs w/ high capability development costs: Radiochemistry, Air, Food/Agriculture; can be "delegated" to 3<sup>rd</sup> party ABs

## Program Design Considerations - 1

- 1) Separate ELAP Services: Laboratory licensure and conformity assessment services are different. Enforcement & Oversight
- 2) Separate fees for licensure and accreditation services. Distinct fees based on resources required to staff and deliver services requested.
- 3) Recognize NELAP reciprocity agreements. In & Out of state NELAP accredited labs pay licensing fees
- 4) Establish ELAP customer service standards
- 5) Establish an Accreditation Council within ELTAC

## Program Design Considerations - 2

- 6) ELAP Staff: Assess ELAP assessors performance annually. Implement an employee development program
- 7) Quality Assurance: Implement a QA program for process improvement. Root cause evaluation, and tracking corrective actions
- 8) Transparency: develop and post an AB Operations Program Plan defining ELAP organization and accountabilities, policies, practices, procedures, staff training and quality assurance plans.

## Program Design Considerations - 3

- 9) Transparency: Establish ELAP management review procedures in accordance with ISO/IEC 17025:2005(E), Clause 4.15) Post management reviews on ELAP website.
  
- 10) Ethics: Establish an ethics and integrity program within ELAP that supporting ethical behaviour of all ELAP employees that provides sufficient disciplinary measures to enforce the code.



Dr. C. Bruce Godfrey

Curtis & Tompkins Labs  
2323 5<sup>th</sup> Street  
Berkeley, CA, 94710  
[bgodfrey@montrose-env.com](mailto:bgodfrey@montrose-env.com)

Mobile: 510-409-2211

Websites:  
[www.curtisandtompkins.com](http://www.curtisandtompkins.com)  
[www.montrose-env.com](http://www.montrose-env.com)  
[www.acil.org](http://www.acil.org)