

Third Party Accreditation why California needs it

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Accreditation Goals

- Ensure data used in making decisions affecting human health and the environment is generated by competent laboratories
- Detect and correct substandard practices
- Ensure protections for lab data users



ACIL Labs

- Large commercial laboratories performing thousands of tests per month in every FOT for public and private sector clients
- ACIL labs perform ~70% of environmental testing in the USA, and >50% of testing performed in California

ACIL is engaged in this process to educate California policy makers to assist them in creating a world class, standards based laboratory accreditation program



Lab Expectations





- Appropriately accredited AB
- Equal assessment to a standard regardless of lab size
- Consistency for all labs;public/private, large/small
- Effective, transparent, and accountable program management
- Value received for fees charged.



California ELAP

- Accreditation Authority (AA) acting as an unaccredited
 AB providing inadequate, substandard services
- Inexperienced management & undertrained staff struggling to repair >10 years of neglect
- Reform efforts significantly impaired by state personnel management policies & procedures
- Lab expectations and accreditation goals will be unmet for many years into the future

ELAP's service provision model must be changed to meet accreditation goals & lab expectations



Changing ELAP Service Model

- Adopt the TNI-NELAP Standard of Practice for Labs
- Establish licensing fees
- Recognize ISO 17011 conforming NonGovernmental Accreditation Bodies (NGAB) to provide ELAP conformity assessments to TNI standard



The Fix...Recognize ISO 17011 conforming NGABs to provide accreditation services for California laboratories

What's in it for the labs?

- •One accreditation service provider for all conformity assessment needs
- Better value, improved consistency, reduced uncertainty

What's in it for ELAP?

Lower costs, mechanism to address rare FOTs, improved consistency, reduced backlog of unassessed labs, competition & "benchmarking"

What's in it for Taxpayers?

Improved lab conformity, reduced ELAP impact on state budget Expedient replacement of an inadequate status quo with "World Class" laboratory accreditation program



Requirements for TPA

- A Standard of Practice: Choose NELAP, or....develop/implement an ELAP Standard
- License conforming nongovernmental AB's to provide accreditation services to the standard using TNI NGAB recognition model
- Separate fees for licensing and accreditation services



ELAP Customers

- 80% ELAP accredited small labs
- 20% NELAP licensed larger labs

Nonstandard ELAP performance fuels *two tier* laboratory accreditation system in California

Large commercial labs only want ELAP licensure services



ELAP Standard of Practice

- ELAP standard development process will likely take 2-3 years to complete
- Contention in the process will be largely manifest around the *two tier* issue



Two Tier System

- Unacceptable to ACIL
- A "Process Control" standard could be implemented for small utilities not providing fee-for-services to public
- If California is to have a two tier system, all fee for service labs must conform to the NELAP standard



Accredit all ABs

- Conformity to ISO 17011 standard for all providers of AB services, including ELAP
- AB credibility requires periodic ILAC, NACLA or TNI assessments
- US-EPA is not standards driven



Design Considerations

- ISO Standards based Labs & AB's including ELAP
- One standard for all labs, and all ABs in the program
- Level of effort based fees: assessment & licensing
- Labs choose AB from recognized conforming providers
- Sustainable maintenance & evolution of the standard
- Enforcement: Lose accreditation, lose license



Don't change the ELAP service model

Any argument for retaining California's monopoly on the provision of laboratory assessment services is a tacit request for many more years of ELAP inadequacy.