



## **REINVENTING CALIFORNIA'S LAB ACCREDITATION PROGRAM...AN ACIL PERSPECTIVE**

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### **ABSTRACT**

The author summarizes ACIL's views of the work accomplished and required to bring California's Environmental Laboratory Accreditation Program (ELAP) to a position of credibility. ACIL advocates a system incorporating 3<sup>rd</sup> party nongovernmental Accreditation Body (AB) companies performing lab assessments to the TNI standard as essential for the timely correction of issues troubling ELAP. Similarly, ACIL supports TNI's recognition of nongovernmental AB's for the provision of NELAP assessment services.

During the Expert Review Panel (ERP) process that evaluated ELAP and presented options for ELAP corrective actions, panelists apparently recommended a 3<sup>rd</sup> party approach as both a rapid and sustainable solution to program deficiencies. ELAP leadership apparently quashed this solution without appropriate stakeholder review of the merits of the 3<sup>rd</sup> party approach. The author presents the case for implementing the 3<sup>rd</sup> party AB approach for ELAP.

Under a 3<sup>rd</sup> party AB system ACIL advocates, California laboratories will have the option of selecting alternatives to ELAP for the provision of conformity assessment services. This is beneficial in many ways, two of the more compelling reasons are; 1) ELAP's capability to provide AB services to any standard is unknown today and inability could persist several years into the future. Allowing third party ISO 17011 conforming nongovernmental AB's to replace ELAP's provision of onsite assessment services provides a rapid and sustainable fix for persistent ELAP deficiency issues. ELAP needs existential incentives to improve services and control fees.

The American Council of Independent Laboratories (ACIL, [www.acil.org](http://www.acil.org)) is the national trade association representing independent, commercial scientific and engineering firms. Accreditation is a key area of concern for ACIL laboratories that provide the overwhelming majority of test and measurements for environmental regulatory purposes in America.

### **BACKGROUND**

ACIL's members are professional services firms engaged in testing, product certification, consulting, and research and development and represent 85% of the commercial environmental testing capacity in the United States. The mission of ACIL is to promote quality, ethics, independence, objectivity, and free enterprise.

Testing & measurement data from laboratories accredited by recognized Accrediting Bodies (AB) to defined standards of practice are essential to data users making decisions on environmental projects. Through its member laboratory representatives working with the program's leadership, ACIL has been active and committed to the effort to reinvent ELAP. The author has been continuously engaged in the process of ELAP improvement in various capacities for more than seven years.

Under Waterboard "ownership" over the prior two years, ELAP has made considerable progress identifying issues and discussing the range of possible corrective actions. Unfortunately, many significant steps necessary to correct neglect suffered by the program under prior ownership have yet to be implemented.

ACIL is committed to supporting laboratory accreditation programs based on international standards of practice. A critical deficiency in current California ELAP regulations is the absence of an organized, credible, and complete consensus standard of laboratory practices. Existing regulations are either incomplete or insufficiently specific with respect to requirements for laboratory quality systems, technical performance standards, and specifications for practices necessary to ensure consistent laboratory assessments performed by ELAP personnel. At ELAP, each accreditation application is handled differently and each on-site laboratory assessment is conducted differently. A defined standard of practice is required for ELAP to achieve consistent high quality onsite lab assessments.

With the input of stakeholder groups, the public, and the Environmental Laboratory Technical Advisory Committee (ELTAC, ELAP's technical advisory board, on which the author is a member) is evaluating a decision to implement the TNI or an alternative, as yet unidentified standard of practice for labs. ACIL supports ELAP's adoption of the ISO 17025 based TNI standard of practice for all laboratories in California. Further, ACIL opposes any "two tier system" that employs different standards of practice for laboratories based on size, or any other attribute. Similarly, ACIL supports ELAP's conformance to the international standards of practice for ABs, ISO 17011. The TNI standard is the only available field tested, validated, consensus laboratory standard for environmental laboratories. During the process of evaluating the standard adoption, no alternative standards of practice have been either designed or proposed. Adopting the TNI standard in CA is crucial to the progress of ELAP reform.

Over the last two years, the ELAP leadership, starting with no experience, has learned much about laboratory standards, practices, and managing a conformity assessments organization. While the authors wishes to emphasize their diligence and effort as highly commendable, they have much more to learn. Their increasing experience along with hard work and changes proposed herein, are key to reinventing the program and developing a regulatory service that appropriately and efficiently addresses the needs of the California regulatory apparatus.

One critical issue plaguing the program is an answer to the question; *How long will ELAP remain in their current state of functionality?* The confluence of political/legislative processes

required to implement necessary changes coupled with public employee workplace rules look to render the duration of ELAP's predictable dysfunctionality to a timeframe between 3 and 5 years.

## **THE ACIL SOLUTION FOR ELAP**

California needs a functional system for laboratory accreditation and regulation today. A 3-5 year interim period tacked on to the 2 years of effort invested in the ERP process, reconfiguring ELTAC, and seeking stakeholder input renders ELAP's ineffectual time at 5-7 years since the change of ownership. This interim between ineffective and effective operations is unacceptable to ACIL and should be unacceptable to any observer, stakeholder, or regulator.

California is not reinventing their lab accreditation program, partly due to regulatory constraints imposed upon them by prior legislation, and what can only be considered organizational stasis, they appear well down the path to recreating the basic structure of the failed program that operated under the Department of Health Services.

California has to date, missed a key opportunity to implement a superior accreditation system based on nongovernmental AB's working with ELAP to perform laboratory assessments to the TNI standard in place of ELAP on site conformity assessment services. ACIL supports primary NELAP conformity assessments performed by appropriately recognized nongovernmental ISO/IEC 17011 compliant AB's as a means to both improve laboratory quality systems and reduce the costs imposed by multiple redundant accreditation schemes and nonperforming governmental AB's.

ACIL members developed a solution with wide ranging benefits for all parties and supported the implementation of this 3<sup>rd</sup> party based assessment solution recently in Florida and worked with New Jersey to implement a similar 3<sup>rd</sup> party based program. The primary benefits to the 3<sup>rd</sup> party system advocated here and implemented in FL are a reduction in the period of ELAP ineffectiveness, and significant performance improvements to the program. If constructed appropriately, reduced costs for ELAP client laboratories and the state of California could result as well.

The ACIL vision for effective laboratory accreditation enables California to significantly reduce the costs required to offer a laboratory accreditation program while allowing it to maintain its existing revenue streams from laboratory licensing fees. The background of this issue and details of the proposed solution and its benefits have been presented to the people engaged in the process of reinventing CA's ELAP, and apparently, rejected. Importantly major state ABs NJ and FL are implementing or have implemented similar solutions as ACIL proposes for CA.

## **PROGRAM DESIGN CONSIDERATIONS**

ACIL members support both deliberate corrective actions for program deficiencies and a comprehensive review of ELAP regulations involving all stakeholders in the process. In addition to appropriate consensus standards of practice and operating plans for ELAP assessors that provide consistent laboratory assessments, ELAP needs internal quality systems and other management practices and controls to restore its performance to laboratory standards established and enforced elsewhere in the US.

ACIL proposes the following steps to support ELAP reform:

- 1) Separate laboratory licensure and laboratory accreditation services within ELAP
- 2) Separate fee structures for licensure and accreditation services provided by ELAP
- 3) Recognize reciprocity for NELAP accreditation services provided to California laboratories by 3rd party private sector Accrediting Bodies (AB) that will allow ELAP to license California and out of state laboratories accredited to NELAP standards of practice by recognized 3rd party AB's.
- 4) Establish standards for ELAP service to its customer laboratories and a mechanism for holding ELAP employees accountable for service delivery and transparency.
- 5) Establish through the Environmental Laboratory Technical Advisory Committee (ELTAC) an Accreditation Council comprised of ELAP employees, and representatives of the laboratory community that is empowered to resolve compliance disputes and provide guidance for ELAP laboratory assessment operations.
- 6) Establish provisions for control of nonconforming ELAP laboratory assessment work.
- 7) Establish provisions for process improvement and corrective action within ELAP
- 8) Impose requirements for ELAP to develop and post on their website, an Accrediting Body Operations Program Plan that defines the ELAP organization and accountabilities, policies, practices, procedures, staff training and quality assurance plans.
- 9) Establish transparent ELAP management review procedures in accordance with ISO/IEC 17025:2005(E), Clause 4.15)
- 10) Establish a program of ethics and integrity within ELAP that supports the ethical behaviour of all ELAP employees and provides disciplinary measures to enforce the code.