

The Effect of California's withdrawal from NELAP

Bruce Godfrey, Ph.D., Laboratory Director

Curtis & Tompkins Laboratories

2323 5th Street, Berkeley, CA 94710

Co-Chair ACIL Environmental Sciences Section

Voting Member, California Environmental Laboratory Technical Advisory Committee (ELTAC)

bruce.godfrey@ctberk.com

Abstract

Laboratory accreditation services performed by appropriately recognized Accrediting Bodies (AB) are essential to the National Environmental Laboratory Accreditation Program (NELAP). In January 2014, rather than be dropped as a recognized NELAP AB by the NELAC Institute (TNI, www.nelac-institute.org) for failing to plan or implement corrective actions for long term substandard performance, California (CA) withdrew from NELAP. The facts behind CA's decision and the effect of this withdrawal on commercial laboratories inside and outside of CA are explored below.

Commercial laboratories represented by ACIL, the national trade association for independent scientific organizations (www.acil.org), place a high value on NELAP, and they are justifiably concerned about NELAP's future. The laboratory community's view is that California's program is a "worst case" example of a nationwide problem that underlies the need for public sector ABs to start complying with ISO 17011 the international standard of practices for ABs. ACIL laboratories support 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. Below, the author presents the basis for ACIL laboratories support for TNI's recognition of nongovernmental AB's for the provision of NELAP AB services in the context of CA's withdrawal from NELAP.

California ELAP's Current Situation

California's Environmental Laboratory Accreditation Program (ELAP) is currently operated as unmanaged agency, simultaneously ineffective and out of control. Nearly half of ELAP's customers surveyed by ACIL in 2012 reported serious issues related to timeliness of service, unprofessional/unethical staff behaviour, and incompetent/untrained laboratory assessors. ELAP is currently being transferred to the state water board from the department of public health. ELAP, operated without a Director or any sort of management for nearly 5 years is staffed with 20-25 full time professional and clerical employees split between offices in Northern and Southern California. ELAP licenses and/or accredits nearly 300 environmental and drinking water laboratories, the majority of which as smaller municipal and utility laboratories with staff of six employees or less. ELAP operates with a budget of \$2.2-\$2.4 million/yr and predominantly funded by user fees. The California Environmental Laboratory Technical Advisory Committee (ELTAC-the author is a voting member) provides nonbinding advisories related to policies, rules, and operations to ELAP leadership by meeting three times each year.

Three root causes underlie the current dysfunctionality of California's ELAP. They are, in order of importance.

- 1) ELAP's history of poor management, oversight, and organization.

- 2) ELAP was configured by legislation lacking a mechanism to effectively link laboratory assessments to any standards of laboratory practice.
- 3) ELAP is staffed and organized as separate from the state drinking water laboratory

TNI/NELAP Audit Findings-“*You can’t fire us, we quit!*”

In January 2014, California ELAP withdrew from the National Environmental Laboratory Accreditation Program (NELAP). The action taken by ELAP’s leadership was a political move to avoid the embarrassment of being publically rejected by TNI as a supplier of AB services to NELAP. The commercial laboratory community supports TNI’s efforts to ensure AB services conforming to NELAP standards of practice underlie their laboratory accreditation program. Surveys of ELAP customers conducted by ACIL in 2012 fully support TNI’s findings on ELAP’s poor performance as an AB.

Commercial laboratories value NELAP highly, and are supportive of TNI’s efforts to motivate below standard state accreditation programs to either improve their programs or provide alternative means to allow laboratories located within their borders to access NELAP.

A TNI onsite assessment team completed an onsite evaluation of the California’s ELAP on May 2-3, 2012; and they issued their report to ELAP on March 18, 2013. The TNI assessment team concluded ELAP’s response to their 13 findings and 2 observations was unacceptable and recommended CA be dropped from the NELAP program on December 13, 2013. The TNI teams recommendation informed ELAP’s decision to withdraw from NELAP. The TNI California assessment team reported that ELAP’s response to 9 findings of the 13 findings cited reorganization of the program as reason for inaction. The absence of a schedule for required corrective actions lead to the TNI team’s decision to recommend California’s program be dropped from NELAP. The TNI team’s significant findings are summarized below; interested readers can obtain a copy of the TNI team’s report from the author or TNI on request.

The root cause of the problems cited in the TNI’s assessment of California ELAP appear directly related to lack of appropriate management, systems and accountability. The absence of a program Director for the preceding 4 years appears particularly salient, experienced ELAP customers will cite the previous director, Dr. George Kulisingiam as a responsible party.

The TNI assessors found that ELAP lacked the structure necessary to provide appropriate responsibility and implementation of authorities necessary to ensure performance of the management system and implementation of improvements and corrective actions. Management roles and responsibilities were/are found to be inadequately defined and, not surprisingly, ELAP lacked appropriate quality systems to eliminate the causes of nonconformities and prevent their recurrence.

In addition to internal audits that reported ELAP’s noncompliance to NELAP standards of practice without citing any planned effort or action toward correction, the TNI team found critical deficiencies in ELAP staff training and performance including;

- Lack of staff understanding of the ELAP quality assurance program
- Assessors lacked adequate knowledge to perform laboratory assessments
- Absence of ELAP personnel training and performance review records
- Absence of systems for collecting, evaluating, reviewing, and taking action on customer complaints.

- Absence of management reports on quality assurance and corrective actions

The TNI team also found that ELAP accredited and licensed laboratories were allowed to operate at overly long intervals between assessments as prescribed by the standard of practice.

The TNI findings are supported by the author's knowledge that ELAP lacks basic management tracking and reporting systems fundamental to the operation of an agency or indeed any type of enterprise or operation. ELAP employees are unable to measure or provide reports on basic performance metrics either to their leadership within the department of public health or to their ELTAC technical oversight board. These basic metrics include (a) how many laboratories ELAP assessed over any time period; (b) how many labs were assessed within or outside prescribed time intervals; and (c) basic evaluations of staff activities and assignments, training activities. Information a normal business or agency would track to assess efficiency and or effectiveness are unavailable to ELAP leadership and/or its oversight board.

Implications of California's Withdrawal from NELAP

California's withdrawal from NELAP forced environmental laboratories located in California to seek primary accreditation services from another NELAP recognized public sector AB. The author understands that 12 California laboratories secured primary NELAP accreditation services from Oregon and one chose Utah's AB services. These 13 laboratories are required to obtain California accreditation services from California's ELAP. California laboratories must obtain instate accreditation services from ELAP, a program seen as inadequate NELAP and somehow adequate for California. The happy consequence of California's exit from NELAP is an overall reduction in accreditation fees to the participating laboratories. At the author's laboratory, the combination of Oregon (NELAP access) and California ELAP fees are less than the costs of California's previous fees for NELAP access alone.

How do labs outside of CA access California accreditation?

NELAP has faced and surmounted many challenges during its genesis and evolution. Nearly all commercial environmental laboratories are convinced that a national accreditation program is critically important to interstate commerce, effective regulatory compliance, and ensuring best test and measurement practices implemented across state lines. Today, NELAP is challenged to address inconsistent conformity assessments provided by inadequate or underperforming governmental ABs, equitable access to the program for laboratories which lack access to a NELAP recognized AB, and addressing the cost burdens imposed on laboratories that support the program financially. To ensure the development and improvement of NELAP, TNI must work more closely with laboratories and their state AB members to resolve these key issues and challenges.

By their action to judge California's AB services as noncompliant and therefore insufficient for use by the other member states, TNI confirmed their ability to police one of their own member states. By taking the action to expel California ELAP, TNI reestablishes the integrity of NELAP and sends a message to other member states operating in the margin, that TNI can and will enforce compliant performance from its AB members.

Licensing, Accreditation, and NELAP Access

Through establishing reciprocity agreements between states, NELAP created a system that allowed its member state ABs to license laboratories to practice in their states based on a NELAP standard conformity assessment report issued by another NELAP member state AB. Through this reciprocity system, NELAP member states replaced a system of multiple redundant onsite accreditation inspections suffered by laboratories involved in interstate commerce. By adopting a single internationally based consensus standard of laboratory practice, and forging reciprocity agreements that allow licensing services to replace onsite laboratory assessments, NELAP replaced a disjointed, uncoordinated accreditation system implemented by many states with a uniform, effective, more efficient system all laboratories, data users, and stakeholders can be pleased to use.

Reciprocity agreements, an evolving consensus standard of laboratory practice, and ensuring AB performance to standards are the three key foundational pillars of NELAP. A breakdown in any one of these components threatens the existence and functionality of the national environmental laboratory accreditation program.

Most state environmental laboratory certification programs act as both a licensing agency and laboratory accreditation service provider. The goal of ensuring provision of credible environmental measurement data to support federal and state regulatory program data users can be best accomplished by appreciating the distinction between licensing and accreditation. The provision of licensing services involves the largely clerical determination, by report review, that the laboratory has been appropriately inspected and meets standards of practice recognized by state jurisdictions. Accreditation services involve conformity assessment activities that demonstrate, via inspection, evaluation and reporting, that a laboratory meets the defined standards of laboratory practice (e.g. NELAC 2009 Standard) that define the program. The two services require vastly different staff to implement. Accreditation services require qualified laboratory scientists able to assess compliance to detailed standards of practice while licensing services can be provided by staff with basic report reviewing clerical skills.

ACIL laboratories view separating conformity assessment from licensing functions and placing the laboratory assessments in the hands of conformity assessment professionals is the better approach to ensure the longevity and credibility of NELAP. States can and should use their authority to license environmental laboratories just as they license legal, medical, accounting and other professions. In most states, conformity to professional standards of practice are determined by nongovernmental organizations and states license these professional practitioners. By separating environmental laboratory accreditation and licensure services at the states and establishing fees for services appropriate to the level of effort and staff training required to deliver them, states can become more efficient, effective and nimble in the administration and regulation of their professional laboratory measurement practice industries. Updating practices to reflect new technologies and practices can and should be easier as reference to the standards organization in this case TNI, ISO, ILAC, and NACLA will be easier than changing legislation.

The Solution: NonGovernmental AB's for NELAP

Today, all recognized NELAP ABs are state governmental entities. Many NELAP ABs do an acceptable job accrediting laboratories, however, none are ISO/IEC 17011 compliant. Several NELAP ABs accredit labs to the superseded 2003 TNI standard, and many offer accreditation

services for outdated EPA methods while omitting more recently promulgated methods. Due to the program's dependence upon assessment consistency, conformity to standards of laboratory as well as AB practice, and mutual recognition, poorly performing ABs endanger the NELAP program. For this reason alone, ACIL advocates that all governmental ABs demonstrate their compliance to the ISO/IEC 17011 standard for ABs and become recognized by ILAC and/or NACLA to prove the compliance of their personnel, capabilities and conformity assessment systems. Conformity to internationally recognized standards of practice confers credibility upon the AB.

Today, nongovernmental ABs perform at a higher level, endure more rigorous and realistic third party compliance reviews, and are held accountable to meet more demanding performance requirements than any governmental AB this author is familiar with. Today's NELAP system employing exclusively governmental ABs that either cannot or will not be held accountable to the less rigorous and less universally recognized NELAP standard for ABs will be enhanced by the addition of appropriately recognized nongovernmental ABs.

At this time TNI is considering allowing non-governmental ABs to become primary NELAP ABs. Under the nongovernmental AB system supported by ACIL and yet to be adopted by TNI, laboratories will choose the AB that best fits their conformity assessment needs from amongst the NELAP recognized government or nongovernmental ABs. This system provides a higher level of access for labs in states without a NELAP recognized governmental AB and raises the bar for AB services that underlies credibility of NELAP. A primary accreditation assessment provided by a nongovernmental AB will be a valid compliance report allowing the laboratory to provide services in states recognizing these accreditation reports after payment of a licensing fee which presumably addresses the costs of licensing rather than the provision of accreditation services.