

Date: April 27, 2017
To: Felicia Marcus, Chair
California State Water Resources Control Board Members
commentletters@waterboards.ca.gov
From: C. Bruce Godfrey, Ph.D.
ACIL Chair Elect, ELTAC Voting Member
Subject: ACIL Comment on CA ELAP adopting the TNI standard and Third Party Accrediting Bodies to assess all CA environmental laboratories



The American Council of Independent Laboratories (ACIL) is the national trade association for independent scientific, testing, and engineering firms, representing 150 laboratories with over 1,500 laboratory locations. ACIL member laboratories perform more than 60% of all the laboratory tests conducted for drinking water and environmental regulatory compliance purposes in California. The author owned and operated a large (~80 FTE) CA commercial environmental laboratory for 35 years, was an ELAP customer for decades, and served nearly 5 years on ELTAC advocating ACIL views of best practices for lab accreditation programs.

ACIL congratulates Christine Sotelo, the ELAP team, the ERP, participating ELAP stakeholders, and the Waterboard for arriving at the foundation for a standards based lab accreditation program representative of the industry's best practices. ACIL supports the adoption of the full TNI standard and third party Accrediting Bodies (AB) to assess laboratories to the standard.

ELAP is the Accrediting Authority (AA) for environmental laboratories providing test results to support California environmental regulatory programs. ACIL believes all users of environmental test results for regulatory programs require data of known quality generated by laboratories accredited to ISO 17025 based standards of practice by ISO 17011 conforming ABs. ACIL fully supports adoption of the National Standard for environmental lab practices (TNI) for all California laboratories. By retaining final authority for granting laboratory recognition to perform tests and measurements for CA regulatory programs; ELAP is adopting proven best practices for ensuring conformity to program requirements, detecting and correcting substandard practices at labs, and ensuring protections for end users of environmental test & measurement data.

Work remains to define third party AB recognition requirements, ELAP organizational development, and creating the information technology (IT) needed to operate the program efficiently. Defining details of phased implementation of the TNI standard at smaller municipal and utility labs also remains.

ACIL supports requirements for ELAP to recognize ISO 17011 conforming ABs to perform laboratory conformity assessments, and for laboratories to choose the AB that best meets their needs from among the ELAP recognized ABs. The ISO 17011 standard defines practices, processes, and performance criteria for ABs and allows these AB organizations to be assessed by third parties (ILAC, NACLA, TNI) for conformity to the standard. Clearly defined procedures & practices for labs and ABs ensure consistency, ease of implementation and administration by ELAP.

ACIL members are deeply involved in ELAP reform and are committed to completing the work ahead. We understand our smaller laboratory colleague's concerns regarding implementing the TNI standard, and we stand ready to assist them deal with the changes they face.

ACIL opposes any modifications to the language of/in the TNI standard. A modified standard is not "The National Standard", as implemented and revised through practical experience for more than 20 years. Under staged implementation, the national lab standard remains intact, and ELAP has an "*implementation*" status that provides more value than diluting the standard with modifications providing no evidentiary benefit to the lab or data user communities and no predictable advantage, especially when other states have successfully implemented this standard for all types and sizes of environmental labs. A temporary two tier system with an expiration date has value in the progressive implementation of quality improvement at the smaller labs.

The benefits of third party assessments

Laboratory accreditation programs based in defined standards of practice implemented by AAs, third party ABs, and laboratories have outperformed all alternative accreditation program service delivery models across clinical, pharmaceutical, food/agricultural, product, and environmental testing disciplines worldwide. Marked improvement in environmental testing laboratory performance is recognized by ABs after third party assessment models were implemented in Florida and for the US Department of Defense ELAP. California's choice to engage ISO 17011 conforming third party AB's to assess laboratories to the TNI standard not only represents best practices for assessing laboratory conformance, it is also the path to achieve necessary improvements in laboratory practices resulting from decades of substandard ELAP assessments.

Third AB assessors have proven benefits in thoroughness and consistency of laboratory assessments that have resulted in improved laboratory performance wherever implemented. Recognized ISO 17011 conforming third party AB organizations are staffed and ready to address ELAP's assessment needs today. As the ELAP program develops, and as other state ABs adopt third party models, additional AB capacity will likely be created. In Florida, environmental laboratories have observed increased assessment capacity and market forces have reduced third party assessor fees.

CA-ELAP, under both DPH and the Waterboard, has proven unable to staff their program with qualified laboratory assessors for all fields of testing. Proper qualification of laboratory assessors

requires extensive education, training, and experience. By engaging third party assessors, the time required to provide labs access to qualified assessors to support ELAP's implementation of the TNI standard could be expected to be as short as 6-12 months. An ELAP employee assessor implementation across all fields of testing would likely require an additional 6-12 years, at higher costs to ELAP and therefore, ELAP's laboratory customers.

Third party assessors are more flexible than their public sector AB counterparts, they are proven to react faster to changes in measurement technologies, and improvements in processes and procedures. This adaptability results in reduced times for laboratories and instrument manufacturers to bring new technologies for detecting & measuring analytes of environmental and human health interest under a standardized program of scientific rigor. Third party assessors will also reduce the time required to implement validated new technologies that could lower testing costs for laboratory customers or implement changes to affect higher levels of accuracy and precision in environmental measurements. The flexibility provided by third party lab assessors confers the means for ELAP to rapidly implement future waterboard, legislative, or agency partner requirements and/or policies related to testing laboratories.

AA prescribed service delivery models based on/in the ISO 17025 standard for laboratories and ISO 17011 standard conforming third party AB's have proven superior to integrated public sector AA/AB programs in clinical, food, drug, electronic, environmental, & product testing laboratories worldwide. This model represents best practice for state and other laboratory accreditation programs; ACIL supports California's adoption of the full TNI standard and their choice to assess labs to this standard through recognized third party ABs for their environmental laboratory accreditation program.

Sincerely,

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