Enhancing Public Health and Safety Through Quality Testing and Engineering



Public Comment
ELAP Regulations Development/Laboratory Standard
Deadline:9/16/16 12:00 noon

September 25, 2015

Ms. Christine Sotelo
ELAP Env. Prog. Mgr.
Division of Drinking Water
California State Water Resources Control Board

Ms. Karen Larsen
Assistant Deputy Director, Prog. Mgmt. Branch
Division of Drinking Water
California State Water Resources Control Board
1001 I Street
Sacramento, CA 95814

Dear Ms. Sotelo and Ms. Larsen:

ACIL is the national trade association for independent scientific, testing, and engineering firms, representing 150 laboratories with over 1,500 laboratory locations. Our member laboratories perform more than 60% of all the laboratory tests conducted for drinking water and regulatory compliance purposes in California.

We were shocked and dismayed to learn recently of ELAP's intention to hold stakeholder discussions on user fee increases in Sacramento on October 8, coincident with ACIL's annual meeting in Miami, FL. ACIL member labs in California and elsewhere strongly oppose even the discussion of ELAP user fee increases when ELAP services are so demonstrably substandard.

ACIL seeks to understand ELAP's plans and activities related to addressing the following ELAP deficiencies and issues we believe need be addressed prior to any discussion of user fee increases. ACIL members are both uniquely qualified and willing to assist ELAP leadership in their efforts to develop and implement remedial action plans addressing these issues.

ACIL comments fall in the following five areas: (1) ELAP Functionality and Status as an Accreditation Body (AB), (2) Non-Governmental AB Option, (3) ELAP Fees Versus Non-Governmental AB Fees, (4) ACIL Survey of ELAP Accredited Laboratories, and (5) ACIL's Commitment to a Partnership to Reduce Cost, Improve Efficiency and Produce Data of Known and Documented Quality.

ELAP Functionality and Status as an AB

ACIL members are primarily concerned about ELAP's well documented historical inability and indifference to assess laboratories to any recognized standard of laboratory practice.



In its current configuration, ELAP lacks the trained staff, standards of practice, management systems, and technically qualified leadership to offer credible services as a laboratory AB.

ACIL members are puzzled to learn that ELAP plans to hold a stakeholder meeting on fee increases prior to receiving any report from the Expert Review Panel (ERP) assembled to assess ELAP and recommended technical and organizational changes necessary to bring ELAP to an acceptable level of effectiveness as an AB.

ACIL members serve on the ERP and the stakeholder advisory committees in the ERP process. These members expect the ERP report to contain many of the concerns, deficiencies, and issues related to ELAP operations and competencies identified herein.

Further, and related inaction by the leadership on more serious issues than user fees, ELAP has yet to respond, as requested by ELTAC, with a corrective action plan to address the deficiencies noted in TNI's 2013 assessment that lead to ELAP's self-disqualification as a NELAP Accrediting Body.

ACIL would like to learn ELAP's reasons and rationale for proceeding to a discussion of fee increases while the service offering is universally recognized and documented as substandard amongst the laboratory and data user communities. It is the expectation of ACIL and the laboratory community that ELAP would develop and implement a complete reorganization plan that meets the compliance needs of the accredited laboratories, before funding is even considered.

Non-Governmental AB Option

ACIL member laboratories request that appropriately recognized non-governmental accrediting bodies (ABs) be available as an option to ELAP provided assessment services for California laboratories. This option will reduce cost, increase efficiency and produce data of known and documented quality.

This has been ACIL's experience in the State of Florida. The State off-loaded the bulk of the laboratory review process while retaining the licensure decision. It is a proven and successful model that should be duplicated nationwide.

California ELAP charges all laboratories the same fees for licensure or the provision of accreditation services. Lower licensure fees are integral to the consideration of the nongovernmental accreditation services model. If ELAP is to consider adjusting fees to reflect the cost of services provided, ACIL laboratories request ELAP consider the separation of licensure and accreditation services to allow the fees for licensure services to reflect the maximum of 4 hours of clerical staff time required to issue a laboratory license based on reports provided by recognized third party accrediting bodies.

The costs of staffing and managing an agency to provide competent laboratory accreditation services are several orders of magnitude larger than the costs required to provide competent laboratory licensure services.

Value: ELAP Fees Versus Non-Governmental AB Fees

Most ACIL laboratories engage the services of nationally and internationally recognized ABs capable of providing assessment services to any published standard of laboratory practice likely agreeable to ELAP.

Based on ACIL member experiences and the ACIL survey of CA ELAP accredited laboratories, alternative governmental and nongovernmental AB service options available to ACIL members are undoubtedly superior in demonstrable ways to the accreditation services currently provided by ELAP.

The ACIL as well as all other laboratories need the option to select AB services that meets their needs and provides value that is equivalent to the fee. Non-governmental ABs are market motivated to provide high quality services at fees commensurate with the value provided.

ACIL challenges ELAP to benchmark their fees against the non-governmental ABs. This requires an assessment of fees based on the actual value of accreditation service relative to a true comparison with non-governmental ABs where customer service, recognized and certified competency, use of a known and accepted consensus standard, assessor experience and training, and overall customer experience, are the focus. High fees with low value and with no option to select alternative, demonstrably better services, does not allow the laboratory community to improve, and instead stifles lab improvement and limits it only to the expectation of low value service instead of the higher expectation provided by agile market driven continuous change and improvement.

The benchmarking method for assessing fees relative to value is more rational, and demonstrably fairer to ELAP customers than what appears to be a simplistic assessment of fees based on ELAP's operational costs for the provision of substandard AB services. At this time, ELAP fees CANNOT be assessed relative to value since the program is recognized as substandard and its direction has not been fully established.

ACIL Survey of ELAP Accredited Laboratories

The root cause of ELAP's "user fee insolvency" is ELAP's organizational configuration and inexperienced management resulting in deep, persistent operating inefficiencies and ineffectiveness.

The 2012 ACIL survey of ELAP customer laboratories revealed that more than two thirds of the responding labs of all types, regard ELAP fees as "too high" for the service offered. The vast majority of survey respondents expressed some problem with ELAP service quality and assessor competence. Today, many ACIL members report the issues identified in the survey and communicated to ELAP leadership remain unaddressed.

ELAP's considerable inefficiency underlies additional concern regarding the appearance of a governmental agency setting user fees to support continued ineffectiveness justified by an unnecessary monopoly to operate an AB granted by the state legislature.

ACIL will take any steps necessary to defeat any proposed ELAP user fee increases to the Waterboard and we will join with other stakeholders that constitute a majority of ELAP customers sharing ACIL's views of ELAP's inefficiency, ineffectiveness, and demonstrated and documented inability to operate a credible AB.

ACIL's Commitment to a Partnership to Reduce Cost, Improve Efficiency and Produce Data of Known and Documented Quality

ACIL members along with others in the stakeholder community possess considerable expertise related to laboratory and AB operation and function.

ACIL is now, and has been consistently engaged in the ELAP reform process for several years. We are ready and willing to work in a partnership with ELAP to reduce cost to accredited laboratories, improve efficiency and quality in the accreditation process, and ultimately result in the production of data of known and documented quality

Sincerely,

Milton M. Bush, JD, CAE

CEO