



Monday, May 1, 2017

Comments from Allison Mackenzie, President & CEO, Babcock Laboratories, Inc. Submitted for the assessment of progress and final recommendations in the Year 2 Final Report by the Expert Review Panel for ELAP. (909-238-2507 cell)

I. Adopt an accreditation standard:

A. *“The Panel recommends ELAP now move quickly to adopt [The NELAC Institute (TNI) 2016 Standard]...The Panel also recommends ELAP adopt the 58 modifications as implementation guidance rather than as modifications to the underlying standard. Adopting a modified standard would isolate California from invaluable training resources available from the national program.”*

1. I agree with the Panel’s recommendation. I, too, recommend to the SWRCB and ELAP full adoption of The NELAC Institute (TNI) 2016 Standard. As a seasoned veteran of the commercial laboratory sector with first-hand experience of the importance of the laboratory accreditation process in the production of laboratory data of known and documented quality, I agree with the conclusions of the ERP—California is best served by speedy and prompt implementation of the TNI Standard. I appreciate the diligence and care that ELAP has taken to engage all stakeholders in discussions and review of the Standard. Notwithstanding an appreciation of the importance of the Standard review process, I too believe that the appropriate response to the concerns resulting in the proposed 58 modifications is to explain and clarify in a guidance document. Modification of the Standard will only serve to further isolate California from the rest of the environmental laboratory community and the resources available to assist California laboratories with implementation. Creation of a California-only accreditation standard will impede and delay the process of regaining confidence in *all* of the results generated by labs.

B. *“...develop an implementation process that facilitates laboratory participation.”*

1. I recommend phased implementation of the TNI Standard. More specifically, I agree with the Panel’s recommendation that ELAP use a combination of time-based, documentation-based, and requirement-based phasing, and believe this process should not take more than three years after adoption of the Standard.

2. I recommend that, to the extent possible, on-site assessments (OSAs) conducted by ELAP during the phased implementation period include a training component. Generally, deficiencies should be handled as opportunities to improve the laboratory quality systems and not treated as punitive. This is not to suggest that flagrant and egregious deficiencies—such as laboratory fraud, selective reporting of non-compliant data, or time-traveling—should result in a slap on the wrist. The integrity

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of laboratory data generated by any ELAP laboratory definitely requires appropriate investigation and action.

II. Expand resources:

- A. *“The Panel strongly urges ELAP to immediately begin accepting third-party assessments.”*
1. I agree with the Panel’s recommendation that ELAP use third-party assessments to reduce the backlog and to provide expertise for assessment of complex FOTs for the foreseeable future.
 2. The ELAP staff have made great strides in the past two years and gained significantly in knowledge and experience. That said, the ability of the program to attract and retain the technical competence necessary to conduct audits and assessments of all methods and fields of testing in three major regulatory programs has proved insufficient. The financial resources and the number of years necessary to train, develop, and retain a competent accreditation staff is impractical and, arguably, not in the best interest of the Board and the California tax payers.
 3. To make the use of third-party assessment possible, ELAP must provide some financial relief to the laboratories that need to utilize the services of 3rd party assessors. Laboratory fees in California have tripled in the last three years. The additional cost cannot simply be throw on top of existing laboratory accreditation fees, which are excessive by any reasonable comparison. With ELAP no longer burdened to provide for the on-site audit and assessment portion, the cost to use third-party assessment services should be considered in setting the California accreditation fees for labs compelled to use it.
- B. *“Use of software to improve the processing efficiency of information being evaluated for laboratory accreditation should be initiated as soon as possible.”*
1. ELAP staff are spending countless hours manually reviewing the Proficiency Testing reports of the 750 CA accredited laboratories. This is an important task as each laboratory must demonstrate the ability to analyze and report every analyte for every test method for which the laboratory maintains accreditation. It is a minimum requirement of any credible demonstration of competence. It is also a task that virtually every other state accreditation system has automated. I strongly encourage the State Board to prioritize the purchase and implementation of software, which is already available, to make this important task efficient and cost effective.

Thank you for the opportunity to provide comments. If the State Water Board members or staff should have any questions regarding these comments, please do not hesitate to call me.

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