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October 13, 2015

Dr. Steve Weisberg Southern California Coastal Water Research Project 3535 Harbor Blvd., #110 Costa Mesa, CA 92626 stevew@sccwrp.org

SUBJECT: Findings and Recommendations of the Expert Review Panel of the State of

California Environmental Laboratory Accreditation Program

Dear Dr. Weisberg and Expert Review Panel Members:

The Central Valley Clean Water Association (CVCWA) appreciates the opportunity to provide comments on the Findings and Recommendations of the Expert Review Panel of the State of California Environmental Laboratory Accreditation Program (Draft ELAP Report). Representatives from CVCWA member agencies are active stakeholders on the Stakeholder Advisory Committee, and through them CVCWA has been following the Expert Review Panel, and their review of the ELAP program.

CVCWA is a nonprofit association of Publicly Owned Treatment Works (POTWs) located throughout the Central Valley whose primary mission is to represent wastewater agencies in regulatory matters while balancing environmental and economic interests. CVCWA's members, both large and small agencies, have laboratories that are subject to ELAP, and as such, may be directly impacted by the findings and recommendations contained in the Draft ELAP Report.

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Overall, CVCWA appreciates the Expert Review Panel's efforts. However, CVCWA is concerned that the Draft ELAP Report is unnecessarily critical of ELAP as a whole, and fails to acknowledge that many of the "management" recommendations have already began to occur. Further, while CVCWA recognizes that improvements in ELAP are necessary, CVCWA does not believe that the program in its entirety is broken and in need of wholesale change. Specific comments on the recommended solutions are provided here.

A. Establishment of a Management System

The Draft ELAP Report recommends that ELAP establish a management system based on one of two standards, either the International Organization for Standardization (ISO/IEC) 17011 standard, or the National Environmental Laboratory Accreditation Conference (NELAC) 2009 standard. CVCWA respects the management systems established in both of these credible programs. However, ELAP is now subject to new management, and the new management should have flexibility for improving its management system rather than replacing its current management system. Moreover, CVCWA is concerned that adoption of a completely new management system will create upheaval and will not result in the intended outcome of improvements with ELAP.

With respect to the Draft ELAP Report's recommendations on Operational Processes, CVCWA agrees with the document control, record-keeping, and quality system recommendations, and believes these to be appropriate. For enforcement, CVCWA is concerned that ELAP's current authorities may not support the types of enforcement actions referenced in the Draft ELAP Report. Also, CVCWA agrees that enforcement should be taken against laboratories that blatantly violate ELAP regulations. However, CVCWA is concerned, especially for small municipal laboratories, that inadvertent mistakes could result in serious enforcement actions. Thus, CVCWA supports the statement that ELAP's primary purpose and goal should be to ensure compliance with ELAP requirements, and that revocation of a laboratory's accreditation should only occur when violations are purposeful, repetitive in nature after receiving warnings, or significantly egregious in nature.

B. Adopt Laboratory Accreditation Standards

CVCWA agrees that ELAP should have clear standards for laboratory accreditation. From the three options provided, CVCWA supports option 2 – modification of an existing standard. As stated previously, ELAP currently has good standards in place. Further, the standards need to be California based, and not from a third party. Notably, there are laboratories throughout California of different sizes that perform different functions. We believe that ELAP's laboratory accreditation standards need to account for these many differences. For example, for some very small municipal laboratories, the only tests run are very simple straightforward analysis for simple constituents like pH and temperature. Accordingly, the standards applied to laboratories

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should account for and address the various complexities of analytical work being done. CVCWA does not support the Draft ELAP Report's implication that a single standard would not be overly burdensome to small laboratories, and in CVCWA's experience with small laboratories, the reporting associated with the standards recommended in the Draft ELAP Report would be overly burdensome.

Moreover, CVCWA supports use of a representative stakeholder process to develop new and revised standards. The Draft ELAP Report criticizes such an approach because of the time associated with stakeholder processes and because, "in the end, it resulted in an imperfect standard." First, there are no perfect standards, regardless of how developed. Second, while it may take more time, CVCWA believes that it will result in a better end product, and that the representative stakeholders will be vested in its success.

C. Ensure Relevant Analytical Methods

CVCWA agrees that the test methods referenced in title 22 of the California Code of Regulations, section 64811, are outdated and need to be revised. However, although the regulations may be outdated, in CVCWA's experience, ELAP is still enforcing appropriate federal regulations, and requiring application of appropriate analytical methods. For example, as applied to wastewater, CVCWA supports changes to the regulations that clarify title 40 of the Code of Federal Regulations, Part 136, (40 CFR Part 136) applies to wastewater analysis – unless there is an approved alternative test procedure. CVCWA is somewhat concerned with the Draft ELAP Report's recommended "ideal solution" as it could result in analytical methods being applied to wastewater that are not consistent with 40 CFR Part 136. Moreover, while amending regulations can take time and are subject to a certain process, the Administrative Procedure Act process is there to ensure that regulations are adopted openly and in a transparent manner. The Draft ELAP Report's short-term solution circumvents this open process, and thus CVCWA does not support this proposed short-term solution.

D. Expand Resources

CVCWA understands and agrees that the ELAP program is currently underfunded and in need of additional revenue to supports its current efforts. However, in the future, any increases should not be made until the fee structure is revised to be more equitable. Until ELAP addresses some of the management system issues identified in the Draft ELAP Report, CVCWA believes it is premature to impose future ELAP fee increases for activities that may or may not be implemented. After the management system issues have been addressed, ELAP will then have a better understanding of the amount of fees needed to support its activities.

With respect to other more specific recommendations in this section, CVCWA supports the need for enhanced training for the program as a whole. However, training should not be limited to either the ISO or The NELAC Institute standards.

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CVCWA further supports the use of remote, augmented, or distance on-site assessments for some laboratories. Specifically, CVCWA believes that for laboratories that have a history of good performance, there should be streamlined audit processes if the laboratories have not had any significant changes in staff or types of analysis being conducted. However, if there are significant changes, then on-site audits would be more appropriate.

CVCWA does not support the use of third party auditors hired directly by laboratories due to inherent conflict of interest. Additionally, third party auditors under a variety of contracts will likely result in inconsistencies between audits. The use of third party auditors is appropriate only when ELAP already has established a management system and ELAP has control over its third party auditors. If third party auditors are hired under contract to ELAP and provide audits consistent with ELAP's audit procedures, then use of third party auditors is appropriate to assist ELAP with any backlog. Additional cost associated with the use of third party auditors should not be a burden to the laboratories.

E. **Enhance Communications**

CVCWA supports the need for enhanced communication with the laboratory community. To develop the communications plan, CVCWA recommends that ELAP include stakeholders in plan development. This will help to ensure that the laboratory community needs are met. Further, when seeking stakeholders to assist in development of the plan, ELAP should take special care to ensure that there is a fair representation of different types of laboratories (i.e., commercial versus public agency labs), and of different sizes. The communication needs for the different types of laboratories will vary and thus, it will be important to seek input from all types.

CVCWA appreciates the opportunity to provide these comments. Please contact me at (530) 268-1338 or eofficer@cvcwa.org if you have questions with respect to the information provided above.

Sincerely,

Debbie Webster, **Executive Officer**

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