



October 13, 2015

Submitted via Electronic Mail to:

Ms. Lara Phelps, United States Environmental Protection agency, phelps.lara@epa.gov
Dr. Stephen Weisberg, Southern California Coastal Water Research Project, steve@scswrp.org
Ms. Christine Sotelo, Chief, Environmental Laboratory Accreditation Program,
Christine.Sotelo@waterboards.ca.gov

SUBJECT: Draft Findings and Recommendations of the Expert Review Panel to the State of California Environmental Laboratory Accreditation Program

Dear Ms. Phelps, Dr. Weisberg, and Ms. Sotelo,

The City of Roseville (City) appreciates the opportunity to provide comment on the draft *Findings and Recommendations of the Expert Review Panel of the State of California Environmental Laboratory Accreditation Program* (Report). The City has two Water Quality Laboratories (WQLs) maintaining ELAP certifications for both Drinking Water and Waste Water. Both the laboratories are small (2-3 technicians) laboratories performing basic wet chemistry, solids analyses, microbiological analyses and aquatic toxicity testing. All our testing is performed on samples from the City's Waste Water Treatment Plants, Water Treatment Plant, water distribution system, local receiving waters and permitted significant industrial users. We use commercial laboratories for chemistries requiring more advanced methods such as GCMS and ICP. Our primary goals for accurate analytical work are to maintain Water Quality and to help support our treatment plant operations to maintain discharges compliant with Water Quality Standards.

We are pleased that the State Water Resource Control Board (SWRCB) now has responsibility for the administration and oversight of the Environmental Laboratory Accreditation Program (ELAP). Since the inception of ELAP in 1988 until 2014, the California Department of Public Health (CDPH) was responsible for the management of the program. The City's WQLs have benefited from the numerous biennial ELAP inspections and CDPH staff suggestions. This has resulted in our laboratories producing accurate and legally defensible data. While under CDPH, weaknesses in the administration and management of ELAP developed. Transitioning ELAP to the SWQCB has created an opportunity to strengthen and improve the program.

The staff at the SWQCB responsible for managing ELAP has made great gains in just a few short months. The new ELAP leadership is willing to invest the necessary time and effort to restore critical functionality, structure and confidence to the ELAP program. Convening an Expert Review Panel (ERP) to access and suggest improvements to ELAP is but one example of this new leadership.

The ERP has developed a draft report detailing the panel's summation of the present deficiencies of ELAP and making many recommendations for improvements to the program. The City agrees with many of the recommendations in the report; however, has serious concerns with the following general areas of the report:

1. Timeline

The report has set a very aggressive timeline for completion of their recommendations. These recommendations include important issues such as ELAP management structure (adopting ISO/IEC 17011), laboratory accreditation standards (adopting ISO 17025) and the use of third party auditors (TPAs) to perform audits. The Report suggests these should be instituted immediately and completed in six to twelve months. Adopting new laboratory standards and making major program changes expeditiously without consideration of possible consequences could result in further challenges within ELAP. Furthermore, State statutes and regulations may need to be revised to incorporate the changes. ELAP auditors can only enforce the current statutes and regulations. Thorough review of the long term ramifications, needs and costs of these significant changes should be done prior to adoption, not afterwards. The unintended consequences of these expeditious actions could be worse than the current state of ELAP.

ELAP management should not only consider the recommendations of the Report but should take the time to obtain input and recommendations from stakeholders such as SAC, ELTAC and the many diverse ELAP certified laboratories. The current challenges at ELAP did not occur overnight and taking the time for thoughtful due diligence could result in a stronger more robust program.

2. Management Structure

The City agrees with the report that the ELAP management structure needs improvement. However, management problems with ELAP while under CDPH were not always the norm and have only developed within the last few years. ELAP was a well-managed program for many years otherwise it would not have been recognized by TNI-NELAP as a valid laboratory accreditation program. Qualified ELAP auditors ensured laboratory standards were met. ELAP functioned very well for many years and this was in part due to the management oversight of the program.

The Report in Section 3.1 suggests there is a lack of an internal management system and that to avoid a large investment of time and resources ELAP should immediately adopt an already established standard, ISO/IEC 17011. Defining and building a successful management structure takes time and considerable resources and should not be done expeditiously without thorough review of other state programs and stakeholder input to ensure prudent use of the ELAP funds and resources.

3. Laboratory Accreditation Standards

Section 3.2 of the Report states; "ELAP should adopt an existing standard for conducting laboratory accreditations as an immediate remedy, and look to modify an accreditation standard in the future to more effectively meet State-specific needs." The City believes ELAP does have laboratory accreditation standards and they are defined in the California Health and Safety Code (CH&SC) and the California Code of Regulations (CCR). Furthermore, sections of the Code of Federal Regulations (CFR), listing analytical methods laboratories are required to use are cited by reference within the CH&SC and CCR. ELAP auditors can only enforce what is in the California statutes.

ELAP does have laboratory accreditation standards and has been using them since the inception of the program. Without standards ELAP would not have been recognized by TNI-NELAP for over 10 years. Improvements can be made such as updated methods list, improved

auditor training and enforcement. However, these deficiencies are due to the current lack of strong management not the lack of standards.

The biennial audits of City laboratories have always involved an on-site visit with review of a checklist that ensures compliance with the appropriate statutes and regulations, review of laboratory practices, SOPs, QA/QC manuals, and critical review of the WP/WS/DMRQA results. The findings and recommendations that result from these audits have always improved and strengthened our program and have resulted in accurate and legally defensible data.

The report makes some very good recommendations such as improved management structure, updated methods list, more equitable fee structure, as well as the use of TPAs to alleviate the audit backlog. The report does however, show a very strong bias towards adopting the TNI-NELAP standards. Other laboratory accreditation programs were not reviewed or included in the report. The TNI standards are very good, but adopting them in their entirety may not be suitable for a program that must address as large and diverse laboratory community as exists in California. Using TNI-NELAP standards for across the board laboratory certifications will not only increase ELAP expenditure but also put a tremendous burden on the smaller laboratories such as ours which do not require NELAP certification to achieve our goals of generating accurate, defensible data and meeting Water Quality Standards.

California ELAP operated for many years as a respected well managed laboratory accreditation program. Problems and challenges have developed in recent years and the transition from CDPH to SWRCB is the first positive step to reestablishing ELAP's credibility. In addition to the recommendations by the ERP, current ELAP management is very talented and has tremendous resources they can draw from such as SAC, ELTAC, staff scientists, engineers, and lawyers that can help create a program that is manageable, adaptable and meets the data users' needs as well as the certified laboratory's needs.

Thank you for the opportunity to comment on this report. Should you have any questions please contact me at rsubramanian@roseville.ca.us or by phone at (916) 746-1885.

Sincerely



Raji Subramanian
Water Quality Laboratory Supervisor

cc: Kenneth Glotzbach, P.E., Wastewater Utility Manager
Kim Spear, EU Compliance Administrator