

## **THE SMALL COMMERCIAL ENVIRONMENTAL LABORATORIES GROUP**

August 5, 2015

Ms. Lara Phelps, Chairperson, and Members of the Environmental Laboratory Accreditation Program (ELAP) Expert Review Panel (ERP)

Submitted and to be presented in the ELAP-ERP public hearing, August 10, 2015, Sacramento, California

Dear Ms. Phelps and the Expert Review Panel:

### **1.0 EXECUTIVE SUMMARY**

Our group of licensed small commercial laboratories presents to the Environmental Laboratory Accreditation Program (ELAP) Expert Review Panel our assessment of ways to improve and streamline policies, processes and procedures under ELAP. We addressed six areas where improvements are necessary and feasible. If implemented, the result will be an excellent agency with authority and enforcement capabilities. The missing attributes are necessary for public health protection and environmental enforcement.

It is our opinion that laboratory audit is an integral element of the ELAP certification process. Therefore, outsourcing it will result in a fragmented agency and fragmented enforcement with little control. Furthermore, the agency will have the daunting task to evaluate and control work products of multiple contract entities. This will increase costs both to the government and environmental laboratories. The cost increase will have adverse financial impact on the small business laboratories, making them less competitive compared to national/multinational laboratories. The excellent National Environmental Laboratory Accreditation Program (NELAP), and International Organization for Standardization (ISO), certifications should remain voluntary.

### **2.0 INTRODUCTION**

The undersigned group of laboratories represents licensed commercial environmental laboratories that are small businesses located and operating in California. Some of the group members are minority and woman owned. We are not represented by the large and/or multistate and/or multinational commercial environmental laboratories that made previous public presentations to the ERP. We are also not represented by American Council of Independent Laboratories (ACIL), a private organization which merely voices the interest of its few California members.

We welcome, support and encourage the State Water Resources Control Board (SWRCB) timely initiative to improve the performance of the state's Environmental Laboratory Accreditation Program (ELAP).

We believe that ELAP is an important unbiased public agency with important role of protecting public health and safety. We also believe that only government agencies have no conflict of interest in drafting, implementing and enforcing regulations. Therefore, ELAP and the SWRCB must seek and receive the necessary additional legislative and financial support to reorganize with new management and leadership. The goal must be improvement of ELAP performance, coupled with enforcement of the regulations by ELAP and the SWRCB. California deserves a model agency with complete and comprehensive control, and seamless enforcement of its own regulations and environmental destiny. The state agencies should not rely on other states' regulatory goals, or other commercial interests.

The interest of our small business commercial environmental laboratories group is in production of high quality and defensible data and analytical results that can be used reliably. We are interested in preserving the independence of the California regulators for drafting regulations, auditing, licensing, and enforcement of the California regulations. All this must be achieved with no adverse financial impact on the small laboratories community, and without increasing our regulatory costs.

Our businesses suffered from: lack of quality enforcement; competitors shipping samples for analysis out of state; wild price cutting associated with unverifiable quality assurance and quality control. We all must correct this situation.

### **3.0 ACTIONS NECESSARY TO IMPROVE ELAP PERFORMANCE**

In our opinion, only a reenergized ELAP can solve the current problems. Therefore, it is our opinion that ELAP deserves all the help from the California legislators and SWRCB in addressing the solvable issues listed below.

#### **3.1 Update regulations and procedures**

Review, upgrade, and update the regulations and procedures that are not up to date, and do not meet current standards and reality.

#### **3.2 Standardize ELAP standard procedures (SOPs)**

Update and standardize ELAP SOPs including auditors training procedure and consistent laboratory auditing procedures.

#### **3.3 The current ELAP budget is inadequate to allow appropriate program execution**

Since ELAP is a public health and safety program, ELAP budget should not rely entirely or in large part on laboratory license fees. ELAP should be supported by a legislative budget, where the laboratories contribution to license fees is minor and supplemental. It will allow ELAP to have the resources to construct and execute a correct, concise and effective program.

#### 3.4 Review ELAP budget to allow it to perform its revised scope of work

The ELAP budget should be sufficient to support an expanded and well-managed program.

#### 3.5 Proportional license fees

The laboratories license fees and expenses have been increasing tremendously in the last few years and are not proportional to each laboratory's size. The license fee structure should be revised to remove inequalities, and the current in-effect subsidizing of large commercial laboratory businesses, where the fees are insignificant compared to their business volume.

The State of California is known to have interest in encouraging small businesses that are vital to its economy, employment, and product quality. Therefore, ELAP fees and performance testing expenses should be based on the size of the laboratory and should be decreased for small laboratory businesses.

The ERP should also be aware that while the ELAP fees have been increasing with time, the commercial laboratories are experiencing serious price erosion in the last eight years. To aggravate this situation, the performance testing (PT) unknowns are no longer supplied by ELAP free of additional charge. As a result, each laboratory needs to purchase its own performance evaluation samples, an additional cost burden to small laboratories. We believe that proportional fees and resupply of PT samples for small laboratories should be implemented. This will increase analytical quality by allowing small businesses to invest more in training, hiring quality staff members, and investments in new equipment.

#### 3.6 Improve ELAP documents management and control

Documents such as reports are sometimes displaced, and certificates are not always issued in a timely manner. This issue can be easily addressed by proper professional administration and program management. We are certain that the appropriate document management system can be adapted from another state agency.

### **4.0 THIRD PARTY CERTIFICATION – THE LOSS OF STATE CONTROL AND INCREASED COST TO THE STATE AND LICENSEES**

The existing ELAP problems will not be solved by contracting laboratory certification by NELAP or third party. It will create significant additional costs for all.

There are excellent commercial and semi-commercial programs such as ISO and NELAP that are used to certify laboratories or certify certain tests. Some of these programs are excellent and currently voluntary in California. Using only a third party certification however has some inherent problems:

- The state cost and administrative burden will not go down. In fact, it may go up since third party programs are administered by different agencies and/or commercial

organizations. The state WRCB will be confronted with difficulty and challenged to determine the quality of multiple organizations and their cultures, employees' training, and performance.

- Past experience has shown that outsourcing public certification and enforcement programs in the U.S. is problematic.
- The state will lose control of a uniform audit process and comparable results. Audits by a variety of third parties will be easily challenged in courts, and therefore create enforcement vulnerability.
- Third party will add an additional layer of cost both to the state and the licensed laboratories. This will create difficulties for small businesses that are already confronted with increased costs and serious price erosion.
- Another layer of cost to small businesses is significant, while large multistate, multinational laboratories already have third party certifications due to their multistate businesses. This will put small businesses in California at a disadvantage, drive some quality small laboratories out of business, and therefore reduce competition and analytical quality.
- Large multinational/state laboratories already ship California samples to specialized laboratories throughout the country. The state regulatory community has no control over samples integrity during long distance shipment, or recourse on the quality of work done outside the state, in locations with different regulations and diverse cultures.

In summary, outsourcing to a third party will not solve the current issue. Reenergizing ELAP will address and solve the current needs.

## 5.0 SUMMARY

In summary, it is our opinion that ELAP must be reenergized along the lines described above. The contracting of licensing and audits to a third party will not eliminate the need to reenergize and make changes to ELAP, since such a third party program does not run itself. We believe that third party programs such as ISO or NELAP are excellent and valuable and should remain voluntary programs. The state's agencies are the public health custodians and therefore must have full control of a seamless ELAP program from start to end.

Reenergized ELAP is the best option for ensuring environmental health and safety in California, enabling efficient and seamless regulatory enforcement that cannot be easily challenged or circumvented due to non-uniform auditing and licensing by diverse third parties. Reenergized ELAP will ensure unbiased and uniform enforcement, will keep commercial competition and quality up, while keeping alive small businesses that are vital to the economy and environmental enforcement. Revitalizing ELAP is good for health and safety, the environment, and for the California public interest and the state economy.

Sincerely,

The Small Commercial Environmental Laboratories Group

Signatures (original signatures on file) Executives of California Environmental Laboratories

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