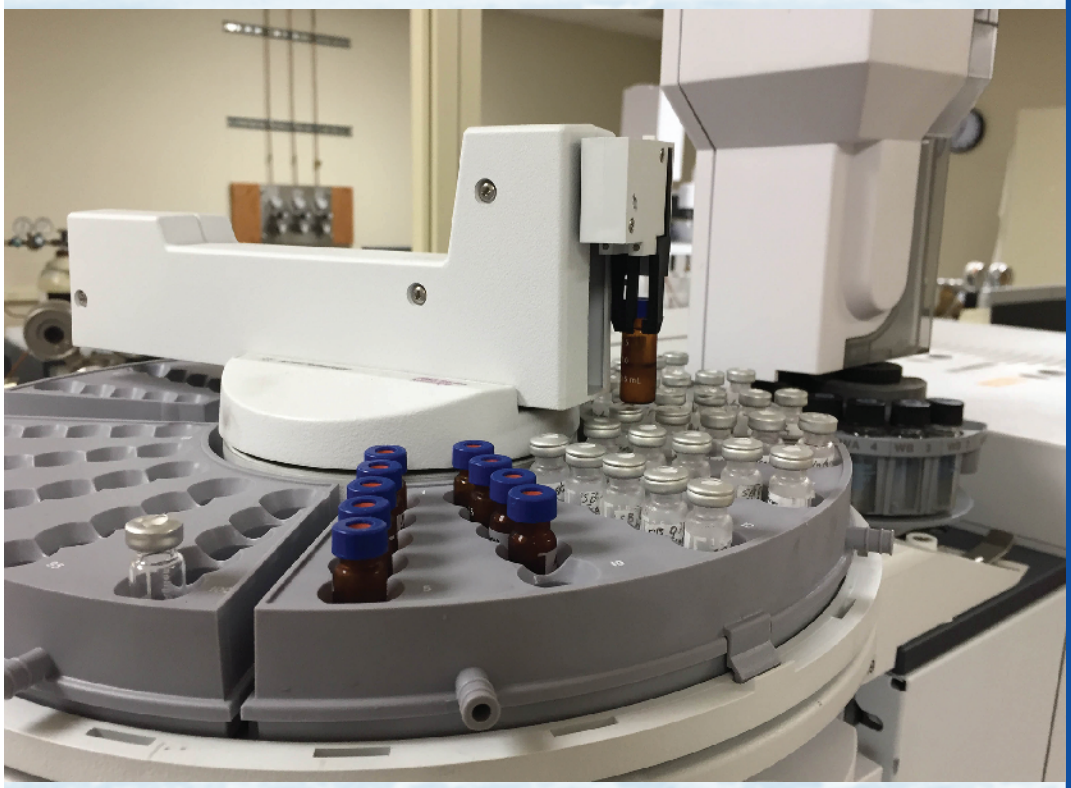
Findings and Recommendations by the Expert Review Panel for the State of California's Environmental Laboratory Accreditation Program

Year One Final Report



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Southern California Coastal Water Research Project

SCCWRP Technical Report 887

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FOREWORD

This report was produced under California State Water Resources Control Board contract to the Southern California Coastal Water Research Project (Agreement Number 15-037-400) under the direction of Dr. Stephen Weisberg. The views and perspectives expressed in this report by the members of the Expert Review Panel are their own, and do not necessarily reflect the views of their employer or any other entity with which they are affiliated.

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EXECUTIVE SUMMARY

An Expert Review Panel was convened in 2015 to conduct an external examination of the State of California's Environmental Laboratory Accreditation Program (ELAP). The Panel identified a number of fundamental weaknesses in ELAP that hinder the program's ability to achieve its mission of ensuring the State has access to quality data for use in its environmental decision-making. More importantly, the Panel observed that these deficiencies have cost the program credibility among key constituencies – notably, the state agencies that rely on data generated by ELAP-accredited laboratories.

During three in-person meetings to assess ELAP and gather perspectives from stakeholders, the Panel identified five main programmatic deficiencies: (1) ELAP lacks a clear management system with established procedures to which staff are trained and held accountable; (2) ELAP does not have a relevant accreditation standard on which to base its laboratory inspections; (3) the list of analytical methods for which ELAP accredits laboratories is outdated; (4) ELAP has insufficient resources to accomplish its mission; and (5) ELAP's poor communication has caused a rift with its clients.

There is, however, hope. The recently installed ELAP management team recognizes these challenges and appears receptive to change. Some stakeholders also have embraced a fresh start, although for ELAP to be successful in the future, all parties must let go of the past. The Panel believes ELAP is well-positioned to reestablish itself as a respected accreditation program, and recommends moving forward with a series of immediate reforms. These reforms should be weighed and evaluated through the lens of a clear Mission Statement, which the Panel recommends as: "Implementation of a sustainable accreditation program to effectively evaluate the competency of organizations generating environmental and public health data of known and documented quality to meet stakeholder needs." The Panel's recommended reforms fall into five main themes:

- **Establish a management system:** ELAP should rapidly establish standards of operation for itself. At present, there are no procedures that define internal processes and job requirements for staff. ELAP should design a management system with performance criteria to which all staff and management can be held accountable.

- **Adopt laboratory accreditation standards:** The use of an appropriate accreditation standard by which laboratories are assessed is critical to ELAP's credibility, to the usability of the data generated, and to the general success of the program. The laboratory standards ELAP is using are insufficient and out of date. The State should adopt an existing, external set of accreditation standards as an immediate remedy and, in the future, refine it to enhance alignment with State-specific needs. The accreditation standards chosen must include quality system and method-based requirements.

- **Ensure relevant analytical methods:** ELAP should update the list of analytical methods to which laboratories are accredited and assessed. The list of methods the program is using are incorporated into the California Code of Regulations, which have not been updated since 1994 and are seriously out of date. State regulations should be altered to remove references to specific methods, which will provide ELAP the flexibility to adopt

current, relevant methods that laboratories and regulatory authorities need to adequately protect California's health and environment.

- **Expand resources:** ELAP should take several steps to expand the resources at its disposal: (1) Additional investment in staff development to increase productivity, including a management plan that defines employee expectations and establishes employee performance metrics; (2) a revised fee structure that eases ELAP's financial constraints and allows the program to fully recover its costs; and (3) incorporation of third-party, private-sector assessors and acceptance of qualifying laboratory accreditation programs as components of ELAP's accreditation process, to clear ELAP's immediate backlog and to provide long-term support as necessary. Maintaining staffing at the current level will only work if management sets requirements and holds staff accountable.

- **Enhance communication:** ELAP should develop a communications plan, have ELAP staff undergo communication training, and codify expectations into a management system that ensures staff are held accountable for proper responsiveness and communication etiquette. ELAP should also reinvigorate the Environmental Laboratory Technical Advisory Committee (ELTAC), which serves as a vital conduit by which the laboratory community can help improve ELAP's programmatic foundation.

Although ELAP is not presently achieving its mission, ELAP's new management team understands its charge to comprehensively overhaul the program. The State should support ELAP's efforts to implement these initial recommendations and hold ELAP accountable for their execution. The Panel will revisit ELAP's progress in late 2016 or early 2017 and prepare a second Panel report that codifies any mid-course corrections and additional recommendations. If ELAP is successful in implementing the recommended reforms, the Panel believes ELAP can regain credibility, achieve financial sustainability, operate an accreditation process that the State and stakeholders can support, and reliably ensure that environmental and public health data being used in State decision-making are of known and documented quality.

CHAPTER 1: INTRODUCTION

1.1 Background

Effective stewardship of the environment and protection of public health require generation of data to inform managers of the effectiveness of regulatory actions. Such data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or toxicity of sediments. The field and laboratory methods employed to obtain these measurements are often complex, and the procedures and analytical instrumentation evolve as technology improves. Through the use of accreditation to oversee laboratories that provide these analytical services to the State, the State is able to ensure that laboratories generate data of a known minimum quality, that data obtained from different laboratories are comparable, and that laboratories compete on an even playing field.

1.1.1 ELAP History

In January 1988, the California Environmental Laboratory Improvement Act (i.e., Assembly Bill 3739, Chapter 894, Statutes of 1988) established the State's Environmental Laboratory Accreditation Program (ELAP) to provide evaluation and accreditation of environmental testing laboratories. ELAP ensures the analytical data used for regulatory oversight of the State's drinking water, wastewater, shellfish, food, and hazardous waste programs meet State requirements. All environmental testing laboratories are required to receive accreditation prior to providing analytical data used for State regulatory purposes.

ELAP was one of the eleven original state accreditation programs to become a recognized accreditation body by the National Environmental Laboratory Accreditation Program (NELAP), which was formed in 1999. The goal of NELAP is to foster cooperation among accreditation activities of different states and other governmental agencies, and to unify state and federal agency standards. Each state-level accreditation body agreed to implement standards written by the National Environmental Laboratory Accreditation Conference (NELAC), and accept the accreditation of laboratories accredited by other NELAP accreditation bodies. In 2006, The NELAC Institute (TNI) was established for the long-term management of NELAP and development of standards.

ELAP withdrew from TNI NELAP in 2014 following the identification of programmatic deficiencies in a TNI programmatic evaluation. The evaluation affirmed the concerns expressed by local California laboratories regarding ELAP's effectiveness as an accreditation body. Shortly after ELAP's withdrawal from TNI, ELAP transitioned from the California Department of Public Health to the California State Water Resources Control Board's Division of Drinking Water (herein referred to as the State Board). With new ELAP management in place under the State Board, ELAP asked for an external, independent programmatic review to help the program frame its future directions. This review was intended to cover internal management procedures, staffing, finances, the laboratory assessment process, and communication strategies, with an overarching goal of improving ELAP's effectiveness.

1.1.2 ELAP Operation

ELAP presently has a staff of 25 full-time employees and an annual budget of $3.3 million. According to the Environmental Laboratory Improvement Act, ELAP is to be fully fee-

supported; however, accreditation fees only bring in annual revenue of $1.9 million, with the deficit covered by State general funds. The ELAP fee structure is based on the number of fields of testing (FOTs) in which the laboratory applies for accreditation. Laboratories are accredited by ELAP per FOT, which defines a set of analytes in a particular environmental matrix and the method of measurement (e.g., Toxic Chemical Elements in Wastewater, Microbiology of Drinking Water).

ELAP accredits nearly 600 in-state and 100 out-of-state laboratories. Approximately 55% of the laboratories are privately owned; the remainder are government-operated, including federal, state, and municipal laboratories (Table 1). According to a non-scientific survey conducted by ELAP, 40% of the laboratories reviewed by ELAP have 5 analysts or less, 75% have 20 analysts or less, and 5% have 85 analysts or more.

Table 1. Number and type of laboratories accredited by ELAP, as of August 31, 2015.

Government	127 Public Wastewater System
	65 City
	58 Public Water System
	46 County
	12 Public Water and Wastewater System (Other)
	10 Federal
	6 State
	4 Academic Institute
	2 Recycling Facility
	1 Tribal
	331 Total
Private	317 Commercial
	45 Industrial
	362 Total
In-State	**602**
Out-of-State	**91**

ELAP provides accreditation for FOTs based on the needs of its clients (i.e., the State agencies that are required to use laboratories that are accredited). FOTs are reviewed for accreditation through two mechanisms: proficiency testing (PT) and laboratory assessments against specific method requirements. PT programs evaluate whether a laboratory can analyze a sample of unknown composition and produce results within specified acceptance criteria. Laboratory assessments are carried out by ELAP assessors using checklists that cover multiple aspects of the sample preparation, instrument operation, and quality assurance (QA)/quality control (QC) required by the method specified in the FOT.

The Environmental Laboratory Technical Advisory Committee (ELTAC) was created by ELAP to provide assistance and advice regarding technical, scientific, and administrative matters, which is required under Section 100863 of the Health and Safety Code. The members of ELTAC

are representative of different technical fields within the laboratory community and regulatory agencies.

1.1.3 General Program Operation

Other states also accredit environmental testing laboratories. Some operate as independent accreditation bodies and develop their own standards by which to assess laboratory performance. At present, 14 accreditation bodies in 13 states belong to the national program organized by TNI, and two additional states require accreditation from another source, with NELAP being one option. As previously noted, TNI has been managing NELAP since 2006 and maintaining a common set of consensus standards for state accreditation bodies to follow. The latest TNI standard (2009) contains two relevant sections for accreditation bodies and the laboratories they accredit: *Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis*, and *Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories*. The other volumes in the 2009 TNI standard cover requirements for PT providers and the accreditors of PT providers.

TNI Volume 1 describes management and technical requirements for environmental laboratories, including implementation of a quality system. A quality system is a structured and documented management system describing how the laboratory ensures the quality of its processes and products. TNI Volume 2 describes requirements for the internal activities of accreditation bodies, such as ELAP, including management, document control, human resources, and how the accreditation process is tracked. Prior to its separation from TNI in 2014, ELAP operated a two-tiered accreditation system, wherein laboratories could be accredited and assessed under either the full TNI standard or the State's own standard.

Although some elements of the TNI standard are similar to ELAP's own standard, such as the technical requirements for the analytical methods, laboratory quality systems are not required by ELAP. ELAP also does not explicitly follow TNI Volume 2.

The TNI standards are based on International Organization for Standardization (ISO) 17025 for testing laboratories and ISO 17011 for accreditation bodies (i.e., ELAP-type organizations), with added specificity for environmental laboratories and their accreditation bodies. For more details about ELAP and the standards under which its accreditation processes operate, go to http://www.waterboards.ca.gov/drinking_water/certlic/labs/index.shtml.

1.2 Expert Review Panel

In 2014, ELAP's newly installed management team asked for an external, independent programmatic review to improve ELAP's effectiveness. The State Board turned to the Southern California Coastal Water Research Project Authority (SCCWRP) to establish an Expert Review Panel (Panel) to develop recommendations for improving ELAP.

An 11-member Stakeholder Advisory Committee (SAC) was formed to vet the Panel nomination process. SAC members (listed in Appendix C) represented municipal and private environmental laboratories operating in California, as well as State agency users of data from ELAP-accredited laboratories. Candidates for the Panel were nominated based on nationally recognized expertise and a requirement they not be part of an organization regulated by or having official interactions

with ELAP. To ensure the Panel was well-rounded, candidates were grouped according to their categories of expertise, such as laboratory operation, operation of accreditation bodies, and on-site assessment. The SAC then ranked the nominated panelists within each category and was given the opportunity to eliminate any of the candidates from consideration. This vetting process ensured the Panel members were both highly qualified and free from bias regarding the issues on which they would deliberate.

The five-member Panel, established in early 2015, consists of:

- Dr. Jordan Adelson, U.S. Navy
- Stephen Arms, State of Florida
- Mitzi Miller, Dade Moeller & Associates
- Lara Phelps *(Panel Chair)*, U.S. Environmental Protection Agency
- David Speis, Eurofins QC, Inc.

Brief biographies of the Panel members are provided in Appendix B.

To orient the Panel to ELAP and allow public participation in the Panel's review process, three public meetings (March, August, and October) and one public webinar (June) were held in 2015. Meeting agendas (provided in Appendix D) were developed by the Panel and SCCWRP, with SAC assistance on topic development and identification of speakers, to provide the Panel with a comprehensive range of information and perspectives. For presentations on topics intended to inform the direction of Panel recommendations (as opposed to informational or background presentations), the Panel deliberately invited speakers with different perspectives. For example, the Panel heard from speakers representing both large commercial laboratories and smaller government laboratories, and heard both the pros and cons of utilizing third-party, on-site assessors. Members of the Panel, SAC, and public were given time to ask questions of the speakers, and an email listserv was created to inform interested parties about upcoming meetings and other updates. The meeting agendas, background materials provided to the Panel, presentation slides, and written public comments were posted to a public website (http://www.sccwrp.org/ELAP).

1.3 The Panel Charge

Panel charge questions were developed by ELAP with the assistance of the SAC. The Panel has addressed all eight questions throughout this document, and Appendix A provides direct answers to these charge questions.

1. What should the State's role be in the accreditation process? Are the philosophies, objectives and scope of ELAP clearly defined? Are they appropriate? Does ELAP have the capacity to support the program?
2. How can California's accreditation standards be improved?
3. What should California's approach be to recognizing accreditation by other states, national entities or private accreditation services? Should California rejoin NELAP?
4. How can ELAP's laboratory inspection program be made more robust? What are the appropriate qualifications for auditor/inspector team members in each of the specialty areas that ELAP certifies laboratories?
5. How can California improve its PT program for quantifying laboratory quality?

6. How can California improve its process for responding to concerns expressed by (a) laboratories that have concerns about the certification process, or (b) clients who have concerns about the quality of a laboratory that has been accredited by ELAP?
7. How should ELAP plan for future programmatic, testing and management needs?
8. Which program improvements are most urgent and can be accomplished within existing resources and authorities? Which are the highest-priority, longer-term program improvements?

1.4 The Report

This report provides the Panel's observations about the present condition of the program, recommended solutions, and an implementation timetable for the recommendations. This is the first of two reports that the Panel will produce. The Panel will reconvene in approximately one year to assess ELAP's responsiveness to the recommendations in this report and to provide additional recommendations, as well as make any suggested course corrections based upon the successes and challenges experienced by the program during the year.

CHAPTER 2: PROGRAMMATIC PROBLEMS IDENTIFIED DURING THE REVIEW

The Panel identified a number of problems during its review that hinder ELAP's ability to achieve its mission to ensure the quality of data used by the State of California in its environmental decision-making. The problems fall into four main categories: (1) Poor credibility with the stakeholder community; (2) lack of effective accreditation practices; (3) absence of routine management processes; and (4) inadequate resources. These problems are described in the following sections of this chapter.

2.1 Poor Credibility with the Stakeholder Community

During the course of its deliberations, the Panel had an opportunity to interview numerous stakeholder groups to assess their perceptions of the program. During these discussions, it was apparent that overall perception of the program is low and that ELAP is no longer trusted by the stakeholder community to operate an effective process for verifying laboratory competency. The program also lacks transparency, with the decision process for determining an unacceptable laboratory ill-defined, and evidence that ELAP has failed to remove noncompliant laboratories from the accredited community. These sentiments were shared across a range of stakeholders, including clients of the program and the ELAP-accredited laboratory community, as elaborated below.

2.1.1 Program Clients

ELAP provides services to a range of State agencies, which rely upon the data produced by laboratories that ELAP accredits. The Panel found that ELAP had not communicated with these clients for many years. ELAP was not even aware of the identity of all the clients it serves, which has led to a poor understanding of the data needs and competency requirements of each program.

In meeting with these clients, it was also apparent that ELAP staff does not possess the technical expertise to meet some of the client needs. ELAP does not have an accreditation process for laboratories conducting ambient air analysis in California because there is not air monitoring expertise on staff. There are other programs, such as shellfish, where ELAP has expertise, but where the program would better reside in the Department of Public Health, where monitoring can be performed according to U.S. Food and Drug Administration specifications.

2.1.2 Laboratories

Laboratories accredited by ELAP provided extensive input regarding the program's lack of competency. They feel that laboratory assessments lack consistency from assessor to assessor and, in many cases, do not reflect knowledge of the accreditation requirements or technical aspects of the methods being assessed. Laboratories reported that assessors have expertise in only a limited number of FOTs, meaning that assessments are conducted sequentially and inefficiently. They complained that assessors frequently documented deficiencies in areas they had not even evaluated.

Laboratories expressed a reticence to file complaints to ELAP management for fear of retaliation by ELAP staff. Without a clear, documented process for filing complaints, laboratories do not envision management holding staff accountable or having a mechanism to properly respond to complaints.

Laboratories that provided input to ELAP stated that ELAP customer service is poor, including a lack of professionalism when interacting with clients during laboratory assessments and in telephone communications. The feedback provided by the laboratories during in-person meetings with the Panel is consistent with the findings from a survey of laboratories conducted by the American Council of Independent Laboratories, which was provided to the Panel as additional background information.

2.1.3 Other States

ELAP is no longer part of NELAP, nor is ELAP's accreditation recognized by other states. ELAP was one of eleven original states to be recognized by NELAP, which was created to foster cooperation among accreditation activities of different states and other governmental agencies, and to unify the state and federal agency standards. ELAP withdrew from NELAP in 2014, after being cited for a number of programmatic deficiencies during a routine evaluation in 2012.

NELAP's evaluation of ELAP's accreditation process, which was conducted by other NELAP member states, showed ELAP's execution of NELAP's requirements were unsatisfactory, resulting in numerous activities that required corrective action. The Panel met with the lead NELAP evaluator as part of its deliberations and found that all of the NELAP-identified deficiencies were accurate and relevant to program integrity. The Panel further observed that ELAP failed to subsequently address those deficiencies.

2.2 Lack of Effective Accreditation Process

ELAP has lost the ability to effectively evaluate the quality and competency of laboratories, which jeopardizes the validity of data produced by accredited laboratories and creates the perception of a lower level of confidence in data used to make decisions regarding human health and the environment. This results from (1) poorly defined assessment standards, (2) assessing for outdated methods, and (3) inadequate staff qualifications.

2.2.1 Poorly Defined Assessment Standards

Current ELAP standards codified in regulations are inadequate. The assessment and accreditation processes are not properly defined in regulations, resulting in inconsistencies when laboratories are assessed. ELAP does not have a systematic approach for determining the competency of a laboratory that is seeking or maintaining accreditation.

The Panel heard from multiple stakeholders who commented that addressing ELAP's management system alone was adequate and that there was no need to improve regulations; the Panel disagrees and believes the regulations are part of the root cause of ELAP's problems. The regulations should be changed.

Moreover, ELAP does not address quality management in its assessing practices. The lack of a systematic process for quality assurance absolves the laboratory's management of responsibility for ensuring data quality, while placing the entire burden on the bench analysts. Part of this problem is due to the fact that ELAP lacks current assessment standards. For example, ELAP's enabling statute for NELAP accreditation specifies the November 1998 version of the NELAC

standards, which were never adopted by NELAC itself nor used by NELAP accreditation bodies. The current NELAP standard employed by NELAP-recognized states is the 2009 version, which contains numerous updates and specification changes from previous editions.

ELAP lacks a systematic process for reviewing PT samples results, which laboratories are required to submit annually. These data are not regularly reviewed for compliance by ELAP staff as part of the assessment process. Reviews of corrective actions for failed PTs performed by the laboratory are also not evaluated by ELAP staff during on-site assessments. Laboratory suspension of accreditation for continued PT failures is sporadic to nonexistent. Staff performs PT evaluations manually, which is an inefficient process compared to the utilization of computer software solutions.

2.2.2 Assessing to Outdated Methods

ELAP's assessment processes are woefully out of date, referencing analytical methods and quality specifications that have since been replaced. States typically adopt laboratory methods that are promulgated by the U.S. Environmental Protection Agency, which advances consistency among states. However, in California's case, those methods were incorporated into regulation (Title 22 Division 4 Chapter 19 Article 6 – Section 64811 of the California Code of Regulations). As a result, these methods have not been updated since the article's inception in 1994. Although the State ostensibly permits the use of alternate test methods, the State does not specify a defined procedure for approving new methods, nor an approach for laboratories to receive accreditation with them.

The State law does not make clear whether ELAP is legally permitted to accredit a laboratory for analytes that do not appear in either an approved method or in California regulations. There are no defined procedures to obtain accreditation for parameters not listed under an ELAP FOT. This is needed by laboratories that have a regulatory or client requirement to report data for non-standard contaminants. This further complicates accreditation assessments, and often forces laboratories to obtain this recognition from another accreditation body at a significant additional expense.

2.2.3 Inadequate Staff Qualifications

The Panel had the opportunity to interview multiple ELAP staff members. The Panel found several exceptional staff members, but also encountered several staff members who lack the necessary training to perform laboratory assessments and other aspects of their jobs, including customer service. Unfortunately, the inadequacies of those staff are known to their peers, which lessens morale among the highly committed employees. The result is a subjective, inconsistent accreditation process that varies significantly among assessors and between assessments. There is also an absence of trained, skilled staff in some technical areas for which laboratories are required to hold accreditation to produce regulatory data in California. In some cases, ELAP cannot even accredit commonly used technologies or FOTs, affecting the sustainability of the program and placing an additional accreditation burden on affected laboratories.

2.3 Absence of Routine Management Processes

ELAP management prior to the program's transfer to the State Board was ineffective. Panel interviews with current management and staff indicated that past management did not define employee expectations or adequately assess their performance. Previous management also did not use metrics to assess the performance of the program as a whole. Consequently, ELAP management did not have a process for verifying whether laboratory assessments were being performed correctly, was indifferent to known operational problems, and was unresponsive to client complaints.

These shortcomings fostered a work environment plagued by a lack of understanding of staff responsibilities and program direction. Some employees were operating with their own agenda and without accountability to superiors.

2.4 Inadequate Resources

Staff resources are inadequate to meet minimum accreditation requirements or timeliness. Many drinking water laboratories have not been assessed on site in five years or more, exceeding the U.S. Environmental Protection Agency requirement of at least once every three years. Assessors have an excessive backlog of unprocessed laboratory assessments, exacerbating the on-site assessment backlog. The result is an inability to verify competency of the laboratories producing data for acceptable drinking water quality and other key areas.

2.4.1 Staffing Resources

ELAP accredits the largest number of laboratories of any state program in the nation, but it does not have the capacity to fulfill its mission, as evidenced by the backlog of assessments. While the size of ELAP's staff may appear adequate, many ELAP staff members lack the qualifications and expertise necessary to perform on-site laboratory assessments. ELAP has 25 employees, a staffing level that should be sufficient for a state the size of California. However, only seven of these employees are presently conducting assessments, about half the number needed to fulfill the program's workload. This deficiency is more than a staffing allocation issue, and reflects the lack of a well-defined management system with performance criteria to which staff and management are held accountable.

2.4.2 Financial Resources

ELAP is required to run a self-sustaining program. Despite collecting fees that are among the highest in the nation, ELAP is operating at a loss and relying on general fund subsidies to continue operations. Last year, operation of the program cost $3.3 million, and fees generated only $1.9 million. The laboratory community also expressed concerns that the ELAP fee structure is inequitable, demonstrating a financial bias toward specific groups. This issue is likely to become more antagonistic as essential systems are added to the program, necessitating further fee increases due to higher operating costs.

CHAPTER 3: SOLUTIONS

Although ELAP continues to face a number of challenges (see Chapter 2), the Panel believes ELAP can be reestablished as a respected, financially solvent entity by implementing the reforms recommended in this chapter. These recommendations, which are divided into five main categories, build upon program improvements made by ELAP staff over the past few months, including improvements to ELAP's transparency, communication, and sense of mission.

Since ELAP's reconstitution under the State Board, ELAP management has demonstrated a renewed commitment to correcting the shortcomings of the past and developing a vision focused on its future. For ELAP and the stakeholder community to achieve their mutual goals, all parties should focus on ELAP's vision for the future, rather than dwelling on its past. Simultaneously, each party should hold all others accountable for their respective responsibilities under the revitalized accreditation program.

3.1 Establish a Management System

ELAP should immediately work to establish a management system built around performance criteria under which both the management and staff can be trained and held accountable. To avoid the time and resource investments of developing a complex new standard, the Panel recommends that ELAP adopts an already established standard (see Section 3.2) covering multiple aspects of accreditation body operations.

3.1.1 Issue

Lack of a robust, comprehensive internal management system for conducting operational functions is at the root of several chronic problems identified by the Panel and stakeholders. This shortcoming has resulted in a workplace environment characterized by widespread lack of understanding of staff responsibilities and program direction. ELAP management needs processes in place to verify whether laboratory assessments are being performed effectively, to respond to operational problems, and to address client complaints. ELAP also needs to more clearly define employee expectations, metrics for assessing these expectations, and metrics for assessing program performance as a whole.

3.1.2 Recommendation

To establish its management system, ELAP should adopt one of two widely respected standards:

- **Option 1:** *Conformity Assessment: General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*, 2004-09-01, by the International Organization for Standardization (ISO)/International Electro-technical Commission (IEC) 17011. This ISO/IEC standard is generally applicable to a variety of situations. In this case, the term "conformity assessment bodies" refers to laboratories.
- **Option 2:** Volume 2 of *General Requirements for Accreditation Bodies (ABs) Accrediting Environmental Laboratories*, EL-V2-2009, published by The NELAC Institute (TNI). This standard is based on the ISO/IEC 17011:2004, with added detail for state agency environmental laboratory accreditation programs, particularly for enforcement actions under legal requirements.

ISO 17011 would provide numerous benefits to the laboratories being assessed and to ELAP. An ISO 17011 assessor has the defined role of fact finder – as opposed to accreditation decision-maker – and the laboratory has an appeals process to deal with unfounded findings or a failure by the assessor to follow established processes. This formal complaint process for laboratories would help ELAP to identify the root cause(s) of problems and proper corrective action(s). Furthermore, establishment of a management system under ISO 17011 would define which assessment procedures to use to document, process, and review applications, and how to utilize proficiency testing (PT) data, among other elements.

Not only does ISO 17011 promote transparency and consistency among accreditations, but ISO 17011 also comes with a suite of well-established training activities, international support, and processes that have been proven to work in laboratories worldwide. Regardless of which standard is adopted, the Panel recommends that ELAP's management structure contains at minimum two elements: (1) Operational processes to carry out ELAP's functions, and (2) internal reviews to assess performance.

3.1.2.1 Operational Processes

ELAP management should clearly define the procedures that staff are expected to carry out, convey this to the staff, and use these definitions to assign appropriate training. The procedures should be defined for each operational function. For example, they could encompass: (1) applications for accreditation, including gathering required information, the application review process, and maintenance of records; (2) assignment of the laboratory assessment team, preparation, and schedule; and (3) laboratory assessment reports that describe the evidence for a decision. More specific operation process items that should be included in the management system are outlined below.

- **Document control:** ELAP should develop guidelines and, if necessary, obtain tools for document control, an area that should encompass version control, quality system documentation, and forms for distribution. To ensure the proper document is being used for a given task and to safeguard confidential documents, there should be a control element that includes steps such as requiring an approval date, a change control number, and/or a version number. Additionally, ELAP should expand the number of documents outlining key procedures, such as assessment, corrective action review, and generating assessment reports.
- **Record-keeping**: ELAP should establish a procedure for maintenance of records. Records being produced include application submissions, PT results from laboratories, accreditation certificates, records of actions taken, and staff training records. By developing processes to document and maintain records, and by training staff to use these processes, laboratory services will be improved. For example, the loss of application documents and the time needed to deliver assessment reports to the laboratories will be minimized. These processes also should serve as an objective method that ELAP management can use to assess staff and manage staff performance.
- **Quality system:** Because a basic template for a quality system is recommended for every laboratory, ELAP should develop a management quality system that contains the same basic components that California laboratories use in their quality systems, ensuring ELAP assessors work within a system similar to that of the laboratories they accredit. When

assessors are trained to this system, they will develop a better understanding of quality processes.

- **Proficiency testing:** Although proficiency testing is only one component of an accreditation program, it is critical for the accreditation body to review PTs at regular intervals. ELAP requires one PT per year, but does not effectively use the results in its evaluation process. ELAP should focus on making better use of the PT results. Under ISO 17011, PTs are required, but the AB can set the frequency. Under the TNI standard, two PTs are required each year from a TNI-accredited provider, one in each half of the year. Because ELAP should focus on more effectively using its existing PT results, the Panel does not recommend requiring a second PT annually at this time.
- **Enforcement:** The Panel heard testimony that ELAP either lacks the ability or the will to conduct enforcement activities when warranted. ELAP should work closely with the State Board's Office of Enforcement to develop a unit of ELAP staff that focuses on developing enforcement procedures, reviewing laboratory data for irregularities, and issuing enforcement actions when there are violations of ELAP regulations. Although there will be cases in which decisive enforcement action is prudent, ELAP should view its primary goal as achieving compliance, with legal action against a laboratory's accreditation used as a last resort. While enforcement is a necessary function of accreditation bodies (enforcement is described in ISO 17011, Section 7.13), enforcement in and of itself should not be the main goal. ELAP should focus on defining a clear, documented pathway for progressive compliance, a process that ELAP presently lacks. ELAP also should establish procedures for addressing nonconformities identified in laboratories and for documenting corrective actions with root causes.
- **Complaints:** ELAP should have a documented process for addressing complaints from laboratories about ELAP, as well as complaints about the laboratories. It also should include procedures for corrective actions, and systems to evaluate the effectiveness of those actions.

3.1.2.2 Internal Reviews

- **Internal audits**: ELAP should establish periodic internal audits that verify the program adheres to the adopted standard (e.g., ISO/IEC 17011). These audits should be performed by ELAP staff who are qualified to do so and who are not assigned to the audited activity. ELAP should have a quality assurance manager who oversees the quality systems of the program, including the internal audits. During the audit process, the performance of all individual staff should be assessed according to their assigned responsibilities. In particular, assessor performance should be periodically evaluated through direct monitoring of the assessor's laboratory assessment work. Management should inform staff of the outcomes of the internal assessments and engage the staff in identifying opportunities for improvement.
- **Full programmatic review**: Separate from the internal audit, ELAP should establish a process for a periodic programmatic review. Whereas the internal audit should assess conformance to the adopted standard only, the programmatic review should be more comprehensive and forward-looking. ELAP management should assess information from a variety of internal and external sources, including stakeholder feedback, complaints received by the program, a review of potential new areas of accreditation, and status and trends of performance metrics for ELAP functions. These results should be used to

determine if budget, resource allocation, internal policies, and program objectives are optimal and, if not, how they can be improved. In particular, the review should demonstrate that ELAP has an adequate number of competent personnel with skill sets necessary to carry out each programmatic function. Typically, these reviews should occur once per year and result in an annual plan for the coming year. Upon completion, the review would serve as the basis for an improvement plan to be executed by management.

3.2 Adopt Laboratory Accreditation Standards

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.

3.2.1 Issue

Accreditation bodies need accreditation standards that are clearly written, auditable, enforceable and, perhaps most importantly, relevant to the intended use of the data. As stated in Section 2.2.1, the assessment and accreditation processes are not properly defined in regulation, resulting in inconsistencies when laboratories are assessed.

3.2.2 Recommendation

ELAP should adopt a clear standard to which it accredits laboratories, and it should implement this standard as soon as possible because it is a foundation of many of the other Panel recommendations. Standards that are based on quality systems provide ongoing checks to help ensure that all functions of the laboratory, regardless of size, are in compliance, resulting in greater confidence in the data produced. The Panel envisions three possible routes the State could take to achieve this: (1) Create ELAP's own State-specific standard; (2) modify and adopt an existing standard; or (3) adopt an existing standard.

- **Option 1: ELAP-created standard**: The major benefit of creating a State-specific standard is that it would ensure the resulting laboratory requirements meet program and client needs. This effort will allow the State to include only those requirements it considers important for laboratory performance. Major drawbacks are the difficulty, cost, and time associated with writing an original document. Additionally, this option would require the State to develop State-specific training protocols for ELAP assessors, and provide resources to communicate the new requirements to the laboratories. These drawbacks make selecting this option time- and cost-prohibitive.
- **Option 2: Modification of an existing standard**: The major benefit of modifying an existing standard is that it would save time and resources compared to the development of a State-specific standard. The major drawback is that the savings of time and resources might be relatively small in comparison to Option 1. The Panel heard testimony at its August 2015 meeting about an effort by the State of Wisconsin to modify an existing standard. The Panel learned that reaching consensus on the modifications to the standard and the adoption process took an extensive amount of time and, in the end, resulted in an imperfect standard. This, in effect, isolated Wisconsin's laboratory program, which is not recognized by other states, adding costs and placing restrictions on Wisconsin

laboratories conducting business across state lines. Because California's laboratory community is much larger than Wisconsin's, the Panel believes that the timeframe for development and adoption of a modified standard would be more protracted than Wisconsin's timeframe. From the information presented, it became clear to the Panel that this option is not practical for ELAP in the immediate future.

- **Option 3: Adopt an existing standard**: The major benefit of adopting an existing standard is that the time and resources needed to implement it will be greatly reduced. The major drawback is the lack of ability to customize it to meet State-specific needs. Thus, it would be critical to select the correct standard. The State would need to ensure that the standard it selects meets its clients' requirements and contains proper resources for both assessors and laboratories to ensure a smooth, consistent implementation.

The Panel devoted considerable time to examining the type of standard ELAP should utilize, and recommends that the State adopt an existing standard as an immediate remedy. The Panel is aware of a number of state, national, and international laboratory standards that could meet the State's needs, but recommends the standard developed by TNI as the most viable one for the State in the short term. The TNI standard is a standard the State has used in some form previously, albeit not for all laboratories. Adopting a standard that has been implemented as broadly as the TNI standard would allow the State to take advantage of a wealth of available resources and support. Regardless of what existing standard is adopted in the short term, the State should look over the long-term to modify the existing standard to maximize the standard's applicability to the State's needs.

The Panel feels strongly that the State should implement a single standard that incorporates quality management requirements. Because all data produced for regulatory environmental purposes and environmental decision-making are produced for the same broad purpose, a single standard that provides for equal levels of quality regardless of laboratory size is optimal. The Panel received comments indicating that adoption of a standard that incorporates a quality system approach would be overly burdensome for at least some small laboratories. The Panel disagrees and believes that the small laboratories, which are vulnerable to inconsistencies in approach when there is employee turnover, will benefit most from incorporation of a quality systems approach that will establish consistency in procedures. Moreover, all of the Panel members have worked extensively with groups that have incorporated quality systems in other states and have observed that the long-term benefits far outweigh any short-term inconvenience of establishing that system; this perspective is consistent with feedback received from two of the presentations made during the Panel's June 2015 webinar.

Regardless of the option chosen, the transition will take time and ELAP should work with ELTAC to develop a schedule for adoption that is not overly burdensome to the laboratories, Moreover, ELAP should provide effective outreach, compliance assistance, and education to stakeholders. ELAP also should integrate into its communication strategy a suite of tools that meets the diverse needs of the laboratories (e.g., small, medium, large) and decision-makers that ELAP serves. Just as some standards come with programs that offer resources to help with this process, ELAP should ensure it communicates the availability of those tools to all stakeholders and take advantage of additional opportunities to simplify the transition for everyone, including via workshops, videos/films, webinars, training, and speaking engagements at conferences or symposiums.

3.3 Ensure Relevant Analytical Methods

ELAP should update the list of analytical methods it uses to conduct assessments to ensure the most relevant methods are used, and State regulations should be altered to remove references to specific methods, which will give ELAP more flexibility in updating its methods.

3.3.1 Issue

The list of analytical methods for which ELAP accredits is outdated. The analytical methods were incorporated into Title 22 Division 4 Chapter 19 Article 6 – Section 64811 of the California Code of Regulations, which have not been updated since 1994. State law appears to permit the use of alternate test methods, but the State lacks a defined procedure for approving new methods. In other words, although the law allows for accreditation to the latest approved methods for drinking water and wastewater, the regulation effectively restricts those methods to the 1992 versions. Moreover, there is no defined procedure to obtain accreditation for parameters not listed under an ELAP FOT. As such, ELAP is not accrediting laboratories for the methods that ELAP, its clients, and regulatory authorities need and in some cases require (e.g., 40 CFR Part 136 for Waste Water Analysis) to adequately protect California's health and environment.

3.3.2 Recommendation

3.3.2.1 Ideal solution

The simplest solution is to eliminate references to specific analytical methods in the regulations, allowing ELAP the flexibility necessary to accredit laboratories according to the methods that ELAP, its clients, and regulatory authorities need to adequately protect California's health and environment. Other states (e.g., Florida) have successfully used this tactic to great advantage. If California's Article 6 is not repealed, then it should be rewritten. The Panel believes that the intent of the ELAP's enabling legislation may have been to provide for increased flexibility with analytical methods. The enabling legislation in the Health and Safety Government Code suggests that "performance based measurement system methods" are allowable and needed, which seems to the Panel to indicate that the legislative intent was for ELAP to have the ability to accredit laboratories comprehensively – and even to accredit to methods yet to be contemplated. However, this interpretation would need to be subjected to review by State legal counsel.

3.3.2.2 Short-term solution

Recognizing that the process of changing State regulations is arduous and time-consuming, the Panel looked for possible short-term alternatives within the context of the current rules. The Panel's position is that the language of Subsections (f), (g), and (h) of Title 22 Division 4 Chapter 19 Article 6 – Section 64811 enables ELAP to use alternate methods as ELAP deems appropriate. Each of these three subsections opens with, "Laboratories may substitute alternate test methods for those allowed," and then specifies how to obtain approval from ELAP to use these alternate methods. Because it is of mutual benefit to both ELAP and the laboratories to use newer analytical methods, ELAP should compile and publish a comprehensive list of all approved methods, and allow laboratories to seek accreditation via every method. ELAP should actively involve its regulatory program clients in the development of this list, and then widely advertise it and the new process to the laboratory community. To emphasize ELAP's

commitment to accreditation via this list, ELAP should establish a streamlined process by which laboratories can apply for and receive accreditation in an expedited fashion.

Simultaneously, ELAP should seek out advice and assistance from ELTAC as it begins training its own staff in the evaluation of these methods. ELAP's assessors will need to be competent in a wide array of technologies. At a minimum, each assessor will need to have a fundamental understanding of the scientific disciplines and techniques under his/her purview, such that the assessor can competently assess a laboratory according to various methods and laboratories' Standard Operating Procedures (SOPs). No single assessor needs to be an expert in all possible methods, but all assessors should have the requisite education and skills to adequately evaluate whether a laboratory is following the proper protocols. To ensure standardization and consistency, ELAP should develop standardized, thoroughly peer-reviewed checklists.

3.3.2.3 Fall-back solution

If it is not possible for ELAP to expand and/or modify the rigid, prescriptive language that characterizes its test methods, then ELAP should act with great speed in updating its permissible methods with the most current versions.

3.4 Expand Resources

ELAP should expand the resources at its disposal through: (1) additional investment in staff development to increase productivity, (2) a revised fee structure that allows ELAP to fully recover its costs, and (3) incorporation of commercial third-party assessors and the acceptance of qualifying laboratory accreditations from other states into ELAP's accreditation process.

3.4.1 Issue

ELAP's staff members are unqualified to meet the demands of their accreditation program. While the size of ELAP's staff may appear adequate, many ELAP staff members lack the qualifications and expertise necessary to perform on-site laboratory assessments. These staffing limitations stem from a lack of training and insufficient management accountability for personnel performance. Even as ELAP brings new staff on board, these staff members cannot make up for the lack of qualifications and expertise of existing staff. These staffing challenges have led to inconsistent assessments, which pose a significant ongoing issue for laboratories, as well as a backlog that prevents the program from meeting the needs of its stakeholders.

ELAP's financial constraints also remain an ongoing challenge for the program. ELAP's inadequate fee structure was exacerbated by the program's withdrawal from NELAP, as ELAP is no longer able to collect fees for NELAP accreditations. Simultaneously, ELAP has been filling previously vacant positions to meet programmatic needs, further compounding its funding imbalance.

3.4.2 Recommendation

3.4.2.1 Additional Investment in Staff Development

Given that ELAP has an established staff, with minimal opportunity for staff expansion, ELAP should work to enhance productivity of existing staff to resolve the persistent programmatic backlog. The Panel recommends the following three approaches to increasing productivity of

ELAP's existing staff: (1) Enhance training, particularly for assessors, (2) establish performance criteria to hold staff accountable, and (3) develop electronic support measures. Each of these approaches is described in more detail below.

3.4.2.1.1 Enhance training

Assessor training should be based on both quality system requirements and technical methods. Because ELAP's existing regulations are not definitive with respect to quality systems, the Panel recommends using either ISO 17025 or TNI 2009 – the two most common quality system-based standards – to improve assessor training.

All ELAP assessors should be trained to assess quality systems. They should be trained to review the quality manual, to conduct staff interviews, and to recognize behaviors that are acceptable vs. those that are unacceptable. Standard assessor training also should teach the assessor how to deal with difficult laboratory employees and how to obtain information without coming across as judgmental and arrogant. The training should include preparing for the assessment, in-briefing, debriefing, and how to write up deficiencies.

The second part of assessor training – how to assess technical methods – should start with a classroom-based component: SOP review, data review, interviewing analysts, and how to write deficiencies. It should focus on showing staff how to compare laboratory SOPs to the published methods, and how to develop questions to ask the laboratory based on the provided technical SOPs and the data.

Following the classroom portion of technical assessor training, the trainee should shadow an experienced assessor who is performing the assessment, and then perform a part of the assessment with the experienced assessor observing. ELAP could ask some of the State laboratories to use their facilities and staff as practice locations for assessor training. The experienced assessor should mentor and train the trainee. Documentation of this experience should be kept to show that the person is trained. ELAP management should require this oversight training on a regular basis (Note: ISO 17011 recommends this training be conducted every three years). If performance is inadequate and feedback from the laboratories is negative, more frequent oversight training should be done.

3.4.2.1.2 Establish performance criteria

Training is a first step, but it should be coupled with performance criteria to ensure staff accountability. As indicated in Section 3.1.2.2, ELAP should conduct periodic reviews of its staff relative to these performance criteria and then take personnel actions for staff who are not achieving the required level of performance. For the management team, ELAP should seek out performance management training to better understand how to set goals, document performance issues, and outline improvement processes.

3.4.2.1.3 Add electronic support measures

Proficiency testing database: ELAP manages data for laboratory PT studies manually, which is inefficient and may be one of the reasons that PT sample data have not been incorporated into the routine accreditation process. ELAP should acquire a commercially available database to manage all of its PT data and train ELAP staff on its use.

Remote, augmented, or distance on-site assessments: To manage the geographical expanse of the program and more efficiently utilize resources, ELAP should embrace remote, augmented, or distance technologies to conduct on-site assessments. With the right combination of technology – laptop computers with cameras and Wi-Fi access plus the appropriate software – an assessment could either be partly or completely conducted from a remote location, which could increase efficiency and lower costs. For example, instead of relying on a single assessor who travels to the site and then fails to consider FOTs or methods beyond his or her areas of expertise, a team of assessors with all the expertise necessary could participate in an assessment with just one member of the team physically on site. Although this approach comes with inherent risks because remote assessors cannot see what is being hidden or not shown, this approach also engenders mutual trust, as each laboratory must attest to the assessor that all relevant information has been disclosed. The Panel does not endorse this strategy as a solution for every review and every laboratory, but it should be treated as a viable option.

3.4.2.2 Revise the ELAP Fee Structure

ELAP is required to operate a fully fee-supported program. Although ELAP fees are among the highest in the nation, ELAP is operating at a loss and relying on general fund subsidies to continue operations. The laboratory community conveyed to the Panel that the fee structure is inequitable, demonstrating a financial bias toward certain groups.

The Panel recommends that ELAP develop a new fee structure that improves fairness of the cost burden. ELAP has already taken an initial step toward acquiring legislative authority to increase fees, but the fee structure remains undetermined. The Panel realizes that any change to the fee structure will be controversial because the laboratories that ELAP accredits vary widely in the number of accredited FOTs, in addition to being of varying sizes and differing financial resources. To mitigate these concerns, ELAP should seek stakeholder input on options for the new fee structure as part of the process of rewriting its regulations. While fees are likely to rise, the Panel believes the laboratories will realize increased value from their fees as the accreditation process improves. ELAP should consider a fee structure based on three functions: assessment, accreditation maintenance (e.g., PT evaluation, application processing, adding scope without assessments), and compliance assessments for significant issues or cause.

3.4.2.3 Incorporate Third-Party Assessors and Submission of Accreditation from Qualifying ABs

While there is a need for ELAP to provide its staff with training and resources to enhance staff productivity, the Panel acknowledges that improving staff proficiency is a gradual process. Thus, to immediately expand the resources at its disposal, ELAP should consider several approaches to link to external programs as a way of expanding its resources.

First, ELAP should consider temporarily accepting accreditation from laboratories that are accredited by other States with acceptable accreditation programs. ELAP's backlog is unacceptable, and the program does not have enough qualified staff to resolve the backlog on its own. Accepting accreditation from other recognized accreditation bodies will allow staff members to prioritize their efforts on those labs most in need of examination. The program has already begun to implement this option.

Recognition of other State programs will not relieve ELAP of the responsibility of registering these laboratories, granting them an accreditation license for specified FOTs, or addressing irregularities identified by the program clients or in the evaluation of PT samples. However, it will ease the resource burden on ELAP staff and expand the staff's access to accreditation resources.

Second, ELAP should consider authorizing laboratories to directly employ third-party assessors to assess its laboratories. This includes either qualified individual assessors or internationally recognized third-party ABs. Commercial ABs that operate under ISO 17011 are routinely evaluated to ensure compliance with this standard. Third parties have been shown to be technically competent and operate with a high degree of bias-free professionalism. Permitting the use of third-party assessors also would provide an opportunity for the State to reduce assessment and accreditation expenses by allowing laboratories to contract with third-party ABs directly. The Panel understands that the use of third-party assessors may not be suitable for all laboratories, but allowing this option will provide viable alternatives for some laboratories.

The use of qualified third-party assessors would be beneficial because it would supplement staff resources for resolving the assessment backlog, and present an alternative opportunity for laboratories unhappy with the professionalism and quality of ELAP assessors. Although use of third-party assessors is an expense for laboratories, some of them already employ assessors to obtain accreditation in other states that do not recognize California's process as equivalent to their own. Note that this recommendation can only be implemented if the third-party AB is proficient in the standard that will be used for the assessment, and if ELAP has adopted an accreditation standard as identified in Section 3.2. Because a number of third-party assessors are already operating under the TNI standard, this would be another advantage of ELAP adopting the TNI standard.

Third, the State should consider adopting as a permanent program feature the interim solutions of recognizing third-party AB laboratory accreditation and recognizing other qualifying ABs. Because ELAP would be gaining experience in the short term with using third-party ABs and with recognizing other states' programs, the outcomes from these activities could inform whether making this feature a permanent program component is appropriate.

3.5 Enhance Communication

ELAP should develop a robust, comprehensive communications plan that requires staff to undergo communication training and codifies expectations into a management system. Also, ELAP should also reinvigorate ELTAC, which serves as a vital conduit by which the laboratory community can improve ELAP's programmatic foundation.

3.5.1 Issue

ELAP has not been effective in serving its clients because of poor staff communication and outreach to stakeholders. The communications-related complaints that ELAP has received include chronically failing to respond to phone inquiries, late responses on reports, and lack of responsiveness to suggestions from ELTAC. This communications breakdown has led to frustration and has cost the program credibility among its many constituents.

3.5.2 Recommendation

To ensure ELAP is communicating effectively with its clients, ELAP should develop a communications plan. At minimum, this plan should be targeted at three groups: ELAP staff, the laboratories the ELAP accredits, and clients of the program.

3.5.2.1 ELAP Staff Communication

Developing a communications plan should be initiated by codifying expectations for staff communication into a management system (see Section 3.1), ensuring every staff member is held accountable for proper communication procedures and etiquette. Once the communications plan is developed, all ELAP staff should undergo communication training. The communications training should stress policies regarding how to answer phone calls and emails in a polite manner, as well as ensuring consistently prompt responses to laboratories and clients.

3.5.2.2 Laboratory Communication

The communications plan should create a means for ELAP to inform and engage the laboratory community. The program is expected to undergo considerable change over the next several years, so it is important that laboratories be fully informed of programmatic changes before they occur. ELAP should provide effective outreach, compliance assistance, and education that meet diverse laboratory (e.g., small, medium, large) needs. ELAP should ensure it communicates the availability of its programmatic tools and takes advantage of other opportunities for engagement, such as workshops, videos/films, webinars, and speaking engagements at conferences or symposiums. Going forward, communication should be viewed by ELAP and other parties as a two-way street, and past communications breakdowns should not be allowed to stand in the way of productive dialogue going forward.

A significant part of enhancing communication should involve training laboratories on any new requirements established by ELAP. This training could be done in person or via webinar; it should be designed around helping laboratories understand and implement key processes, such as quality systems and application completion. ELAP should become a partner in helping laboratories achieve all new requirements created by the program.

Another significant part of enhancing communication with laboratories is to reinvigorate ELTAC. Doing so will provide a valuable feedback loop by which ELAP is able to weigh and receive feedback on future program alterations. The Panel is impressed by the level of involvement that the greater laboratory community is willing to offer to help the program; the problem is that there is not yet an effective ELTAC through which this community can offer its support.

Reenergizing ELTAC will require creating a new ELTAC Charter that defines its membership, the kinds of tasks that will be assigned to ELTAC and, most importantly, the mechanism by which the ELAP management team adopts and/or responds to information provided by ELTAC. ELAP has already initiated this recommendation by working with the Stakeholder Advisory Committee to revise the ELTAC by-laws in a way that is likely to increase effectiveness of this advisory body. ELTAC's membership should continue to be predominantly laboratories, with some representation by the State agencies using ELAP.

As ELAP is developing the ELTAC Charter, the program should consider the following technical tasks as a starting point for ELTAC. Each of these tasks is important in helping to foster cross-communication with ELTAC and providing training opportunities to newly hired ELAP assessors.

- Instruct ELTAC to review the technical checklists developed and used by ELAP, and merge ELAP and ELTAC checklists to one per method or technology.
- When conducting assessor training, instruct ELTAC labs to allow practice assessments at a few of the laboratories, with no regulatory penalty associated with findings uncovered by the practice assessments.
- Allow new assessors to visit some of the ELTAC laboratories to learn about technologies that these assessors have not previously assessed. This will allow the new assessors to gain firsthand instruction on how the process is supposed to work.

3.5.2.3 Communication with Program Clients

Communication with data users is key, as the data generated by accredited laboratories are used by these clients to make regulatory decisions. During the Panel's meetings with representatives from several client organizations (see the August 2015 meeting agenda in Appendix D), the Panel noted that all of these clients seemed eager to engage with and assist ELAP. In particular, these clients expressed an interest in helping ELAP specify data needs, develop quality control criteria, and implement performance-based methods. The program clients also noted that implementing a process for accrediting performance-based methods would be helpful to them. However, it is the role of the program clients to identify all methods needed to support their programs and to communicate their needs to ELAP.

ELAP should build off these initial positive interactions by establishing a regular forum for interacting with these groups. A partnership with the program clients is critical to the success of ELAP.

CHAPTER 4: TIMELINE FOR ACTION

The recommendations made in the previous chapter have varying degrees of urgency, difficulty, and time required for completion to improve the performance and reputation of ELAP. This chapter presents a suggested timeline to assist ELAP in organizing and prioritizing its efforts to implement the Panel's recommendations. The timeline for completion of each recommendation also is presented as a chart (Table 2). In particular, this chapter addresses Charge Question #8: "Which program improvements are most urgent and can be accomplished within existing resources and authorities?"

For each recommendation, the completion date listed refers to the amount of time following finalization of this report. Additionally, each timeline rationale indicates whether a recommendation cannot be initiated pending the completion of another. It should be noted that ELAP has already begun addressing some of these recommendations, based on verbal reports provided at the Panel's March 2015, August 2015, and October 2015 meetings.

The Panel applauds ELAP for its initiative and early successes, and has noted in the sections below where progress has already been made. To continue monitoring the State's progress, the Panel recommends that ELAP holds bimonthly public webinars to brief the Panel on actions taken and next steps in the process. Planned briefings will provide the program with short-term progress incentives that several commenters felt they needed to keep moving forward, while also serving as a valuable communication tool to keep the stakeholder community aware of the many changes the program will be implementing.

The Panel's second and final report, which will be produced after the Panel returns in late 2016 or early 2017 to comprehensively gauge ELAP's progress, is expected to include additional recommendations intended to help elevate the program from adequate to exemplary. However, the Panel has not yet focused on developing these recommendations because the program first requires immediate attention to achieve adequacy. The Panel will place effort on these more forward-looking recommendations when it has determined sufficient progress has been made on items critical to ELAP's success.

4.1 Establish a management system for ELAP based on ISO/IEC 17011

Timeline rationale: ELAP should establish standards of operation for itself. ELAP's own internal procedures should define and achieve a minimum level of performance prior to implementation of recommendations that involve client and laboratory interaction.
Completion: Within six months.

4.1.1 Implement an internal ELAP auditing process

Timeline rationale: Once fully implemented, ELAP's management system should be regularly reviewed to ensure that the standard procedures are followed and that corrective action is implemented for deficiencies identified in the review.
Completion: Within one year.

4.2 Select accreditation standards for laboratories

Timeline rationale: Adopting appropriate assessment standards will help address many program inconsistencies, as well as form the foundation for assessor training and use of third-party assessors.
Completion: Within six months, ELAP should select an accreditation standard and define a timetable for regulatory adoption and full implementation.

4.2.1 Establish a training and evaluation program for ELAP's assessors

Timeline rationale: This recommendation will address the concern that not all assessors are equally trained or adequately qualified. This recommendation should be implemented after the accreditation standard is adopted, so that assessors can be trained against the established standard.
Completion: Within one year.

4.2.2 Reduce the assessor backlog by developing a program that utilizes third-party assessors

Timeline rationale: This recommendation will optimize efficiency of the assessment process, but cannot be implemented until ELAP has adopted a laboratory accreditation standard and third-party assessors can utilize the established standard.
Completion: Within one year.

4.3 Implement a structured system for communicating with stakeholders, including communications training for staff

Timeline rationale: ELAP will be undertaking many changes over the next year and should be keeping the community informed of those changes. The program also should have a mechanism for determining the effectiveness of the actions being taken.
Completion: Within three months. ELAP has already initiated this recommendation by developing a system for communicating with stakeholders. ELAP is seeking community feedback on this system as of the publication of this report. Communications training for staff remains to be implemented.

4.3.1 Reinvigorate ELTAC

Timeline rationale: ELTAC is an essential part of the ELAP's communication strategy, and can help the program decide on and implement the many changes that will take place over the next several years.
Completion: Within three months. ELAP has already initiated this recommendation by working with the Stakeholder Advisory Committee to revise the ELTAC by-laws in a manner that is likely to increase the effectiveness of this advisory body. The composition of ELTAC membership and the tasks that will be assigned to ELTAC have not been determined as of the publication of this report; however, these decisions are scheduled to be made by the end of 2015.

4.3.2 Working with ELTAC, revise method checklists so that all assessors are using the same version

Timeline rationale: Once ELTAC is reinvigorated (see Section 4.3.1), ELTAC should vet the checklists assembled by ELAP for correctness.
Completion: Within six months. ELAP has already revised the method checklists to create a single set. Vetting these checklists with ELTAC remains to be completed.

4.3.3 Training laboratories in the new ELAP standards

Timeline rationale: Once the new ELAP standards are in place (see Section 4.2), ELAP should provide training and document templates to the laboratories.
Completion: Within six months of completion of the new standards.

4.4 Accept accreditation from other recognized accreditation bodies

Timeline rationale: The Panel recognizes that the program backlog is unacceptable and that the program does not have enough staff to resolve the backlog on its own. Accepting accreditation from other recognized accreditation bodies will allow ELAP staff to focus efforts on reviewing laboratories most in need of examination.
Completion: The program has already acted on this suggestion and has been successful in reducing the State's backlog. Completion of this recommendation is now dependent on the State documenting this process to ensure consistency and transparency associated with recognition by other programs.

4.4.1 Assess whether the short-term solution of recognizing laboratory accreditation from other programs to reduce backlog should be extended as a permanent program feature

Timeline Rationale: Once ELAP has experience with this short-term solution, it should assess the outcomes and determine if making external accreditation a permanent program component is appropriate and, if so, in what form.
Completion: Within three years.

4.5 Establish procedures for enforcement actions

Timeline rationale: Enforcement requires a clear understanding and documentation of a laboratory's compliance status. Development of the procedures should take place following establishment of ELAP's management system (especially for document control), staff training, and accreditation standards. Therefore, this recommendation should not be implemented until completion of the related timeline items of establishing a management system for ELAP (see Section 4.1) and adopting accreditation standards for laboratories (see Section 4.2).
Completion: Within one year.

4.6 Ensure accreditation is based on current and relevant analytical methods

Timeline rationale: ELAP is using out-of-date methods to assess laboratories, based on a constrained statutory interpretation. This interpretation should either be broadened or the statute should be repealed/modified. This recommendation can be initiated independent of the others outlined in this chapter.
Completion: Broaden interpretation within one year and repeal/modification within two years.

4.7 Further reduce assessor backlog by (a) using commercial software for managing PT data, and (b) investigating mechanisms for remote laboratory assessments

Timeline rationale: These recommendations have the potential to further optimize efficiency of the assessment process. These recommendations can be initiated independent of the others outlined in this chapter.
Completion: Within one year.

4.8 Revise ELAP fee structure

Timeline rationale: The program is not financially self-supporting as required by its enabling legislation. The State Board has provided supplemental resources temporarily as it looks to refine a troubled program, but an equitable new fee structure that allows the program to be self-sufficient should be developed. This recommendation can be initiated independent of the others outlined in this chapter.
Completion: Within one year, although this may be iterative because it will require considerable community involvement, as fee hikes are likely to be substantial.

Table 2. Timeline for completion of recommendations

Recommendation	Complete within 6 months or less	Complete Within One Year	Complete Within Two Years	Complete Within Three Years
(4.1) Establish a management system for ELAP based on ISO/IEC 17011				
(4.1.1) Implement an internal ELAP auditing process				
(4.2) Select accreditation standards for laboratories				
(4.2.1) Establish a training and evaluation program for ELAP's assessors				
(4.2.2) Reduce the assessor backlog by developing a program that utilizes third-party assessors				
(4.3) Implement a structured system for communicating with stakeholders, including communications training for staff				
(4.3.1) Reinvigorate ELTAC				
(4.3.2) Working with ELTAC, revise method checklists so that all assessors are using the same version				
(4.3.3) Provide training on new ELAP standards following completion of Recommendation 4.2				
(4.4) Temporarily accept accreditation from other recognized accreditation bodies				
(4.4.1) Assess whether the short-term solution of recognizing laboratory accreditation from other programs to reduce backlog should be extended as a permanent program feature				
(4.5) Establish procedures for enforcement actions				
(4.6) Ensure accreditation is based on current and relevant analytical methods				

(4.7) Further reduce assessor backlog by (a) using commercial software for managing PT data, and (b) investigating mechanisms for remote laboratory assessments				
(4.8) Revise ELAP fee structure				

APPENDIX A: PANEL'S RESPONSE TO CHARGE QUESTIONS

1. What should the State's role be in the accreditation process?

ELAP is required to accredit laboratories within the State under the Safe Drinking Water Act to verify their competency for the analysis of drinking water. The certification requirement has been extended to laboratories producing data for use by other environmental programs within the State under the California Environmental Laboratory Improvement Act.

The certification process includes four sets of activities: (1) An application process where essential information regarding laboratory operations and management is provided to the State for review; (2) an on-site assessment to verify that the laboratories are conducting operations according to the methods and procedures detailed in their application and that their practices are compliant with ELAP regulations; this includes assuring that they follow the accepted analysis protocols for each field of testing for which they seek certification; (3) proficiency testing using performance evaluation samples to ensure that the laboratories are producing acceptable data; and (4) remedial and/or enforcement activities when laboratories fail to successfully navigate the assessments and/or performance evaluation samples, or when there are complaints from clients about suspect laboratory processes. The Panel believes that all of these activities are appropriate to the State and that California's role in the accreditation of laboratory competency should continue.

Several commenters at the Panel meetings suggested that ELAP is an inefficient program and that some or all of these functions could be better achieved using a third-party system. The Panel believes that it is appropriate for the State to conduct all of these activities, although it agrees with the commenters that the program could be more efficient. As such, the Panel feels the State should look for opportunities to use third parties to augment the State's activities.

Are the philosophies, objectives and scope of ELAP clearly defined? Are they appropriate?

None of these are clearly defined at the present time, and the program currently operates with little regard, beyond drinking water, to the needs of the internal programs being served. ELAP's process should be clearly defined and include uniform specifications for technical competency and quality system management to ensure that data being used to make decisions regarding human health and the environment can be used with confidence.

As such, the Panel offers the following recommended mission and vision statements for ELAP:

Mission statement: Implementation of a sustainable accreditation program to effectively evaluate the competency of organizations generating environmental and public health data of known and documented quality to meet stakeholder needs.

Vision statement: Through the effective implementation and demonstration of a sustainable program, California should become a leader in accreditation of environmental and public health programs.

Does ELAP have the capacity to support the program?

ELAP has the largest number of laboratories seeking accreditation of any state program in the nation and does not have the capacity to fulfill its mission, as evidenced by the backlog of assessments. This affects ELAP's ability to complete its mission and satisfy the objectives that should be its primary focus.

This deficiency is more than a staffing allocation issue. It reflects a need for staff accountability and the ability to maintain the discipline necessary to execute assigned responsibilities in a manner that is responsive to programmatic needs.

It also reflects a need for technical and management competency and the ability to interact with internal and external clients in a professional manner. Although these issues are challenging, they are correctable and should be of primary focus to restore the program's credibility.

2. How can California's accreditation standards be improved?

California's accreditation standards do not reflect the rigor needed to verify the competency of laboratories producing data for environmental programs within the State. The current laboratory accreditation standards utilized are insufficient. As a result, laboratories do not know what to expect when on-site assessments are conducted. The use of an appropriate standard is critical to the credibility of ELAP, eventual usability of the data generated, and general success of the program.

ELAP's current regulations focus on test method requirements, with an emphasis on quality control. Although an argument can be made that quality control is a standard of performance, it is a one-dimensional view that does not reflect the need for a comprehensive approach to quality management. Without requiring laboratories to implement a quality management system, the laboratories will not have processes in place to train future staff or to require laboratory management to plan for implementation of quality control on an ongoing basis. A method-based accreditation system without quality system requirements does not ensure the laboratory has processes for training future staff or examining quality control for trends to prevent problems from occurring.

The State should incorporate a standard that reflects a focus on quality systems and technical requirements. These two elements complement each other in a manner that underscores technical rigor and methodological quality control. Quality control should be performed using a systematic process that ensures the quality is being managed in a manner that promotes process improvement.

There are three options for resolution:

- Option 1: Creation of ELAP's own State-specific standard
- Option 2: Modification and adoption of an existing standard
- Option 3: Adoption of an existing standard

Chapter 3 explains the detailed logic of the Panel's recommendation. In brief, the Panel recommends the State adopt a single existing standard as an immediate remedy. All data produced for regulatory environmental purposes or environmental decision-making are produced

for the same broad purpose, underscoring the importance of holding accredited laboratories to a single standard. In this report, the Panel describes several state, national, and international laboratory standards that exist that could meet the State's needs.

3. What should California's approach be to recognizing accreditation by other states, national entities or private accreditation services?

The Panel envisions three possible approaches by which activities of other accreditation services can aid the California program. In addition, some laboratories conduct interstate business and need an accreditation system with mutual (state-to-state) recognition to other States. Mutual recognition demands that the requirements of the accreditation program are acceptable to these other states.

The first is for the State to accept accreditation from laboratories that are accredited by recognized accreditation programs meeting the requirements of the program specified in Question 2 above. This ensures that laboratories accredited by these states will meet the requirements of ELAP. The program's backlog is unacceptable, and the program does not have enough qualified staff to resolve the backlog on its own. Accepting accreditation from other recognized accreditation bodies will allow staff to prioritize their efforts on those labs most in need of examination. The program has already begun to implement this recommendation.

Recognition of other State programs does not relieve California of the responsibility of registering these laboratories or of granting them an accreditation license for the specific FOTs, which is inherently a State function. However, it eases the resource burden on the ELAP staff and expands the staff's access to accreditation resources, and it should be incorporated.

The second is for the State to consider authorizing laboratories to directly employ third-party assessors, including either qualified individual assessors or internationally recognized third-party accreditation bodies (ABs), to assess them. These commercial ABs operate under ISO 17011 for *Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies* to manage their accreditation processes. These ABs use the TNI 2009 standards based on ISO/IEC 17025 to assess and accredit environmental laboratories. Third parties have been shown to be technically competent and operate with a high degree of bias-free professionalism. Third-party assessors also provide an opportunity for California to reduce assessment and accreditation expenses by allowing laboratories to contract with third-party ABs directly.

The use of qualifying third parties would resolve several issues. First, it would supplement the program's staff resources and further contribute to resolving the backlog. Second, it would present an alternative opportunity for laboratories that are unhappy with the professionalism and quality of the State assessors. Use of third-party assessors would require added expense for these laboratories, but many of them already have assessments being conducted for accreditation in other states that do not recognize California's certification process. This recommendation can only be implemented if the third-party AB knows the standard that will be used for the assessment, which requires that the accreditation standard identified in response to Charge Question 2 has been established.

The third is for the State to consider whether to extend the short-term solution of recognizing laboratory accreditation from other programs (to extend the program's resources and reduce backlog) as a permanent program feature. In the short term, ELAP will be gaining experience with the use of third-party ABs and recognition of other State programs, and can use the outcomes of these activities to determine if making it a permanent program component is appropriate.

Should California rejoin NELAP?

California should eventually consider a return to NELAP, although this should not be a goal for the next several years. There are much higher-priority issues that should be resolved before a NELAP return should be considered, including the need to develop a program that is internally robust and acceptable to program clients, as well as the laboratories it certifies.

The Panel does believe that an eventual return to NELAP is warranted and will provide programmatic benefits. First, NELAP membership ensures that California will offer mutual recognition with every NELAP state and that every non-NELAP state recognizing NELAP accreditations will accept ELAP's accreditations, providing a service to laboratories that operate in multiple states. Second, NELAP membership includes regular evaluations of the ELAP program by other NELAP states to ensure compliance with the conformity assessment requirements of the NELAP standard. A return to NELAP will provide benefits that will promote the credibility of ELAP.

If the Panel recommendations are taken related to implementing ISO 17011 for ELAP accreditation management and updating the regulations for laboratory accreditation using an ISO/IEQ 17025-based program, then obtaining NELAP recognition as an AB should be easily achieved.

4. How can ELAP's laboratory inspection program be made more robust?

ELAP's laboratory accreditation program suffers from many challenges, including poor on-site assessments. ELAP's absence of a management plan and program accountability is the root cause of the unfocused approach to laboratory assessments.

ELAP should rapidly establish a management system based on ISO 17011 with performance criteria to which staff are trained and held accountable. An internal management standard is required to establish procedures that are consistently followed for conducting an accreditation program. Several additional recommendations described in Chapter 4, such as regular staff training and internal audits, will ensure these recommendations are properly carried out over the long term.

Improving ELAP's assessment program begins with defining and documenting assessment procedures. Rather than inventing a process, ELAP should employ the existing procedures routinely being used throughout the country, modifying these procedures as necessary to meet ELAP's needs. Doing so requires adoption of both internal management standards (i.e., a quality management system) and accreditation standards, as identified in the response to Charge Question 2. Both are in immediate need of improvement.

ELAP should conduct its technical assessments by focusing on the most current versions of the environmental methods used for regulatory programs in the United States. This requires that ELAP updates the methods incorporated into Title 22 Division 2 Chapter 9 Article 6 – Section 64811 of the California Code of Regulations, which have not been updated since the article's inception in 1994. The methods the program is using for technical evaluations are seriously out of date. The simplest approach to avoid being bound to outdated methods is to eliminate specific methods from the regulation, which restricts use to only those methods specified in the rules. Doing so would allow ELAP the flexibility necessary to accredit laboratories according to the methods that ELAP, its clients, and the regulatory authorities need to adequately protect California's health and environment.

The assessment process is ELAP's opportunity to develop a relationship with external clients through face-to-face contact. Improving this relationship and restoring credibility to the program demand that ELAP employ a systematic assessment process that functions smoothly, regardless of the laboratory setting.

What are the appropriate qualifications for auditor/inspector team members in each of the specialty areas that ELAP certifies laboratories?

A robust assessment procedure should be accompanied by competent staff who have the training, technical background, and discipline to conduct each assessment. Assessor qualifications are specified in the standards recommended for ELAP adoption (ISO 17011 or TNI 2009 Volume 2), and are addressed as part of the recommended assessor training. Before conducting assessments, the staff should initially attend an assessor training course. Technical competency is also required to conduct an evaluation of all FOTs being assessed. The assessor staff should have demonstrated technical competency in any FOT being assessed. Additional staff training, which is readily available from numerous sources, should include quality systems, assessment of organic and inorganic methods, professional behavior, interviewing, and assessment reporting. Training records should be documented to verify staff training.

To ensure that ELAP has the appropriate skills to conduct assessments, ELAP management should assemble an assessor team that has the knowledge to address all areas of technology being offered for accreditation. This can be supplemented with outside consultants if staff expertise is unavailable. A laboratory assessment should never be conducted by assessors who do not have the technical foundation to address all FOTs requested. Finally, the management staff should hold the assessment team accountable for professionally executing each assessment according to procedure and for processing each report in a timely manner. The performance of the assessor staff should be evaluated regularly and refocused.

5. How can California improve its proficiency testing program for quantifying laboratory quality?

California ELAP does not have a managed, systematic procedure for evaluating PT data or for initiating required action against laboratories that routinely fail PT analysis. Failure to perform this function enables incompetent laboratories to continue to produce questionable data for California environmental programs.

There are two main activities the program should focus on to improve its PT program. The first is a timely examination of the data submitted by the laboratories. ELAP has recently developed a unit responsible for examining the performance evaluation samples, and the Panel applauds the program for doing so. ELAP consists of a large number of laboratories performing PT analysis, making PT data review an arduous task. Nonetheless, the program should also look to enhance and update its recordkeeping. This can be accomplished by making use of existing software and electronic tools that facilitate tracking and evaluation of PT data, enabling the program to take necessary action on a timely basis.

The second is to connect review of the performance evaluation samples to a remedial process. Action should be taken as required under existing statutes to ensure that deficient laboratories perform corrective action before they can continue to offer analysis for failed parameters. Furthermore, assessment teams should review a laboratory's PT status before conducting the assessment, following up on any corrective actions to ensure they have been properly implemented.

Correcting the deficiencies in the PT program is a function of management accountability and discipline, which has been absent. The most straightforward approach is to develop an evaluation procedure using the suggestions above, assign staff to the evaluation unit, and make this staff accountable for timely completion of the evaluation tasks. Management should take responsibility for ensuring these steps occur.

Currently, California requires one successful PT per FOT per year. In order to move forward to meet TNI standards, PT requirements would need to change. The TNI standards require two PTs per year for the Fields of Proficiency Testing (FOPTs) in the TNI FOPT tables. TNI also requires that PT providers be accredited to its standards.

6. How can California improve its process for responding to concerns expressed by: (a) laboratories that have concerns about the certification process, or (b) clients who have concerns about the quality of a laboratory that has been certified by ELAP?

California ELAP does not have a procedure for responding to concerns expressed by any stakeholder. A well-defined, documented complaint procedure is clearly needed. The Panel heard numerous comments from both laboratories that are accredited and from clients of the program that complaints were systematically ignored, and that management did not accept any responsibility for ensuring they were addressed, which was acknowledged by the new program management team. Concerns were expressed by laboratories that complaints regarding ELAP's processes would result in repercussions against them.

The Panel recommends that ELAP implement a structured system for communicating with stakeholders and laboratories. A documented complaint process is an essential part of that communication strategy. The process is also a component of the quality management system that the Panel is recommending, and management should take responsibility for timely responses and corrective action investigations without bias.

The complaint procedure should be periodically audited internally and externally to verify it is functioning. External oversight of this procedure is essential for restoring ELAP's credibility. A

benefit of employing a quality system that follows an established conformity assessment standard is that it includes regular external reviews of the complaint procedure. This results in an open process that can be readily reviewed by all stakeholders.

7. How should ELAP plan for future programmatic, testing and management needs?

ELAP's responsiveness to future programmatic need is a vital component of its approach to client service. The primary driver of the program's responsiveness is the ability to maintain the flexibility to make adjustments as dictated by the needs of internal and external clients, and by changes in regulations.

ELAP should establish a regularly scheduled management review process to allow planning for improvement, follow-up actions, changes that could affect program management, analysis of complaints, trends of nonconformance, and corrective actions. The output of the management review will inform the allocation of budget and resources, the addition of new areas of accreditation, and actions to improve services to the laboratories. Typically, these reviews occur once per year and result in an annual plan for the coming year.

ELAP also should maintain open lines of communication with the internal programs being served. This will enable ELAP to clearly understand the future needs of the programs and make adjustments to the accreditation process to ensure that the program continues to serve that need. Making these adjustments will enable ELAP to continue to verify that laboratories are competent to produce data to changing program needs. An important component of this relationship is developing procedures that enable ELAP to offer accreditation for new methods, parameters, or compounds that have regulatory significance or that the State has indicated a desire to use that are not currently part of the State's accreditation offering, which is directly related to the charge question. This includes developing the technical understanding to assess the new offering before on-site assessments are offered. Regardless of the type of change, the implementation of such changes in response to new or updated environmental regulations should be performed in a systematic and timely manner.

Procedures also should be in place to enable ELAP to respond to the accredited laboratory community's request for new accreditation offerings. Because of the timeliness requirements that typically accompany these requests, these procedures should be sufficiently streamlined to enable the community to receive the requested accreditations quickly.

ELAP requires immediate attention to achieve adequacy, so the Panel has not yet focused on developing more forward-looking recommendations. The Panel will be returning in about a year to gauge ELAP's progress, and will provide additional recommendations for future program growth once the program had demonstrated sufficient progress in addressing the initial items appearing in this report that are critical to the program's success.

8. Which program improvements are most urgent and can be accomplished within existing resources and authorities? Which are the highest-priority, longer-term program improvements?

The most urgent programmatic needs are described in Chapter 4 of this document.

APPENDIX B: BIOGRAPHIES OF PANEL MEMBERS

Jordan Adelson

Dr. Jordan Adelson has a Ph.D. in environmental analytical chemistry, and currently serves as the Director of the Navy's Laboratory Quality and Accreditation Office (LQAO) and as the Chair of the DoD Environmental Data Quality Workgroup (EDQW). As Director of the LQAO, Dr. Adelson manages the accreditation programs for the Naval Shipyard Material Testing Laboratories and implements quality system requirements on all NAVSEA testing laboratories. As the Chair of the EDQW, Dr. Adelson oversees the DoD Environmental Laboratory Accreditation Program (DoD ELAP) and develops and recommends DoD policy with respect to environmental sampling and testing operations.

Stephen Arms

Stephen Arms is Administrator of the Florida Department of Health's Environmental Laboratory Certification Program. He is responsible for oversight of the program's quality system and day-to-day operations, and is the central point of contact for information, interpretations, and decision-making in all areas of certification for the State. He supervises staff assessors, and developed and manages contracts for provision of on-site assessment services. Mr. Arms works closely with the Florida Department of Environmental Protection to help ensure that programmatic needs are being met by having competent certified laboratories perform the testing upon which environmental decisions are made.

Mitzi Miller

Mitzi Miller is Vice President of Environmental Programs for Dade Moeller & Associates. Ms. Miller has served as a third party assessor to support State laboratory accreditation programs in Louisiana, Kansas, Florida, Minnesota, Texas and Illinois, averaging 25 audits a year. She is qualified in drinking water, non-potable and solid waste methods for chemistry, microbiology, whole effluent toxicity, and air. Ms. Miller is an expert in implementation of the data quality objectives process (DQO) and environmental data validation. She teaches classes in mass spectrometry and data interpretation, ISO 17025, internal auditing, corrective actions, TNI assessment, and data validation.

Lara Phelps

Lara Phelps (Panel Chair) is the Senior Advisor for Measurement, Modeling, Monitoring, and Laboratory Science Issues with the U.S. Environmental Protection Agency (EPA) in the Office of the Science Advisor (OSA). Over her years of government service, she has gained expertise in a wide range of areas including budgeting and program planning, quality systems, laboratory accreditation, monitoring and testing issues, proficiency testing, regulatory issues, modeling, statistical design and analysis, and innovative strategies and technologies. At present, she is not only an advisor for science issues, but is serving as the Director of the Forum on Environmental Measurements, Director for the Environmental Modeling Community of Practice, Designated Federal Official for the Environmental Laboratory Advisory Board, and Quality Assurance Manager for OSA. She has received numerous honors including the Association of Public Health Laboratories 'On the Front Line' award, four bronze medals, and service recognition in support of the Nation's response to the Deepwater Horizon Oil Spill. Lara is also involved in several professional organizations.

David Speis

David Speis is the President of Eurofins QC, Inc. in Southampton, Pennsylvania. He has extensive senior staff and management experience in commercial environmental laboratories including technical operations, quality assurance, business development, and facility general management. Mr. Speis has served on the USEPA's Environmental Laboratory Advisory Board as a member and Past Chair. He also serves as a Board member and Treasurer of The NELAC Institute (TNI) and had also served as past chair. He is a member of the Executive Committee of ACIL's Environmental Sciences Section. He served on the board of the International Association of Environmental Testing Laboratories (IAETL), and during this time assisted in development of the initial framework for National Environmental Laboratory Accreditation.

APPENDIX C: STAKEHOLDER ADVISORY COMMITTEE (SAC) MEMBERSHIP

The members of the Stakeholder Advisory Committee are:

- Socorro Baldonado, Metropolitan Water District
- Cindy Ziernicki, Helix Water District
- Andy Eaton (Chair), Eurofins Eaton Analytical, Inc.
- Bruce Godfrey, Curtis & Tompkins Labs
- Calvin Liu, Contra Costa Water District
- Terry Powers, South Tahoe Public Utility District
- Pamela Schemmer, Test America, Inc.
- Josie Tellers, City of Davis
- Anthony Gonzalez, Sacramento County Public Health Laboratory
- Allison Mackenzie, Babcock Laboratories
- Pete Ode, California Department of Fish and Wildlife

APPENDIX D: MEETING AGENDAS

STATE OF CALIFORNIA ENVIRONEMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

March 17-19, 2015
Meeting agenda

To be held at:
Southern California Coastal Water Research Project
3535 Harbor Blvd. Costa Mesa, CA 92626
Meeting will be webcast at conference.sccwrp.org

***Day 1* – Tuesday, March 17 (open to public)**

8:00	Coffee & pastries	
8:30	Welcome and introductions	Steve Weisberg SCCWRP
8:40	Purpose of the review	Cindy Forbes SWRCB
8:50	Panel charge questions	Steve Weisberg SCCWRP
9:00	Origins and goals of ELAP	Karen Larsen SWRCB
9:30	Program overview	Christine Sotelo SWRCB
10:15	Break	
10:30	Laboratory inspection program	Angela Anand SWRCB
11:00	Qualifications of the auditor/inspector team members	Christine Sotelo SWRCB
11:30	Proficiency testing program	Renee Spears SWRCB
12:00	Lunch (provided on site for $10)	
1:00	Reasons for California's dismissal from NELAP	Kristin Brown Utah Dept. of Health
1:30	Perspectives from a State not participating in NELAP	Steve Baker State of Arizona
2:00	Results from laboratory inter-calibration exercises conducted during regional monitoring in southern California	Rich Gossett Physis Laboratories
2:30	Break	

Stakeholder Perspectives

2:45	Commercial laboratory perspective	Andy Eaton

		Eurofins Eaton Analytical
3:25	Municipal laboratory perspective	David Kimbrough City of Pasadena
4:05	American Council of Independent Laboratories perspective	Judy Morgan ESC Lab Sciences
4:45	Public comments	
5:15	Adjourn for the day	
6:00	Dinner (Panel members & State personnel)	

***Day 2* – Wednesday, March 18**

8:00 Panel deliberations (panel members only)

Panel Interviews (closed session)

10:00 Interviews with ELAP inspectors
11:00 Interviews with Environmental Laboratory Technical Advisory Committee (ELTAC)
12:00 Lunch (On site - Panel members & State personnel only)
1:00 Panel deliberations (panel members only)
5:00 Adjourn for the day
6:00 Dinner (panel members only)

***Day 3* – Thursday, March 19**

8:00 Panel deliberations (panel members only)

Panel Report Out (open to public)

10:30	The Panel's Approach to the Tasks	Panel Chair
11:00	Public comment and questions for the Panel	
11:45	Summary and future meeting dates	Steve Weisberg SCCWRP
12:00	Adjourn	

STATE OF CALIFORNIA ENVIRONEMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

Informational webinar for the Panel to hear pros/cons from laboratories that added quality systems to their laboratory operations

June 23, 2015
9:00 AM - 10:30 AM

9:00
Why has the Panel requested presentations on quality systems?
Mitzi Miller
Review Panel Member
9:10
Speaker 1: Nan Thomey
Environmental Chemistry Inc.
Houston, TX
9:30
Questions from the Panel
9:40
Speaker 2: Robin Cook
Regulatory Compliance Officer
City of Daytona Beach
Daytona Beach, FL
10:00
Questions from the Panel
10:10
Questions from the audience
10:30
Adjourn

STATE OF CALIFORNIA ENVIRONEMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

August 10-13, 2015
Meeting agenda

To be held at:
CalEPA Headquarters
1001 I Street
Sacramento, CA 95812
Public portions of the meeting will be webcast via CalEPA Live Webcast by visiting this webpage:
http://www.calepa.ca.gov/broadcast/

***Day 1* – Monday, August 10 (open to public)**
Byron Sher Auditorium

9:30	Welcome and introductions	Steve Weisberg SCCWRP
9:40	Opening remarks	Lara Phelps Review Panel Chair
10:00	Actions taken in response to initial Panel recommendations	Christine Sotelo SWRCB
	a) Develop a communications strategy b) Meet with your clients c) Re-energize ELTAC d) Review/update method checklists e) Temporarily accept accreditation/evaluations from a recognized program to lessen your backlog	
11:15	Stakeholder Advisory Committee Comments on actions taken to date	Andy Eaton Eurofins Eaton Analytical
11:30	Public comments on actions taken to date	
12:00	Break	

Input requested by the Panel on issues they are considering

1:00	What is the best way for California to develop auditing standards?	
	ISO 17025 and/or TNI standards	Chris Gunning A2LA
	Develop State-specific or hybrid standards	Alfredo Sotamayor Formerly State of Wisconsin
	ELAP view for the best way to develop auditing standards	Christine Sotelo

		SWRCB
2:30	Break	
2:45	Should California use third parties to assist with inspections and/or accreditation?	
	Challenges faced by California program, auditor qualifications/training, staffing needs	Christine Sotelo SWRCB
	Alternative models for using third parties	Chris Gunning A2LA
	Arguments for a third party program	Bruce Godfrey Curtis & Tompkins
	Concerns with using third parties	David Kimbrough City of Pasadena
4:00	Comments from the Stakeholder Advisory Committee	Andy Eaton Eurofins Eaton Analytical
4:30	Public comments	
5:30	Adjourn for the day	
6:00	Dinner (Panel members & State personnel)	

***Day 2* – Tuesday, August 11**
CalEPA Room 550

8:00 Panel deliberations (panel members only)
9:00 Interviews with clients of ELAP (panel members only)

Department of Toxic Substance Control
Carol Wortham, QA Manager
John Quinn, Supervisor-Environmental Chemistry Laboratory
Bruce LaBelle, Chief-Hazardous Materials Laboratory

California Air Resources Board
Michael Werst, Branch Chief
Michael Benjamin, Chief - Monitoring and Laboratory Division

California Department of Public Health
Dave Mazzera – Former Acting Chief of the Drinking Water Program

California Department of Fish and Wildlife
Gail Cho – Quality assurance manager
Pete Ode – Laboratory Director, Water Pollution Control Laboratory
Dave Crane – Laboratory Program Manager

US Food and Drug Administration - Shellfish Sanitation
Linda Chandler – Auditor/ELAP Trainer

State Water Resources Control Board/Regional Board Programs
Bruce Burton, Assistant Deputy Director, Division of Drinking Water

11:00 Panel deliberations (panel members only)
5:00 Adjourn for the day
6:00 Dinner (panel members only)

***Day 3* – Wednesday, August 12**
CalEPA Room 2510

8:00 Panel deliberations (panel members only)

Panel Report Out (open to public)
CalEPA Coastal Hearing Room (also available through webcast)

3:00	The Panel's recommendations	Lara Phelps Panel Chair
3:30	Public comments and questions for the Panel	
4:45	Summary and future meeting dates	Steve Weisberg SCCWRP
5:00	Adjourn for the day	

***Day 4* – Thursday, August 13**
CalEPA Room 2510

8:00 Panel deliberations to consider public comments, develop assignments for preparing the Panel report, and begin report preparation (panel members only)
5:00 Adjourn

STATE OF CALIFORNIA ENVIRONEMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) EXPERT REVIEW PANEL

October 14-15, 2015
Meeting agenda

To be held at:
Southern California Coastal Water Research Project
3535 Harbor Blvd. Costa Mesa, CA 92626
Meeting will be webcast at conference.sccwrp.org

***Day 1* – Wednesday, October 14 (open to public)**

8:30	Welcome and introductions	Steve Weisberg SCCWRP
8:45	ELAP actions taken to date	Christine Sotelo SWRCB
9:15	Stakeholder Advisory Committee comments on actions taken	Andy Eaton Eurofins Eaton Analytical
9:45	Public comments on actions taken to date	
10:30	Summary of the Panel's draft report	Lara Phelps Review Panel Chair
11:00	Stakeholder Advisory Committee comments on Panel report	Andy Eaton Eurofins Eaton Analytical
11:30	Public comments and questions for the Panel	
12:00	Lunch (provided on site for $10)	
1:00	Continued public comments and questions for the Panel	
2:30	Panel deliberations to discuss public comments (panel members only)	
5:00	Adjourn for the day	
6:00	Dinner (panel members and State personnel only)	

***Day 2* – Thursday, October 15 (closed to public)**

9:00 Panel deliberations and writing to finalize report (panel members only)

5:00 Adjourn for the day

6:00 Dinner (panel members only)