State of California
Water Resources Control Board

Environmental Laboratory Accreditation Program

Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

Implementation of a Sustainable Accreditation Program Work Plan

December 21, 2015

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List of Acronyms

AB	Accrediting Body
CDPH	California Department of Public Health
DAS	Division of Administrative Services
DT	Department of Technology
DWRL	Drinking Water Radiation Laboratory
ELAP	Environmental Laboratory Accreditation Program
ELTAC	Environmental Laboratory Technical Advisory Committee
ERP	Expert Review Panel
GO-Biz	Governor's Office of Business and Economic Development
OAL	Office of Administrative Law
OCC	Office of Chief Council
OE	Office of Enforcement
OPA	Office of Public Affairs
ORPP	Office of Research, Planning and Performance
PT	Proficiency Testing
RFP	Request for Proposal
SCCWRP	Southern California Coastal Water Research Project Authority
SOP	Standard Operating Procedure
State Water Board	State Water Resources Control Board
TNI	The NELAC Institute

Executive Summary

On July 1, 2014 the California Environmental Laboratory Accreditation Program (ELAP) transitioned from the California Department of Public Health (CDPH) to the California State Water Resources Control Board's (State Water Board) - Division of Drinking Water. Shortly after, the State Water Board contracted with the Southern California Coastal Water Research Project Authority (SCCWRP) to convene an Expert Review Panel (ERP) charged with developing recommendations for improving ELAP. The ERP released its Year One Final Report in October 2015.

With new ELAP management in place, the program will reestablish itself as a respected accreditation program. Using the ERP's report and recommendations as a guide, ELAP is moving forward with a series of immediate and long-term reforms.

Work Plan

In an effort to transform ELAP into a sustainable accreditation program, ELAP management will target five key programmatic components to focus on.

- Management System
- Laboratory Accreditation Standards
- Analytical Methods
- Staff Resources
- Internal/External Communication

This work plan provides a narrative description and a schedule of the tasks and activities necessary to accomplish the scope of work.

1.0 Establish a Management System

ELAP's management team prior to the program's transfer to the State Water Board was ineffective and lacked a robust, comprehensive internal management system. Immediately selecting and implementing a management system for conducting operational functions will provide numerous benefits to ELAP and laboratories.

1.1 Adopt an Established Management System

ELAP's strategy is to implement one of the two widely respected standards as recommended by the ERP. ELAP will establish a management system under The NELAC Institute (TNI) Standard – *Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories.* This management system is built around laboratory accreditation performance criteria under which both management and staff can be trained and held accountable. ELAP will implement the management system with recommendations from the California Environmental Laboratory Technical Advisory Committee (ELTAC) on technical and scientific matters, the ERP regarding

sufficiency of Standard Operating Procedures (SOPs), and the Office of Research Planning and Performance (ORPP) on ELAP performance metrics.

		Completion Date
1.1.1	Select management system	November 2015
1.1.2	Reinvigorate ELTAC a. Release Final Draft By-Laws b. New ELTAC implemented	March 2016
1.1.3	Draft SOPs with input from ERP and ORPP a. SOPs for administrative processes b. SOPs for operational functions	April 2016
1.1.4	Develop a training program for internal ELAP processes, and an evaluation program for ELAP assessors	April 2016
1.1.5	Institute operational processes a. Document control b. Records maintenance c. Quality Assurance Manual	April 2016
1.1.6	Develop internal review program	May 2016
1.1.7	Collaborate with ORPP on performance measures	June 2016

Resources: ELAP Staff
Partners: ERP, ELTAC, ORPP

2.0 Adopt Laboratory Accreditation Standards

Auditable and enforceable laboratory accreditation standards are the foundation of a sustainable accreditation program. The assessment and accreditation processes in ELAP's current regulations are insufficient and out of date, resulting in inconsistencies when laboratories are assessed. The solution is for ELAP to enact a new standard for conducting laboratory accreditations that meets its clients' requirements and contains proper resources for both assessors and laboratories.

2.1 Enact a Standard for Conducting Laboratory Accreditations

ELAP anticipates new accreditation standards will be controversial and is likely to require adoption of new regulations. Critical to the overall success will be ELAP's ability to effectively partner with the Office of Chief Council (OCC), Office of Administrative Law (OAL), ELTAC and the entire laboratory community regulated by the standards.

Phase 1 – Select Accreditation Standard

		Completion Date
2.1.1	Research accreditation standard options and assess feasibility (pros/cons)	January 2016

		Completion Date
2.1.2	Provide stakeholder outreach and education on accreditation standard options	March 2016
2.1.3	Compile stakeholder feedback a. Analyze comments b. Draft response to comments c. Publish response to comments	April 2016
2.1.4	Select proposed accreditation standard a. Draft report on proposed accreditation standard for management review and approval b. Publicize proposed accreditation standard	May 2016

Resources: ELAP Staff
Partners: ERP, ELTAC

Phase 2 – Rulemaking

		Completion Date
2.1.5	Finalize proposed regulation package a. Regulation language b. Initial Statement of Reasons c. Std. 399 d. CEQA – Notice of Exemption e. Submit for peer review f. Revise as necessary	July 2016
2.1.6	Prepare final draft regulation package for OAL submittal a. Submit for internal review/sign off b. Submit for OCC review/sign off c. Submit for Budgets review/sign off d. Submit for EXEC review/sign off e. Submit for Cal/EPA Agency Secretary review/sign off f. Submit for Dept. of Finance review/sign off g. Prepare Form 400, etc	January 2017
2.1.7	Submit to OAL for notice of publication a. Notice published in OAL Register b. Send Notice of Proposed Rulemaking to Interested Parties (Notice published on Web) c. 45-Day public comment period followed by Public Hearing	March 2017
2.1.8	Prepare Final Statement of Reasons	May 2017

		Completion Date
2.1.9	Submit proposed regulations for State Water Board consideration a. Prepare draft agenda item and resolution b. Submit proposed regulations and draft resolution to State Water Board - Clerk c. State Water Board approves proposed regulations at monthly Board Meeting	July 2017
2.1.10	Submit Part B of Notice of Publication/Regulations Submission form to Executive Director for signature (include approved State Water Board regulations and resolution)	August 2017
2.1.11	Final OAL review a. Submit Form 400, regulations, and rulemaking file b. OAL notifies State Water Board of any identified deficiencies c. OAL notifies State Water Board of approval/disapproval of regulations	September 2017
2.1.12	OAL transmits approved regulations to the Secretary of State for filing	September 2017
2.1.13	Regulations become effective	November 2017

Resources: ELAP Staff
Partners: ELTAC, OCC, OAL

Phase 3 – Implement Accreditation Standard

		Completion Date
2.1.14	Provide stakeholders with a schedule for implementation	November 2017
2.1.15	Provide compliance assistance to stakeholders	February 2018

Resources: ELAP Staff
Partners: ELTAC

2.2 Explore Third-Party Training and Assessment Contract

As reforms are made, ELAP must provide training to ensure that all ELAP assessors have a fundamental understanding of accreditation standards, and the appropriate skills to conduct assessments of analytical methods being offered for accreditation. ELAP does not have the resources to manage an in-house training program. As a result,

ELAP will explore a contract with a third-party accrediting body (AB) to formalize a training curriculum. In addition, ELAP may include a measure in the contract to temporarily allow the selected third-party AB to assess its laboratories.

Phase 1 – Third-Party Accrediting Body Contract

		Completion Date
2.2.1	Research third-party AB training/auditing options and assess feasibility (pros/cons)	May 2016
2.2.2	Prepare State Water Board Resolution for third-party AB contract funding	June 2016
2.2.3	Submit Resolution to State Water Board for third-party AB contract funding approval	July 2016
2.2.4	Solicit and evaluate RFPs and contract packages	August 2016
2.2.5	Award contract	September 2016

Resources: ELAP Staff, Division of Administrative Services (DAS) – Contracts Unit
Partners: ELTAC, OCC

Phase 2 – Incorporate Third-Party Assessment and Training Curriculum

		Completion Date
2.2.6	Allow third-party AB to assess ELAP laboratories	January 2017
2.2.7	Formalize training curriculum with input from ELAP management	December 2019

Resources: ELAP Staff
Partners: ELTAC, OCC, Third-party AB

3.0 Ensure Relevant Analytical Methods

The list of analytical methods ELAP accredits is outdated and incorporated into current regulations (Tittle 22 Division 4 Chapter 19 Article 6 – Section 64811). Due to the extended timeline of enacting new accreditation standards, ELAP will consult with legal counsel to pursue a short-term alternative within the context of the current regulations.

3.1 Update List of Approved Analytical Methods

It is of mutual benefit to both ELAP and laboratories to use newer analytical methods. However, it is the role of the State's Regulatory Authorities to identify the methods needed to support their programs and communicate their needs to ELAP.

		Completion Date
3.1.1	Compile a comprehensive list of approved methods	June 2016
3.1.2	Update Field of Testing Worksheets	June 2016
3.1.3	Collaborate with State Agency Regulatory Partners and Data users	On-going
3.1.4	Partner with ELTAC to draft standardized peer-reviewed checklists	December 2016

Resources: ELAP Staff
Partners: State Agency regulatory partners, Data users, ELTAC, OCC

4.0 Expand Resources

A number of fundamental weaknesses that hinder ELAP's ability to achieve its mission of ensuring that the State has access to quality data can be addressed by expanding programmatic resources.

4.1 Revise Fee Structure

According to the Environmental Laboratory Improvement Act, ELAP is to be fully fee-supported. Despite collecting fees, ELAP is operating at a loss and relying on general fund subsidies to continue operations. ELAP with support from the DAS Fee Branch will develop a fair and equitable fee structure that allows ELAP to fully cover program expenditures.

Phase 1 – Draft New Fee Structure

		Completion Date
4.1.1	Draft fee structure options	January 2016
4.1.2	Conduct stakeholder workshops a. Analyze comments	February 2016
4.1.3	Provide fee structure workshop at State Water Board meeting	March 2016
4.1.4	Select new fee structure and announce to stakeholders	April 2016
4.1.5	Draft proposed fee structure regulations	April 2016

Resources: ELAP Staff
Partners: ELTAC, OCC, DAS Fee Branch

Phase 2 – Adopt New Fee Structure

		Completion Date
4.1.6	Submit proposed fee structure for State Water Board consideration a. Prepare draft agenda item and resolution b. Submit proposed fee structure regulations and draft resolution to State Water Board - Clerk c. State Water Board approves proposed fee structure regulations	May 2016
4.1.7	Rollout new fee invoices	July 2016

Resources: ELAP Staff
Partners: ELTAC, OCC, DAS Fee Branch

4.2 Establish Enforcement Unit

Enforcement is a necessary function of accreditation bodies to ensure that deficient laboratories perform corrective action before continuing to offer services. ELAP will work in conjunction with the Office of Enforcement (OE) to establish a robust enforcement structure aimed at ensuring laboratories are competent to conduct analytical methods for which they are certified for.

		Completion Date
4.2.1	Develop Enforcement Unit staff a. Train on ELAP enforcement authority b. Attend supplemental enforcement training 1. Cal-EPA Basic Inspection 2. Environmental Crimes Training	On-going

		Completion Date
4.2.2	Establish enforcement procedures a. Draft SOPs for 1. PT follow up 2. Comprehensive on-site assessments of laboratories with timely and objective reporting 3. Timely and objective review of laboratory corrective action plans 4. Follow-up assessments 5. Assessment of complaints and response 6. Surveillance/unannounced compliance assessment b. Create checklist for targeted on-site investigations c. Draft template letters for enforcement and citation	June 2016
4.2.3	Establish procedures and authority for issuing violations a. Administrative fines/citation b. Decertification of specific methods/FOTs c. Complete decertification d. Criminal charges	June 2016

Resources: ELAP Staff
Partners: ELTAC, OE

4.3 Establish Proficiency Testing Unit

ELAP lacks a systematic process for reviewing proficiency testing (PT) sample results. ELAP will focus on improving its PT program through the establishment of a PT Unit, where staff will be responsible for timely examination of PT data, and connecting review of PT samples to a remedial process. To assist in tracking and evaluation of PT data, ELAP will work with the Division of Information Technology (DIT) to identify and incorporate a commercially available database.

		Completion Date
4.3.1	Draft SOPs for: a. Evaluating PT samples b. Addressing nonconformities c. Verification of corrective action and enforcement authority	December 2015
4.3.2	Establish PT Unit staff performance metrics	December 2015
4.3.3	Assign staff to the PT Unit	December 2015

		Completion Date
4.3.4	Partner with DT to research database options a. Define project scope b. Business analysis c. Solution development d. Project readiness and approval	December 2018

Resources: ELAP Staff
Partners: DIT

4.4 Invest in Staff Development

ELAP has a diverse set of established personnel, with a subset of recognized high performing assessors. However, the program is plagued by a lack of an on-going training program, poor staff accountability, and out-of-date support measures; which are all negatively impacting staff productivity. ELAP management recognizes these limitations and is committed to investing in staff development through partnerships with other State agencies, including CDPH Drinking Water Radiation Laboratory (DWRL), State Water Board Training Office, and ORPP. In addition, the ELAP management team will invest in training which focuses on performance management by pursuing participation in the Governor's Office of Business and Economic Development (GO-Biz) Lean 6-Sigma Program. The program addresses process-based issues that cause delays in services to both internal and external stakeholders. Over a 6-month period, participants receive training on complex analytical and statistical tools that identify waste and inefficiencies in processes.

		Completion Date
4.1.1	Utilize State Water Board Training Office and Academy for targeted administrative training	On-going
4.4.2	Utilize potential third-party AB contract to train staff	January 2017
4.4.3	Begin 6-Sigma Training/Initiate participation in Lean 6-Sigma program	February 2016
4.4.4	Establish staff performance metrics	May 2016
4.4.5	Implement periodic staff performance reviews	On-going (annually)
4.4.6	Assign performance management training to ELAP management team	April 2016
4.4.7	Institute rotating ELAP mock-assessments at ELTAC laboratories	On-going (start March 2016)
4.4.8	Schedule routine educational visits with ELTAC laboratories	On-going (start March 2016)

Resources: ELAP Staff
Partners: ELTAC, OCC, DAS, ORPP, CDPH-DWRL, GO-Biz

4.5 Reduce Assessor Backlog

Improving ELAP's current staff productivity is a gradual process. To immediately expand the resources at its disposal, ELAP will link to external programs in an effort to reduce the assessment backlog.

		Completion Date
4.5.1	Implement Reciprocity Agreements with equivalent States and TNI/National Environmental Laboratory Accreditation Program recognition	April 2015
4.5.2	Temporarily authorize third-party accreditation using third-party AB contract	TBD
4.5.3	Utilize tablets or other mobile technology to expedite accreditation	TBD

Resources: ELAP Staff
Partners: Third-party AB

5.0 Enhance Communication

ELAP has been less than effective in serving its clients, in part because of poor staff communication and outreach to stakeholders. ELAP has developed a Strategic Communications Action Plan to overhaul its communication strategy.

5.1 Develop Communication Plan for ELAP Staff

In order for ELAP's overall communication strategy to be successful, ELAP must first reform its own internal staff communication plan. The focus will be on proper communication procedures and etiquette.

		Completion Date
5.1.1	Establish expectations for staff communication a. Responsiveness b. Clarity c. Consistency	On-going (annually)
5.1.2	Provide ELAP staff communication training	On-going (annually)
5.1.3	Reinvigorate Staff meetings a. Auditor Roundtable b. All-staff meetings c. Team building events	On-going

Resources: ELAP Staff
Partners: ORPP

5.2 Develop Communication Plan for Laboratory Community

As ELAP undergoes considerable reforms, it is important that the laboratory community be fully informed of programmatic changes. It is equally important that ELAP provide continuous outreach, compliance assistance, and education that meet diverse laboratory (e.g., small, medium, large) needs. ELAP will partner with the Office of Public Affairs (OPA) in its efforts to inform and engage the laboratory community.

		Completion Date
5.2.1	Train laboratories on new requirements established by ELAP a. Electronic applications b. New monitoring practices c. Broadened criteria for certification	On-going
5.2.2	Outreach a. Email messages b. Meet and greet events c. Surveys d. Postcards/newsletter e. Broadcast ELAP produced f. Videos/films g. Promote various laboratory accreditation conferences and workshops	On-going
5.2.3	Host/attend routine technical workshops/webinars a. Compliance assistance b. Enforcement activities c. ELTAC meetings	On-going

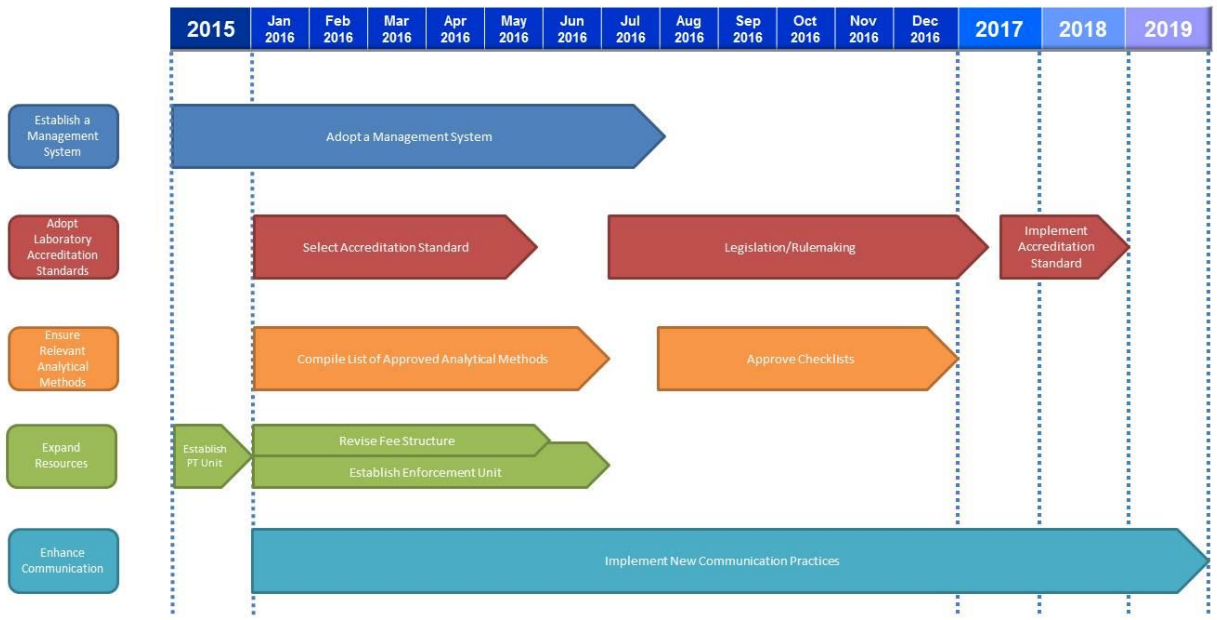
Resources: ELAP Staff
Partners: ELTAC, OPA

5.3 Develop Communication Plan for State Agency Data Users

Communication with data users is key, as the data generated by accredited laboratories are used by these clients to make regulatory decisions. In addition, there is a notable eagerness within ELAP's State Agency partner organizations to engage with and assist ELAP. Therefore, it is essential that ELAP establish an effective communication plan with these State Agency partners.

		Completion Date
5.3.1	Schedule meetings with State Agency Regulatory Partners a. Introductory b. Inter-agency workgroups c. Region 9 US EPA meetings	On-going

		Completion Date
5.3.2	Hold routine technical workshops/webinars a. State assessor's forum	On-going

Resources: ELAP Staff
Partners: State Agency Regulatory Partners, Data users

Appendix A: Work Plan Timeline