Harnessing the Challenges in Reinventing the California Laboratory Accreditation Program - The Expert Panel Perspective

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ACKNOWLEDGEMENTS



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HIGHLIGHTS

- Background
- Executive Summary
- Programmatic Problems
- Recommendations
- Timetable
- Wrap-up



http://www.sccwrp.org/ELAP

BACKGROUND

- Expert Review Panel established to perform a programmatic review of the California (CA) Environmental Laboratory Accreditation Program (ELAP)
- Stakeholder Advisory Committee aided in the Expert Review Panel's selection, charge, and meeting agendas
- Panel Process:
 - ► Four Face-to-Face Meetings over Two-years
 - ► Two Reports:
 - ▶ Findings and Recommendations Year One Report
 - ▶ Evaluation of ELAP to Recommendations Year Two Report

CHARGE QUESTIONS

- 1. What should State's role be in the accreditation process?
- 2. How can CA accreditation standards be improved?
- 3. What should CA's approach be to recognition of other accreditation programs?
- 4. How can CA's laboratory inspection program be more robust?
- 5. How can CA improve its proficiency testing program?
- 6. How can CA improve its process for responding to concerns?
- 7. How should CA plan for future needs?
- 8. Which program improvements are most urgent?

EXECUTIVE SUMMARY

- California's Environmental Laboratory Accreditation Program (ELAP) is in trouble
- Credibility The quality of being trusted and believed in
- California ELAP lacks credibility with:
 - ► Clients,
 - Laboratories, and
 - Other states



PROGRAMMATIC DEFICIENCIES

- No management system
- No training program or accountability for staff
- Out-of-date analytical methods
- ▶ No stakeholder communication

RECOMMENDATIONS

- Establish a management system
- Adopt accreditation standards
- Ensure use of relevant methods
- Expand resources
- ► Enhance communication

MANAGEMENT SYSTEM

- Programmatic Problem
 - Lack of a robust, comprehensive internal managment system is at the root of several chronic problems
 - ► There are no employee expectations, no performance metrics, no defined responsibilities
- Recommendation
 - Adopt a widely respected standard and establish a management structure that contains at a minimum
 - ▶ Operational processes to carry out ELAP's functions
 - ▶ Internal reviews to assess performance
 - Numerous benefits with well defined roles, processes, transparency, consistency, and support tools among others

LABORATORY ACCREDITATION STANDARDS

- Programmatic Problem
 - ► Lack rigor to verify competency of laboratories
 - Insufficient staff qualifications to objectively assess all methods
 - Lack comprehensive approach to quality management
- Recommended options
 - Create ELAP's own State-specific standard
 - Modify and adopt an existing standard
 - Adopt an existing standard

RELEVANT ANALYTICAL METHODS

- Programmatic Problem
 - ▶ The list of analytical methods for which ELAP accredits is outdated
- Recommendation
 - ▶ Ideal solution Eliminate references to specific analytical methods in regulations
 - ► Short-term solution Subsections of Title 22 enable ELAP to use alternate methods as ELAP deems appropriate
 - ► Fall-back solution Update methods ASAP, if prescriptive language cannot be removed or modified

RESOURCES

- Programmatic Problem
 - Staff are unqualified to meet the demands of the program and inadequate fees have made the program unsustainable
- Recommendations
 - Invest in staff development including enhanced training, established performance criteria, and electronic support tools
 - Revise fee structure
 - Incorporate use of expanded resources to accept accreditation by other State programs and allowing laboratories to directly contract with third-party assessors to assess them

COMMUNICATION

- Programmatic Problem
 - ► ELAP has not been effectively serving its clients because of poor communication and outreach
- Recommendation
 - Develop a communication plan
 - Reinvigorate the Environmental Laboratory Technical Advisory Committee (ELTAC)
 - Regular interaction with program clients

TIMETABLE

- Complete within 6 months or less:
 - Establish a management system for ELAP based on ISO/IEC 17011 (4.1)
 - ▶ Implement a structured system for communication with stakeholders, including communications training for staff (4.3)
 - Reinvigorate the ELTAC (4.3.1)
 - ▶ Working with ELTAC, revise method checklists so that all assessors are using the same version (4.3.2)
 - Provide training on new ELAP standards following completion of Recommendation 4.2 (4.3.3)
 - ▶ Temporarily accept accreditation from other recognized accreditation bodies (4.4)

TIMETABLE (continued)

- Complete within one year:
 - Adopt accreditation standards for laboratories (4.2)
 - Establish a training and evaluation program for ELAP's assessors (4.2.1)
 - ▶ Reduce the assessor backlog by developing a program that utilizes thirdparty assessors (4.2.2)
 - Establish procedures for enforcement actions (4.5)
 - Ensure accreditation is based on current and relevant analytical methods (4.6)
 - Further reduce assessor backlog by (a) using commercial software for managing PT data and (b) investigating mechanisms for remote laboratory assessments (4.7)
 - Revise ELAP fee structure (4.8)

TIMETABLE (continued)

- Complete within two years:
 - ▶ Establish an internal ELAP auditing process (4.1.1)
 - Provide training on new ELAP standards following completion of Recommendation 4.2 (4.3.3)
 - ► Ensure accreditation is based on current and relevant analytical methods (4.6)
- Complete within three years:
 - Assess whether the short-term solution of recognizing laboratory accreditation from other programs to reduce backlog should be extended as a permanent program feature (4.4.1)

SUMMARY

- ELAP was not achieving its mission, but ELAP's new management team understand need for comprehensive overhaul to program
- State should support ELAP's efforts and hold ELAP accountable
- Panel believes ELAP can:
 - Regain credibility
 - Achieve financial sustainability
 - Operate accreditation process State and stakeholders support
 - Reliably ensure environmental and public health data used are of known and documented quality

QUESTIONS



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