



The California ELAP Expert Review Panel: Summary of Draft Report

OCTOBER 14, 2015

ACKNOWLEDGEMENTS

Certificate of Appreciation

Presented in appreciation of

With sincere thanks for

Awarded On _____ / _____ / _____



HIGHLIGHTS

- ▶ Executive Summary
- ▶ Charge Questions
 1. Role in Accreditation Process
 2. Improve Accreditation Standards
 3. Recognition of Other Accreditation Programs
 4. Robust Laboratory Assessment Program
 5. Improve Proficiency Testing Program
 6. Response to Concerns
 7. Future Needs
 8. Urgent Program Improvements
- ▶ Next Steps



EXECUTIVE SUMMARY

- ▶ Credibility – The quality of being trusted and believed in
- ▶ California ELAP lacks credibility with:
 - ▶ Clients,
 - ▶ Laboratories, and
 - ▶ Other states

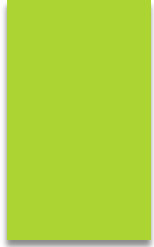
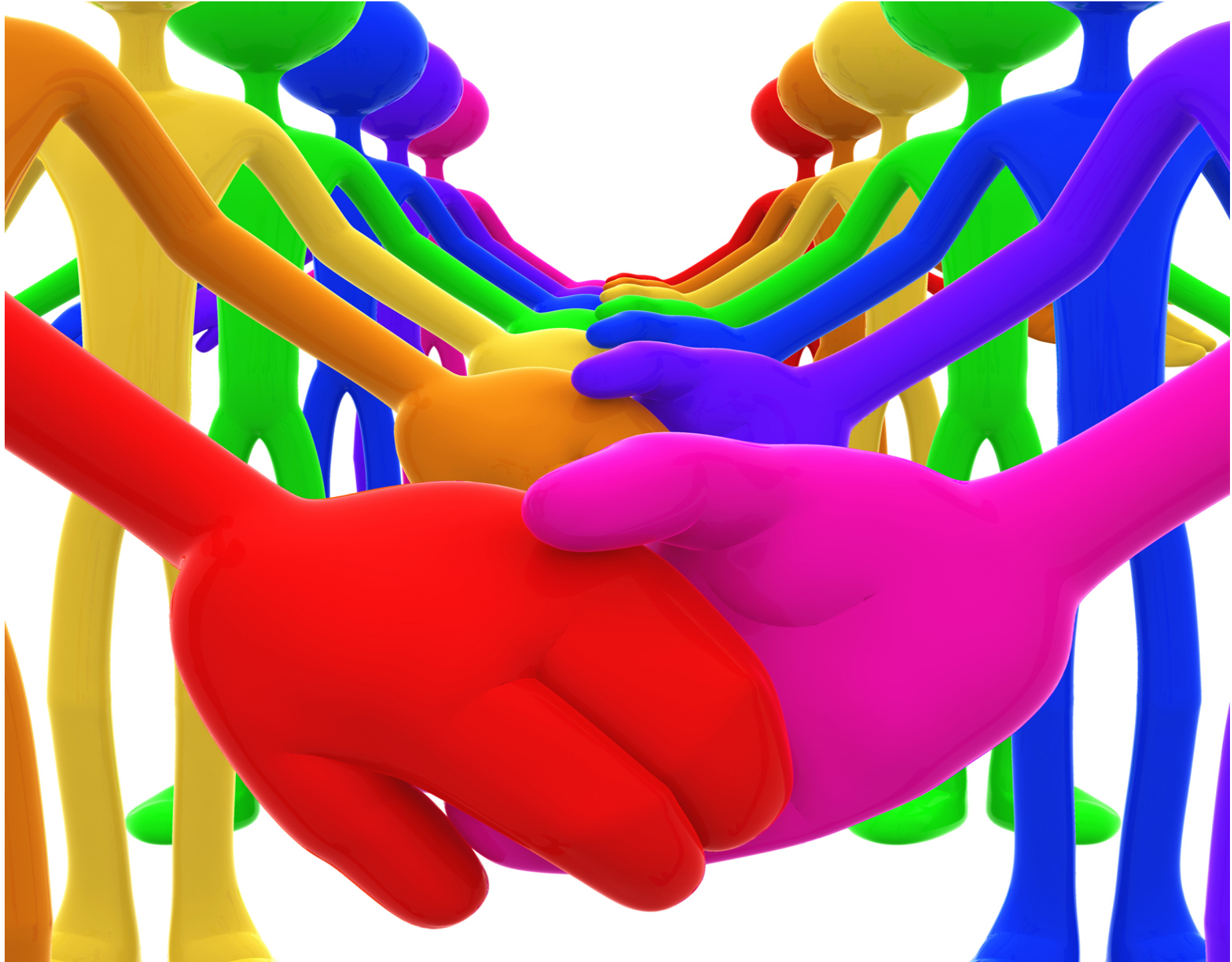


PROGRAMMATIC DEFICIENCIES

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 The list of analytical methods for which ELAP accredits laboratories is outdated;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.

RECOMMENDATIONS

- ▶ Establish a management system
- ▶ Adopt laboratory accreditation standards
- ▶ Ensure relevant analytical methods
- ▶ Expand resources
- ▶ Enhance communication



ROLE IN ACCREDITATION PROCESS

- ▶ Accreditation process:
 - ▶ Application process
 - ▶ On-site assessment
 - ▶ Proficiency testing
 - ▶ Remedial and/or enforcement activities
- ▶ Recommendation:
 - ▶ Appropriate to the State and California's role in the accreditation of laboratory competency should continue
 - ▶ Program could be more efficient and should look for opportunities to use third-parties to augment the State's activities

ROLE IN ACCREDITATION PROCESS_(cont.)

- ▶ Philosophies, Objectives, and Scope
 - ▶ Not presently defined or with regard beyond drinking water
 - ▶ Recommendation – Mission statement and vision statement
- ▶ Program Capacity
 - ▶ ELAP does not have the capacity to fulfill its mission:
 - ▶ More than staffing allocation
 - ▶ Need for accountability
 - ▶ Need for technical and management competency
 - ▶ Recommendation – Challenging, but correctable and should be primary focus to restore program's credibility

IMPROVE ACCREDITATION STANDARDS

- ▶ California's accreditation standards:
 - ▶ Lacks rigor to verify competency of laboratories
 - ▶ Insufficient 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

RECOGNITION OF OTHER ACCREDITATION PROGRAMS

- ▶ Accept accreditation from laboratories accredited by recognized accreditation programs with program requirements specified above
- ▶ Consider authorizing laboratories to directly employ third-party assessors to assess them
 - ▶ Qualified individual assessors
 - ▶ Internationally recognized third-party accreditation bodies
- ▶ Consider extending short-term solution of recognizing laboratory accreditation from other programs permanently
- ▶ Rejoin NELAP
 - ▶ Eventually beneficial, but not immediate goal

ROBUST LABORATORY ASSESSMENT PROGRAM

- ▶ ELAP's program is challenged:
 - ▶ Poor on-site assessments
 - ▶ Absence of a management plan
 - ▶ Absence of program accountability
- ▶ Recommended program improvement:
 - ▶ Establish management system with performance criteria
 - ▶ Define and document assessment procedures
 - ▶ Conduct assessments based on current environmental methods
- ▶ Auditor Qualifications
 - ▶ Competent staff with training, technical background, and discipline (ISO 17011)

IMPROVE PROFICIENCY TESTING PROGRAM

- ▶ ELAP lacks a managed, systematic procedure for evaluating PT data or taking action against failed PT analysis
- ▶ Recommend two main activities:
 - ▶ Timely examination of data submitted by laboratories
 - ▶ Connect review of PT to remedial process

RESPONSE TO CONCERNS

- ▶ ELAP does not have a procedure for responding to concerns from any stakeholder
- ▶ Recommendations:
 - ▶ Implement a structured system for communicating with stakeholders and laboratories
 - ▶ Document complaint process, which is a component of recommended quality management system
 - ▶ Response should be timely with unbiased corrective action investigations

FUTURE NEEDS

- ▶ ELAP's responsiveness to future programmatic need is vital
- ▶ ELAP should establish a management review process
- ▶ ELAP should maintain open lines of communication
- ▶ ELAP should be responsive to accredited laboratory needs
- ▶ ELAP immediately needs to achieve adequacy – before moving forward

URGENT PROGRAM IMPROVEMENTS

- ▶ Complete within 6 months or less:
 - ▶ 4.1 – Establish a management system for ELAP based on ISO/IEC 17011
 - ▶ 4.3 – Implement a structured system for communication 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

URGENT PROGRAM IMPROVEMENTS (cont.)

- ▶ Complete within one year:
 - ▶ 4.2 – Adopt 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
 - ▶ 4.5 – 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

URGENT PROGRAM IMPROVEMENTS (cont.)

- ▶ Complete within two years:
 - ▶ 4.1.1 – Establish an internal ELAP auditing process
 - ▶ 4.3.3 – Provide training on new ELAP standards following completion of Recommendation 4.2
 - ▶ 4.6 – Ensure accreditation is based on current and relevant analytical methods

- ▶ Complete within three years:
 - ▶ 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

SUMMARY

- ▶ ELAP is not presently 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

NEXT STEPS

- ▶ First Report Released – October 22, 2015
- ▶ Formal Report Presentation – November 4, 2015
- ▶ Fourth Meeting – Costa Mesa, CA; Late 2016
- ▶ Final Second Report Release – Target Early 2017

QUESTIONS???

