

Expert Review Panel Report

Released October 2015, the report recommended ELAP select a laboratory accreditation standard within 6 months that includes a quality management system. The report is available at www.sccwrp.org/elap.

A quality management system (QMS) is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.

Standard Options Considered

- Add U.S. EPA QMS language to current regulations
- Use another state
- Create a new, California-specific
- Use International Organization for Standardization (ISO) 17025
- Use The NELAC Institute (TNI)

ELAP's Preliminary Recommendation

Develop regulations incorporating *The NELAC Institute (TNI) Standard, Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016)*, considering revisions to select sections identified to have the least value by the laboratory community and develop a compliance assistance program for laboratories.

How did we arrive at our recommendation?

ELAP established two program advisory committees and asked for advice on the three elements of an accreditation standard.

- State Agency Partner Committee
- Environmental Laboratory Technical Advisory Committee

Who is the State Agency Partner Committee (SAPC)?

ELAP's charge is to accredit laboratories to submit data for regulatory purposes. This committee is made up of representatives from the regulatory agencies. They advise ELAP of their agency needs. They are ELAP's primary clients.

California Regulatory Agency
Department of Public Health
Department of Toxic Substances Control
State Water Resources Control Board
Department of Pesticide Regulation
Department of Fish and Wildlife
Division of Drinking Water
Regional Water Quality Control Boards

Who is Environmental Laboratory Technical Advisory Committee (ELTAC)?

ELTAC's voting members are stakeholders who represent ELAP's diverse laboratory community, report out to their constituency, and advise ELAP on issues that affect certified laboratories.

Voting Member	Representing
Mindy Boele	NorCal – California Water Environment Assn. (CWEA)
Jill Brodt	Small, NorCal commercial labs
Stephen Clark	Specialty labs
Ronald Coss	SoCal – California Water Environment Assn. (CWEA)
Huy Do	California Association of Sanitation Agencies (CASA)
Andy Eaton (Chair)	Large, multistate commercial labs
Miriam Ghabour	Large municipal labs
Bruce Godfrey	American Council of Independent Labs (ACIL)
Anthony Gonzalez	CA Assn. of Public Health Lab Directors (CAPHLD)
Rich Gossett	Commercial and academic labs
David Kimbrough	Small, SoCal municipal labs
Mark Koekemoer	Small, NorCal municipal labs
Allison Mackenzie	Medium/large CA commercial labs
Gilda Neshvad	Hazardous waste labs

What is a "Laboratory Accreditation Standard"?

A set of requirements laboratories must meet to be accredited.

Three elements:

- ✓ 1. Technical – Analytical test method procedures and QA/QC
- ✓ 2. Monitoring – Required analysis of blind samples (Proficiency Testing)
- ✓ 3. Management – Documented laboratory management practices

Committee Recommendations

On the three elements of a laboratory accreditation standard, the advisory committees recommended:

1. Technical Requirement: Both committees agree. Require the procedures specified in an approved analytical method.
2. Monitoring Requirement: Both committees agree. Require 1 Proficiency Test per year.
3. Management Requirement: Both committees agree add a QMS to the requirement, but disagree on which one.
 - SAPC: The 2016 TNI Standard.
 - ELTAC: Incorporate US EPA requirements (7 votes); TNI (6 votes)

How did ELAP Decide on TNI Standard?

- State Agency Partners want it
- Consensus-based
- Ready for adoption NOW
- Training and implementation resources are available NOW
- Legally defensible documentation requirements
- Regularly updated

How can we “revise” the TNI Standard?

- Not require sections
- Adjust requirements in sections
- Delay implementation

How will we decide on revisions?

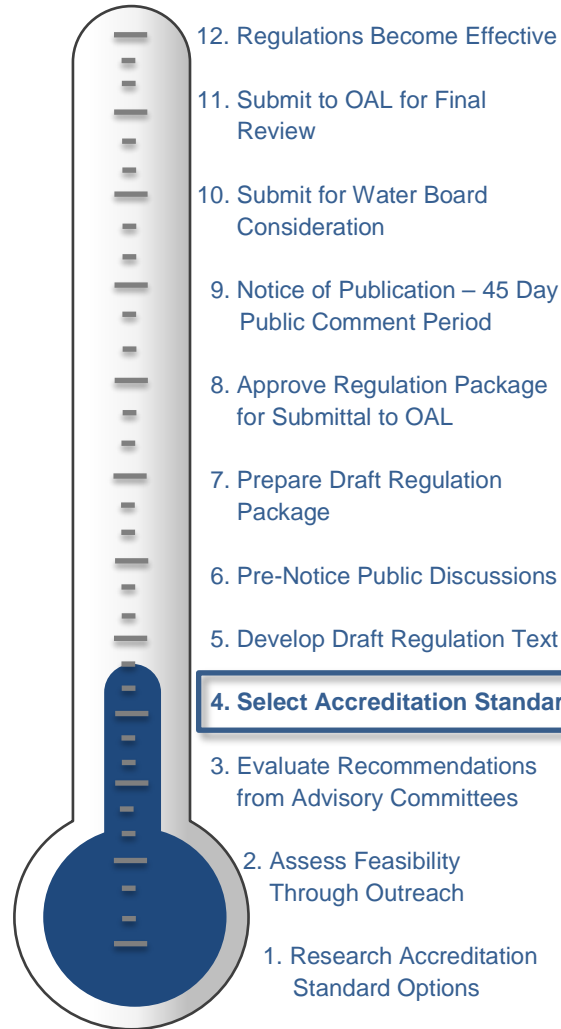
1. ELTAC is identifying sections for consideration.
2. Verify with State Agency Partners that revisions do not lessen the value of certification.

Concerns about the TNI Standard

- The document must be purchased.
 - We have negotiated preferred rates for California laboratories.
- Documentation requirements are unnecessary.
 - We disagree, as do the State Agency Partners.
 - Still, we are open to revisions.
- Not relevant to small laboratories.
 - We disagree. Small laboratories are most vulnerable to inconsistencies when turnover occurs.
 - We’ve heard testimony to the contrary from small laboratories that have implemented TNI.
- The cost could cause laboratory closure.
 - Possibly, but affect is uncertain.
 - We are committed to helping minimize the cost by providing compliance assistance:
 - Free templates
 - Free training
 - Free laboratory assistance
 - Extended compliance date

Regulations Readiness Level

A snapshot of where ELAP is at in the regulations development process:



Contact ELAP

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State Water Resources Control Board Public Workshop

Environmental Laboratory Accreditation Program (ELAP) Regulations Development and Preliminary Recommendation for Laboratory Accreditation Standard

October 6, 2016 - 9am – Noon

Agenda

1. Christine Sotelo, ELAP
2. Bruce LaBelle, State Agency Partner Committee
3. Andy Eaton, Environmental Laboratory Technical Advisory Committee
4. David Kimbrough, Coalition of Accredited Laboratories
5. Robert Brownwood, Division of Drinking Water
6. Public Comment Period



Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD