

BACWA Laboratory Committee Meeting

*ELAP Management and
Leadership Team
February 9, 2021*



ELAP Team

- Christine Sotelo – ELAP Chief
- Dr. Christopher Ryan – Monitoring Unit Chief
- Maria Friedman – On-Site Assessment Unit Chief
- Alexandria Turner – Program Development, Research, and Enforcement Unit Chief
- Jacob Oaxaca – Senior technical advisor and regulatory agency liaison
- Katelyn Hilty, Administrative and communications lead

New ELAP Regulations

- 2015 to 2019 – Multi-year stakeholder collaboration
- October 2019 – Started the formal rulemaking process
- May 2020 – Water Board adopted the new regulations
- September 2020 – Submitted to Office of Administrative Law
- January 2021 – Effective date

Summary of Changes

- Modified existing program operations
- Eliminated outdated requirements
- Replaced the state-created accreditation standards with the 2016 TNI Standard, with two California-specific exceptions

Review of New Regulations

Article	Title
1	Definitions
2	Accreditation Requirements
3	Types of Accreditation
4	Types of Laboratories
5	Laboratory Personnel, Facilities, and Equipment
6	Notification, Reporting, Records Retention, Change of Technical Manager or Ownership, and Trade Secrets
7	Reasons for Denial, Citation, Suspension, or Revocation

The “Decoder”

Article 1 – Definitions

- Terms or phrases that are pertinent to the content of the proposed regulations
- Other relevant terms and definitions are in the 2016 TNI Standard
- If a term is defined differently or does not exist in 2016 TNI Standard, then the definitions are included in this section.

What are the Core Requirements for Accreditation?

Article 2 – Accreditation Requirements

- Application requirements
- Quality system requirements
- Proficiency Testing requirements
- On-site assessment requirements

When do I Need to Apply?

Article 3 – Types of Accreditation

- How to renew accreditation
- How to amend accreditation

What if I Have More Than One Lab?

Article 4 – Types of Laboratories

- Main laboratory
- Satellite laboratory
- Mobile laboratory

What are the Roles and Responsibilities?

Article 5 – Laboratory Personnel, Facilities, and Equipment

- Personnel qualifications
- General facility and instrumentation requirements

The “Catch-All”

Article 6 – Notification, Reporting, Records Retention, Change of Technical Manager or Ownership, and Trade Secrets

- Drinking water notification requirements and report formatting
- Subcontracting
- Control of records and records retention
- Change in Technical Manager

What Not to Do

Article 7 – Reasons for Denial, Citation, Suspension, or Revocation

- Denial of accreditation
- Citations
- Suspension or revocation
- How to re-obtain accreditation

Supporting Laboratories

- Cultivating partnerships
- Evolving compliance assistance
- Roadmap to Accreditation
 - Transition appointments
 - Providing tools and training

Roadmap to Accreditation

Certificate expires in 2020	Certificate expires in 2021	Certificate expires in 2022	Certificate expires in 2023	Certificate expires in 2024 or beyond
<ul style="list-style-type: none">• No changes to application requirements• 2016 TNI Standard not required• On-site assessment report and corrective action plan required in application if certificate expires after Jan. 1, 2021, but ELAP is waiving this requirement• Current PT requirements in place• Interim certs expiring in 2020 do not require an application. ELAP will extend your cert until 2021, at which time you must apply and meet the requirements in the 2021 column to the right	<ul style="list-style-type: none">• Changes to PT process if a result is scored "not acceptable" by vendor• 2016 TNI Standard not required• On-site assessment report and corrective action plan required in application, but ELAP is waiving this requirement• Interim certs expiring in 2021 do not require an application. ELAP will extend your cert until 2022, at which time you must apply and meet the requirements in the 2022 column to the right	<ul style="list-style-type: none">• All applications require On-Site Assessment Report and approved Corrective Action Plan• 2016 TNI Standard not required• Changes to PT process if a result is scored "not acceptable" by vendor	<ul style="list-style-type: none">• All applications require On-Site Assessment Report and approved Corrective Action Plan• 2016 TNI Standard not required• Changes to PT process if a result is scored "not acceptable" by vendor	<ul style="list-style-type: none">• All new application requirements are in place• 2016 TNI Standard required for all• On-site assessment report and approved corrective action plan required with all applications• Changes to PT process if a result is scored "not acceptable" by vendor



TNI Standard



Frequently Asked
Questions

ISO 9000:2015 (E).2.4.2.

“Every organization has quality management activities, whether they have been formally planned or not. An organizational quality standard provides guidance on how to develop a formal system to manage these activities”

2016 TNI Standard

- Start with your current quality assurance system
- Three-year implementation period
 - Allows for a phased approach
- Utilize resources

FAQ's



Application Questions

Question

When is my renewal application package due?

Answer

Renewal applications are due 90 days prior to expiration of the laboratory's certificate.

Application Questions

Question

What do I need to include with my renewal application?

Answer

1. Application (laboratory info)
2. Copy of QAM
3. FOA tables
4. Acceptable PTs for each FOA requested
5. Copy of OSAR and approved CAP (NEW!)

Application Questions

Question

Why can't I add a field of accreditation during my laboratory's renewal?

Answer

To streamline application processing and avoid delays, the renewal application process is separated from the amendment application process.

Application Questions

Question

My laboratory wants to use a specific method that is not listed in ELAP's Field of Accreditation offerings. How can I get it added to my laboratory's scope of accreditation?

Answer

Fields of Accreditation are determined by the needs of the State Regulatory Agencies. Contact your regulatory agency to request ELAP to add the method to our offerings.

Application Questions

Question

How far in advance should I schedule my On-Site Assessment (OSA)?

Answer

At least 6 months before submitting a renewal application.

Note: The OSA can be completed anytime within the two years prior to the expiration date of accreditation.

Application Questions

Question

If my lab is ELAP accredited, does that mean the lab is TNI accredited (i.e. is ELAP accreditation equivalent to TNI accreditation)?

Answer

No. ELAP is a State accreditation body and not a TNI recognized accreditation body.

QMS Questions

Question

What qualifications does the Quality Manager (QM) need to have?

Answer

- Be a member of staff with documented training or experience in QA/QC procedures and the lab's quality system.
- Where staffing is limited, the QM may be the same person as the Technical Manager.

QMS Questions

Question

What is required for the annual ethics training?

Answer

The scope is determined by the laboratory. You may use an external agent or company or may develop your own ethics training. The laboratory must maintain records of the training agenda, materials and attendance.

QMS Questions

Question

Does the Quality Manual need to be revised every time laboratory staff changes?

Answer

If the Quality Manual contains the names of staff working in the laboratory, then an update would be required. If the Quality Manual only references the positions, and another referenced document lists the staff names and titles, then only the referenced document would need to be updated.

QMS Questions

Question

What are the current internal audit requirements?

Answer

Perform annual quality assurance audits documenting compliance with all elements of the quality assurance and quality control practices employed by the laboratory, including corrective actions for any noted findings. Audit findings and corrective actions that arise shall be provided to ELAP upon request.

TPA Questions

Question

Why is ELAP using TPAs?

Answer

To supplement current ELAP resources and meet the demands for accreditation in a consistent and timely manner.

TPA Questions

Question

When are labs required to use TPA's?

Answer

Labs with sophisticated technologies must use TPA's.

Note: a lab without sophisticated technology may choose to use a TPA if they wish.

TPA Questions

Question

If my lab has both sophisticated and non-sophisticated technologies, do I need to have two assessments (one by a TPA and one by ELAP)?

Answer

No. If you were to have an assessment done by both bodies, you would need to pay two assessment fees – one to the TPA and one to ELAP. The TPA should assess the full scope for which you plan to apply.

TPA Questions

Question

Which TPA's can be used?

Answer

Labs can select any qualified TPA that has signed an agreement with the State Water Board. A list of TPAs is maintained on ELAP's website.

TPA Questions

Question

Who approves my corrective action plan after the On-Site Assessment (OSA)?

Answer

The TPA is responsible for the actual OSA, issuance of the On-Site Assessment Report, and Corrective Action Plan review.

Contact ELAP

ELAPCA@waterboards.ca.gov