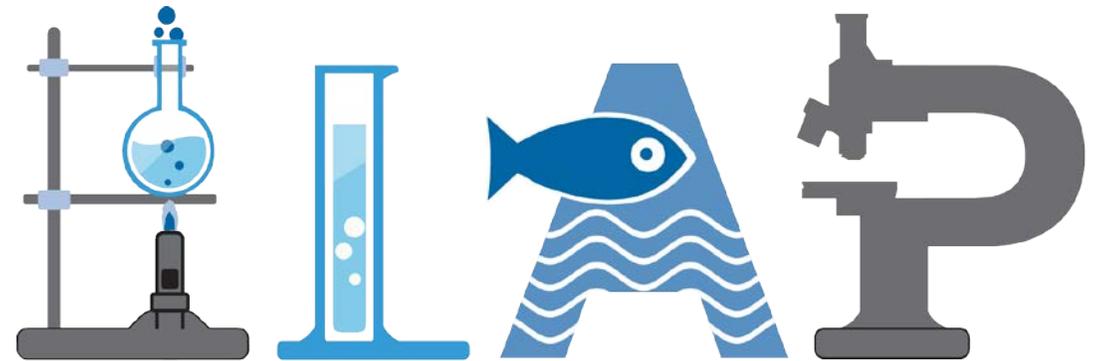


Roadmap to ELAP Accreditation

BACWA Meeting

June 9, 2020, 10:00 AM



Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

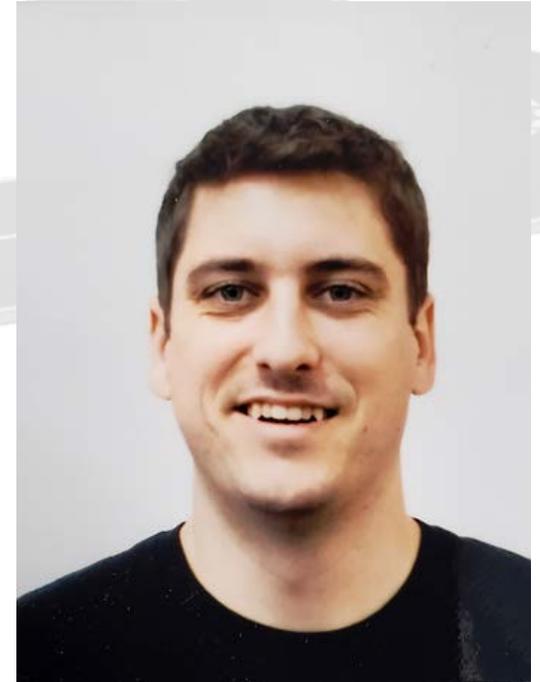
ELAP Team



Eric Yee, QAO



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Environmental Scientist**

Introduction to California ELAP Regulations

Christopher Hand
Environmental Scientist
Regulations Unit



Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

Presentation Overview

Outline

- Review newly adopted CA ELAP regulations
- Introduction to TPA concepts and processes

Purpose

- Prepare attendees to transition to new regulations

Expected Outcomes

- Foundational knowledge

About California ELAP

- Created in 1988 when the Environmental Laboratory Improvement Act consolidated multiple accreditation programs into one
- Exists to evaluate the competency of laboratories that produce data for California state regulatory purposes
- Recently went through a five-year regulation development process to update outdated rules

State Water Board Adopts Regulations

- The State Water Board adopted the proposed regulations at its May 5, 2020 Board Meeting
- Substantial changes to the status quo
 - Laboratories will now have to implement a quality management system
 - The 2016 TNI Standard
 - Some labs will be required to use a third-party assessment (TPAs) agency to perform their routine audits
- The Board directed staff to help labs transition to the new regulations

Roadmap to ELAP Accreditation

- Last month ELAP launched a compliance assistance initiative to help laboratories successfully navigate the path to compliance with the new regulations
- We are focused on providing the tools our labs need
 - Events, training, written publications, mentoring, and more
- Visit our new Roadmap to ELAP Accreditation webpage
 - Accessible from ELAP's main website

Implementation of the Regulations

- Regulations take effect October 1, 2020
 - However, this does NOT mean all requirements are immediately in place
- There is a transition period for some requirements
 - TNI is not required until Oct. 1, 2023
 - Applications don't require on-site assessment report until 2022
- Exact requirements depend on when your certificate expires
 - See our Roadmap to ELAP Accreditation: Application Requirements graphic

Roadmap to ELAP Accreditation: Application Requirements

The State Water Resources Control Board adopted new CA ELAP regulations, which take effect on October 1, 2020. Laboratories should utilize this chart as guidance to determining when changes to application requirements will affect them.

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 Oct. 1, 2020, 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"> • Some applications now require TNI • 2016 TNI Standard required if certificate expires after Oct. 1, 2023 • 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 	<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

More information about the "Roadmap to ELAP Accreditation" will be posted to www.waterboards.ca.gov/elap.



What do the regulations say?

- Applications
- Quality Management Systems
- Proficiency Testing
- Third Party Assessment

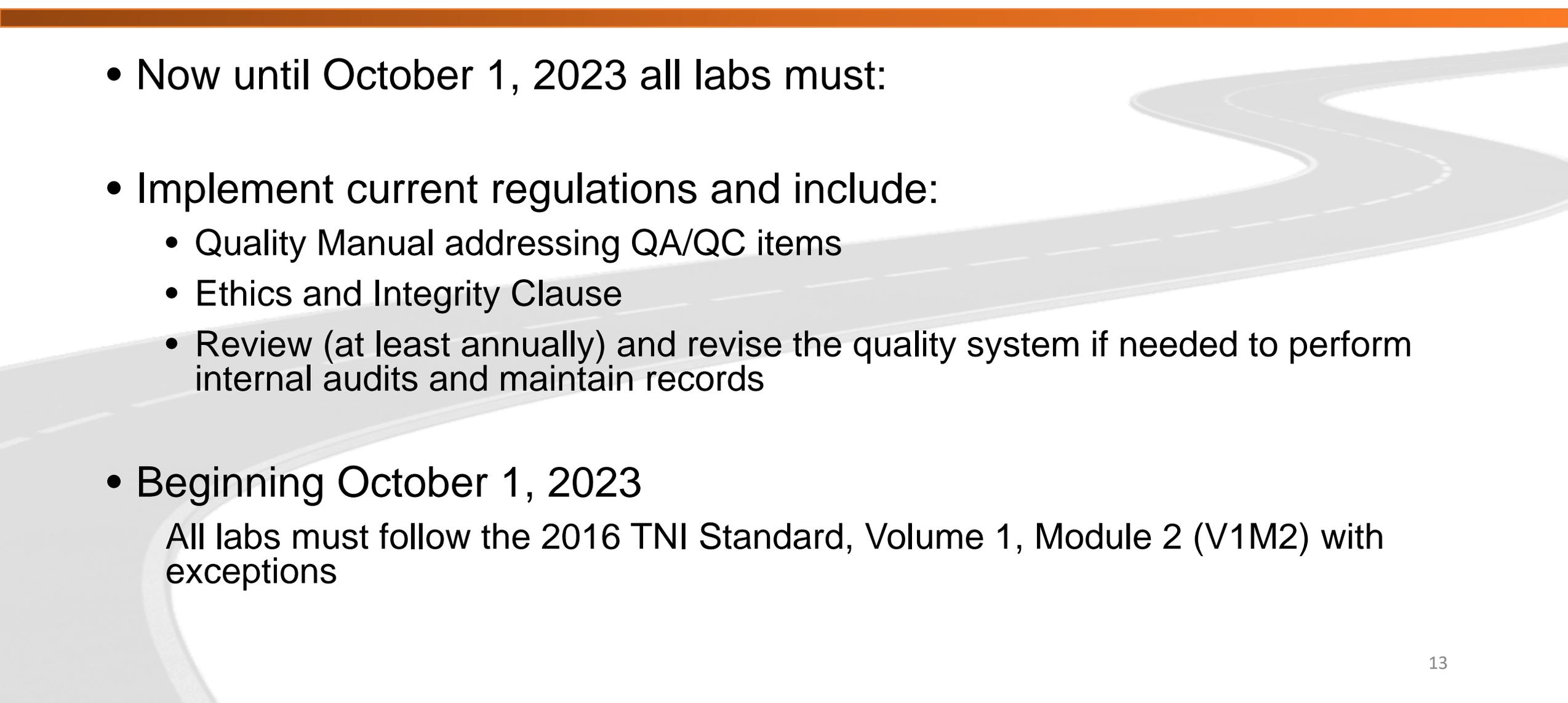
What do the regulations say about applications?

- Must include laboratory name, type, location, ownership, contact info
- A copy of the laboratory Quality Manual
 - TNI – V1M2-4.2.8.3 and 4.2.8.4 **OR** ELAP regs Section 64802.05(b)(1)
- Field of Accreditation Table
- PT reports with acceptable scores
- Completed on-site assessment with correction action plan
- Reference toxicant control chart (for aquatic testing methods)

What do the regulations say about QMS?

- All laboratories must implement the national standard, 2016 TNI by October 1, 2023
- Broadens requirements to include a more robust quality management system and other technical requirements

Transition Period for QMS



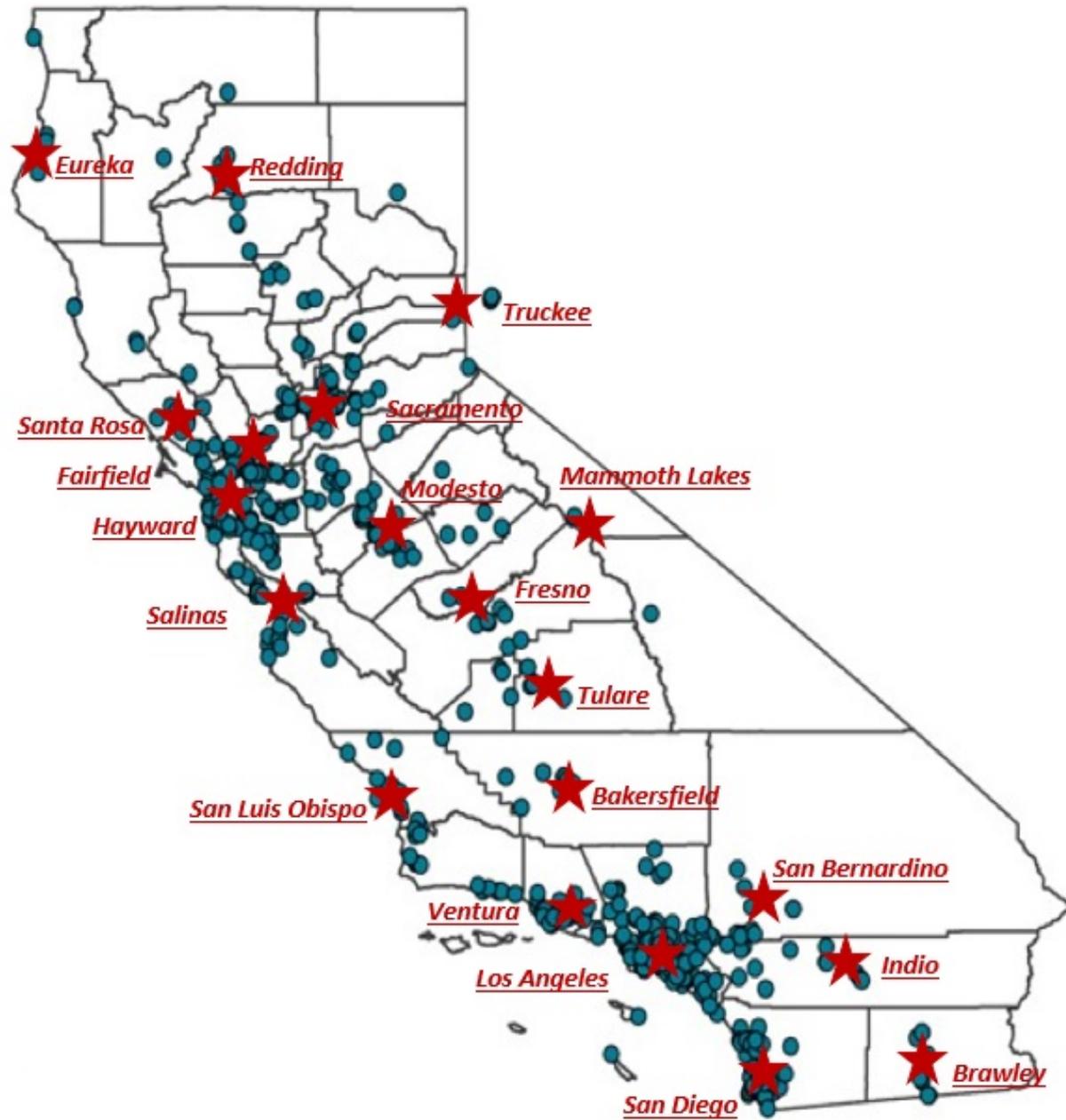
- Now until October 1, 2023 all labs must:
- Implement current regulations and include:
 - Quality Manual addressing QA/QC items
 - Ethics and Integrity Clause
 - Review (at least annually) and revise the quality system if needed to perform internal audits and maintain records
- Beginning October 1, 2023
All labs must follow the 2016 TNI Standard, Volume 1, Module 2 (V1M2) with exceptions

1:1 transition appointments

- Telephone consultations with ELAP staff for lab who request an appointment
- ELAP will provide feedback to lab on their strategy
- Personalized help with questions on
 - Logistics
 - Third party assessors
 - TNI tools, templates and training
 - Anything else they choose to ask about

Documentation workshops

- Twenty single day workshops will be held statewide
 - An expert consultant will train laboratory staff on the TNI Standard
- Each attendee will be given templates for all critical documentation elements
 - Fill-in-the-blank style
 - Examples of compliant procedures will be provided that the labs can use as their own
- Classes will be small so attendees can get personalized feedback and instruction
 - They can even bring in their own documents and work on them real-time



What do the regulations say about PTs?

- Until January 2021, ELAP is providing regulatory relief of notification requirements
- Must follow the 2016 TNI Standard, Volume 1, Module 1 with two exceptions
 - Only need 1 passing PT per year
 - 1st failure within 45 days of receiving a “not acceptable” score from the PT provider the lab must; notify ELAP, perform a root cause, take corrective action, achieve an “acceptable” score from another PT sample, notify ELAP of passing score and provide records .
 - If second attempt is a failure the lab must: notify ELAP, within 3 days, suspend and cease reporting data for that FoPT, notify clients, and within 30 days, perform root cause and take corrective action.

How do you run PT samples?

- 2016 TNI Standard PT requirements:
 - Analyze, *as much as practicable*, in the same maker as the environmental sample (i.e. in accordance with the lab SOP, quality control criteria, and staff).
 - No special QC, calibrations, dilutions, reruns, etc
 - Analyze samples of the same matrix
 - For example, if scope of accreditation includes an analyte for non-potable and potable, cannot run once for drinking water and use both
 - Report results, prior to the closing date, to PT provider and have sent directly to ELAP
 - Retain records to facilitate reconstruction (preparation, analysis, reporting, etc)

Must not engage in:

- Subcontract samples to another laboratory
- Knowingly receive or analyze another lab's PT samples
- Communicate with other labs concerning ongoing PTs
- Attempt to obtain the assigned value from the PT Provider
- Request the PT provider to alter final reports

What do the regulations say about TPAs?

- All laboratories must submit on-site assessment report and approved corrective action plan as part of their application
- Your assessment must be performed by a TPA if your laboratory uses sophisticated instruments or technologies
- Assessment must be completed before you submit an application
 - Including approval of your Corrective Action Plan

Sophisticated Technology

Sophisticated technology: defined in regulation means analytical instruments, detection systems, and/or preparation techniques requiring an advanced level of user understanding

- GC
- GC/MS
- ICP
- ICP/MS
- LC/MS
- AA
- EM
- PLM
- HPLC
- bioanalytical assays
- advanced molecular methods

What is a Third-Party Assessment Agency?

Third-party assessment agency: a TNI-approved agency which can perform on-site assessments of California laboratories for the purposes of accreditation by CA ELAP. These include:

- Any TNI-recognized state accreditation body (FL, IL, KS, LA, MN, NH, NJ, NY, OK, OR, PA, TX, UT, VA)
- Any TNI-recognized nongovernmental accreditation body (A2LA, ANAB, IAS, PJLA)
- Any US Department of Defense- or US Department of Energy-recognized accreditation body (A2LA, ANAB, PJLA)

What will they assess my lab to?

- They will assess the analytical methods and technologies you request
- Labs have options for which quality system they will assess to
 - Full TNI
 - TNI minus two
 - CA regulations (only available until Oct. 1, 2023)
- Your quality system selection will dictate which TPA you can hire

What's the process when using a TPA?

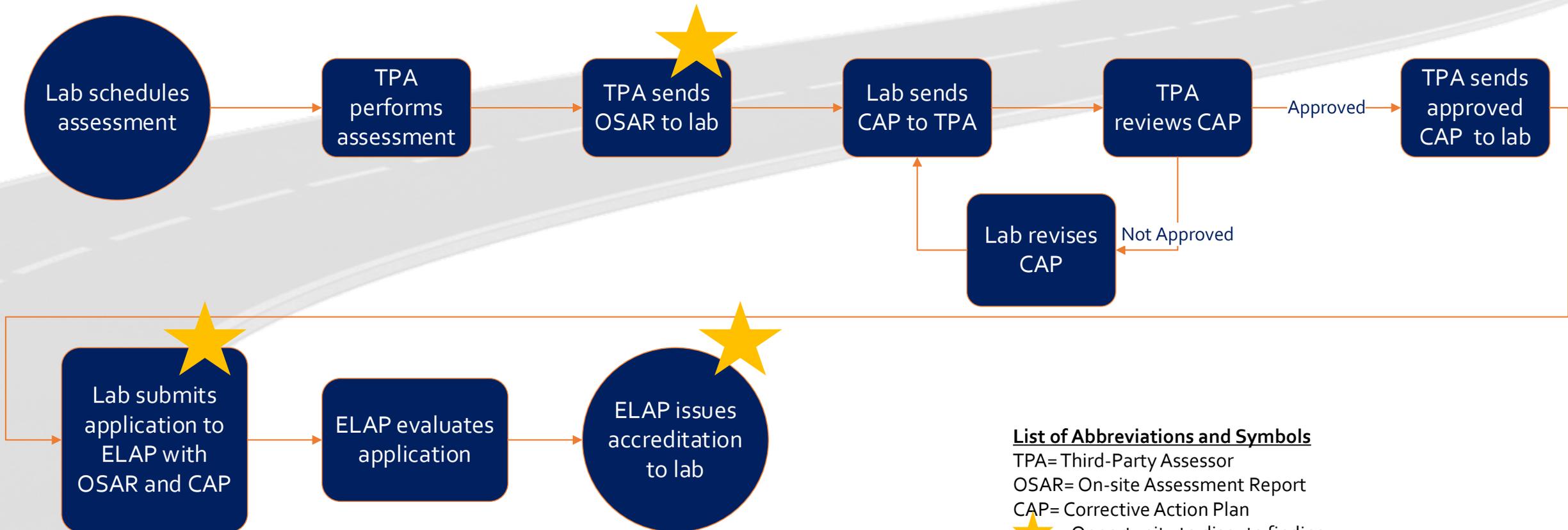
- The laboratory is responsible for scheduling the assessment
 - We recommend at least six months before your assessment needs to be completed
- Required time frames for assessments
 - Within one year before you submit an amendment or initial application, or
 - During the two-year accreditation window of your certificate for renewal applications
- TPA should assess the full scope for which you plan to apply for accreditation

What's the process when using a TPA?

- The TPA will:
 - Plan, schedule, and assemble a qualified assessment team
 - Request and review your laboratory documents prior to the assessment
 - Travel to perform your on-site assessment
 - Issue your On-site Assessment Report (OSAR)
 - Review and approve/deny your Corrective Action Plan (CAP)
- Once complete, submit your application before your deadline to ELAP with the OSAR and CAP
- ELAP reviews the assessment and application and makes the accreditation decision

Roadmap to ELAP Accreditation: Third-Party Assessment Process Overview

The State Water Resources Control Board adopted new CA ELAP regulations, which take effect on October 1, 2020. This diagram gives an overview of the assessment and application process for laboratories utilizing a third-party assessment agency.



List of Abbreviations and Symbols

TPA= Third-Party Assessor

OSAR= On-site Assessment Report

CAP= Corrective Action Plan

★ = Opportunity to dispute finding

More information about the "Roadmap to ELAP Accreditation" will be posted to www.waterboards.ca.gov/elap.

How will ELAP oversee the TPAs?

- ELAP is drafting a Memorandum of Understanding (MOU) that defines qualifications and service terms
 - TPAs that do not comply will not be able to provide assessments for CA
- ELAP will perform an annual audit of TPA activities
- A draft MOU will soon be available for public comment
 - We anticipate giving it to the Board for approval this summer

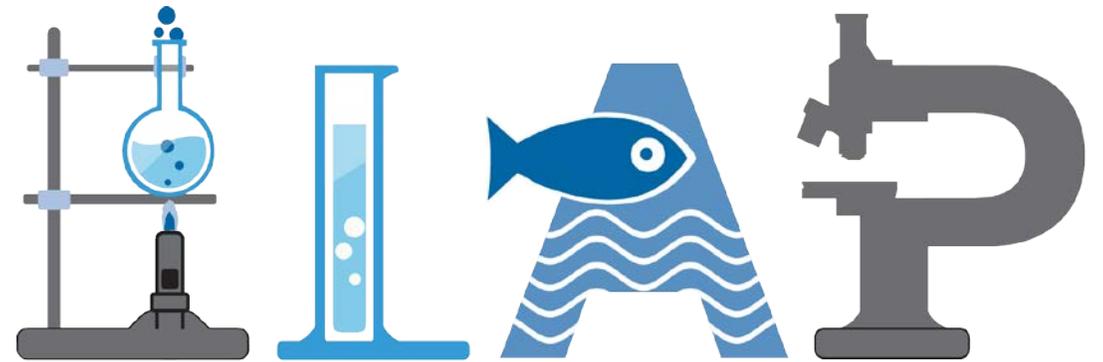
How do we evaluate overall program success?

- ELAP developing metrics to track during the implementation of this new regulatory requirement
- Annual report out on progress
- We want to have the best process possible
 - Contact us with suggestions or to troubleshoot

Next Steps

- Attend the ELAP Fees Stakeholder webinar on Thursday
- Be prepared to comment on TPA oversight terms soon
- Stay tuned for more compliance assistance opportunities

Thank you



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Audience Questions