

ELAP Regulations Update

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CWEA Annual Conference

April 19, 2018



Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

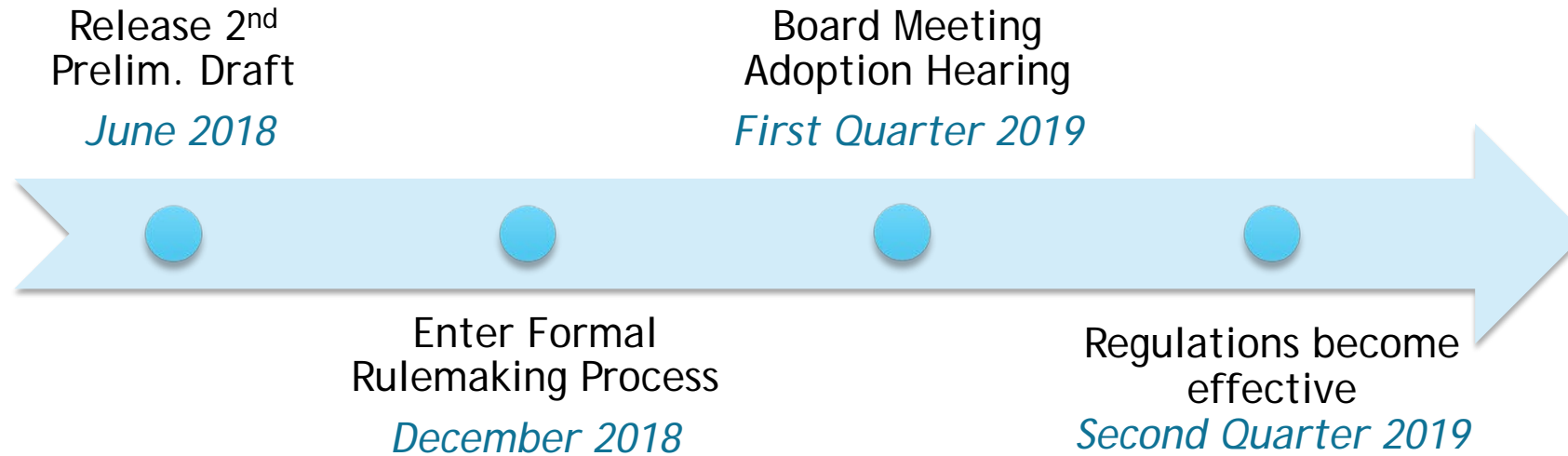
Overview

- ▶ Timeline update
- ▶ Opportunities to submit comments
- ▶ Summary of major changes
- ▶ Benefits of new regulations

Revised Timeline

- ▶ June 2018 - Release second preliminary draft
 - ▶ ELAP will hold a workshop (webcast) to present the changes made to Preliminary Draft 1
- ▶ December 2018 - Enter formal rulemaking process
- ▶ 1st quarter 2019 - Water Board adoption hearing
- ▶ 2nd quarter 2019 - Regulations effective date

Revised Timeline



Opportunities to Submit Comments

- ▶ Following release of 2nd preliminary draft
 - ▶ At the June workshop (webcast)
 - ▶ 30 day comment period
 - ▶ Written comments submitted directly to ELAP at elapca_comments@waterboards.ca.gov
- ▶ During the formal California rulemaking process
 - ▶ 45-day public comment period
 - ▶ Written comments submitted to ELAP through the State Water Board Clerk
- ▶ At the Water Board adoption hearing
 - ▶ Oral and written comments submitted to the State Water Board

How to Form Effective Comments

- ▶ Your comments are valuable to this process
- ▶ Identify the specific section of the text that you are commenting on
- ▶ Be concise!
- ▶ Include your suggested alternative when appropriate
 - ▶ (“I don’t like this section” doesn’t give us much to work with!)

Overview

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Preliminary Draft Regulations Overview

- ▶ Article 1 - Definitions
- ▶ Article 2 - Accreditation Requirements
- ▶ Article 3 - Types of Accreditation
- ▶ Article 4 - Types of Laboratories
- ▶ Article 5 - Laboratory Personnel and Equipment
- ▶ Article 6 - Notification/Sale of Ownership
- ▶ Article 7 -Denial, Suspension, or Revocation

Article 1 – Definitions

- ▶ The relevant definitions listed in the 2016 TNI Standard, Volume 1 apply throughout this regulation except as otherwise defined in this section
- ▶ “California Analyte” means a substance, organism, physical parameter, property, or chemical constituent(s) regulated in California
- ▶ “A Complete Application Package” means the State Board has received an application package for accreditation and the application package contains all the required information
- ▶ “Sophisticated Instrument” means analytical instrumentation such GC, GC/MS, IC, ICP, ICP/MS, LC/MS, AA, EM, PLM, HPLC, alpha particle or gamma ray spectrophotometer, **or other similar instrument** including use of aquatic organisms in toxicity testing of wastewater and hazardous waste.

Clarifying Definitions Based on Your Comments

- ▶ California Analyte
 - ▶ How will ELAP treat constituents that are not currently regulated, but for which agencies are required to monitor and report as per NPDES permit's requirements?
- ▶ Sophisticated Instrument
 - ▶ The inclusion of the phrase "such as" leaves the definition open to various interpretations.

Article 2 - Accreditation Requirements

▶ Accreditation Criteria

- ▶ Requires compliance with 2016 TNI Standard, Volume 1
- ▶ Acceptable PT scores submitted with application

▶ Application Package

- ▶ Application forms repealed from regulations and moved to ELAP website
- ▶ Specifies what is required for initial, renewal, and reciprocity applications
- ▶ Establishes an “Open Enrollment” framework for submittal of renewal applications

Article 2 - Accreditation Requirements

- ▶ **Quality Systems (Laboratory Standards)**

- ▶ Incorporates 2016 TNI Standard, Volume 1 by reference
 - ▶ With the exception of technical manager qualifications
- ▶ Proposing 3 year delayed compliance with TNI requirements from Modules 2-7
 - ▶ Module 1 (Proficiency Testing) and all other part of the regulations would take effect upon adoption
 - ▶ Delayed TNI adopters will be required to submit quarterly reports documenting quality assurance

Changes Being Considered Based on Your Comments

- ▶ Quarterly reporting
 - ▶ The original proposal was to require submittal of quarterly progress reports documenting quality assurance
- ▶ We received many comments that this was overly burdensome to laboratories
 - ▶ We heard your concern
- ▶ Instead, we are proposing laboratories submit a copy of their annual internal audit
 - ▶ Our State Agency Partners have agreed that this is an acceptable substitution for the quarterly reporting until laboratories have implemented TNI

Article 2 - Accreditation Requirements

▶ Field(s) of Accreditation

- ▶ FoA tables repealed from regulations and moved to ELAP's website, which will be updated to accommodate evolving state agency regulatory needs

▶ Proficiency Testing

- ▶ PT requirements consistent with 2016 TNI Standard, Volume 1 (with the exception of PT frequency)
- ▶ Requires acceptable PT scores prior to application for accreditation
- ▶ Modifies PT requirements for toxicity bioassay
- ▶ Accreditation suspended for failing to achieve acceptable PT scores on two consecutive PT studies during annual and renewal cycles
 - ▶ Includes requirements for reinstatement after suspension
- ▶ Adds option for alternative demonstration of capability when there is no PT study available

Article 2 - Accreditation Requirements

▶ **On-Site Assessment**

- ▶ Specifies timelines for:
 - ▶ Laboratory submittal of Corrective Action Report (30 days)
 - ▶ ELAP response to Corrective Action Report (30 days)
 - ▶ Laboratory submittal of revised Corrective Action Report (30 days)
- ▶ If a revised corrective action report still does not satisfactorily address findings, accreditation shall be denied, suspended or revoked for any Field(s) of Accreditation and/or Unit(s) of Accreditation affected

Changes Being Considered Based on Your Comments

- ▶ Considering allowing for a “Corrective Action Plan” when a finding is not correctable within 30 days

Article 3 - Types of Accreditation

▶ Initial Accreditation

- ▶ Incomplete applications will be returned. To continue processing a corrected application must be submitted within 30 days

▶ Renewal Accreditation

- ▶ Within a three year interval be subject to an on-site assessment
- ▶ Incomplete applications will be returned. To continue processing a corrected application must be submitted within 15 days
- ▶ Establishes monetary fines for late submittal of renewal application
- ▶ If accreditation lapses due to late application, laboratories must:
 - ▶ Cease reporting for regulatory compliance
 - ▶ Notify regulatory clients by registered mail

Changes Being Considered Based on Your Comments

- ▶ Clarifying what is considered an incomplete application
- ▶ Within a three year interval
 - ▶ When does the “three year period” begin and end? When the certificate expires? When the new certificate is issued?

Article 3 - Types of Accreditation

▶ Amending an Accreditation

▶ Specifies types of amendments

- ▶ Change of laboratory name
- ▶ Change of laboratory location
- ▶ Adding a satellite laboratory
- ▶ Adding or modifying scope of accreditation

▶ Addresses variances in requirements for each type of amendment

- ▶ Timelines for notification
- ▶ Required documentation to be submitted
- ▶ Frequency of on-site assessments

Article 3 - Types of Accreditation

▶ Interim Accreditation

- ▶ Under current statute, an “interim” accreditation means that ELAP has not had time to perform an on-site assessment, but that the laboratory has demonstrated proficiency through other means to continue testing.
- ▶ Clarifies ELAP’s use of interim accreditation by repealing option allowing laboratory to request interim accreditation

▶ Reciprocity Accreditation

- ▶ Secondary accreditation by California ELAP is invalid if a laboratory’s primary accreditation is expired, suspended, or revoked
- ▶ Secondary ELAP accreditation will align with the dates on a laboratory’s primary certificate

Article 4 - Types of Laboratories

- ▶ Defines criteria for each type of laboratory
 - ▶ Stationary, auxiliary, and mobile
- ▶ Adds additional criteria to existing definition of auxiliary laboratory
 - ▶ Must be included in primary laboratory's quality manual
- ▶ Allows a laboratory to combine a stationary and auxiliary/mobile laboratory under a single accreditation (under certain conditions)

Changes Being Considered Based on Your Comments

- ▶ Suggested ELAP replace “stationary laboratory” with “main laboratory”
 - ▶ Many auxiliary labs are stationary
- ▶ Concerns were expressed about auxiliary laboratory
 - ▶ The criteria for auxiliary laboratory is too limiting
 - ▶ As currently defined it is confusing and could be problematic without further clarification
- ▶ Suggested ELAP replace “auxiliary laboratory” with “satellite laboratory”

Article 5 - Laboratory Personnel and Equipment

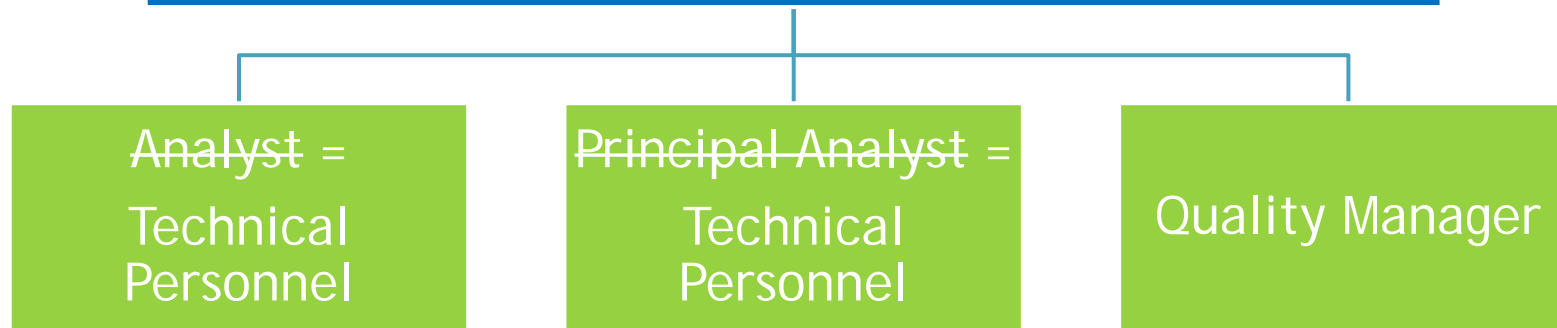
▶ Laboratory Personnel

- ▶ Renames Laboratory Director as Technical Manager
 - ▶ Retains existing education and experience qualifications
- ▶ Removes allowance for a person(s) with lesser qualifications to temporarily serve in the Technical Manager's absence
- ▶ Removes educational and experience requirements for Principal Analyst and allows laboratory management to define

▶ Laboratory and Equipment

- ▶ Incorporates 2016 TNI Standard, Volume 1

~~Laboratory Director~~ = Technical Manager



Changes Being Considered Based on Your Comments

- ▶ We received comments that the CWEA analyst certification descriptions needed to be updated
 - ▶ Thank you for bringing this to our attention
- ▶ ELAP is now working in partnership with CWEA representatives to revise the minimum Laboratory Analyst/Water Quality Analyst certificate grade requirements for Technical Managers

Article 6 - Notification/Sale of Ownership

▶ Client Notification

- ▶ Added 48 hour notification requirements for perchlorate and chlorine dioxide
- ▶ Allows subcontractor laboratories to perform notification
- ▶ Added requirement for submittal of bacterial monitoring report when reporting bacterial quality results
- ▶ Added Division of Drinking Water requirements for electronic reporting of:
 - ▶ Domestic Water Quality and Monitoring
 - ▶ Disinfectant Residuals, Disinfection Byproducts, and Disinfectant Byproduct Precursors
 - ▶ Lead and Copper

Changes Being Considered Based on Your Comments

- ▶ It is too complex to allow subcontractor laboratories to perform notification because the subcontracting lab typically does not provide sufficient information in order to maintain confidentiality
 - ▶ Agreement must be documented in writing

Article 6 - Notification/Sale of Ownership

- ▶ **Timelines for notifying ELAP of changes**
 - ▶ Change of technical manager and/or quality manager
 - ▶ Change of sophisticated instrumentation
- ▶ **Reporting**
 - ▶ Standardizes reporting requirements in accordance with 2016 TNI Standard, Volume 1, Module 2, Sections 4.5, 4.13, and 5.10
- ▶ **Sale or Transfer of Ownership**
 - ▶ Extends notification time frame from 15 to 30 days
 - ▶ Requires record retention for the previous 5 years to continue operation under original certificate
 - ▶ Removes mandatory site visit and PTs for use of certificate to its expiration date

Changes Being Considered Based on Your Comments

- ▶ Requiring notification for change of sophisticated instrumentation is an undo reporting burden to laboratories and the state to track all major instrumentation for each laboratory

Article 7 -Denial, Suspension, or Revocation

- ▶ Denying, Suspending, or Revoking Accreditation
 - ▶ Establishes criteria for denial, suspension, or revocation of accreditation
 - ▶ Establishes measures to allow data users to assess data quality from revoked laboratories:
 - ▶ Remove reference to ELAP accreditation
 - ▶ Return certificate
 - ▶ Cease all testing for regulatory purposes
 - ▶ Notify all regulatory clients
 - ▶ Provide a list of regulatory clients affected
 - ▶ Discontinue subcontracting agreements with accredited laboratories after 7 days

Benefits of Revising ELAP's Regulations

▶ Clarity of expectations

- ▶ Laboratories will understand what is required of them to obtain and maintain accreditation
- ▶ Laboratories will understand what to expect from ELAP
- ▶ ELAP has clear guidelines by which to conduct accreditation activities

▶ Streamline operations

- ▶ Easier application and payment process for laboratories
- ▶ Less burdensome on-site assessment and corrective action process for both ELAP and laboratories

▶ Ability to plan

- ▶ Clear timelines are established

Questions?

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