

CALIFORNIA ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
Preliminary Draft Regulations Outline
July 2017

Article 1 – Definitions

Article 2 – Accreditation Requirements

I. General Accreditation Criteria

- Adds to existing criteria for accreditation by requiring compliance with 2016 TNI Standard, Volume 1 (with the exception of Board recommended modifications)
- Changes requirement for on-site assessment from every two years to every three years

II. Application

- Streamlines administrative processes
 - Updates application
 - Reduces the number of days a laboratory has to correct an incomplete renewal application from ninety days to fifteen days
 - All applications will be due by same date annually, rather than a rolling basis

III. Management and Technical Requirements (Laboratory Standards)

- Only two modifications to the TNI Standard:
 - Technical Manager Qualifications
 - Proficiency Testing (PT) frequency
- Three year delayed compliance with TNI requirements upon adoption of regulations
- Early TNI adopters will be given priority status and reduced accreditation process time

IV. Field(s) of Accreditation

- Repeals Article 6 (Test Methods) and Article 12 (Fields of Testing). Replaces with Field(s) of Accreditation tables located on ELAP's website, which will be updated to address ongoing needs of agency partners

V. Proficiency Testing

- Makes PT requirements consistent with 2016 TNI Standard, Volume 1 (with the exception of PT frequency)
- Requires acceptable PT scores prior to application for certification
- Modifies PT requirements for toxicity bioassay
- Adds and/or clarifies penalty for failing to achieve acceptable PT scores during annual and renewal cycles
- Provides requirements for reinstatement after suspension due to failing to achieve acceptable PT scores
- Adds requirement for alternative demonstration of capability when there is no PT study available for California specific analytes

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VI. On-Site Assessment

- Adds detail to Corrective Action report requirements, including timelines for:
 - Laboratory submittal of Corrective Action Report (45 days)
 - Laboratory submittal of revised Corrective Action Report (30 days)

Article 3 – Types of Accreditation

I. Renewal Accreditation

- Introduces monetary fines of 15%-30% for late submittal of renewal application

II. Amendment Accreditation

- Specifies types of amendments
 - Change of laboratory name
 - Change of key personnel
 - Change of major instrumentation
 - Change of laboratory location
 - Adding an auxiliary 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

III. Interim Accreditation

- Clarifies ELAP's use of interim accreditation

IV. Reciprocity Accreditation

- ELAP accreditation will no longer remain valid if a laboratory's primary accreditation is expired, suspended or revoked

Article 4 – Types of Laboratories

- Defines criteria for each type of laboratory
- Adds additional criteria to existing definition of auxiliary laboratory
 - Must be included in Quality Manual
- Mobile laboratories are regulated as an independent entity and not as an extension of a stationary laboratory

Article 5 – Quality Systems

I. Quality Systems

- Incorporates 2016 TNI Standard, Volume 1 into the existing required elements of the quality manual

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- Adds language for:
 - Standard Operating Procedures
 - Document control procedures
 - Data integrity
 - Demonstration of Capability
 - Record retention
 - Analytical methods lacking quality control procedures

II. 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
- Reduces the allowed time a temporary Technical Manager can serve from ninety days to thirty-five days
- Reduces the number of days an extension will be granted from ninety days to thirty-five days
- Removes educational and experience requirements for Principal Analyst and allows laboratory management to define

III. Laboratory and Equipment

- Incorporates 2016 TNI Standard, Volume 1

Article 6 – Notifications/Reporting/Record Retention and Sale of Ownership

I. Notification, Reporting, and Records Retention

- Added notification requirements for perchlorate and chlorine dioxide
- Allows subcontractor laboratories to perform notification
- Added requirement for submittal of bacterial monitoring report
- Added requirements for electronic reporting of:
 - Results conducted pursuant to Title 22, CCR, Division 4, Chapter 15 Domestic Water Quality and Monitoring
 - Results conducted pursuant to Title 22, CCR, Division 4, Chapter 15.5, Disinfectant Residuals, Disinfection Byproducts, and Disinfectant Byproduct Precursors, and Chapter 17.5 Lead and Copper.
- Standardizes reporting requirements in accordance with 2016 TNI Standard, Volume 1, Module 2, Sections 4.5, 4.13, and 5.10

II. 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

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Article 7 – Reasons for Denial, Suspension, or Revocation

I. 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