INTIAL STATEMENT OF REASONS

Environmental Laboratory Accreditation Program Regulations
Title 22, California Code of Regulations

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INITIAL STATEMENT OF REASONS

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I. BACKGROUND

State regulatory programs designated by the Legislature to protect the environment and public health rely on accurate and reliable environmental testing data to monitor the effectiveness of regulatory actions. Environmental laboratories that report the data used to demonstrate compliance with applicable requirements of these regulatory programs utilize analytical methods and instrumentation that can be complex, sophisticated, and continuously evolving to meet industry and stakeholder needs. Laboratory accreditation programs provide oversight of the analytical testing services that environmental laboratories provide and ensure that the accredited laboratory community can comply with an accreditation standard and demonstrate the capacity, commitment, and competence to generate data of proven and acceptable quality.

California's Environmental Laboratory Accreditation Program (ELAP)

In 1988, the California Environmental Laboratory Improvement Act (ELIA) became law and established the Environmental Laboratory Accreditation Program (ELAP) to evaluate and provide accreditation to environmental testing laboratories in California. ELIA established ELAP as a fully fee-supported program within the California Department of Public Health (CDPH). In 1994, the Environmental Laboratory Accreditation Act (Health and Safety Code, Section 100825-10090), and the California Code of Regulations (CCR), Title 22, Division 4, Chapter 19 were codified to provide ELAP with the authority and structure to accredit laboratories for the analysis of regulatory samples.

The current regulations provide structure to the accreditation program by including requirements for the application process, fee schedules, reciprocity agreements, and Fields of Testing offered for accreditation. Additionally, the current regulations contain the accreditation standards that a laboratory is required to comply with. Together these elements inform laboratories of how to obtain and maintain ELAP accreditation.

Process for Accreditation

To obtain and maintain accreditation, laboratories must submit an application that identifies the specific analytical methods and constituents within a Field of Testing (FOTs) for which the laboratory is requesting accreditation. Additionally, laboratories must submit evidence of participation and successful completion of proficiency testing (testing of blind samples of known concentration) as a demonstration of technical

competency. Lastly, the regulations require an on-site assessment prior to accreditation and every other year thereafter. On-site assessments are conducted to verify a laboratory properly performs the analytical test methods for which the laboratory is seeking accreditation, which includes verifying the sufficiency of laboratory facilities, instrumentation and equipment; quality assurance and quality control procedures, and the competency of laboratory personnel. With successful documentation and completion of these elements, ELAP will issue a certificate of accreditation as indication of their compliance with ELAP regulations.

Insufficient Accreditation Standards in Regulations

ELAP's state-specific accreditation standards, which were codified in the regulations in 1994, are vague, non-descriptive, broad stroked attempts to address requirements of the accreditation program. The lack of specificity and details creates a situation where laboratories are unaware of the required practices and procedures needed to generate data of known quality or misinterpret the requirements, which results in lack of standardized practices and variation across laboratories. This is not suitable for an effective accreditation program.

The hallmark of an effective accreditation standard is the ability to assure both laboratory performance and quality, as well as consistent and uniform implementation. The principal quality assurance requirement of the current accreditation standards is for each laboratory to develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory (CCR Section 64815). As evidence of such a program, the laboratory must develop and maintain a Quality Assurance Program Manual (QAPM). The requirements for the QAPM are vague and simply state that the QAPM must address all quality assurance and quality control practices to be employed by the laboratory. However, specific quality assurance requirements are not listed or described. Instead, the regulations only require that quality assurance practices meet the requirements specified in the methods and that certain subject matter be addressed in the QAPM. Therefore, this is not a standard that laboratories must meet but simply guidance on how to construct the QAPM. Additionally, the language leads to variations in the quality assurance practices employed among the laboratories making these requirements antithetical to effective accreditation standards, as well as, hinders the ability to assess laboratories or enforce the regulations.

As a result of insufficient regulations, accreditation standards, and quality assurance requirements, ELAP struggles to assure laboratory performance and quality. In fact, deficiencies with the current regulations and the ELAP program were identified as early as 1997. In a review of data quality management programs within the California Environmental Protection Agency (CalEPA) it was found that laboratories receiving

accreditation through ELAP would meet the accreditation requirements at a point in time, but ELAP as an accreditation program could not guarantee performance of the laboratories on a daily basis.[1]

National Concern About Environmental Data

California ELAP was not the only program that was having trouble with assuring the performance and quality of environmental laboratories. In the early 1990's, there was heightened concern nationally about environmental data being produced by environmental testing laboratories. This sentiment is highlighted by the fact that the US EPA had 22 laboratories across the nation under review for suspected fraud. Furthermore, in 1996, the US EPA Office of Inspector General found that the US EPA oversight of laboratory data quality at Federal superfund cleanup facilities was not effective and that the Department of Defense (DOD) quality assurance for laboratory data quality had serious weaknesses.[1] This is a clear indication that robust quality assurance measures were not required by laboratory accreditation programs or implemented by environmental laboratories.

Quality Systems

In an effort to rectify misgivings about environmental laboratory accreditation programs and to improve the quality of data reported by environmental laboratories, a national movement for accreditation programs to utilize accreditation standards with quality management system (quality system) requirements began. A quality system is a structured and documented management system detailing how the laboratory ensures the quality of its processes and products. Many national and international laboratory programs require the use of quality systems. For example, below are the positions that reputable organizations have about quality system requirements in their laboratory programs:

U.S. Environmental Protection Agency (EPA): "Agency policy has required participation in an Agency-wide Quality System by all EPA organizations (office, region, national center or laboratory) supporting environmental programs. The Agency-wide Quality System is a management system that provides the necessary elements to plan, implement, document, and assess the effectiveness of QA and QC activities applied to environmental programs conducted by or for EPA. This system embraces many functions including:

[1] Environmental Quality Data Report, California Environmental Protection Agency, 1997.

- Establishing quality management policies and guidelines for the development of organization- and project-specific quality plans;
- Establishing criteria and guidelines for planning, implementing, documenting, and assessing activities to obtain sufficient and adequate data quality;
- Providing an information focal point on QA and QC concepts and practices;
- Performing management and technical assessments to ascertain effectiveness of QA and QC implementation; and
- Identifying and developing training programs related to QA and QC implementation.[2]"

World Health Organization (WHO): "The laboratory is a complex system, involving many steps of activity and many people. The complexity of the system requires that many processes and procedures be performed properly. Therefore, the quality management system model, which looks at the entire system, is very important for achieving good laboratory performance.[3]"

U.S. Food and Drug Administration (FDA): "Quality system is critical to the successful defense of laboratory data. A defensible laboratory quality system results in data accuracy, reliability, and minimization of laboratory errors. Laboratory quality assurance operations must be reliable, and quality control well documented. The management of the system is critical to its success to ensure it is maintained. Without oversight and documentation of the steps a laboratory takes to ensure the highest level of laboratory quality management, the data generated is indefensible.[4]"

The accreditation standard most widely used by national and international laboratory programs that incorporates quality system requirements is the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC): *General requirements for the competence of testing and calibration laboratories (ISO 17025)*. ISO is an independent, non-governmental international organization with a membership of 164 national standards bodies.

ISO 17025 specifies the general requirements for the competence to carry out tests, calibrations, or sampling. It covers testing and calibrations performed using standard methods, non-standard methods, and laboratory-developed methods. ISO 17025 is

[2] Policy and Program Requirements for the Mandatory Agency-Wide Quality System, EPA Order 5360.1 A2, U.S. EPA. 2000.

[3] Laboratory Quality Management System Handbook, World Health Organization, 2011.

[4] Proposal No. 17-114, Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting. U.S. Food and Drug Administration, 2017.

used by laboratories to develop a quality management system, including administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies use ISO 17025 to confirm or recognize the competency of laboratories. As an example, the FDA has a cooperative agreement for microbiological and chemical food analyses to be performed on behalf of state manufactured food regulatory programs conducted within the scope of an ISO 17025 accredited laboratory. Similarly, the California Department of Consumer Affairs Bureau of Cannabis Control requires laboratories achieve accreditation to the ISO 17025 Standard prior to performing analysis for cannabis testing.

However, because ISO 17025 is applicable to any type of testing laboratory, it does not contain requirements specific to the environmental laboratory industry. This is one of the reasons the EPA established the National Environmental Laboratory Accreditation Conference (NELAC). NELAC was a voluntary program comprised of stakeholders from state and federal agencies, local governments, the regulated industry and the laboratories that service them. NELAC was charged with the development of consensus-based national standards for a National Environmental Laboratory Accreditation Program (NELAP). In 2006, The NELAC Institute (TNI), a 501(c)(3) non-profit organization, was established for the long-term management of NELAP and the continued development of the accreditation standards.

The NELAC Standard (later to be called the TNI Standard) incorporates verbatim the language and quality system requirements from ISO 17025 but adds more detail to activities and procedures specific to the environmental laboratory industry. ELAP wanted to be a part of the national movement towards accreditation standards with quality system requirements, so in 1999, ELAP became one of the eleven original state accreditation programs to become a recognized accreditation body of NELAP. As a charter accreditation body, ELAP agreed to implement the TNI (NELAC) Standard. The purpose of using the TNI Standard was to improve the effectiveness of the accreditation program and the performance of laboratories with a specific, detailed, and robust, quality system-based accreditation standard.

ELAP Struggles Continue

In 2004, the Environmental Laboratory Accreditation Act was amended to create a two-tiered accreditation program, wherein laboratories in California could voluntarily seek accreditation to the TNI Standard or continue to be accredited to the state-specific accreditation standards as described in the current regulations. Fees to be TNI-accredited through ELAP were set higher than the fees to be accredited to the state-specific standards so there was little incentive for laboratories to move to the quality system requirements of the TNI Standard. Because accreditation to the TNI Standard was voluntary most laboratories continued to be assessed and obtain accreditation in

the insufficient state-specific accreditation standards and therefore, the addition of the TNI Standard did not have the desired effect of improving the effectiveness of the accreditation program or the performance of the laboratories.

The move to a two-tiered accreditation program was not the right decision for California. ELAP was already the largest state accreditation program in the nation with nearly 800 participating laboratories and was beginning to suffer from a lack of resources and sufficiently trained personnel as a result of program mismanagement and recruitment struggles. The two-tiered accreditation approach heightened the pressures and struggles of the program because laboratory assessors were required to be knowledgeable and assess compliance of laboratories to two independent accreditation standards. Initial and renewal applications were consistently processed late, accreditation was extended without having completed an on-site laboratory assessment, and enforcement of the regulations was sporadic, which promoted an environment where the laboratory community operated outside of regulatory oversight. Despite voiced frustrations from stakeholders, ELAP was unable to make the necessary corrections to maintain an effective accreditation program. In January 2014, ELAP voluntarily withdrew from NELAP following identification of significant inadequacies during a programmatic evaluation by TNI. As a result, the program continues to rely on the insufficient, state-specific accreditation standards codified in the regulations.

ELAP Transferred to State Water Resources Control Board; External Review Commissioned

In an effort to take ELAP in a new direction, SB 851 and SB 861 were passed in July 2014 to transfer ELAP from CDPH to the State Water Resources Control Board (State Water Board), Division of Drinking Water. Immediately following the transfer of ELAP, the State Water Board commissioned an external, independent review of the program to be coordinated by the Southern California Coastal Water Research Project (SCCWRP) to help the program frame its future directions.

SCCWRP organized an Expert Review Panel (ERP) to evaluate the program's internal management procedures, staffing, finances, laboratory assessment processes, and communication strategies with an overarching goal of improving ELAP's effectiveness. The Expert Review Panel was selected by an 11-member Stakeholder Advisory Committee (SAC) whose members represented municipal and private environmental laboratories operating in California, as well as State agency users of data from ELAP-accredited laboratories. Expert Review Panel candidates were required to have no affiliation with any organization regulated by or having official interactions with ELAP and were nominated based on their diverse and extensive experience in laboratory accrediting programs. To ensure the ERP was well-rounded, candidates were grouped according to their specific areas of expertise, such as laboratory operations, operation

of accreditation bodies, and onsite assessments. The SAC ranked the nominated panelists within each category and after collaboration could eliminate any of the candidates from consideration.

The ERP held three public meetings (March, August, and October) and one public webinar (June) in 2015 to allow public participation in the ERP's review process. Meeting agendas and presentation topics were developed by the ERP and SCCWRP to help formulate the ERP's assessment and recommendations for the program. The ERP invited speakers with different perspectives on ELAP, so the information provided at the meetings was comprehensive and representative of the various stakeholder groups.

In late 2015, the ERP released a Year One Final Report[5] and presented their findings at a State Water Board public workshop. The ERP highlighted various deficiencies of the program and made a series of recommendations to help ELAP reestablish itself as an effective accreditation program. Many of the recommendations from the ERP were aimed at helping ELAP overcome struggles with administration of the program and included establishing a program management system, expanding resources, enhancing communication with stakeholders, and ensuring the use of relevant analytical methods for the program. However, a final recommendation from the ERP was to immediately replace the inadequate accreditation standards in the current regulations with accreditation standards that have quality management system (hereafter referred to as quality system) requirements.

The ERP tracked ELAP progress throughout 2016 and reconvened in January 2017 to conduct a second-year review of the program. The Year Two Final Report[6] commended ELAP for implementing the administrative recommendations from the Year One Final Report and for engaging in an extensive collaborative stakeholder process to vet options and reach a decision on a proposed accreditation standard. However, the ERP noted that ELAP had yet to amend the current regulations and adopt new laboratory accreditation standards.

[5] Technical Report 887: Findings and Recommendations by the Expert Panel for the State of California's Environmental Laboratory Accreditation Program, Year One Final Report, Southern California Coastal Water Research Project (SCCWRP), 2015.

[6] Technical Report 977: Progress Assessment and Final Recommendations by the Expert Panel for the State of California's Environmental Laboratory Accreditation Program, Year Two Final Report, Southern California Coastal Water Research Project (SCCWRP), 2017

Program Deficiencies

Following external review from the ERP and internal reviews of the program by executive management at the State Water Board, it was evident that the program was hindered by the following programmatic deficiencies:

- Inadequate Accreditation Standards: Accreditation standards are the criteria ELAP uses to determine the competency of a laboratory to perform environmental testing. The current accreditation standards are outdated, lack quality system requirements, and result in variability in interpretation.
- Organizational Issues: ELAP was not a whole regulatory program. Almost all of the employees at ELAP were laboratory assessors. There was no staff dedicated to administrative concerns, proficiency testing review, program development or enforcement.
- Late and Ineffective Assessments: Mismanagement of ELAP resulted in laboratory assessments occurring later than required or not at all. Also, the non-descript and vague language of the current regulations resulted in laboratory assessments that varied across laboratories or were incomplete and ineffective.
- Lack of Resources: ELAP is a fee-supported program, but the fees were stagnant for more than 10 years and did not compensate for or address increasing programmatic and staffing needs.
- Lack of Enforcement: This was in part because of the lack of enforceability of the regulations, but also a lack of initiative from management. In fact, a lack of consideration of an enforcement matter referred to ELAP by the State Water Board Office of Enforcement was the impetus for ELAP's move to the State Water Board.

Many of the program deficiencies described above have been addressed by new ELAP management. The program was re-organized in 2015 to include dedicated units for administration of the program, monitoring of proficiency testing, on-site assessments, program development, research, and enforcement.

Timeliness and effectiveness of on-site assessments has improved through better coordination and planning, and training of ELAP assessors. However, due to a lack of qualified assessment staff, a backlog of laboratories awaiting on-site assessments remains.

A robust enforcement program has been established in coordination with the State Water Board Office of Enforcement. As a result of this oversight, enforcement actions

have been taken against laboratories in California committing fraud, and numerous laboratories have been cited for statutory and regulatory violations.

Despite the programmatic initiatives that have been implemented, ELAP's efforts and progress will continue to be hindered by the woefully outdated and inadequate requirements in the current regulations.

Challenge

The challenge in updating the regulations and accreditation standards is finding accreditation standards that are applicable to the population of laboratories in the program and their competing needs. As of January 2019, ELAP accredits 675 environmental laboratories to analyze regulatory samples in California, the most laboratories of any state accreditation program. Of the 675 laboratories, 108 operate out-of-state and receive ELAP accreditation through reciprocity from another State or United States agency's accreditation body with criteria that is at least as stringent as the current regulations. The population of accredited laboratories is diverse with laboratories of different size, number of employees, analytical method capabilities, and areas of regulatory focus (drinking water, wastewater, hazardous waste, toxicity, etc.). Additionally, the laboratories can be commercial or governmental (federal, state, county, municipal).

II. STATEMENT OF REASONS

Description of Problem the Proposed Regulations are Intended to Address

Existing regulatory language inhibits ELAP from fulfilling its charge of carrying out the Environmental Laboratory Accreditation Act. The current regulations limit the ability of ELAP to function as an effective accreditation program because they are not sufficiently detailed to provide clear direction to the laboratory community, and lack pertinent requirements or standards for determining the competency of a laboratory to appropriately perform environmental testing. Examples of functional areas of an accreditation program that are not discussed in the current regulations include quality system requirements, ethics and integrity policy requirements, data traceability requirements, method validation requirements, sample handling policies, or conditions for enforcement. The lack of breadth to the regulations has resulted in an ineffective accreditation program, as summarized by the 2015 ERP Year One Final Report.

The lack of specificity and detail in the language of the regulations has resulted in varying interpretations of the regulations by ELAP, environmental laboratories, and other stakeholders. This has led to inconsistencies in the assessment of the quality and competency of laboratories, which jeopardizes the validity of the data produced by

accredited laboratories and creates a lack of trust in data used to make decisions regarding human health and the environment.

Additionally, the current regulations reference specific analytical methods that are outdated or not relevant to the needs of the industry. Therefore, the regulations do not allow ELAP to accredit laboratories for the methods that regulatory agencies require to adequately protect California's health and environment.

Proposed Regulations

The proposed regulations make the necessary improvements needed to operate a fully functional and effective accreditation program. The improvements to the regulatory language are in six fundamental areas of the accreditation program:

- Program Administration
- Quality Systems
- Proficiency Testing
- Laboratory Assessment
- Fields of Accreditation
- Enforcement

Proposed Accreditation Standards

A major change of the proposed regulations is the incorporation of the 2016 TNI Standard, Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016 TNI Standard), with two California-specific exceptions. These new accreditation standards provide prescriptive and comprehensive descriptions of minimum management and technical requirements for environmental laboratories, including quality system requirements.

Below are summaries of the areas in which the TNI 2016 Standard differs from the current accreditation standards.

Laboratory Management:

- Includes content and format for a laboratory quality manual and standard operating procedures (SOPs).
- Requires data integrity training and documentation.

Document Control:

- Requires document control, approval, issuance, and revision management.

Control of Non-Conforming Work:

- Includes defined roles and responsibility of designated authority.
- Requires evaluation, correction, and client notification.

Corrective Action/Preventive Action:

- Requires internal evaluations, corrective action, monitoring, and preventive action audits.

Control of Records:

- Requires procedures for historical reconstruction of data.

Internal Audits:

- Requires documentation of audit findings, corrective action, and follow-up verification.

Management Reviews:

- Requires documentation of findings and incorporation of results into yearly action plans.

Personnel Requirements:

- Requires identification of training needs and providing training of personnel.
- Requires maintaining records to document competency, educational and professional qualifications, training, data integrity disclosure, skills and experience of all technical personnel.

Method Validation:

- Requires validation of non-standardized methods and laboratory developed methods.

Calibration Requirements:

- Requires policy and procedures for selection, calibration, and maintenance of equipment and software.

Traceability of Reference Standards and Materials:

- Requires calibration, traceability, transport and storage of reference materials.
- Requires policy and procedures for documentation and labeling of standards.

Reporting the Results:

- Includes minimum requirements to be included as part of the test report package.

The standards produced by TNI are integrated documents containing language from relevant ISO standards, and therefore, are copyright protected and provided through a license agreement. The purchase of the integrated TNI documents eliminates the need to purchase a separate copy of the relevant ISO standard. The State Water Board has made the 2016 TNI Standard publicly available for viewing at the CalEPA Headquarters Office in Sacramento, each of the nine (9) Regional Water Quality Control Board Offices, and twenty-four (24) Division of Drinking Water District Offices. Interested parties may contact any of the offices to view the 2016 TNI Standard in the designated public record document review area. Additionally, The NELAC Institute has provided access to a read-only, unlicensed version of the 2016 TNI Standard for all interested parties on the TNI website. To access the documents, enter the password: T6E79WS. This link will remain active until public access to the document is no longer needed for the rulemaking process. To obtain a personal copy of the 2016 TNI Standard, interested parties may contact TNI's Executive Administrator, Suzanne Rachmaninoff, at suzanne.rachmaninoff@nelac-institute.org. Discounted rates for the 2016 TNI Standard are available for a limited time.

Summary and Rationale for Each Regulatory Provision

ELAP proposes to bolster the effectiveness of the program by amending CCR, Title 22, Division 4, Chapter 19: Certification of Environmental Laboratories. The proposed regulations include modifications to existing program operations, elimination of outdated requirements and replacement of the state-created accreditation standards with the national consensus-based 2016 TNI Standard, with two California-specific exceptions. A summary of the proposed changes to the organization and format of CCR Chapter 19 is outlined in Table 1 and Table 2, below:

Table 1: Article Titles Amended in Proposed Regulations

Article No.	Title in Current Regulations	Title in Proposed Regulations
Article 1	Definitions	Definitions
Article 2	Certification and Amendment Process	Accreditation Requirements
Article 3	Application Process	Types of Accreditation
Article 4	Site Visits	Types of Laboratories
Article 5	Performance Evaluation Testing Process	Laboratory Personnel, Facilities and Equipment
Article 6	Required Test Methods	Notification, Reporting, Control of Records, Change of Technical Manager or Ownership and Trade Secrets
Article 7	Laboratory and Equipment	Reasons for Denial, Citation, Suspension or Revocation
Article 8	Quality Assurance Documents	
Article 9	Laboratory Personnel	
Article 10	Notification and Reporting	
Article 11	Reciprocity Agreements	
Article 12	Subgroups for Fields of Testing	
Article 13	Trade Secrets	
Article 14	Sale or Transfer of Ownership of a Laboratory	
Article 16	National Environmental Laboratory Accreditation Program (NELAP)	

Table 2: Sections Amended, Adopted, and Repealed in the Proposed Regulations

Article No.	Section(s) Amended	Section(s) Adopted	Section(s) Repealed
Article 1	64801.00 Definitions	None	None
Article 2	None	64802.00 Application Package *64802.05* Quality Systems 64802.10 Field(s) of Accreditation 64802.15 Proficiency Testing 64802.20 On-Site Assessment 64802.25 Accreditation Fees	64803. Certification and Amendment
Article 3	None	64808.00 Initial Accreditation 64808.05 Renewal Accreditation 64808.10 Reciprocity Accreditation 64808.15 Amendment Accreditation	64805. Application 64806. Certification Fees
Article 4	None	64810.00 Main Laboratory 64810.05 Satellite Laboratory 64810.10 Mobile Laboratory	64807. Site Visits
Article 5	None	64812.00 Laboratory Personnel 64812.05 Laboratory Facilities and Equipment	64809. Performance Evaluation Testing
Article 6	None	64814.00 Notification, Reporting, and Records Retention 64814.05 Notification of Change of Technical Manager or Change of Ownership 64814.10 Trade Secrets	64811. Test Methods

Article No.	Section(s) Amended	Section(s) Adopted	Section(s) Repealed
Article 7	None	64816.00 Denial of Accreditation 64816.05 Issuance of a Citation 64816.10 Suspension or Revocation of Accreditation	64813. Laboratory and Equipment
Article 8	None	None	64815. Quality Assurance
Article 9	None	None	64817. Laboratory Personnel
Article 10	None	None	64819. Notification and Reporting
Article 11	None	None	64821. Reciprocity Agreements
Article 12	None	None	64823. Fields of Testing
Article 13	None	None	64825. Trade Secrets
Article 14	None	None	64827. Sale or Transfer of Ownership
Article 16	None	None	64860. NELAP Accreditation Fees

In order to discuss the amended, adopted and repealed sections and the rationale for the changes in a clear and descriptive manner, the sections are presented in the format of the proposed regulations**.**

Rationale for Sections Amended:

Article 1. Definitions.

Section 64801.00 Definitions.

The purpose of the definitions section is to define the meaning of terms or phrases that are specific to the environmental laboratory industry and are pertinent to content of the proposed regulations. The definitions will provide clarity to requirements by explaining the State Water Board's specific use of the term or phrase. Some relevant terms and definitions are not included in this definitions section because the definitions are in the 2016 TNI Standard – Revision 2.1, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016 TNI Standard). However, if a term is defined differently or does not exist in 2016 TNI Standard, then the definitions are included in this section.

Below are the definitions removed or added in the proposed regulations and the rationale for the amendments:

Subsection (a): "*Acceptable Scores" means analytical results for a Proficiency Testing sample are within the specified acceptance criteria for that sample.*

Rationale: The definition for the term "alternate test procedure" was removed because the term is no longer used in the proposed regulations.

Adding the definition for the term "acceptable scores" is necessary to clarify what constitutes an acceptable score on a proficiency testing sample. An acceptable score is required to obtain and maintain accreditation in a Field of Accreditation.

Subsection (b): *"Accreditation" means the recognition of a laboratory by ELAP to conduct analyses of environmental samples for regulatory purposes.*

Rationale: The definition for the term "auxiliary laboratory facility" was removed because the term is no longer used in the proposed regulations. This term is replaced with satellite laboratory and the characteristics and requirements of a satellite laboratory are discussed within the text in Section 64810.05 Satellite Laboratory.

Adding the definition for the term "accreditation" is necessary to provide clarity to the term and distinguish accreditation from certification.

Subsection (c): *"Assessment Agency" means ELAP, or any entity that is contracted by ELAP to conduct laboratory assessments for ELAP.*

Rationale: The definition for the term “complete application” has been revised in the proposed regulations and has been moved to subsection (f).

Adding the definition for the term “assessment agency” is necessary to describe which assessment agencies can be used to fulfill the on-site assessment requirement to obtain or maintain accreditation.

Subsection (d): *“CA-NV/AWWA” means California-Nevada Section of the American Water Works Association.*

Rationale: The definition for the term “contact person” was removed because the State Water Board does not need to distinguish how the contact person was designated as a contact person, but only that a contact person is provided to the State Water Board for the purpose of information exchange.

Adding the definition for the term “CA-NV/AWWA” is necessary because this entity is only referenced within the text by the acronym and needs to be defined to understand the exception to the laboratory manager credentials.

Subsection (e): *“Citation” – means a monetary fine assessed to a laboratory due to non-compliance with ELAP statutes and regulations.*

Rationale: The definition for the term “laboratory” was removed because use of the term “laboratory” within the text of the proposed regulations does not require a definition. The term “laboratory” is a broadly and generally applied in the text so that the context of its use or the interpretation of the requirement is not questionable.

Adding the definition for the term “citation” is necessary to understand how the term will be used by ELAP in enforcement cases and the conditions that may result in an action described in the definition

Subsection (f): *“Complete Application Package” means an application package containing all the elements required in Section 64802.05.*

Rationale: The definition for the term “Laboratory Director” was removed because the term is not used in the proposed regulations but is replaced with Technical Manager. The roles and responsibilities of a Technical Manager are described in the 2016 TNI Standard.

Adding the definition for the term “complete application package” is necessary to clarify what constitutes a complete application package when submitting applications for initial or renewal accreditation. This will serve to distinguish a complete application from an incomplete application, which will not be reviewed by ELAP.

Subsection (g): *"CWEA" means California Water Environment Association.*

Rationale: The definition for the term "facility" or "facilities" was removed because use of the term "facility" or "facilities" within the text of the proposed regulations does not require a definition. The term "facility" or "facilities" is a broadly and generally applied in the text so that the context of its use or the interpretation of the requirement is not questionable.

Adding the definition for the term "CWEA" is necessary because this entity is only referenced within the text by the acronym and needs to be defined to understand the exception to the laboratory manager credentials.

Subsection (h): *"Days" means calendar days, unless otherwise stated.*

Rationale: The definition for the term "mobile laboratory" is removed because the definition is no longer relevant for the proposed regulations. The characteristics and requirements of a mobile laboratory are discussed within the text in Section 64810.10 "Mobile Laboratory."

Adding the definition for the term "days" is necessary to clarify how "days" is used by the accreditation program when describing the length of time allowed for laboratories to submit information to ELAP. This is important to prevent "days" from being interpreted as business days.

Subsection (i): *"Denial" means a decision to reject an application for accreditation due to non-compliance with ELAP statutes and regulations.*

Rationale: The definition for the term "owner" was revised for clarity and moved to subsection (l).

Adding the definition for the term "denial" is necessary to understand how the term will be used by ELAP when reviewing applications for accreditation.

Subsection (j): *"ELAP" means the California Environmental Laboratory Accreditation Program, a program within the State Water Resources Control Board.*

Rationale: The definition for the term "owner's agent" or "agents of owners" was revised for clarity and moved to subsection (m).

Adding the definition for the acronym "ELAP" is necessary to describe the State Water Board program that oversees the application, management, and enforcement of the proposed regulations. It is important to define the acronym because it is used to discuss

the roles and responsibilities of the program compared to those of the environmental laboratories.

Subsection (k): *"Field(s) of Accreditation" is defined in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2 and replaces the term Field(s) of Testing.*

Rationale: The definition for the term "principal analyst" is removed because the term and the characteristics and requirements of a Principal Analyst are depicted within the text of the proposed regulations, so a definition is not required.

Adding the definition for the term "Field(s) of Accreditation" is necessary because the term replaces Field(s) of Testing, which was used previously in the program to organize and structure the accreditation units.

Subsection (l): *"Owner" means a public agency, or any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.*

Rationale: The definition for the term "stationary laboratory" is removed because the term is not used in the proposed regulations. The characteristics and requirements of a main laboratory are discussed within the text in Section 64810.00 Main Laboratory.

The definition for the term "owner" was moved from subsection (i) and revised for clarity.

Subsection (m): *"Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act on its behalf for purposes of complying with ELAP regulations or the statutes under which ELAP regulations are adopted.*

Rationale: The definition for the term "trade secret" is moved to subsection (x).

The definition for the term "owner's agent" or "agents of owners" was moved from subsection (j) and revised for clarity.

Subsection (n): *"Primary Accreditation Body" means the organization that actually executes the accreditation process, including but not limited to, receiving and reviewing applications, supporting documents, Proficiency Testing sample results, and on-site assessments.*

Rationale: The definition for the term "trailer" is moved to subsection (y).

Adding the definition for the term “primary accreditation body” is necessary to understand what information is required for ELAP to accept and review applications for reciprocity accreditation.

Subsection (o): *“Quality Manager” means a member of the laboratory staff who is responsible for ensuring the management system related to quality is implemented and followed at all times.*

Rationale: The definition for the term “utility owned” is removed because the term is no longer used in the proposed regulations. There is no distinction between public or private laboratories in the proposed regulations because a laboratory is required to comply with the regulations regardless of their ownership.

Adding the definition for the term “Quality Manager” is necessary because the Quality Manager has a distinct role and responsibility in the 2016 TNI Standard but is not defined within the text.

Subsection (p): *“Quality Manual” is defined in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2 and replaces the term Quality Assurance Manual.*

Rationale: The definition for the term “vehicle” is removed because use of the term “vehicle” within the text of the proposed regulations does not require a definition. The term “vehicle” is broadly and generally applied in the text so that the context of its use or the interpretation of the requirement is not questionable.

Adding the definition for the term “quality manual” is necessary because this term replaces the term “Quality Assurance Manual”, a term that was historically used by the program.

Subsection (q): *“Revocation” means the permanent loss of a certificate of accreditation due to non-compliance with ELAP statutes and regulations.*

Rationale: The definition for the term “verified application” is removed because the term is no longer used in the proposed regulations and does not need to be defined.

Adding the definition for the term “revocation” is necessary to understand how the term will be used by ELAP in enforcement cases and the conditions that may result in an action described in the definition.

Subsection (r): *“Sophisticated Technology” means analytical instruments, detection systems, and/or preparation techniques requiring an advanced level of user understanding including gas chromatography/mass spectrometry (GC/MS), inductively coupled plasma spectrometry (ICP), inductively coupled plasma/mass spectrometry*

(ICP/MS), liquid chromatography/mass spectrometry (LC/MS), atomic absorption spectrophotometry (AA), gas chromatography (GC), alpha particle or gamma ray spectrophotometry, electron microscopy (EM), polarized light microscopy (PLM), high pressure performance liquid chromatography (HPLC), bioanalytical assays, advanced molecular methods and other similar instruments or technologies.

Rationale: The definition for the term “vessel” is removed because use of the term “vessel” within the text of the proposed regulations does not require a definition. The term “vessel” is broadly and generally applied in the text so that the context of its use or the interpretation of the requirement is not questionable.

Adding the definition for the term “sophisticated technology” is necessary because a similar term is defined in the current regulations within the Principal Analyst definition as “sophisticated laboratory instruments”. The context of how the term is used with respect to experience and knowledge requirements of a Principal Analyst has not changed. However, the definition is expanded upon to incorporate more modern technologies and methods. Additionally, to provide clarity the term was defined separately and not embedded within a definition.

Subsection (s): *“State Regulatory Agencies” means those state agencies whose statute or regulations require it to use laboratories that have been accredited by ELAP.*

Rationale: Adding the definition for the term “state regulatory agencies” is necessary to clarify that regulatory agencies are end users of data produced by ELAP-accredited laboratories and are responsible for determining the Fields of Accreditations offered by ELAP.

Subsection (t): *“State Water Board” means the California State Water Resources Control Board, which includes ELAP.*

Rationale: Adding the definition for the term “State Water Board” is necessary to signify the agency of authority used in the proposed regulations. ELAP was moved under the State Water Resources Control Board in 2014 and is no longer a program under the Department of Public Health.

Subsection (u): *“Suspension” means the total or partial removal of a laboratory’s accreditation to allow the laboratory to correct findings that identified non-compliance with ELAP statutes and regulations.*

Rationale: Adding the definition for the term “suspension” is necessary to understand how the term will be used by ELAP in enforcement cases and the conditions that may result in an action described in the definition.

Subsection (v): *"Technical Manager" is described in 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.1.7.2 (with the exception of part [f]) and replaces the title of Laboratory Director.*

Rationale: Adding the definition for the title "Technical Manager" is necessary because the title and position of Technical Manager, which has distinct roles and responsibilities in the 2016 TNI Standard replaces the title, Laboratory Director, which is used and defined in the current regulations.

Subsection (w): *"TNI" means The NELAC Institute.*

Rationale: Adding the definition for the acronym "TNI" is necessary to identify the institute that publishes the accreditation standards that are referenced in the proposed regulations.

Subsection (x): *"Trade Secret" means any information that meets the definition in Section 6254.7(d) of the Government Code.*

Rationale: The definition for the term "trade secret" remains the same as in the current regulations and was moved from subsection (m).

Subsection (y): *"Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.*

Rationale: The definition for the term "trailer" remains the same as in the current regulations and was moved from subsection (n).

Article 2 through 7

The titles of Article 2 through 7 were amended to reflect the reorganization and restructure effort of the proposed regulations (see Table 1).

Rationale for Sections Adopted:

Article 2. Accreditation Requirements.

Section 64802.00. Application Package.

This purpose of this section is to list the elements of an application that need to be submitted to ELAP to prove that a laboratory has complied with the requirements of accreditation. The information for this section is adapted from elements of Section 64805 Application in the current regulations.

Subsection (a): This subsection lists the different elements that are required in an application package to ELAP to obtain initial or renewal accreditation. This section aligns with the current regulations and does not constitute substantive changes to current practices with the exception of some added elements or added specificity to the requirement. The substantive changes are discussed below:

Subsection (a)(2)(A): "*A copy of the laboratory Quality Manual meeting the requirements of 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.2.8.3 and 4.2.8.4"*

Rationale: This references a specific requirement from the national consensus-based 2016 TNI Standard for the quality manual. This is the first mention of a requirement that references TNI accreditation standards and is included to make the program more effective through reference to specific and detailed requirements. This will provide direction to the laboratories on the specific requirements of the program.

Subsection (a)(2)(C): "*Subdivision (a)(2)(B), above, will become invalid three (3) years from the effective date of these regulations at which time accredited laboratories will be required to comply with subdivision (a)(2)(A), above"*

Rationale: Any requirement that references the 2016 TNI Standard will also have parallel requirements that apply during the three-year delayed implementation period, that will automatically sunset after the three years end. This is needed to provide laboratories with time to transition to the new accreditation standards.

Subsection (a)(5): "*A copy of the most recently completed on-site assessment report from an Assessment Agency in accordance with Section 64802.20, including all findings and approved corrective action report and/or corrective action plan; and*"

Rationale: This is a new element to the application package that is required in the proposed regulations. The purpose of this requirement is to ensure that the on-site assessment is being performed within the required time frame and that a review of the assessment occurs during the application process.

Subsection (a)(6): "*For aquatic toxicity testing, a current reference toxicant control chart for each method, species, and endpoint requested"*

Rationale: This is a requirement that is added in the proposed regulations that is specific to aquatic toxicity testing. The reason to include this requirement is to have another tool to assess competency in aquatic toxicity testing laboratories because there are very few commercially available proficiency testing samples for aquatic toxicity testing.

Subsection (b): This subsection lists the different elements that need to be included in an application package to ELAP to obtain reciprocity accreditation. This section aligns with the current regulations and does not constitute substantive changes to current practices with the exception of some added elements or added specificity to the requirement. The substantive changes are discussed below:

Subsection (b)(1)(E): "*Signed declaration to comply with applicable ELAP statutes and regulations*"

Rationale: This section is needed so that laboratories with their principle place of business outside of California that do business in California agree to comply with ELAP regulations.

Subsection (b)(7): "*Proof of accreditation from a primary accreditation body, including:*
(A) Official certificate of accreditation and scope of accreditation;
(B) Official on-site assessment report and findings; and
(C) Corrective action report(s) reviewed and approved by the primary accreditation body"

Rationale: This section is needed so ELAP has proof of accreditation from a primary accreditation body and that requires compliance with a standard at least as stringent as the proposed regulations. In addition, it provides ELAP with the term of the primary accreditation, which is needed because the length of accreditation is only as long as the accreditation from the primary accreditation body.

Subsection (c): "*A complete amendment application package shall be submitted to ELAP in accordance with Section 64808.15"*

Rationale: This section is needed because the application package requirements for amendment accreditation are different than the application requirements for initial, renewal, or reciprocity accreditation. This subsection directs the reader to the appropriate location in the proposed regulations to determine the requirements of an amendment application package.

Section 64802.05. Quality Systems.

The purpose of this section is to outline new quality system requirements for ELAP. Adopting a quality system-based accreditation standard, like the 2016 TNI Standard, was recommended by the Expert Review Panel (ERP) as a way to make the program more effective. The requirements are more detailed and encompass all functional areas of the laboratory, which makes assessments of laboratories more standardized and comprehensive. Additionally, laboratories have very specific requirements to reference, unlike the current regulations which are vague and non-descriptive. The quality system

requirements will not be required until three years from the effective date of the proposed regulations. Therefore, the quality assurance program requirements of the current regulations will be retained until the effective date of the 2016 TNI Standard.

Below are the requirements added to this section:

Subsection (a): "*Comply with quality system requirements in accordance with 2016 TNI Standard – Revision 2.1, Volume 1:*

(1) Module 2, with the following exceptions:

(A) Module 2, Section 4.1.7.2(f) – Technical Manager Qualifications; and

(B) Module 2, Section 5.2.6 – Technical Manager Requirements;

(2) Modules 3 through 7, where appropriate based on laboratory operations; or"

Rationale: This subsection references the accreditation standards of the 2016 TNI Standard that ensure that data produced by a laboratory is of known and documented quality. The sections of the 2016 TNI Standard referenced are detailed, specific, and provide minimum criteria for all laboratory functions and activities.

Subsection (b): *"Develop and implement a quality assurance program. As evidence of such a program, the laboratory shall:*

(1) Develop and maintain a Quality Manual. The Quality Manual shall address the quality assurance and quality control practices to be employed by the laboratory and shall include at a minimum:

(A) The quality assurance and quality control requirements specified in the test methods for which the laboratory seeks to obtain or maintain accreditation for; and

(B) Documents, or references to documents, that contain the following elements:

(i) Laboratory organization and job descriptions;

(ii) Ethics and integrity clause;

(iii) Quality assurance objectives for measurement data;

(iv) Sampling procedures (when the laboratory performs the sampling);

(v) Procedures for sample acceptance/rejection, custody, handling, and disposal of samples;

(vi) Calibration procedures and frequency;

(vii) Analytical procedures;

(viii) Acquisition, reduction, validation and reporting of data;

(ix) Internal quality control checks;

(x) Performance and system audits;

(xi) Preventive maintenance;

(xii) Assessment of precision and accuracy;
(xiii) Corrective action; and
(xiv) Quality assurance reports;
(2) The Technical Manager or designee shall review and amend, if necessary, the quality assurance program and Quality Manual at least annually and when the following occurs:
(A) Changes to Standard Operating Procedures;
(B) Changes to laboratory equipment or instrumentation;
(C) Changes to laboratory structure or physical arrangements; or
(D) Changes in the laboratory organization;
(3) Perform annual quality assurance audits documenting compliance with subdivision (b)(1), above, including corrective actions for any noted findings. Audit reports shall be provided to ELAP upon request;
(4) Maintain records of the implementation of the quality assurance program. Records of the implementation of the quality assurance program shall be provided to ELAP upon request"

Rationale: Subsection (b)(1) lists the quality assurance program requirements that are retained from the current regulations. Subsections (b)(2-4) are added subsections. These added subsections are needed to ensure that the quality assurance program is reviewed by qualified personnel and records of the program are properly retained.

Section 64802.10. Field(s) of Accreditation

The purpose of this section is to describe the Field(s) of Accreditation (method, analyte, and matrix combination) that ELAP will accredit laboratories for and how they are determined. Field(s) of Accreditation is defined in the 2016 TNI Standard, which is how the term is used in this section. The framework of accreditation in the proposed regulations deviates from the framework of accreditation in the current regulations. Historically, Field(s) of Accreditation (subgroups) are grouped into Field(s) of Testing based on the matrix and analyte type of the Field of Accreditation. For example, Field(s) of Accreditation (subgroups) for microbiological analytes in drinking water are grouped into one Field of Testing. These Field(s) of Testing and Field(s) of Accreditation (subgroups) are listed in Section 64823 "Fields of Testing" in the current regulations. This section is repealed (see Section "*Rationale for Repealed Sections"*, below) and the Field(s) of Testing groupings are eliminated in the proposed regulations.

The new subsections and language used to describe Field(s) of Accreditation and the rationale for the subsections are listed below:

Subsection (a): "*ELAP will accredit laboratories in Field(s) of Accreditation required by State Regulatory Agencies as identified in permits, orders, and other regulatory requirements.*"

Rationale: The reason for this subsection is to illustrate that Fields of Accreditation are determined by the regulatory purposes of State Regulatory Agencies and this is how the program determines which Field(s) of Accreditation to offer. This is important, because ELAP does not determine what Field(s) of Accreditation will be offered by the program.

Subsection (b): "*Field(s) of Accreditation offered for the purpose of drinking water analyses shall include United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations parts 141.21 through 141.42, 141.66, 141.89, and Appendix A of Subpart C, or as otherwise directed by the State Water Board"*

Rationale: This subsection is included as directed by the State Water Board Division of Drinking Water to ensure that laboratories are accredited for and only use federally approved methods for drinking water analyses, unless otherwise directed by the State Water Board.

Subsection (c): "*Field(s) of Accreditation offered for the purpose of compliance monitoring under the Clean Water Act shall include United States Environmental Protection Agency approved methods as prescribed in 40 Code of Federal Regulations part 136, or as otherwise directed by the State Water Board or other State Regulatory Agency"*

Rationale: This subsection is included to ensure that laboratories are accredited for and only use federally approved methods for compliance monitoring under the Clean Water Act.

Subsection (d): *"Field(s) of Accreditation offered for the purpose of solid and hazardous waste material analyses shall include United States Environmental Protection Agency approved methods as prescribed in SW-846, Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, or as otherwise directed by the State Water Board or other State Regulatory Agency"*

Rationale: This subsection is included to provide clarification to laboratories on which methods will be included in the Field(s) of Accreditation for analysis of solid and hazardous waste materials.

Subsection (e): "*ELAP publishes the lists of Field(s) of Accreditation, called Field(s) of Accreditation tables, on the ELAP website. The Field(s) of Accreditation tables are*

updated, as needed, by publishing a revised Field(s) of Accreditation table on the ELAP website"

Rationale: The State Regulatory Agencies are the primary users of the data and they determine what fields of accreditation laboratories need to be accredited for. They identify those needs in the permits, orders and other regulatory requirements, which have their own separate public process. The State Regulatory Agencies notify ELAP of their needs, and ELAP adds it to the list of fields of accreditation that laboratories can be accredited for. As a courtesy, ELAP keeps a list of those fields of accreditation on its website for easy accessibility for the laboratories. No laboratory is required to be accredited for any particular analytical methods, and whether or not a laboratory seeks accreditation for a particular filed of accreditation is a business decision for the laboratory.

Section 64802.15. Proficiency Testing.

This section is used to describe the Proficiency Testing requirements of laboratories. This section is important because passing Proficiency Tests is required by statute for accreditation, and the results from Proficiency Testing are used by ELAP to evaluate the competency of laboratories in Field(s) of Accreditation. This section outlines the requirements for the Proficiency Testing. Some of the information in this section is derived from Section 64809 "Performance Evaluation Testing" in the current regulations with non-substantive changes to the wording of the requirements. However, the current regulations lack detailed and specific proficiency testing requirements for the laboratory and does not provide direction on laboratory actions during the accreditation process. Therefore, subsections were added or more detail was added to existing requirements to bolster this section.

The added subsections and the rationale for the additions are listed below:

Subsection (a): "The *Proficiency Testing requirements in this section shall not negate or supersede the Proficiency Testing requirements of other state or federal regulatory programs."*

Rationale: This is included because state or federal regulatory programs may have additional proficiency testing requirements, and laboratories must comply with each program's requirements. ELAP proficiency testing requirements do not negate or supersede other program requirements. For example, testing requirements and frequency of the Discharge Monitoring Report Quality Assurance program.

Subsection (b)(1): "*Comply with 2016 TNI Standard - Revision 2.1, Volume 1, Module 1 for each Field of Accreditation for which the laboratory is requesting accreditation, with the following exceptions:*

(A) Volume 1, Module 1, Section 5.0 – Proficiency Testing Study Frequency Requirements for Accreditation; and
(B) Volume 1, Module 1, Section 8.0 – Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation"

Rationale: The referenced proficiency testing requirements in the TNI Standard are important because it addresses requirements for accreditation; sample handling, preparation and analysis requirements; and reporting requirements that are not addressed in the current regulations. These requirements provide more detail and specificity for the laboratories. The exceptions are necessary because these sections of the 2016 TNI Standard are in conflict with California's statutory requirement of one Proficiency Testing sample per year.

Subsection (b)(2): "*Comply with the following Proficiency Testing requirements:*
(A) Analyze Proficiency Testing samples in accordance with the laboratory's routine Standard Operating Procedure using the same quality control, acceptance criteria and staff as used for the analysis of routine environmental samples;
(B) Analyze Proficiency Testing samples of the same matrix as the Field(s) of Accreditation for which the laboratory holds or seeks accreditation;
(C) On or before the closing date of the study, direct the Proficiency Testing provider to report the Proficiency Testing study results directly to ELAP;
(D) Report in such a way that the Field of Proficiency Testing corresponds to the Field of Accreditation offered by ELAP; and
(E) Retain all records necessary to facilitate reconstruction of the preparation, processing, and reporting of analytical results for Proficiency Testing samples for a minimum of five (5) years and provide them to ELAP upon request; and"

Rationale: These are the proficiency testing requirements that will be in effect until the above referenced proficiency requirements in the 2016 TNI Standard take effect (three years from the effective date of the proposed regulations). These requirements are needed to direct the laboratories in the analysis, reporting, and retention of records for proficiency testing. These requirements are not present in the current regulations, so laboratories were provided no direction in the matter.

Subsection (b)(3): "*Not engage in the following activities:*

(A) Send Proficiency Testing study samples, in which the laboratory is participating, to another laboratory for the analysis of a Field of Accreditation for which it seeks accreditation or is accredited;
(B) Knowingly receive or analyze any Proficiency Testing samples from another laboratory for which the results are to be used for accreditation;
(C) Communicate with any individual at another laboratory concerning the analysis of Proficiency Testing samples of an ongoing study;
(D) Attempt to obtain the assigned value of any portion of a Proficiency Testing study from the Proficiency Testing provider; and
(E) Request the Proficiency Testing provider to alter any portion of the laboratory's Proficiency Testing report after it was issued as final"

Rationale: This subsection is needed to outline what actions are not acceptable when performing proficiency testing for ELAP. This information is not present in the current regulations.

Subsection (d): "*If there are no available Field(s) of Proficiency Testing for Field(s) of Accreditation, then ELAP may require verification of quality control data as an alternative demonstration of capability"*

Rationale: This subsection is important because there are some Field(s) of Accreditation that do not have a corresponding Field of Proficiency Testing and an alternative demonstration of capability may be required. This is not detailed in the current regulations.

Subsection (g): "*To add or reinstate a Field of Accreditation, a laboratory shall achieve acceptable scores in a Field of Proficiency Testing for each Field of Accreditation for which the laboratory is requesting to add and submit an amendment application in accordance with Section 64808.15"*

Rationale: This subsection is important because a laboratory that is applying to add or reinstate a Field of Accreditation must first demonstrate competency in that Field of Accreditation before applying for amended accreditation.

Subsection (h): *"If a laboratory does not achieve an acceptable score for a Field of Proficiency Testing, then within forty-five (45) days of receipt of the "Not Acceptable" score from the Proficiency Testing provider, the laboratory shall:*
(1) Notify ELAP of the "Not Acceptable" score;
(2) Investigate and document the root cause of the failure;
(3) Take corrective action;
(4) Achieve an acceptable score for that Field of Proficiency Testing in a subsequent Proficiency Testing study;

(5) Notify ELAP of the "Acceptable" score; and
(6) Upon request from ELAP, provide documentation of the root cause investigation and corrective action"

Rationale: This subsection is needed to provide detailed instructions and requirements of laboratories upon failure to achieve an acceptable score in a Field of Proficiency Testing. This topic was alluded to in the current regulations, but the language was ambiguous and not specific enough to ensure compliance.

Subsection (i): *"If a Proficiency Testing study for a Field of Proficiency Testing is not available within forty-five (45) days of receipt of a "Not Acceptable" result, the laboratory shall:*
(1) Submit to ELAP, a plan that states when the next Proficiency Testing study will be completed, and;
(2) Achieve acceptable scores for the Field of Proficiency Testing when the subsequent Proficiency Testing study becomes available and submit to ELAP."

Rationale: This subsection is important because it identifies the actions a laboratory is required to take if a subsequent Field of Proficiency Testing is not available within 30 days of a failure.

Subsection (j): "*If on the second attempt, a laboratory does not achieve acceptable scores for a Field of Proficiency Testing, a laboratory shall:*
(1) Be suspended for that Field of Accreditation effective upon receipt of the second "Not Acceptable" result from the Proficiency Testing provider;
(2) Cease reporting of results for regulatory purposes for that corresponding Field of Accreditation upon receipt of the "Not Acceptable" result from the Proficiency Testing provider;
(3) Notify clients affected by the suspended status of the field of accreditation by registered mail, email with return receipt, or electronic signature document;
(4) Within thirty (30) days:
(A) Notify ELAP of the "Not Acceptable" result; and
(B) Investigate and document the root cause of the failure and take corrective action;
(5) Upon request from ELAP, provide documentation of the root cause investigation and corrective action"

Rationale: This subsection outlines the repercussions and required actions of laboratories upon failure to achieve an acceptable score in a Field of Proficiency Testing on a second attempt. This topic was not discussed in the current regulations, so this subsection provides specificity and details needed for laboratories to comply.

Subsection (k): *"To be reinstated after suspension of a Field(s) of Accreditation, the laboratory shall:*

(1) Achieve acceptable scores for the corresponding Field(s) of Proficiency Testing; and

(2) Submit an amendment application package, in accordance with Section 64808.15"

Rationale: This subsection is needed to provide laboratories direction on the option to reinstate accreditation following failure to achieve an acceptable score in a Field of Proficiency Testing after two attempts.

Subsection (l): "*For toxicity bioassay analyses, each laboratory shall:*

(1) Achieve acceptable scores in a Field of Proficiency Testing, where available, for each Field of Accreditation for which the laboratory is requesting accreditation, in accordance with (b), above;

(2) Perform reference toxicant tests, at a minimum, annually for each method, organism, and endpoint; and

(3) Plot and maintain control charts of reference toxicant test results for each method, organism, and endpoint"

Rationale: This section is important because it provides direction for compliance to laboratories that perform aquatic toxicity testing. This subsection lists the unique aquatic toxicity testing requirements separately from general laboratory testing.

Subsection (m): "*For pesticide residue in food, each laboratory shall obtain Proficiency Testing samples from a Proficiency Testing provider that meets TNI standards"*

Rationale: This subsection is important because proficiency testing studies for pesticide residue in food vary.

Subsection (n): "*If a laboratory has a financial interest, familial relationship, or contractual agreement for consultation with the provider of a Proficiency Testing study, then the results from that study shall not be used to meet the Proficiency Testing study requirements for accreditation"*

Rationale: This subsection is needed to prevent laboratory relationships with Proficiency Testing providers that may be a conflict of interest.

Section 64802.20. On-Site Assessment.

The language and requirements for this section are adapted from Section 64807, "Site Visits" in the current regulations. The purpose of this section is to outline how the on-site

assessments are conducted, the frequency of on-site assessments required, and the responsibilities of the laboratory to complete the on-site assessment process.

The added subsections and the rationale for the additions to this section are discussed below:

Subsection (b): "*An on-site assessment shall be conducted:*

(1) For initial accreditation, no more than twelve (12) months prior to obtaining accreditation;

(2) For renewal accreditation, once every two years;

(3) For amendment accreditation, when required, in accordance with Section64808.15; and

(4) For enforcement purposes, when ELAP decides to conduct an assessment in accordance with Health and Safety Code 100865"

Rationale: This section serves as guidance to laboratories on the time frames that on-site assessments are required to be conducted. This is important because the time frames are different, and this subsection delineates the differences of on-site assessments for initial, renewal, amendment accreditations or enforcement reasons.

Subsection (c): *"An on-site assessment shall be conducted by ELAP or a third-party Assessment Agency contracted by ELAP to perform on-site assessments.*

(1) A laboratory requesting assessment to a field of accreditation that utilizes sophisticated technology shall use a third-party Assessment Agency;

(2) A third-party Assessment Agency shall be one of the following:

(A) A National Environmental Laboratory Accreditation Program (NELAP)-recognized accreditation body;

(B) A NELAP-recognized non-government accreditation body.

(C) An agency that is recognized by the Department of Defense or Department of Energy as an accrediting body; or

(D) An agency that is contracted by ELAP."

Rationale: This subsection is needed to identify which on-site assessments ELAP will conduct and which on-site assessments shall be conducted by a third-party Assessment Agency, as well as, identifies how third-party Assessment Agencies are approved by ELAP.

Subsection (d): *"The laboratory is responsible for requesting an on-site assessment through ELAP or a third-party Assessment Agency."*

Rationale: Historically, ELAP would schedule the on-site assessment with the laboratory. This subsection is needed because in the proposed regulations, ELAP will

accept on-site assessments from third-party assessment firms to satisfy the on-site assessment requirements. Therefore, the decision to use ELAP or third-party assessment firms will be up to the laboratory and it is important that the scheduling of the assessment be the responsibility of the laboratory. Third-party assessment agencies are needed to lower the number of laboratories required to be assessed by ELAP. Currently, the on-site assessments are not being conducted in a consistent and timely manner.

Subsection (f): "*When an on-site assessment is performed by a third-party Assessment Agency contracted by ELAP to perform on-site assessments, a laboratory shall pay the third-party Assessment Agency its market rate for onsite assessments."*

Rationale: This subsection is needed to inform the laboratories that third-party assessment agencies will need to be paid by the laboratory directly and not through the accreditation program.

Subsection (g): "*Within thirty (30) days of the on-site assessment, a laboratory will receive an on-site assessment report. If there are findings in the on-site assessment report, a laboratory shall:*

(1) Within thirty (30) days of receipt of the on-site assessment report, submit a corrective action report that contains a root cause analysis of the finding(s);
(2) If finding(s) are not correctable within thirty (30) days, a laboratory shall submit a corrective action plan, identifying the corrective actions that will take place and the date the finding(s) will be corrected;
(3) Subsection (g)(1), above, will be invalid three (3) years from the effective date of these regulations, at which time laboratories will be required to submit, within thirty (30) days of receipt of the on-site assessment report, a corrective action report in accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.11"

Rationale: This subsection is derived from the current regulations but adds new requirements under subsection (g)(3). The reference to corrective action report requirements in the 2016 TNI Standard is needed to supplant corrective action requirements from the current regulations. The current regulations on corrective action report lack detail and specificity, but the corrective action report requirements in the 2016 TNI Standard standardize the process and provide direction for the laboratory.

Subsection (h): *"If a laboratory is notified that a corrective action report does not address the finding(s) identified, then the laboratory shall have an additional thirty (30) days from the receipt of the notification to submit a revised corrective action report. If the revised corrective action report does not demonstrate the required corrections have*

been made, then ELAP will take action to deny, suspend or revoke accreditation for the Field(s) of Accreditation affected by the failure to take corrective action"

Rationale: This subsection outlines the required action to be taken by a laboratory in the event that a corrective action report does not fulfill the requirements, and summarizes the actions allowed by statute that ELAP may also take in response to the failure to correct the deficiencies in the report. This is not present in the current regulations.

Subsection (k): "*If a laboratory has submitted a complete renewal or amendment application package in accordance with Section 64808.05 or 64808.15, respectively, and additional time is needed by the Assessment Agency to complete an on-site assessment, then the laboratory shall be issued an interim certificate of accreditation.*

(1) A laboratory that holds an interim certificate of accreditation is accredited for Field(s) of Accreditation listed on the laboratory scope of accreditation.

(2) An interim certificate is non-renewable and shall be valid until one of the following occurs:

(A) An on-site assessment has been completed and a certificate of accreditation issued;

(B) The laboratory fails to meet the requirements for accreditation in accordance with Article 2; or

(C) The expiration date on the interim certificate of accreditation is reached"

Rationale: This subsection is needed to describe the conditions in which an interim certificate will be issued in the proposed regulations. This is a deviation from the current regulations. ELAP will no longer accept application for interim certificates and will only issue an interim when ELAP cannot meet the on-site assessment needs of a laboratory, which is more consistent with Health and Safety Code section 100850(c).

Section 64802.25. Accreditation Fees.

The proposed regulations are not making any changes to the fees. Pursuant to Health and Safety Code Section 100829(f)(3), the State Water Board adopts the schedule of fees by emergency regulation. The emergency regulation process is presided over by the State Water Board Division of Administrative Services. The current plan is for the emergency regulations to be presented to the State Water Board concurrently with the proposed regulations.

An example of a schedule of fees based on fee references in the proposed regulation is included in Subsections (a) through (e) and is subject to change during the emergency fee regulation process.

Persons interested in changes to the fee schedule should sign up for notifications on ELAP's list serve.

Article 3. Types of Accreditation.

The current regulations describe the application process, and the various criteria that have to be met by a laboratory. However, the current regulations do not clearly distinguish between the different types of accreditations and the associated criteria for each accreditation type in a clear and structured manner. The information is disorganized and not centrally located. Therefore, the objective of all the sections within Article 3, "Types of Accreditation" is to describe the criteria needed for each type of accreditation in a structured and organized format.

Section 64808.00 Initial Accreditation.

The purpose of this section is to describe the criteria that have to be met to obtain initial accreditation. The substantive changes to existing requirements or the addition of new requirements to this section are listed below:

Subsection (c): "*If any of the elements in Section 64802.00 are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory of the missing elements. When reviewing for completeness of an application package ELAP will only ensure each element has been submitted with the application package, and not that each element meets minimum requirements.*

(1) To resume processing, a complete application package shall be returned to ELAP within thirty (30) days from the date of ELAP's notification.
(2) If a complete application package is not returned to ELAP within thirty (30) days of receiving notice, then the application shall be withdrawn from consideration by ELAP"

Rationale: This subsection is needed to describe the requirements of a laboratory if an incomplete application is submitted to ELAP. The language on the response from ELAP is adapted from the current regulations. However, there is no language in the current regulations that describes the necessary response from the laboratory. This subsection is needed to establish a reasonable and enforceable timeframe for a laboratory to re-submit an application. It is necessary to determine a timeframe to consider an application no longer active because the program cannot commit resources and time on an application that is incomplete.

Section 64808.05 Renewal Accreditation.

The purpose of this section is to describe the criteria that must be met to obtain renewal accreditation. The substantive changes to existing requirements or the addition of new requirements to this section are listed below:

Subsection (c): *"If any of the elements in Section 64802.00 are missing from the application submission, then within thirty (30) days of the receipt of the application, ELAP will notify the laboratory. When reviewing for completeness of an application package ELAP will only ensure each element has been submitted with the application package, and not that each element meets minimum requirements.*

(1) To resume processing, a complete application package shall be returned to ELAP within thirty (30) days from the date of ELAP's notification.

(2) If a complete application package is not returned to ELAP within thirty (30) days, the application shall be withdrawn from consideration by ELAP"

Rationale: As with the section on initial accreditation, this subsection is needed to describe the requirements of a laboratory if an incomplete application for renewal is submitted to ELAP. The language on the response from ELAP is adapted from the current regulations. However, there is no language in the current regulations that describes the necessary response from the laboratory. This subsection is needed to establish a reasonable and enforceable timeframe for a laboratory to re-submit an application. It is necessary to determine a timeframe to consider an application inactive because the program cannot commit resources and time on an application that is incomplete.

Subsection (d): *"If a laboratory submits a renewal application package after the application due date, the laboratory shall be subject to a late fee equal to 15% of the accreditation fee.*

(1) ELAP will use the date a complete application package is received as the submittal date.

(2) Submittal of late renewal application could result in a lapse in accreditation. If accreditation is not renewed by the expiration date on the certificate of accreditation, the laboratory shall cease all reporting of results for regulatory purposes and notify clients of the lapse in accreditation by registered mail, email with return receipt or electronic signature document"

Rationale: This subsection is needed to establish a penalty for late submission of an application. A penalty is warranted to deter late submittals because late submittals can result in lapses in accreditation for laboratories or negative impacts to the program because of the need to dedicate resources to expedite application reviews in order to prevent lapses in accreditation. The penalty is an appropriate and proportionate

response to the lateness of the application. Laboratories can no longer analyze samples for regulatory purposes if their accreditation has expired.

Subsection (e): *"If a laboratory submits a renewal application package after the expiration date on its certificate of accreditation, the laboratory shall be subject to a late fee equal to 30% of the accreditation fee.*

(1) ELAP will use the date a complete application is received as the submittal date.

(2) The laboratory shall cease all reporting of results for regulatory purposes on the expiration date on its certificate of accreditation and notify clients of the lapse in accreditation by registered mail, email with return receipt, or electronic signature document"

Rationale: This subsection is needed to establish a penalty for late submission of an application. A penalty is warranted to deter late submittals because late submittals can result in lapses in accreditation for laboratories or negative impacts to the program because of the need to dedicate resources to expedite application reviews in order to prevent lapses in accreditation. The penalty is an appropriate and proportionate response to the lateness of the application. Laboratories can no longer analyze samples for regulatory purposes if their accreditation has expired.

Subsection (f): *"If a laboratory submits a renewal application package ninety (90) days after the expiration date on its certificate of accreditation, then accreditation shall not be renewable.*

(1) ELAP will use the date a complete application is received as the submittal date.

(2) The laboratory shall cease all reporting of results for regulatory purposes on the expiration date of its certificate of accreditation and notify clients of the lapse in accreditation by registered mail, email with return receipt, or electronic signature document"

Rationale: This subsection is needed to establish a time period where late application submittals are no longer accepted by ELAP and accreditation is no longer renewable. This subsection is needed to prevent applications from being in a perpetual renewal status, which can cause uncertainty in the program and the laboratory. A laboratory would have to file an application for an initial accreditation if it wanted to restart the accreditation the process.

Section 64808.10 Reciprocity Accreditation.

The purpose of this section is to outline the conditions and requirements of reciprocity accreditation. The substantive changes to existing requirements or the addition of new requirements to this section are listed below:

Subsection (a): "*Laboratories physically located outside of the State of California shall obtain accreditation through reciprocity."*

Rationale: This subsection is needed so laboratories operating outside of California will obtain accreditation through reciprocity and not through the normal accreditation process.

Subsection (b): *"For laboratories physically located outside the State of California, the environmental laboratory accreditation program of another state or federal agency shall be recognized for the purposes of reciprocity if the accreditation program requirements related to quality systems, test methods, Proficiency Testing, on-site assessments, personnel, and laboratory facilities and equipment are at least as stringent as ELAP accreditation requirements"*

Rationale: This subsection is needed to identify which laboratories are eligible for reciprocity accreditation. Only laboratories outside of California are eligible because laboratories within the state will request and obtain accreditation through the initial or renewal accreditation process. This determination is not made clear in the current regulations.

Subsection (c): "*The environmental laboratory accreditation programs of other state or federal agencies shall be recognized for reciprocity through a written agreement with ELAP"*

Rationale: This subsection is required to establish a formal, written agreement process to recognize other laboratory accreditation programs for reciprocity. The current regulations do list the criteria the accreditation program must meet to be eligible for a reciprocity agreement, but it does not establish a formal agreement process.

Subsection (d): "*For reciprocity accreditation, the period of accreditation shall be the time remaining on the certificate of accreditation provided by the primary accreditation body. If a laboratory submits a certificate of accreditation from more than one primary accreditation body, then the period of accreditation will be the time remaining on the certificate of accreditation that expires first."*

Rationale: This subsection is needed to identify the length of time a reciprocity accreditation certificate will be active. This is not explicitly detailed in the current regulations.

Subsection (g): "*If a laboratory, accredited through reciprocity, is notified of suspension or revocation of its certificate of accreditation by its primary accreditation body, then the laboratory shall:*

(1) Cease all reporting of results for regulatory purposes. The laboratory's ELAP certificate of accreditation shall be automatically withdrawn effective the date of the action taken by the primary accreditation body; and
(2) Notify ELAP within ten (10) days of the notification of suspension or revocation"

Rationale: This subsection is needed to outline the requirements of a laboratory that has had accreditation suspended or revoked by its primary accreditation body. The current regulations are silent on this requirement for reciprocity agreements.

Section 64808.15 Amendment Accreditation.

The purpose of this section is to outline the reasons for and requirements of amendment accreditation. The substantive changes to existing requirements or the addition of new requirements to this section are listed below:

Subsection (a): "*When a certificate of accreditation is amended, the period of accreditation shall be the time remaining on the certificate of accreditation from the date it was amended*"

Rationale: This subsection is needed to explain the length of accreditation when a laboratory amends a certificate of accreditation. This information is not in the current regulations.

Subsection (c): *"A laboratory shall submit an amendment application package for the following reasons:*

(1) Change in laboratory name, except if the change in laboratory name is in connection with a sale or transfer of ownership, then the laboratory shall comply with Section 64814.05;
(2) Change in laboratory location;
(3) Addition of a satellite laboratory or mobile laboratory to the existing accreditation; or
(4) Addition or reinstatement of Field(s) of Accreditation to the laboratory's current certificate of accreditation"

Rationale: This subsection is needed to list the various reasons that an amendment application is required. The current regulations only discuss the amendment related to addition of Field(s) of Accreditation, but do not address the other three reasons for

amendment applications. This is important because there are no requirements to direct laboratories in the other three scenarios.

Subsection (d): *"Amendments to a laboratory's accreditation are not accepted in the renewal application package. A separate amendment application package shall be submitted to amend accreditation"*

Rationale: This subsection is added because amendment application review can be more extensive than a renewal application review. Amendment application review may require additional staff time to update ELAP databases, perform an on-site assessment, or review standard operating procedures and quality manuals. Therefore, this subsection is needed to ensure that the amendment application process occurs separately than the renewal process.

Subsection (e): *"A laboratory applying for a change in laboratory name shall submit an amendment application package that includes the following:*

(1) Existing name of the laboratory;
(2) Certificate number of the laboratory;
(3) Address of the laboratory;
(4) Proposed new name of the laboratory;
(5) Signature of the laboratory owner, owner's agent, or officer; and
(6) Signature date"

Rationale: This subsection is needed to describe the required elements of an amendment application package when a laboratory changes name. There is no language in the current regulations that directs laboratories in this process.

Subsection (f): "*A laboratory applying for a change in laboratory location shall:*

(1) Within thirty (30) days prior to the change of location, submit a relocation plan to ELAP that includes the following laboratory identifying information:
(A) Name of the laboratory;
(B) Certificate number of the laboratory;
(C) Existing address of the laboratory;
(D) Address of the new location;
(E) Description of the new location;
(F) Timeline of the change in location;
(G) Signature of the laboratory owner, owner's agent, or officer; and
(H) Signature date;

(2) During the change in location, the laboratory shall:
(A) Comply with quality system requirements at the new location, in accordance with Section 64802.05;

(B) Not report data for regulatory purposes at the current and new location under the same accreditation;

(C) Cease reporting at the old location once the new location is reporting data for regulatory purposes;

(3) Within Ninety (90) days after the change of location, submit an amendment application package that includes the following:

(A) Laboratory identifying information, which includes:

(i) Name of the laboratory;

(ii) Certificate number of the laboratory;

(iii) Existing or previous address of the laboratory;

(iv) New address of the laboratory;

(v) Description of the new location;

(vi) Signature of the laboratory owner, owner's agent, or officer; and

(vii) Signature date;

(B) A copy of the laboratory Quality Manual, with updates necessitated by the change of location;

(C) A copy of new or revised Standard Operating Procedure(s) necessitated by the change of location;

(D) Proficiency Testing report(s) with acceptable scores for the Field(s) of Accreditation for which the laboratory is requesting accreditation, whereby analysis occurred at the new location; and

(E) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved corrective action report and/or corrective action plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20, whereby the assessment occurred at the new location"

Rationale: This subsection is needed to outline the process and requirements of a laboratory that is amending an accreditation certificate because of change in location. There is no language in the current regulations that directs laboratories in this process.

Subsection (g): *"A laboratory applying to add a satellite or mobile laboratory to an existing accreditation shall:*

(1) Prior to applying, ensure the laboratory meets the criteria for a satellite laboratory or mobile laboratory in accordance with Sections 64810.05 and 64810.10, respectively;

(2) Submit an amendment application package that includes the following:

(A) Laboratory identifying Information including:

(i) Name of the laboratory;

(ii) Details on the laboratory's type, size, location, business entity type, contact information and ownership;

(iii) Name and qualifications of the Technical Manager(s), including copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;
(iv) Name of the Quality Manager, if applicable;
(v) Agreement to comply with applicable ELAP statutes and regulations;
(vi) Signature of the laboratory owner, owner's agent, or officer; and
(vii) Signature date;

(B) Signed and populated Field(s) of Accreditation tables for which the satellite laboratory or mobile laboratory is requesting accreditation;
(C) Proficiency Testing report(s) with acceptable Field(s) of Proficiency Testing scores for each Field of Accreditation for which the satellite laboratory or mobile laboratory is requesting accreditation, whereby analysis occurred at the satellite or mobile laboratory; and
(D) A completed on-site assessment report from ELAP or a third-party Assessment Agency, including all findings and approved corrective action report and/or corrective action plan for each Field of Accreditation for which accreditation is requested in accordance with Section 64802.20, whereby the assessment occurred at the new laboratory;

(3) Pay the required fee in accordance with 64802.25"

Rationale: This subsection is needed to outline the process and requirements of a laboratory that is amending an accreditation certificate to add a satellite or mobile laboratory. The current regulations are silent on the amendment accreditation process to add a mobile or satellite laboratory to the existing accreditation certificate.

Subsection (i): "*The on-site assessment requirement for an amendment accreditation package may be waived if ELAP determines the amendment to accreditation would not affect the quality of the data."*

Rationale: This subsection is needed so ELAP can grant waivers for on-site assessments in the case where amendments to accreditation would not affect the quality of data produced.

Article 4. Types of Laboratories.

Section 64810.00 Main Laboratory.

The purpose of this section is to describe the criteria of a main laboratory. The language for this section was derived from the "stationary laboratory" definition in the current regulations.

Subsection (a): "*A laboratory may apply for accreditation as a main laboratory, in accordance with Section 64808.00, if the laboratory is:*

(1) Designated as the primary location;
(2) A fixed, permanent facility; and
(3) May include fixed-in-place vehicles"

Rationale: The criteria of a main laboratory are needed to distinguish between the other types of laboratories.

Section 64810.05 Satellite Laboratory.

The purpose of this section is to describe the criteria of a satellite laboratory and the conditions by which a satellite laboratory can be accredited. The language for this section was derived from the "auxiliary laboratory" definition in the current regulations.

Subsection (a): *"A satellite laboratory is a fixed, permanent facility (which includes fixed-in-place vehicles) that operates under a single scope of accreditation with a main laboratory*"

Rationale: This subsection is included to provide a definition and description of what constitutes a satellite laboratory.

Subsection (b): *"A main laboratory may apply for accreditation of a satellite laboratory under a single scope of accreditation, in accordance with Section 64808.15, if the following criteria are met:*

(1) The main laboratory and satellite laboratory operate under the same owner;
(2) The satellite laboratory operates with oversight from the main laboratory;
(3) The main laboratory and satellite laboratory are under the supervision of the same Technical Manager;
(4) The main laboratory and satellite laboratory operate under the same quality management system and Quality Manual;
(5) Reports identify which laboratory performed the analyses; and
(6) A single contact person is identified to communicate with ELAP regarding accreditation activities for the main laboratory and satellite laboratory"

Rationale: Subsection (a)(4) and (a)(6) is adapted from the definition of "auxiliary laboratory" in the current regulations. However, the other subsections are needed to require oversight of the satellite laboratory by the main laboratory and to clearly identify the boundaries that exist to the operation of a satellite laboratory to ensure the quality of data produced is not compromised by lack of oversight by the main laboratory. The current regulations do not clearly identify these criteria.

Subsection (c): "*Satellite laboratories shall comply with proficiency testing requirements in Section 64802.15 and on-site assessments in accordance with Section 64802.20"*

Rationale: This subsection was needed so that satellite laboratories are required to comply with the accreditation requirements independent of the main laboratory.

Section 64810.10 Mobile Laboratory.

The purpose of this section is to describe the criteria of a mobile laboratory and the conditions by which a mobile laboratory can be accredited. The criteria of a mobile laboratory are taken from the definition of "mobile laboratory" in the current regulations. The conditions by which a mobile laboratory will be offered accreditation is an added subsection.

Subsection (a): "*A mobile laboratory is a portable, enclosed structure (such as a vehicle, vessel, aircraft, or trailer) designed and equipped with the necessary and appropriate accommodations and environmental conditions for the transportation and use of laboratory equipment to perform analyses in the Field(s) of Accreditation for which accreditation is requested*"

Rationale: This subsection is included to provide a definition and description of what constitutes a mobile laboratory.

Subsection (d): *"A laboratory may apply for accreditation of a mobile laboratory under a single scope of accreditation, in accordance with Section 64808.15, if the following criteria are met:*

(1) The main laboratory and mobile laboratory operate under the same owner;
(2) The mobile laboratory operates with oversight from the main laboratory.
(3) The main laboratory and mobile laboratory are under the supervision of the same Technical Manager;
(4) The main laboratory and mobile laboratory operate under the same quality management system and Quality Manual;
(5) Reports identify which laboratory performed the analyses; and
(6) A single contact person is identified to communicate with ELAP regarding accreditation activities for the main laboratory and satellite laboratory"

Rationale: This subsection is needed to define the criteria of accreditation for a mobile laboratory. This is important to distinguish a mobile laboratory from a main laboratory or satellite laboratory, as well as, ensure the quality of the data from the mobile laboratory is not compromised by the mobility of the laboratory and lack of oversight from the main laboratory.

Subsection (e): "*Mobile laboratories operating under a single scope of accreditation as a main laboratory shall comply with proficiency testing requirements in Section 64802.15 and on-site assessments in accordance with Section 64802.20"*

Rationale: This subsection was needed so that mobile laboratories that are under the same scope of accreditation as a main laboratory are required to comply with the accreditation requirements independent of the main laboratory.

Article 5. Laboratory Personnel, Facilities and Equipment.

Section 64812.00 Laboratory Personnel.

The purpose of this section is to describe the roles and responsibilities of key laboratory personnel and the credentials and experience that must be held by these positions. Some of the requirements for this section were adapted from requirements in Section 64817, "Laboratory Personnel" in the current regulations.

The new requirements added in this section are described below:

Subsection (d): "*The Technical Manager, and/or their designee, shall:*
(1) Comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Sections 4.1.7.2 (with the exception of part [f]); or"

Rationale: This subsection is added to reference the roles and responsibilities of the Technical Manager as described in the 2016 TNI Standard, which will be effective three years from the effective date of the proposed regulations. The referenced requirements are more detailed and specific on the roles and responsibilities of the Technical Manager than the current regulations, which will require more managerial oversight of laboratory activities by the Technical Manager. This will also provide more enforceable language when Technical Mangers are not providing proper management of the laboratory. The referenced exception is the section in the 2016 TNI Standard that lists the required credentials of a Technical Manager. This is one of the two sections of the 2016 TNI Standard that is not included in the proposed regulations.

Subsection (f): "*If a Technical Manager is absent for a period of time exceeding:*
(1) Fifteen (15) consecutive days, a person meeting the qualifications of the Technical Manager shall be designated to serve as a temporary Technical Manager; or
(2) Thirty-five (35) consecutive days, ELAP shall be notified in writing"

Rationale: This subsection is needed to ensure that the laboratory is properly supervised by experienced and qualified personnel when a Technical Manager is not

present for an extended period of time. A similar requirement is absent from the current regulations.

Subsection (g): "*Three (3) years from the effective date of these regulations, a laboratory shall designate a Quality Manager. The Quality Manager, and/or their designee, shall comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.1.5(i), 4.1.7.1, 4.2.6, 4.2.8.2 and 4.14.1"*

Rationale: This subsection introduces a new required position within the laboratory that will ensure the quality of the data produced and the Quality Manual used by a laboratory. This position does not require a new hire, but just that the responsibilities of the position are undertaken by an individual. The roles and responsibilities are clearly defined in the referenced sections of the 2016 TNI Standard. This position is not required in the current regulations despite being a central position to ensure the quality of a laboratory. This subsection is needed to make sure the responsibilities of the position are clearly defined and designated to a qualified individual within the laboratory.

Section 64812.05 Laboratory Facility and Equipment.

This purpose of this section is to ensure that laboratory facilities and laboratory equipment are maintained and operated in a way that ensures the quality of data produced. Some of the requirements of this section are adapted from Section 64813, "Laboratory and Equipment" in the current regulations.

The added requirements of this section are listed below:

Subsection (a): "*A laboratory facility shall:*

(1) Comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Sections 5.3, 5.5, and 5.6; or

(2) Be arranged and operated so that:

(A) Utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Field(s) of Accreditation for which the laboratory is accredited;

(B) Ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond established quality control limits as specified in the approved test methods or in the laboratory's Quality Manual;

(C) The design, arrangement, housekeeping, and operation of the laboratory minimizes the potential for sample contamination;

(D) Each piece of laboratory equipment meets all operational, quality assurance, quality control, and design criteria established in the approved method(s) employed by the laboratory;

(E) Each piece of laboratory equipment is operated and maintained by the laboratory as specified in the Quality Manual and Standard Operating Procedures; and
(F) Records are kept of all operational and maintenance activities associated with the operation of laboratory equipment"

Rationale: This subsection is needed to ensure that laboratory facilities and laboratory equipment are maintained and operated in a way that ensures the quality of data produced.

The added requirements include referenced sections of the 2016 TNI Standard that provides detailed and specific requirements of laboratory facilities and instrument operations, as well as, language adapted from current regulations that will be in effect during the three-year delayed TNI implementation period. Subsections (a)(2)(D-F) were added to the language from the current regulations to ensure that the facility and instrumentation operation is consistent with analytical methods and a laboratory's Quality Manual and that records of activities are maintained during the three-year implementation period.

Subsection (e): *"When there is a change of sophisticated technology the laboratory shall:*
(1) Update the Quality Manual necessitated by the change of sophisticated technology;
(2) Update or create Standard Operating Procedure(s) necessitated by the change of sophisticated technology;
(3) Submit an amendment application package in accordance with 64808.15(g), if the sophisticated technology is a new technology to the laboratory; and
(4) Retain all records necessary to determine compliance with this subdivision and provide these records to ELAP upon request"

Rationale: This subsection is needed to make sure that changes to sophisticated technology is documented throughout all pertinent records and accurately reflect current laboratory activities. The current regulations do not have requirements of these documentation practices.

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

Section 64814.00 Notification, Reporting, and Control of Records.

The purpose of this section is to outline the notification, reporting, and records retention requirements of the laboratories. These requirements are adapted from Section 64815,

"Quality Assurance" and Section 64819, "Notification and Reporting" in the current regulations. The subsections with new requirements are discussed below:

Subsection (a): *"State Regulatory Agencies and federal agencies to whom data is reported may have notification, reporting, and record retention requirements that are in addition to requirements here, and it is the responsibility of the laboratories to know those additional regulatory requirements"*

Rationale: This subsection is needed to inform the laboratories that State Regulatory Agencies and federal agencies they are reporting data to may have notification and reporting requirements that differ the requirements stated here, and that these requirements do not supersede the requirements of other agencies or programs.

Subsection (b): "*If an analytical result warrants a client notification, then the notification shall occur after the Technical Manager or designee, set forth in the laboratory's Quality Manual, has approved of the result"*

Rationale: This subsection is needed to clarify when the notification of the laboratory can occur. The notification cannot be given until the results of an analysis are approved by the Technical manager or designee. Therefore, preliminary results shall not be used for notification purposes.

Subsection (c): "*A laboratory accredited to perform analyses on drinking water samples shall notify a water supplier's designated contact person:*

(1) Immediately within 24 hours, when the following results are confirmed:
(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli);
(B) A bacterial sample result is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b);
(C) A nitrate sample result exceeds the maximum contaminant level; or
(D) A chlorite sample result collected at the entry point of a water distribution system exceeds the maximum contaminant level;
(2) Immediately within 48 hours, when the following results are confirmed:
(A) A perchlorate sample result exceeds the maximum contaminant level;
(B) A chlorine dioxide sample result exceeds the maximum residual disinfectant level; or
(C) A chlorite sample result exceeds the maximum contaminant level"

Rationale: This subsection is needed to provide more clarity into the notification requirements for acute toxins. These requirements are derived from the California Code

of Regulations Section 64423.1(b) and approved by the State Water Board Division of Drinking Water.

Subsection (f): *"When a laboratory subcontracts work:*

(1) The subcontracting laboratory shall comply with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.5; or

(2) The subcontracting laboratory shall comply with the following requirements:

(A) The subcontracting laboratory shall inform the customer(s) of arrangement with subcontractor(s);

(B) The subcontracting laboratory shall maintain a register of all subcontractors that are used for analytical testing;

(C) The subcontractor shall be accredited by ELAP in the Field(s) of Accreditation for analyses being performed for regulatory purposes;

(D) The subcontracting laboratory shall include the original of any report(s) prepared by the subcontractor; and

(E) The subcontracting laboratory shall provide the required notification in accordance with subdivision (c), above, unless there is an arrangement in writing that the subcontractor will provide the required notification"

Rationale: This subsection is needed to clarify the relationship and responsibilities of subcontracting and subcontracted laboratories. This information is not in the current regulations and is needed for accountability and enforcement of responsible parties. The added requirements include referenced sections of the 2016 TNI Standard that provides detailed and specific requirements for subcontracting, as well as language adapted from current regulations that will be in effect during the three-year delayed TNI implementation period to ensure that certain procedures are followed when subcontracting work.

Subsection (h): *"A laboratory shall report to clients:*

(1) In accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 5.10; or

(2) In accordance with the request for analysis, the full and complete results of all requested contaminants and pollutants from the analyses of the sample or components thereof"

Rationale: This subsection is needed to establish the responsibilities of laboratories when reporting to clients. The 2016 TNI Standard requirements for reporting to clients are specific and detailed on these responsibilities. Subsection (h)(2) is from the current regulations and lacks guidance for laboratories on these responsibilities.

Subsection (j): *"A laboratory performing bacteriological analyses on drinking water samples shall submit a bacterial monitoring report with bacteriological results to the*

State Water Board in accordance with Title 22, California Code of Regulations, Section 64423.1(c)(2) and (c)(3)"

Rationale: This subsection is included per the request of the State Water Board Division of Drinking Water to inform laboratories of their reporting responsibilities. This language is derived from the California Code of Regulations Section 64423.1(c).

Subsection (k): *"A laboratory performing chemical analyses on drinking water samples in accordance with Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring shall report analytical results to the State Water Board by the 10th day of the month following the month in which the analyses were completed. The results shall be reported electronically using the following:*

(1) Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001; or

(2) The California Laboratory Intake Portal (CLIP) using the federal CMDP schema with quality control elements related to individual sample results in PDF or electronic format;

Rationale: This subsection is needed to update the reporting requirements of laboratories to incorporate technologies and services used in current practices. Some of the language of this requirement is adapted from current regulations.

Subsection (l): *"A laboratory performing chemical analyses on drinking water samples in accordance with Title 22, California Code of Regulations, Division 4, Chapter 15.5, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors, and Chapter 17.5, Lead and Copper, or other required monitoring shall report analytical results directly to the State Water Board by the 10th day of the month following the month in which the analyses were completed. If the State Water Board is unable to accept results for these specific analytes electronically as set forth in subdivision (k), above, then results shall be submitted by hard copy or as otherwise directed by the State Water Board"*

Rationale: This subsection is needed to inform laboratories of their responsibility to report drinking water data to the State Water Board by the 10th day of the month following the month the analyses were completed. This requirement is stated in State Water Board Division of Drinking Water regulations but is not included in the current regulations.

Subsection (n): *"A laboratory shall establish and maintain a system to control records:*

(1) in accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 4.13; or

(2) That allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and or extracts. Records shall be retained for a minimum of five (5) years from generation of the last entry in the records"

Rationale: This subsection is needed to establish a robust and detailed records retention policy. The records are important to retain to ensure that historical recreation of laboratory activities and results can be achieved for legal defensibility and accountability. The current regulations lack detail on this requirement.

Section 64814.05 Notification of Change of Technical Manager or Change of Ownership.

The requirements in this section are adapted from Section 64827, "Sale or Transfer of Ownership" in the current regulations and consistent with Health and Safety Code Section 100845(d). The added requirements in this section are discussed below:

Subsection (a): *"When there is a change of Technical Manager and/or Quality Manager, the laboratory shall, within thirty (30) days, submit notification to ELAP that includes:*

(1) Name of the laboratory;
(2) Certificate number of the laboratory;
(3) Address of the laboratory;
(4) Name(s) of existing or previous Technical Manager and/or Quality Manager;
(5) Name(s) of new Technical Manager and/or Quality Manager;
(6) Qualifications of new Technical Manager in accordance with Section 64812.00;
(7) Copies of applicable degrees and/or Laboratory Analyst/Water Quality Analyst Certificates from CWEA or CA-NV/AWWA;
(8) Signature of the laboratory owner, corporate officer authorized to act on behalf of the laboratory, or owner's agent (including authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and
(9) Signature date"

Rationale: This subsection is needed to provide direction to laboratories on the process to inform ELAP of a Technical Manager or Quality Manager change. This process is needed because Technical Manger and Quality Manager are essential personnel for a laboratory and the process is mandated by law in Health and Safety Code Section 100845(d).

Subsection (b): *"When the ownership of a laboratory is changed or transferred, the new owner may request to operate under the laboratory's existing ELAP certificate of accreditation as stated in Health and Safety Code Section 100845 subdivisions (b) and (c)*

(1) To request to operate under the laboratory's existing ELAP certificate of accreditation, the new owner shall, within thirty (30) days after the effective date of ownership change, submit a written request to ELAP and pay the fees in accordance with Section 64802.25. The written request shall include:

(A) Name(s) of the new owner(s) and the owner(s) designee, if applicable;
(B) Effective date of the change in ownership;
(C) Name(s) and qualifications of current Technical Manager;
(D) Name of current Quality Manager;
(E) Statement that the new owner will operate pursuant to the laboratory's existing Quality Manual. If changes to the laboratory are made that may adversely affect the quality of the analyses in Field(s) of Accreditation, the new owner shall submit:

(i) An updated Quality Manual; and
(ii) Proficiency Testing report(s) with acceptable Field(s) of Proficiency Testing scores for each Field of Accreditation affected by the change in ownership;

(F) Statement that the laboratory will remain in the existing location;
(G) Statement that the new owner has retained more than half of laboratory personnel upon assuming ownership;
(H) Statement that the new owner will retain all records and data from analyses performed under the previous ownership for a minimum of five (5) years;
(I) Statement that the new owner will comply with applicable laws and regulations;
(J) Signature of the new owner, corporate officer authorized to act on behalf of the owner, or owner's agent (including documentation of authority to act on behalf of the owner) attesting to the truthfulness of the information submitted; and
(K) Signature date.

(2) ELAP may conduct an on-site assessment in response to a change in ownership. If an on-site assessment is conducted, the laboratory shall comply with requirements in accordance with Section 64802.20"

Rationale: This subsection is needed to clarify the requirements in Section 64827, "Sale or Transfer of Ownership" in the current regulations. The current regulations are less specific and leave the process up for interpretation by laboratories. The requirements are mandated by law in Health and Safety Code Section 100845(b) and (c).

Additionally, the on-site assessment requirement is needed to ensure that ownership changes do not negatively affect laboratory operations, or data produced by the laboratory. The current regulations are silent on this requirement.

Section 64814.10 Trade Secrets.

This section comes directly from the current regulations Section 64825. “Trade Secrets”.

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

Section 64816.00 Denial of Accreditation.

The purpose of this section is to establish conditions under which accreditation may be denied. The authority for this section is granted in Health and Safety Code Section 100850(b). All subsections in this section are new and listed below:

Subsection (a): *“Reasons for denying a laboratory’s application for accreditation shall include:*

(1) A laboratory fails to submit a complete application package in accordance with Section 64802.00;
(2) A laboratory fails to implement a quality system in accordance with Section 64802.05;
(3) A laboratory fails to comply with the analytical method(s) listed on the laboratory’s application for accreditation;
(4) A laboratory fails to analyze or report acceptable scores of Field(s) of Proficiency Testing samples in accordance with Section 64802.15;
(5) A laboratory submits, as its own, Proficiency Testing sample results generated by another laboratory;
(6) A laboratory fails to complete a required on-site assessment in accordance with Section 64802.20;
(7) A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.20;
(8) A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.20;
(9) A laboratory fails to pay fees in accordance with Section 64802.25;
(10) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;
(11) A laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;
(12) A laboratory knowingly makes any false statement or representation pertinent to receiving accreditation;

(13) A laboratory knowingly makes any false statement or representation in an application, record, or other document; and/or
(14) The laboratory fails to comply with any other provision of these regulations"

Rationale: This subsection is needed to provide conditions under which an accreditation request is denied by the program. The conditions for denial of accreditation is not limited to the infractions listed because the State Water Board is granted authority in the Health and Safety Code to deny accreditation for any violation of the regulations. A list of conditions for denial of accreditation serves as guidance to the laboratories and, therefore, added in the proposed regulations.

Section 64816.05 Issuance of a Citation.

The purpose of this section is to establish conditions under which a citation may be issued to a laboratory. The authority for this section is granted in Health and Safety Code Section 100880. However, current regulations do not list the conditions that may lead to enforcement actions and rely on the authority in the Health and Safety Code to make an enforcement determination. All subsections in this section are new and listed below:

Subsection (a): *"Reasons for issuing a citation shall include:*
(1) A laboratory fails to maintain a quality system in accordance with Section 64802.05;
(2) A laboratory fails to comply with the analytical method(s) listed on the laboratory's certificate of accreditation;
(3) A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;
(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;
(5) A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.20;
(6) A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.20;
(7) A laboratory fails to pay fees in accordance with Section 64802.25;
(8) A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15(d)(e) and (f);
(9) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;
(10) A laboratory makes consistent errors in analyses or erroneous reporting;
(11) A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;

(12) A laboratory knowingly makes any false statement or representation in an application, record, or other document;
(13) A laboratory fails to notify ELAP of a change in ownership; and/or
(14) A laboratory fails to comply with any other provision of these regulations"

Rationale: This subsection is needed to provide conditions under which a citation may be issued by the program. The conditions for issuance of a citation are not limited to the infractions listed because the State Water Board is granted authority in the Health and Safety Code to issue a citation for any violation of the regulations. A list of conditions for issuance of a citation is not in the current regulations, but serves as guidance to the laboratories and, therefore, added in the proposed regulations.

Section 64816.10 Suspension or Revocation of Accreditation.

The purpose of this section is to establish conditions under which accreditation may be suspended or revoked. The authority for this section is granted in Health and Safety Code Section 100905. However, current regulations do not list the conditions for enforcement actions and rely on the authority in the Health and Safety Code to make an enforcement determination. All subsections in this section are new and listed below:

Subsection (a): *"(a) Reasons for suspending or revoking accreditation shall include:*
(1) A laboratory fails to maintain a quality system in accordance with Section 64802.05;
(2) A laboratory fails to comply with the analytical method(s) listed on the laboratory's certificate of accreditation;
(3) A laboratory fails to complete Proficiency Testing studies in accordance with Section 64802.15;
(4) A laboratory fails to complete an on-site assessment in accordance with Section 64802.20;
(5) A laboratory fails to respond to an on-site assessment report with a corrective action report in accordance with Section 64802.20;
(6) A laboratory fails to implement the corrective actions detailed in the corrective action report within the required timeframe in accordance with Section 64802.20;
(7) If, during an on-site assessment, ELAP determines that suspension or revocation is necessary to protect public interest, safety or welfare;
(8) A laboratory denies entry during normal business hours for either an announced or unannounced on-site assessment;
(9) A laboratory fails to pay fees in accordance with Section 64802.25;
(10) A laboratory fails to notify ELAP of changes in key accreditation criteria referenced in Section 64808.15(d)(e) and (f);

(11) A laboratory fails to employ staff that meet the personnel qualifications in accordance with Section 64812.00;
(12) A laboratory makes consistent errors in analyses or erroneous reporting;
(13) A laboratory knowingly makes any false statement or representation pertinent to receiving or maintaining accreditation;
(14) A laboratory knowingly makes any false statement or representation in an application, record, or other document;
(15) A laboratory fails to notify ELAP of a change in ownership; and/or
(16) A laboratory fails to comply with any other provision of these regulations"

Rationale: This subsection is needed to provide conditions under which an accreditation is suspended or revoked by the program. The conditions for suspending or revoking accreditation are not limited to the infractions listed because the State Water Board is granted authority in the Health and Safety Code to suspend or revoke accreditation for any violation of the regulations. A list of conditions for suspending or revoking accreditation is not in the current regulations, but serves as guidance to the laboratories and, therefore, added in the proposed regulations.

Subsection (b): *"If a laboratory's accreditation for a Field(s) of Accreditation is suspended, the laboratory shall cease all reporting of results for regulatory purposes for the Field(s) of Accreditation that were suspended"*

Rationale: This subsection is needed to ensure data is not being reported by laboratories that are not accredited in a Field of Accreditation.

Subsection (c): *"To reinstate a suspended Field(s) of Accreditation, a laboratory shall submit an amendment application in accordance with Section 64808.15"*

Rationale: This subsection is needed to inform laboratories of the process to reinstate Field(s) of Accreditation following suspension.

Subsection (d): *"If a laboratory's accreditation has been revoked, the laboratory shall:*
(1) Discontinue use of all catalogs, advertising, business solicitations, proposals, quotations, or materials that contain reference to their past accreditation status;
(2) Return its certificate of accreditation to ELAP;
(3) Cease all reporting of results for regulatory purposes;
(4) Notify all regulatory clients of the revocation status within three (3) days of receiving notice of revocation from ELAP. Notification shall be made by registered mail, email with return receipt, or electronic signature document;
(5) Provide ELAP with a list of regulatory clients affected by the revocation; and

(6) Discontinue use of subcontracting agreements for regulatory purposes with laboratories within seven (7) days of receiving notice of revocation from ELAP"

Rationale: This subsection is needed to inform laboratories of actions required of the laboratory following revocation of accreditation.

Subsection (e): *"To be reinstated after revocation, the laboratory shall apply for initial accreditation, in accordance with Section 64808.00, as if it were a new laboratory"*

Rationale: This subsection is needed to inform laboratories of the process to reinstate accreditation following the revocation of accreditation.

Rationale for Sections Repealed:

Many of the sections listed below were repealed because the entire structure and format of the proposed regulations differs greatly from that of the current regulations. It was more pragmatic to repeal the sections of the current regulations and add and restructure the proposed regulations with new sections then to try and reorganize the existing structure. However, some requirements and language from the repealed sections were retained and adapted for the new sections in the proposed regulations. Requirements that were retained and reworded for clarity but did not change the intent of the requirement were considered non-substantive changes to the regulation and not described above. Alternatively, the requirements that were retained but had subsections or additional elements added to the requirement are considered substantive changes and described above.

Below are the sections that were repealed and the rationale for the repeal.

Section 64803. Certification and Amendment: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64802.00 "Accreditation Criteria" and Section 64808.15 "Amendment Accreditation" in the proposed regulations.

Section 64805. Application: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64802.05, "Application Package" in the proposed regulations.

Section 64806. Certification Fees: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. A new section about fees, Section 64802.25, “Accreditation Fees,” is in the proposed regulations.

Section 64807. Site Visits: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64802.25, “On-Site Assessment” in the proposed regulations.

Section 64809. Performance Evaluation Testing: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64802.20, “Proficiency Testing” in the proposed regulations.

Section 64811. Test Methods: The entire section is repealed.

Rationale: This section was repealed to remove analytical test methods from the regulations. The proposed regulations instead state that ELAP will offer accreditation in field(s) of accreditation, which are analytical test method, analyte, and matrix combinations that ELAP will accredit, related to analytical test methods required by the State Regulatory Agencies in their permits, orders or other regulatory requirements. A list of fields of accreditation would be maintained on ELAP’s website for convenience to the laboratories and updated as State Regulatory Agencies notify ELAP that they have changed what analysis is required for their regulatory programs.

Each agency, pursuant to its own particular statutes and regulations, would identify monitoring requirements in its permits, orders and other regulatory requirements, such as in statute or regulations. For example, regulations regarding the testing of drinking water samples require in regulation the use specific analytical test methods. Other times, a specific analytical test method may be set out in the individual permit or order issued by the state agency or a detection limit is identified, which the analytical test method used by the laboratory must meet. The public, regulated entities, and the laboratories that perform the testing for the regulated entities would have the opportunity to weigh in on the analytical test methods being required during the development and adoption of those requirements. For example, permits issued by the regional water boards for discharges of wastewater to surface water may include specific testing requirements, and those permits are required to undergo a public comment period before adopted by a regional water quality control board.

This proposal is also consistent with the recommendations of the Expert Review Panel. The current list of analytical test methods the program is using were incorporated into the California Code of Regulations in 1994 and are woefully out of date. A key recommendation of the ERP was for ELAP to update the regulations and remove references to specific methods in order to provide more flexibility and breadth to the accreditation program and accredit current, relevant methods that regulatory authorities need to adequately protect California's health and environment. In 2016, the legislature made an important step toward this recommendation by removing a list of specific analytical test methods and fields of accreditation from statute.

Section 64813. Laboratory and Equipment: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64812.05, "Laboratory Facilities and Equipment" in the proposed regulations.

Section 64815. Quality Assurance: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64802.10, "Quality Systems" in the proposed regulations.

Section 64817. Laboratory Personnel: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64812.00, "Laboratory Personnel" in the proposed regulations.

Section 64819. Notification and Reporting: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64814.00, "Notification, Reporting, and Records Retention" in the proposed regulations.

Section 64821. Reciprocity Agreements: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section

were retained and used in Section 64808.10, “Reciprocity Accreditation” in the proposed regulations.

Section 64823. Fields of Testing: The entire section is repealed.

Rationale: This section was repealed because the proposed regulations introduce a different framework to accreditation from the Fields of Testing. In the proposed regulations, the laboratories are accredited in fields of accreditation, which are analytical method, analyte, matrix combinations offered by ELAP. The list of fields of accreditation will be published on ELAP’s website and updated based on the regulatory needs of state agencies. The need to incorporate the fields of accreditation by reference is discussed in Section 64811, “Test Methods”, above.

Having the analytical test methods (or fields of accreditation) that ELAP will accredit for be decided by the State Regulatory Agencies in their permits, orders and other regulatory requirements does not create new obligations for the laboratories. Any updates to the analytical test methods offered for accreditation would not create new obligations on the laboratories. Laboratories are not required to be accredited for any specific analytical method. The choice of which analytical methods (field of accreditation) to be accredited for is completely up to the laboratory. Therefore, if new fields of accreditation are offered because they are required by a State Regulatory Agency’s permit, order or other regulatory requirement, a laboratory could choose not to be accredited for that field of accreditation. The process for obtaining accreditation for fields of accreditation is set forth in regulation and is the same regardless of what field of accreditation a lab requests to be accredited in. Therefore, the requirements of the laboratory for accreditation would not change when new fields of accreditation are added, unless a laboratory wanted to be accredited for the new offering.

ELAP exists for the benefit of the state agencies that are required to use accredited laboratories to analyze environmental samples for regulatory purposes, and having a laboratory be accredited gives the agencies greater confidence in the data that they are relying on to make decisions that affect the environment and public health. Although laboratories may believe that accreditation generally provides them independent benefits, such as providing status as a well-run laboratory, the fields of accreditation that laboratories are accredited for is ultimately for the benefit of state agencies. Therefore, having the fields of accreditation be determined and identified by agencies in their permits, orders or other regulatory requirements fits with the purpose of the regulatory program. In addition, having the state agencies identify which fields of accreditation they want ELAP to offer does not impact the rights and obligations of the laboratories. How laboratories are accredited will be set out in regulations and would not substantially change based on what the laboratory was being accredited for.

Section 64825. Trade Secrets: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Requirements and language from this section were retained and used in Section 64814.10, “Trade Secrets” in the proposed regulations.

Section 64827. Sale or Transfer of Ownership: The entire section is repealed.

Rationale: This section was repealed because of the reorganization and restructure effort of the proposed regulations. Some requirements and language from this section were retained and used in Section 64814.05, “Notification of Change of Technical Manager or Change of Ownership” in the proposed regulations.

Section 64860. NELAP Accreditation Fees: The entire section is repealed.

Rationale: This section was repealed. ELAP is no longer a NELAP-recognized Accrediting Body so NELAP Accreditation Fees do not apply.

III. SPECIFIC CONSIDERATIONS REGARDING PROPOSED REGULATIONS

Below are specific considerations that support incorporating the 2016 TNI Standard with two California-specific exceptions into the proposed regulations.

Data of Known and Consistent Quality

California statutes require the use of accredited laboratories to analyze environmental samples for regulatory purposes.[7] State agencies rely upon data produced by laboratories to make decisions that affect the environment and public health and that have significant economic impacts on California citizens. Therefore, state agencies are extremely invested in the effectiveness of a viable laboratory accreditation program and were a major voice in the accreditation standard selection process.

ELAP invited representatives from state and federal regulatory agencies to discuss analytical and data quality needs. Seven agencies participated, including the State Water Resources Control Board, Regional Water Quality Control Boards, Department of Toxic Substances Control, Department of Pesticides Regulation, Department of Public Health, Department of Fish and Wildlife and the Federal Food and Drug Administration. These seven agencies represent the end users of data produced by the environmental testing laboratories regulated by ELAP.

[7] Health and Safety Code Section 25198, Section 25298.5, Section 25358.4, Section 110490 & Section 116390 and Water Code Section 13176

ELAP first convened with the state agency representatives in March 2016 to discuss the needs of each agency and how the three alternative accreditation standard paths could meet those needs. The major need of the representing agencies was data of known and consistent quality. This need was broken down into four major areas: accuracy, consistency, quality assurances and legal defensibility of the data. Based on the needs of the agencies, the majority of representatives voted to recommend ELAP adopt the 2016 TNI Standard as the program's accreditation standard. This recommendation was a major factor in the decision to incorporate the 2016 TNI Standard into the proposed regulations.

Assessments of Drinking Water Laboratories

As part of ELAP's reform efforts following the program assessment from the ERP, ELAP entered into a contract with NV5/Dade Moeller, a national laboratory assessment firm, to help train ELAP assessors and help perform on-site assessments of ELAP-accredited laboratories analyzing drinking water contaminants in California.

In 2018, NV5/Dade Moeller reported their findings from 68 on-site assessments with a focus on laboratory compliance with drinking water analytical methods and current regulations. The findings were presented to the State Water Board at its October 2, 2018 meeting. ELAP staff analyzed the reported findings and deficiencies from these assessments and the results were alarming. Many of the laboratories assessed had large numbers of deficiencies, and the laboratories with large numbers of deficiencies had deficiencies that were significant in nature. Multiple significant deficiencies indicate a laboratory is not meeting minimum competency levels and that the quality of data produced could be impacted. Furthermore, 25% of all deficiencies were related to Quality Assurance requirements, with small laboratories having three times as many Quality Assurance-related deficiencies than other laboratory subgroups. A review of the assessment data by an independent company came to similar conclusions.[8]

The poor performance of drinking water laboratories, highlighted by these assessment findings, was not determined until after ELAP moved forward with incorporating the 2016 TNI Standard into the proposed regulations. However, these findings further support the need for a much better and more robust set of accreditation standards, but also accreditation standards that are specific, detailed, and enforceable. Additionally, it underscores the urgency by which the accreditation standards need to be updated. The 2016 TNI Standard satisfies all these prerequisites and would serve as a roadmap for laboratories.

[8] Lawver, Diane (2018) CA ELAP: NV-5/Dade Moeller Audit Findings Summary. Quality Assurance Solutions, LLC.

Enforcement Cases

Although regulatory oversight through establishment of ELAP's Enforcement Unit has improved, the ability to demonstrate non-conformance with the current regulations, and thereby, the effectiveness of enforcement is impeded by the vague and insufficiently detailed accreditation standards. Furthermore, the inadequate accreditation standards in the current regulations are easily exploited by laboratories, both knowingly and unknowingly. Consequently, the standards for quality and compliance varies greatly among laboratories.

For example, as part of a criminal enforcement case against a laboratory that had been accredited by ELAP for nearly 15 years[9], ELAP uncovered evidence of laboratory management exploiting ELAP's vague and insufficiently detailed accreditation standards to alter data, disregard failed quality control tests, ignore gaps in the chain of custody (sample handling), improperly reuse sample containers, and neglect to maintain laboratory equipment and facilities.

From 2015 to 2018, ELAP's Enforcement Unit has responded to over forty (40) referrals from state agency programs. At the core of the statutory and regulatory violations that have been identified through enforcement inspections, including the criminal case discussed above, is the lack of a systematic process for ensuring quality. Under the framework of the current accreditation standards, quality assurance is one dimensional with a focus on requirements identified in the test methods. This places the burden for data quality on the laboratory analyst; which absolves laboratory management of responsibility and is antithetical to the generation of defensible data. Additionally, the current accreditation standards do not promote historical reconstruction of the data and lack data integrity requirements including confidential reporting of data integrity issues.

The detailed quality system requirements included in the 2016 TNI Standard are designed for consistent and uniform implementation by laboratories, creating an equal standard for quality and compliance. Furthermore, the technical, managerial, and documentation requirements specified in the 2016 TNI Standard are designed to produce data of a known and documented quality, such that data can be historically reconstructed. Collectively, this will improve ELAP's ability to identify non-conformance and effectively verify laboratory competency on any given day, not just when conducting announced routine on-site assessments.

[9] ELAP enforcement case: https://www.waterboards.ca.gov/water_issues/programs/enforcement/docs/2017/caltech_felony_PR_final.pdf

Laboratory Mentorship Program

Other state accreditation programs that converted their program's accreditation standards to the nationally recognized, consensus-based TNI Standard suggested that smaller laboratories may have a harder time with TNI implementation.[10] Although there is no requirement in the TNI Standard that cannot be implemented by a small laboratory, other state programs observed that smaller laboratories required more time to implement the TNI Standard. Despite a three-year staged implementation period that will be granted to laboratories to implement the 2016 TNI Standard, the State Water Board assumes that a percentage of small laboratories will be unable to retain ELAP accreditation and may close or forego accreditation and only run analysis for internal operational, non-regulatory purposes.

Potential laboratory closures are of great concern for the State Water Board, which is why ELAP supports the TNI Mentorship Initiative, which was initiated in California by the American Council of Independent Laboratories (ACIL). This initiative unites mentor laboratories that have implemented TNI and are currently TNI-accredited with small laboratories of the state. The objective of the program is for mentor laboratories to help the small laboratories with the implementation process and identify needs of the laboratory to become compliant with the proposed regulations and the 2016 TNI Standard (with two California-specific exceptions). This program initially targeted laboratories that service remote areas and communities in the state where a laboratory closure may result in loss of service for that community. However, interest in in the program, from both potential mentor laboratories and small laboratories, is growing. This program has been very successful, with five small laboratories implementing the 2016 TNI Standard within six to eight months. without additional costs or new personnel.

This TNI Mentor Initiative or similar programs would not be possible with the adoption of a state-created accreditation standard. The 2016 TNI Standard is an existing standard, utilized by laboratories across the nation and well supported by templates and trainings that aid in the implementation process. This was the main reason that the mentorship initiative was able to be launched with successful results.

IV. EVALUATION OF REGULATORY ALTERNATIVES

Government Code section 11346.2(b)(4) requires that the State Water Board consider reasonable alternatives to the regulation and the agency's reasons for rejecting those alternatives. The State Water Board considered two alternative accreditation standards

[10] Interview with New Jersey Department of Environmental Protection, Office of Quality Assurance

to incorporate into the proposed regulations: (1) a state-created accreditation standard, and (2) a modified version of an existing accreditation standard.

The State Water Board's reasoning for rejecting the alternatives is that they are lacking in effectiveness and credibility and represent the status quo. As identified below, the 2016 TNI Standard is consensus-based, EPA approved, and technically superior to the alternative accreditation standards. ELAP engaged in a multi-year, stakeholder-involved process (Figure 1) to evaluate the accreditation standard options and select the best accreditation standard for the program. An explanation of how the alternatives were evaluated, and the reasons for rejecting the alternatives are discussed below.

Selecting an Accreditation Standard

In late 2015, the ERP released a Year One Final Report[11] and presented their findings at a State Water Board public workshop. The ERP highlighted various deficiencies of the program and made a series of recommendations to help ELAP reestablish itself as an effective accreditation program. Many of the recommendations from the ERP were aimed at helping ELAP overcome administrative struggles. However, a primary recommendation from the ERP was to adopt new laboratory accreditation standards. ELAP is not able to adopt the new laboratory accreditation standards without amending the California Code of Regulations (Title 22, Division 4, Chapter 19).

The ERP recommended that ELAP adopt an accreditation standard that is clearly written, auditable, enforceable, and relevant to the intended use of the data. Additionally, the ERP recommended that the selected standard include quality system requirements. The ERP outlined three options for ELAP to consider that achieve the recommendations: (1) develop a state-created standard, (2) modify an existing standard, or (3) adopt an existing standard. The end result of each option would be a unique laboratory accreditation standard. The benefits and drawbacks of each option are discussed below:

State-created standard: The ERP believed the benefit of creating a state-specific standard is that it would ensure the resulting laboratory requirements meet program and client needs. This effort would allow the State Water Board to include only those requirements it considers important for laboratory performance. However, it saw the major drawbacks to this option as the difficulty, cost, and time associated with developing, writing and keeping an updated original standard. Additionally, this option would require ELAP to develop state-specific training protocols for ELAP assessors and

[11] SCWWRP Technical Report 887. 2015. Findings and Recommendations by the Expert Review Panel for the State of California's Environmental Accreditation Program: Year One Final Report.

provide resources to communicate the new requirements to the laboratories. Furthermore, a state-created standard would significantly inhibit the State Water Board from relying on third-party assessment agencies to fulfill onsite assessment requirements for laboratories This option is analogous to the accreditation standard in the current regulations, which have been ineffective, and the time and cost restraints of this option are in opposition to the urgency the State Water Board has placed on selecting a new accreditation standard.

Modification of an existing standard: The benefit to modifying an existing standard is the time and resources saved compared to the total development of a state-specific standard. However, the savings of time and resources might be relatively small. The ERP heard testimony in 2015 about the efforts of the State of Wisconsin to modify an existing standard. The ERP learned that reaching consensus on the modifications to the standard and the adoption process took over ten years and resulted in a less effective standard. California's laboratory community is much larger and divided than Wisconsin's, so it is believed that the timeframe for development and adoption of a modified standard would be more extensive than Wisconsin's timeframe. Like a state-specific standard, this option would require ELAP to develop state-specific training protocols for ELAP assessors and provide resources to communicate the new requirements to the laboratories. Furthermore, use of third-party assessment agencies is prohibitively limited with a modified standard. For these reasons this option was considered less desirable to the State Water Board.

Adopt an existing standard: The major benefit of adopting an existing standard is that the time and resources needed to implement it will be greatly reduced. The major drawback is the lack of ability to customize it to meet state-specific needs. Thus, it would be critical to select the correct standard. ELAP would need to ensure that the standard it selects meets its client's requirements and contains proper resources for both assessors and laboratories to ensure a smooth, consistent implementation. The existing standard that was most appropriate for this option is the 2016 TNI Standard.

The ERP recommended adopting an existing standard as the best option for the immediate future of ELAP. However, ELAP opened the selection process to public debate and comments before deciding on a standard.

ELAP Presents Options to Technical Advisory Committee

To receive input on the perspective of the laboratory community, ELAP presented the three options to the program's Environmental Laboratory Technical Advisory Committee (ELTAC). ELTAC was established to provide support, critical stakeholder review, scientifically valid advice, and guidance to ELAP on technical issues and the foreseeable effects that ELAP regulatory decisions may have. The committee is

composed of eighteen representatives from the laboratory community and regulatory agencies to speak on behalf of accredited laboratories and interested parties. ELTAC has had a valuable role in the selection process by being a conduit for information exchange between the laboratory community, regulatory agencies, data users, and ELAP.

The three options were discussed in detail at ELTAC meetings in May, June, and July of 2016, with presentations given by ELAP, ELTAC members, and representatives from laboratories. All ELTAC meetings are conducted in accordance with the Bagley-Keene Open Meeting Act, so the meetings were open to public viewing and participation. This process was designed to spark public discussion and debate about the best accreditation standard option for ELAP.

At the August 2016 ELTAC meeting, a formal vote was taken on the options presented to ELTAC members with the hopes of providing a majority-driven recommendation to ELAP. Unfortunately, no clear recommendation came from the vote as the ELTAC members, and thus the laboratory community, were divided on the best option for ELAP. Since ELTAC was unable to provide a clear recommendation, ELAP relied more heavily on regulatory agency data users for input on the best option for the program.

ELAP Presents Options to State Regulatory Agencies

ELAP meets regularly with representatives from other state regulatory agencies, who are the end users of data produced by ELAP accredited laboratories, to discuss synergies and address program needs. Participating agencies include, but are not limited to, the State Water Resources Control Board, Regional Water Quality Control Boards, Department of Toxic Substances Control, Department of Pesticides Regulation, Department of Public Health, and the Department of Fish and Wildlife.

At a March 2016 meeting with the state regulatory agency representatives, ELAP discussed the data needs of each agency and how the three accreditation standard options could meet those needs. The major need was confidence in the quality of the data. This need was broken down into four major areas: accuracy, consistency, quality assurance, and legal defensibility of the data. These needs were presented to ELTAC at the June 2016 ELTAC meeting.

To address the need for confidence in the quality of the data, the state regulatory agency representatives recommended ELAP adopt the 2016 TNI Standard as the program’s accreditation standard. This recommendation was presented to ELAP and ELTAC at the July 2016 ELTAC meeting.

ELAP Presents Preliminary Recommendation to the State Water Board

During an October 6, 2016, workshop, ELAP presented the progress of the program and the preliminary staff recommendation for an accreditation standard to the State Water Board. In support of the needs and recommendation of the state regulatory agencies, ELAP presented the preliminary recommendation of adopting the 2016 TNI Standard by reference into the proposed regulations. However, ELAP stressed that concerns of the community have not gone unnoticed and also recommended that ELAP, ELTAC, and the state regulatory agencies discuss exceptions to the TNI Standard that would eliminate requirements that are not necessary for California and could be presented to the State Water Board at a later date. The State Water Board expressed support for the 2016 TNI Standard with California-specific exceptions as the proposed laboratory accreditation standard in California.

Exceptions to 2016 TNI Standard

Public comments were solicited for proposed exceptions to portions of the 2016 TNI Standard that the laboratory community could support. Exceptions were discussed at the November 2016 ELTAC meeting. Initially, 56 exceptions to the TNI Standard were proposed by ELTAC based on a majority vote. After ELAP presented these exceptions to the ERP and the state regulatory agency representatives, many of the exceptions were revealed to be essential to the quality of data produced by laboratories and the needs of the state regulatory agencies. Therefore, after a careful review of the 56 recommended exceptions, only two were included in the proposed regulation text. The two exceptions focus on the frequency of the required proficiency testing of laboratories and the minimum credential requirements of a technical manager (laboratory director).

Proposed Regulation Text Presented to the Public

The 2016 TNI Standard with two California-specific exceptions is the laboratory accreditation standard that ELAP includes in the draft text of the proposed regulations.[12] ELAP solicited public review and comment on preliminary drafts of the regulation text prior to submittal of the proposed regulation text for the formal rulemaking process. Although public release and review of preliminary drafts is not required in the rulemaking process, ELAP wanted public involvement in the regulation process. ELAP released three separate revisions of the preliminary draft regulations text with public

[12] The rest of the regulations are technical and procedural requirements that laboratories must meet in order to become accredited as an ELAP-accredited laboratory, including completing an application, providing proficiency passing samples, passing an onsite assessment, and are similar to existing regulations and would not have a noticeable economic impact on laboratories.

comments reviewed, considered and incorporated, as appropriate, into the next revision.

The first draft of the proposed regulations was released for public review and comment on July 27, 2017. The proposed regulation introduced the new accreditation standards, as well as shifts in the program administrative requirements and timelines. ELAP negotiated with TNI to provide California laboratories a discounted rate on membership and the 2016 TNI Standard so laboratories could adequately comment on the first draft. Additionally, ELAP provided controlled copies of the 2016 TNI Standard to ELTAC members. Copies were also made available for public review at the nine Regional Board offices and thirteen Division of Drinking Water district offices. ELAP wanted to ensure that the laboratory community was engaged in the regulation adoption process, so six workshops were organized across the state to solicit comments, answer questions, and review the First Preliminary Draft Regulations text for clarity and completeness. The workshops were held from July 2017 through August 2017 in Fresno, Sacramento, Redding, Los Angeles, San Diego and San Francisco. Copies of the 2016 TNI Standard were also made available during the workshops. Comments received at the workshops were considered in the development and organization of the Second Preliminary Draft Regulations text. Additionally, public comments sent to ELAP's email account and in writing, including comments submitted by ELTAC members on behalf of their constituents, were considered for the Second Preliminary Draft Regulations text. The public comment period for the first preliminary draft was thirty days.

The Second Preliminary Draft Regulations text was released to ELTAC members on June 14, 2018 with a thirty-day comment period. ELTAC members reserved time in the July ELTAC meeting to discuss concerns with the second preliminary draft with ELAP prior to the end of the comment period. All comments received from ELTAC members on the second draft were considered in the development and organization of the Third Preliminary Draft Regulations text.

A third preliminary draft was released to the public on December 19, 2018. A thirty-day public comment period was originally given for comment on the third draft, but the comment period was extended by ELAP to seven (7) weeks per request from stakeholder groups. Also, ELAP hosted workshops in Sacramento and Los Angeles where the laboratory community could relay comments to ELAP on each section of the third preliminary draft.

Call for an Alternative

Despite the multi-year, stakeholder-involved effort, advocacy groups for municipal laboratories remained opposed to the 2016 TNI Standard, and shortly before ELAP's

release of the third preliminary draft requested that the State Water Board consider a two-tiered accreditation program where laboratories could choose to be accredited in either the 2016 TNI Standard or a modified version of the 2016 TNI Standard. ELAP's position was to move forward with a single accreditation standard because all data is produced for the same broad regulatory purposes and is used in state-wide assessment and monitoring programs for environmental and public health decision-making; therefore, a single standard that provides for equal levels of quality regardless of laboratory size is optimal. Additionally, ELAP cannot administratively support a two-tiered accreditation program. However, the advocacy groups further requested a special ELTAC meeting where an alternative standard would be presented as a modification to the 2016 TNI Standard for review by ELTAC members and provided to ELAP for consideration.

The special ELTAC meeting was held on December 13, 2018 and the advocacy groups presented an alternative accreditation standard. The alternative accreditation standard was loosely based off of the requirements of the 2016 TNI Standard but excluded essential quality system requirements. Despite considerable pushback from ELTAC committee members and state agency representatives, a motion passed to form a formal Subcommittee where the alternative accreditation standard could be further developed and presented to ELAP for consideration. The Subcommittee's charge was to develop an accreditation standard that applies to all laboratories, thus eliminating the request for a two-tiered accreditation program. The Subcommittee consisted of three ELTAC members and five public participants. Except for one consultant, all other Subcommittee members were employed by or affiliated with municipal laboratories.

The ELTAC Subcommittee presented their alternative accreditation standard to ELTAC and ELAP at the April 17, 2019 ELTAC meeting.[13] The alternative standard presented included some requirements of the 2016 TNI Standard but still excluded many of the quality system and management requirements and lacked the necessary detail and specificity that is needed to prevent varying interpretation of the requirements by laboratories and ELAP assessors.[14] Although the alternative was not supported by ELAP, and ELTAC continued to remain divided, ELAP agreed to consider the Subcommittee's proposal as an alternative accreditation standard.

Recognizing that the alternative accreditation standard was lacking essential quality system and management requirements, as well as auditability functions, the Subcommittee recommended additional time to further develop the proposed alternative

[13] DRAFT CA QMS Regulations 2019-04-03 submitted by the CA QMS Subcommittee to ELTAC 4/3/19.
[14] Comment Letter on ELTAC Subcommittee alternative, The NELAC Institute, submitted via email on April 25, 2019.

and requested that ELAP provide staff support. Furthermore, the Subcommittee recommended that there be an opportunity to combine the not yet fully developed future version of the alternative accreditation standard into the proposed regulations. Despite continued disagreement from some ELTAC members and state agency representatives, the ELTAC Chairperson formalized the recommendations of the Subcommittee in an email sent to ELAP on April 19, 2019.

ELAP responded to ELTAC's formal recommendations on April 26, 2019[15] denying the recommendations submitted to ELAP on April 19, 2019. ELAP's position is that it did not support the alternative standard, and after a multi-year effort of substantial engagement with the public and interested parties, ELAP would move forward with incorporation of the 2016 TNI Standard with two California-specific exceptions into the proposed regulations. ELAP, however, would consider the ELTAC Subcommittee's accreditation standard as an alternative in the rulemaking process, and did not object to the Subcommittee continuing to further develop the alternative accreditation standard.

A second draft of the alternative accreditation standard was submitted to ELAP on May 24, 2019[16] and is used as the alternative standard considered for the rulemaking process (see *State Water Board's Perspective on the Alternative Standard and the Selection Process*). The second draft contained new language about analytical methods to be accredited under the program and subcontracting requirements along with editorial revisions to the text. However, the second draft failed to address the core issues that were addressed in the April 19, 2019 ELTAC meeting including a lack of essential quality system requirements and the inaudibility of the alternative standard.

State Water Board's Perspective on the Alternative Standard and the Selection Process

The three options for development and selection of accreditation standards were reviewed and debated within the ERP, ELTAC and the state regulatory agencies. Recommendations from these parties eventually led to the State Water Board's decision to incorporate the 2016 TNI Standard with two California-specific exceptions into the proposed regulations. A thorough review of the options was warranted for the selection process. However, it is the State Water Board's conclusion that all alternative options considered would ultimately lead to the development and selection of an accreditation

[15] ELAP's formal response letter, retrieved from https://www.waterboards.ca.gov/drinking_water/certlic/labs/documents/response_eltac_april17_recommendation.pdf
[16] DRAFT CA QMS Regulations 2019-05-24 submitted by the CA QMS Subcommittee to ELAP 05/24/19.

standard that closely mirrors the 2016 TNI Standard but lacks the core quality system requirements to retain the benefits of the 2016 TNI Standard.

All advisory committees involved in the selection process agreed that the selected accreditation standards should have quality system requirements.[17] A quality system requires direct management and constant improvement of laboratory processes and procedures to ensure the quality of data. This is a core requirement of a modernized accreditation standard and a requirement that encompasses all areas of the laboratory. The quality system requirements described in the 2016 TNI Standard are specific, thorough, and consistently upgraded through a consensus-based standard development process that incorporates best industry practices.

Therefore, the quality system requirements of an accreditation standard that the State Water Board can support would end up being very similar to what is included in the 2016 TNI Standard. In fact, in an effort to reach consensus support from ELTAC and ELAP, each iteration of the alternative accreditation standard presented by the ELTAC Subcommittee contained increasingly more of the quality system requirements of the 2016 TNI Standard. Each iteration was considered but not supported by ELTAC or ELAP because it excluded the necessary detail and specificity for an effective accreditation standard.

The quality system requirements in the 2016 TNI Standard are also the major drivers behind assumptions made regarding the implementation and operational costs (hiring new personnel and a consulting firm) described below (see section on *Economic Impact Analysis*). It is assumed that the alternative accreditation standard proposed by the ELTAC Subcommittee, which contains elements of the quality system requirements of the 2016 TNI Standard, would have similar costs to laboratories. That is, the 2016 TNI Standard quality system elements that were excluded in the alternative accreditation standard take away from the effectiveness of the standard but do not remove enough elements that the assumed need to hire new personnel or a consulting firm would be eliminated.

A strong driving force behind the selection of the 2016 TNI Standard was the needs of the state regulatory agencies. The state regulatory agencies are the end users of data produced by the laboratories and they utilize the data to make complicated and difficult decisions on environmental and human health matters. These regulatory decisions can have a direct economic impact on public water systems, wastewater utilities, cleanup sites, or other regulated facilities, which makes the need for an effective accreditation standard even more critical. The state regulatory agencies advocated for the 2016 TNI Standard because the standards ensure data of known and documented quality.

[17] ELTAC Meeting: July 2016

Although two California-specific exceptions to the 2016 TNI Standard are included in the proposed regulations, the exceptions were accepted by the state regulatory agencies because they do not have a major effect on the quality of the data.

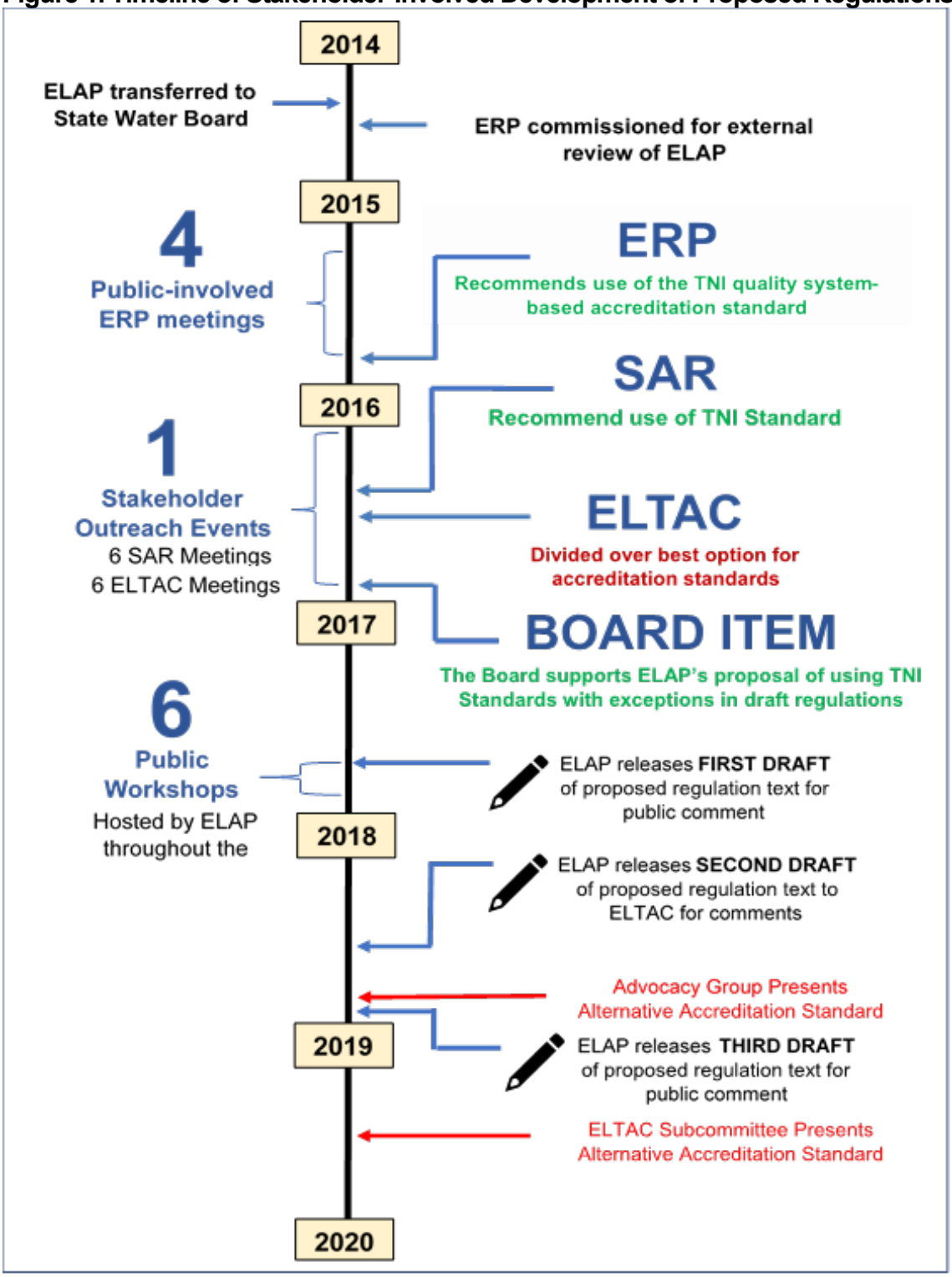
The TNI Standard, which is approved by the EPA as an acceptable alternative to the federal laboratory certification program and can be used by state laboratory accreditation programs to retain certification authority of laboratories analyzing drinking water samples for compliance monitoring[18,19], has been widely effective and successful for other state programs in part because of the known and inclusive consensus-based standard development process. The alternative standard proposed by the ELTAC Subcommittee, which has not been reviewed or considered by the EPA as an alternative to the federal laboratory certification program, was developed by three ELTAC members and five public participants and is not comparable to the TNI Standard in effectiveness and acceptability by stakeholders.

Additionally, the lack of specificity and detailed requirements in the alternative standard proposed by the ELTAC Subcommittee allows for varying interpretation by laboratories. For example, the alternative accreditation standard proposed by the ELTAC Subcommittee requires that a laboratory have procedures for achieving traceability of measurements in the laboratory's quality manual (a 2016 TNI Standard requirement). However, the ELTAC Subcommittee excluded what those procedures should be or the minimum criteria to achieve the traceability. Therefore, each laboratory could have different procedures that result in varying degrees of effectiveness at achieving traceability of measurements, which means that the requirement does not standardize the laboratories activities and is not auditable This is continued throughout the alternative, where laboratories are only required to include or reference content in the quality manual but are not provided the minimum criteria required to be compliant to the standard. The varying interpretations of the alternative standard by laboratories disqualifies the alternative as an effective accreditation standard because it does not standardize laboratory activities and practices. Ultimately, the lack of sufficiently detailed and auditable quality system requirements leads to the same fundamental problem that ELAP faces with the current accreditation standard and regulations.

[18] U.S. EPA. 2002, October 1. Memorandum: Drinking Water Laboratory Program Oversight.

[19] U.S. EPA. 2007, May 14. Memorandum: Drinking Water Laboratory Program Oversight.

Figure 1. Timeline of Stakeholder-Involved Development of Proposed Regulations



ELTAC = Environmental Laboratory Technical Advisory Committee;
ERP = Expert Review Panel; SAR = State Agency Representatives

V. ENVIRONMENTAL JUSTICE

The proposed regulations will not have a disproportionate effect on any geographic region, income level, or race.

VI. ECONOMIC IMPACTS ANALYSIS[20]

Legal Requirements

Sections 11346.3 and 11346.5 of the Government Code require state agencies to assess the potential adverse economic impacts on California business enterprises and individuals when proposing to adopt or amend any administrative regulation. This economic impact analysis will assess whether the regulatory proposal will affect the creation of new businesses or the elimination of existing businesses within the state, the expansion of businesses currently doing business within the state, the creation or elimination of jobs within the state and the benefits of the regulation. Additionally, the costs and savings to state or local agency will be assessed in this analysis.

Costs from Proposed Regulations

Costs of Implementation of the 2016 TNI Standard:

A majority of the costs of the proposed regulations are associated with the implementation of the new accreditation standards, the 2016 TNI Standard. An essential requirement to the TNI Standard, and a new concept to ELAP, is for laboratories to have a quality system. A core element of the quality system requirement in the 2016 TNI Standard is for laboratories to document their processes, control the documents, and maintain the records to allow for the historical recreation of data. These requirements help ensure that the data produced by the laboratory is of known and documented quality.

The proposed regulations, including the referenced 2016 TNI Standard, do not specifically require the purchase of new technology or laboratory equipment, hiring new personnel, or any additional investments to comply. A laboratory could make the necessary changes to laboratory practices to comply with the proposed regulations without any additional expenditures or investments.[21] However, for the purpose of conservatively estimating cost impacts, the State Water Board assumes that

[20] Detailed analysis of the economic impacts of the regulations are in the supplemental attachment to the Department of Finance's STD 399 Form.
[21] See p. 66 for information about the Water Board's laboratory mentorship program that has enabled small laboratories to implement TNI 2016 Standard in around 6 months, without additional costs or new personnel.

laboratories will need to hire additional personnel and a laboratory consulting firm, to help with the implementation process.

Cost Estimates: The cost to implement the 2016 TNI Standard for a typical laboratory is conservatively estimated to be from $40,000.00 to $77,334.40, depending on laboratory size and implementation strategy (see Table 3 below). The different implementation strategies and scenarios that the laboratories in California can use to implement the 2016 TNI Standard are dependent on the business and management decisions of the laboratory, not the proposed regulations. However, for the purpose of estimating the economic costs (impacts) of the implementation of the 2016 TNI Standard, it is assumed that all laboratories within a size class will have the same implementation strategy despite the inherent variations that may be used by the laboratory community.

Table 3. Estimated Costs to Implement 2016 TNI Standard

Size Class[22]	Small	Medium	Large
Laboratory Consulting Firm	$ 31,000.00	$ 31,000.00	$ 40,000.00
Laboratory Personnel	$ 46,334.40	$ 16,548.00	-----
TOTAL COST	**$ 77,334.40**	**$ 47,548.00**	**$ 40,000.00**

Implementation Strategies: Reasonable assumptions of the implementation strategies of the various size classes were determined based on responses from ELAP-accredited laboratories on the proposed regulations. Below are the assumed implementation strategies used for the economic impact analysis:

Small Laboratories: All small laboratories will hire a laboratory consulting firm to help implement the 2016 TNI Standard and 70 percent of small laboratories will hire one, full-time laboratory personnel.

Medium Laboratories: All medium laboratories will hire a laboratory consulting firm to help implement the 2016 TNI Standard and 50 percent of medium laboratories will hire one, part-time laboratory personnel.

Large Laboratories: It is assumed that larger laboratories will hire a laboratory consulting firm to assess the laboratory's current operations and determine the areas of the laboratory that need modifying to be compliant with the 2016 TNI Standard but will not hire new laboratory personnel.

[22] Size classifications were determined by the number of fields of accreditation on a laboratory's scope of accreditation a proxy for the size of a laboratory, with the assumption that a larger laboratory would require more fields of accreditation to sustain laboratory operations. For more information, see the supplemental attachment to STD 399 Form.

Cost to Hire Laboratory Personnel: 2017 Occupational Employment Statistics from the Bureau of Labor Statistics state that Chemical Technicians in California had a median salary range of $47,280.00.[23] The median salary of a new employee does not fully represent to costs to employers. Therefore, a multiplier of 1.4 was applied to the salary to account for costs of benefits and employment taxes.[24] To hire laboratory personal at a median salary of $47,280.00 would cost the employer $66,192.00 ($33,096.00 for part-time employee).The adjusted full-time employee cost of $66,192.00 was multiplied by 0.70 and the adjusted part-time employee cost of $33,096.00 was multiplied by 0.50 for small laboratories and medium laboratories, respectively, to represent the average costs of laboratory personnel for these two size classes (Table 3).

Cost to Hire a Laboratory Consulting Firm: The costs to hire a laboratory consulting firm were estimated based on interviews with laboratory consulting firms listed on the TNI website. The service quotes provided from the consulting firms ranged from $22,000 to $40,000 and were dependent on the level of effort required to transition the laboratory to the TNI Standard.[25] The State Water Board used $31,000 as the estimate of costs to hire a laboratory consulting firm for small and medium laboratories because it represents the average of the quotes provided to the State Water Board. Although no direct quotes for large labs were received, the State Water Board estimated $40,000 as the consultant costs for the larger laboratories because these laboratories would have more SOPs and documents to review and would potentially require more effort from the consulting firms.

Costs of Third-Party Assessment Requirement:

In addition to the requirement to comply with the TNI Standard, the proposed regulations require laboratories accredited in methods that utilize sophisticated technology to use third-party assessment firms to fulfill the on-site assessment requirement. This requirement is aimed at offsetting programmatic costs and redistributing staff responsibilities. Although the use of third-party assessment firms is allowed in state statute, the use of third-party assessment firms is not currently required in the regulations or utilized as an option by the program. Therefore, qualifying laboratories will incur costs for services provided by third-party assessment firms because of the proposed regulations. Laboratories that are not accredited in methods that utilize sophisticated technology can continue to be assessed by ELAP. The cost of this assessment will continue to be included in the fees assessed to laboratories under the current fee structure so there is no incurred cost to these laboratories as a result of

[23] 2017 Occupational Employment Statistics, Bureau of Labor Statistics. https://www.bls.gov/oes/2017/may/oes194031.htm, accessed January 9, 2019.
[24] Hadzima, Joe, “How Much Do Employees Cost?” Boston Business Journal, 2015.
[25] Interviews with DDMS Inc and Environmental Laboratory Consulting Services, LLC.

the proposed regulations. However, ELAP will recommend that an assessment fee be included in future proposed fee schedules that is separate from the base fee and fees for fields of accreditation to cover the costs of the accreditation program. This is addressed in a separate emergency regulation package and, therefore, is not addressed in this economic analysis.

For the purpose of this economic impact analysis, it is assumed that all of the medium and large laboratories, as well as, 40% of the small laboratories impacted by the implementation of the TNI Standard will utilize methods with sophisticated technologies and will be subject to the third-party assessment firm requirement. Estimated costs for an on-site assessment of the three size classes were provided by an existing third-party assessment firm.[26] Completion of an on-site assessment is only required once every two years, so total costs per size class were divided by two to represent the annual costs of the requirement for each size class. Table 4 summarizes the annual costs for services provided by third-party assessment firms as a result of the proposed regulations.

Table 4. Estimated Costs of Third-Party Assessment Firms

Laboratory Size Class	Small	Medium	Large
Laboratories required to use TPAs	174	55	55
Costs per Assessment[27]	$ 5,100.00	$ 10,100.00	$ 18,800.00
Total Costs of Assessments	$ 887,400.00	$ 555,500.00	$ 1,034,000.00
Once every 2-Year Requirement	$ 443,700.00	$ 277,750.00	$ 517,000.00
Annual Cost for Third-Party Assessment Firms		**$1,238,450.00**	

Potential Impact on Business Creation, Expansion, or Elimination

Potential Business Creation:

To help successfully implement the 2016 TNI Standard, laboratories could hire a laboratory consulting firm. These businesses are not currently prevalent in California because ELAP accredits laboratories using the State-own's accreditation standards that limit these businesses to only consulting laboratories in California. However, the adoption of the proposed regulations would utilize the national consensus-based TNI Standard (with two California-specific exceptions), which are widely used by many accreditation programs across numerous states and already support many laboratory accreditation consulting firms. Therefore, the adoption of the proposed regulations could

[26] A2LA. Assessment Quotes. Submitted by email on June 13, 2019.
[27] Assessment costs include travel fees of $500, $1000, and $1500 for small, medium, and large laboratories, respectively

spark the creation and growth of laboratory accreditation consultant businesses in California. Currently, there are three laboratory consulting firms in California and the proposed regulations are assumed to create an additional nine.

The proposed regulations will also provide the ability for laboratories to use third-party assessment firms to perform on-site assessments. This is an option that is currently not utilized by laboratories in California because of ELAP's state-specific accreditation standard. However, TNI Standard is a national consensus-based accreditation standard that current third-party contract assessors have experience assessing laboratories to. The size and untapped potential of the third-party assessor market in California could be inviting enough to create a new industry in California.

Potential Business Expansions:

Closures of environmental laboratories or environmental laboratories that forgo ELAP accreditation may result in expansion of ELAP accredited laboratories that are able to implement the proposed regulations and remain ELAP-accredited. The regulatory samples that are being analyzed by laboratories that lose accreditation will still be required and will need to be analyzed and reported by an ELAP-accredited laboratory. Therefore, laboratories that remain accredited could see an increase in business and revenues suitable for expansion.

Additionally, the proposed regulations may result in expansion of the industries supporting environmental laboratories, like laboratory consulting firms and laboratory assessment firms. The incorporation of the 2016 TNI Standard in the proposed regulations supports these industries and drives the potential expansion.

Potential Business Closures:

The proposed regulations might result in closures of laboratories that are unable to implement the 2016 TNI Standard. Other state accreditation programs that converted their program's accreditation standards to the nationally recognized consensus-based TNI Standard observed that smaller laboratories may have a harder time with TNI implementation.[28,29] Estimating the number is difficult because laboratories face pressures like heightened competition and pricing constraints, which have already resulted in many closures over the past year. Additionally, a saturated laboratory industry in California has resulted in a spree of laboratory consolidations or purchases. Therefore, it is hard to estimate if a closure is a result of a proposed regulation or because of current industry conditions. For the purpose of estimating the economic

[28] Interview with Florida Department of Health, Laboratory Certification Program.
[29] Interview with New York Department of Environmental Protection, Laboratory Certification Program

impact of the proposed regulations, it is assumed that the number of laboratories closures will be ten.

Potential Impact on Business Competitiveness

The proposed regulations would not have an impact on California business competitiveness. The proposed regulations are about California's state laboratory accreditation program and how to regulate and accredit the environmental testing laboratories that analyze environmental samples for California. All businesses would be subject to similar costs to comply with the proposed regulations to provide services in California. Furthermore, other states adopt their own regulations, accreditation standards or requirements for environmental testing laboratories. If California environmental testing laboratories want to provide services to other states, then they would have to comply with that state's regulations, accreditation standards, and requirements.

Potential Impact on Jobs

Potential Job Creation:

The State Water Board estimates that a total of 355 jobs will be created in the environmental testing laboratory industry and supporting industries (see section A.6. of Supplemental Attachment to Department of Finance's STD399 Form).

Laboratories may elect to hire more staff to successfully implement the proposed regulation amendments. The assumption is that the new staff will help with analyst duties so that management can focus on the implementation of the proposed regulations. This is assumed to be true for small or medium laboratories that operate with limited staff, especially in cases where laboratory personnel are serving both laboratory management and analyst roles. Similarly, laboratories that successfully implement the proposed regulations may see an increase in business as a result of closures of laboratories that are unable to successfully implement the proposed regulations. This is because regulatory samples that were analyzed by these laboratories that are closing will still be required and still need to be analyzed by an ELAP-accredited laboratory. This transfer of business will result in workload and revenue increases at the laboratories that successfully implement the proposed regulations and may result in the need to hire new laboratory personnel.

The proposed regulations may also result in the creation of jobs in supporting industries to the environmental laboratory industry. For example, the incorporation of the 2016 TNI Standard may result in laboratories hiring laboratory consulting firms with experience in the TNI Standard to help implement the proposed regulations and may result in increased hiring at these firms. Similarly, the proposed regulations will allow laboratories

to use third-party laboratory assessment firms to perform on-site assessments and fulfill the on-site assessment requirements of the program. Increased need for this service may result in hiring at existing assessment firms or the creation of new assessment firms in California.

Potential Job Elimination:

The economic impact analysis assumes that there will be 20 job positions eliminated by the proposed regulations. This analysis assumes that five small public and five small private laboratories will close due to the proposed regulations and that these laboratories will employ one to two individuals. Therefore, the total number of jobs that would be lost due to the closures would be 20. However, it is assumed that the laboratory closures would result in a transfer of business. The regulatory samples that were being analyzed by the laboratory that closed would have to be analyzed by an ELAP-accredited laboratory. An increase in business at laboratories that take on the regulatory samples from closed laboratories could result in the hiring of additional laboratory personnel. If the samples stay local, then it is reasonable to assume that the same individuals that lost employment when a laboratory closed could be hired by the other laboratories that received the additional samples. Therefore, for the purpose of this analysis, there will be no net loss of jobs because of the proposed regulations.

Benefits of the Proposed Regulations

Benefits to the Laboratories:

The proposed regulations minimize the misinterpretations and confusion for laboratories by providing specific and detailed requirements for accreditation. The proposed regulations clearly outline the process of accreditation and the administrative and technical requirements that must be met to be in compliance with the regulations.

Specifically, the referenced 2016 TNI Standard, which is comprised of the specific accreditation standards of all functional areas of the laboratory, provides a framework and structure for laboratory operations, management, and technical activities. This roadmap can elevate the performance of laboratories because it specifies the managerial and technical activities that can affect the quality of the laboratory and results produced. For example, the current regulations require the quality manual to contain information on “corrective actions.” However, there is no description of what a corrective action is, when it should be implemented, how it is implemented, and how it is monitored. In contrast, the proposed regulations have specific requirements for implementation of corrective actions, the corrective action process, and how to monitor and audit the policies and procedures of the laboratory to ensure the corrective action is not needed again. By incorporating the 2016 TNI Standard, laboratories are provided

clear direction and a roadmap to improvement; thereby, moving laboratories towards a "self-auditing" management system that addresses issues in real-time and away from relying on ELAP assessments to come into compliance.

An important characteristic of the 2016 TNI Standard is that it is scalable to all laboratory sizes. The TNI Standard provides what is required of laboratories (the "what") but allows the laboratory to decide how it is implemented (the "how"). Therefore, implementation can occur at all levels of laboratory sophistication and size. Additionally, the NELAC Institute (TNI) has developed and provided technical training and documentation templates to aid in the implementation of the Standard, which would not be available with the adoption of alternative accreditation standards.

Benefits to the State Regulatory Agencies:

The proposed regulations will benefit state regulatory agencies because the 2016 TNI Standard requirements will standardize laboratory activities and practices to ensure data produced is of known and documented quality. The current regulations do not describe the management of quality assurance procedures or processes to properly scrutinize and promote confidence in the data. To ensure data quality, the 2016 TNI Standard has quality system requirements. An effective quality system acts as a feedback loop for laboratories, so deviations and non-conformities in the data are identified, investigated and resolved. Therefore, the state regulatory agencies and other data users will have confidence that the data produced has been sufficiently scrutinized through appropriate quality assurance measures before being released by the laboratory.

The current regulations also lack the documentation requirements to ensure legal defensibility of the data, which is important for state regulatory agencies making decisions on environmental and human health concerns. The 2016 TNI Standard requires documentation of all procedures and processes utilized by the laboratory to generate data. The 2016 TNI Standard also requires traceability of the data such that the history of samples and associated data is retraceable and easily understood through the records. Having the supported documentation of the processes of the laboratory, as well as, traceability of the data produced increases the confidence and trust in the laboratory and the data.

Benefits to the Accreditation Program:

The proposed regulations benefit ELAP by providing more clarity and specificity in requirements. This will make the program more efficient and effective and will eliminate the need to help laboratories navigate and interpret the current regulations. The specificity of

the proposed regulations will also help with enforcement actions against noncompliant laboratories.

Continuous review and update of the accreditation standards by TNI eliminates the need for ELAP to dedicate substantial resources on accreditation standard review. Expert Committees of TNI, with representative members from the national laboratory community, improve the TNI Standard based on best professional practices in the industry. The knowledge and experience of Expert Committee members utilized in the consensus-based standard development process greatly exceeds that of ELAP staff, which makes the updates to the Standard more appropriate and effective. ELAP is able to review the changes and incorporate them into the regulations through the Administrative Procedure Act rulemaking process.

The 2016 TNI Standard is scalable. This is a benefit at a programmatic level because all laboratories can be assessed and standardized to one accreditation standard instead of having different standards for laboratories of different size or sophistication. The use of one accreditation standard for all laboratories will benefit many areas of the accreditation program including on-site laboratory assessments, fee structures and assessments, and employee training.

The proposed regulations will also help with the resource challenges that ELAP faces. Implementation of the 2016 TNI Standard will allow laboratories to use third-party laboratory assessment firms to satisfy the onsite assessment requirements of the accreditation program. For laboratories accredited in methods that utilize sophisticated technologies, the use of third-party assessment firms is required. This may reduce the number of onsite assessments that ELAP has to perform annually by half. Reducing the number of laboratory on-site assessments that ELAP has to perform will be very beneficial to resource management efforts of the program. Currently, ELAP struggles to perform the on-site assessments in a consistent and timely manner because of the number of participating laboratories in the program and the minimal number of qualified laboratory assessors employed by ELAP.

Benefits to the Health and Welfare of California Residents, Worker Safety, and the State's Environment:

Data produced for regulatory purposes by accredited laboratories is used in state-wide assessment and monitoring programs for protection of human health and the environment. The proposed regulations update California's accreditation standards with a national and industry-recognized accreditation standard and will help ensure that environmental and human health related decisions by state regulatory agencies and other data users are based on data of known and documented quality. In turn, this will benefit the health and welfare of California residents and the environment.

Fiscal Impact to State and Local Agencies

Fiscal Impacts to Local Agencies:

For the purpose of the proposed regulations, the State Water Board considers public water and wastewater treatment facility laboratories as "local government," and considers the economic impact of the proposed regulation on public water and wastewater treatment facility laboratories as a fiscal impact. Based on the implementation costs and operating costs associated with the implementation of the TNI Standard, the State Water Board estimates the costs to implement the TNI Standard for public laboratories are $17,268,908.00 (see Table 5) and the annual ongoing operating costs (post implementation) are $9,448,908.00 (see Table 6).

Table 5. Public Sector Implementation Costs

Laboratory Size Class	Small	Medium	Large
Public Laboratories	195	25	25
Implementation Costs	$ 77,334.40	$ 47,548.00	$ 40,000.00
Implementation Costs per Size Class	$ 15,080,208.00	$ 1,188,700.00	$ 1,000,000.00
Total Implementation Costs	**$ 17,268,908.00**		

Table 6. Public Sector Annual Operating Costs

Laboratory Size Class	Small	Medium	Large
Public Laboratories	195	25	25
Operation Costs	$ 46,334.40	$ 16,548.00	$ 0.00
Operation Costs per Size Class	$ 9,035,208.00	$ 413,700.00	$ 0.00
Total Operating Costs	**$ 9,448,908.00**		

In addition to the impact of the TNI Standard, public laboratories may be subject to the third-party assessment firm requirement, which will incur costs to public laboratories. The estimated annual costs of the third-party assessment firm to public laboratories is $1,120,300.00, as shown in Table 7.

Table 7. Public Sector Costs to Use Third-Party Assessment Firms

Laboratory Size Class	Small	Medium	Large
Private Laboratories	78	25	25
Assessment Costs	$ 5,100.00	$ 10,100.00	$ 18,800.00
Assessment Costs per Size Class	$ 397,800.00	$ 252,500.00	$ 470,000.00
Total Assessment Costs	**$ 1,120,300.00**		

The total costs of the proposed regulation to pubic laboratories is equal to the sum of the costs of the TNI Standard and the costs of third-party assessment firm requirement.

Therefore, during the three-year implementation period, the total cost of the proposed regulations is $18,389,208.00, and the annual ongoing costs of the proposed regulations is $10,569,208.00.

Fiscal Impacts to the State:

The proposed regulations may have a fiscal effect on State government. The fiscal effect will relate to increases in the amount of time dedicated to program tasks and core functions because of the proposed accreditation standard. For example, on-site assessments of laboratories will take longer because the laboratory will be assessed to more detailed and specific requirements. A contrary argument could be made that assessments will take less time because the assessors will have clear and specific requirements to assess laboratories to. Additionally, the State Water Board issued a three-year contract to NV5/Dade Moeller, a laboratory assessment firm with vast experience in assessing laboratories to the TNI Standard, to train ELAP assessment staff on assessing laboratories to the 2016 TNI Standard. This contract provided training courses, checklists, assessment materials and resources, and hands-on training during assessments of California laboratories. The skills developed from this training have elevated ELAP assessment staff and prepared them for the transition to the 2016 TNI Standard. However, at least initially, the on-site assessments will take longer as staff who perform the onsite assessments get familiar with the new accreditation standards. The total cost to the State for additional time to perform onsite assessments is $63,198.72.

Time dedicated to laboratory community outreach will also increase dramatically with the adoption of proposed regulations. The outreach would be necessary with the adoption of any new accreditation standard and could include answering questions from laboratories about the standard, putting together informational items and tools for laboratories, hosting webinars on the standard, or any activity that helps the laboratory during the transition to the 2016 TNI Standard. The assumption is that there will be one staff member from ELAP dedicated to laboratory outreach. The staff member will be an annual cost to the state of $53,484.00.

The total cost of the regulation to the state is $116,682.72, which equals the sum of the costs of increased time to perform onsite assessments and the costs of an employee dedicated to laboratory outreach.

California Health and Safety Code Section 57005 – Major Regulation Requirements

The estimated economic impact of the proposed regulation to business enterprises and individuals located in or doing business in California does not exceed $50 million in any

12-month period. The annual economic impact of the proposed regulation during a three-year implementation phase is estimated to be $14,031,206.53 as shown in Table 8.

Table 8. Estimated Costs of Regulations (Implementation Phase)

Laboratory Size Class	Small	Medium	Large
Impacted Laboratories	434	55	55
Costs per Laboratory	$ 77,334.40	$ 47,548.00	$ 40,000.00
Total Costs	$ 33,563,129.60	$ 2,615,140.00	$ 2,200,000.00
3-Year Staged Implementation Period	$ 11,187,709.87	$ 871,713.33	$ 733,333.33
Total Cost of TNI Standard (Implementation Phase)		$ 12,792,756.53	
Total Cost of Third-Party Assessment Requirement		$ 1,238,450.00	
Annual Cost of Regulation (Implementation Phase)		**$ 14,031,206.53**	

The annual economic impact of the proposed regulation in any 12-month operational period following full implementation is estimated to be $22,257,719.60 as shown in Table 9. The difference in economic costs of the operational phase and the implementation phase result from eliminating costs associated with hiring a laboratory consulting firm and the end of the three-year phased implementation period.

Table 9. Estimated Costs of Regulations (Operational Phase)

Laboratory Size Class	Small	Medium	Large
Impacted Laboratories	434	55	55
Costs per Laboratory	$ 46,334.40	$ 16,548.00	-----
Total Costs	$ 20,109,129.60	$ 910,140.00	-----
Total Cost of TNI Standard (Operational Phase)		$ 21,109,269.60	
Total Cost of Third-Party Assessment Requirement		$ 1,238,450.00	
Annual Cost of Regulation (Operational Phase)		**$ 22,257,719.60**	

VII. JUSTIFICATION FOR ADOPTION OF REGULATIONS DIFFERENT FROM FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS

There are no federal regulations that already address the subject matter in the proposed regulations. However, the accreditation requirements of the proposed regulations align with requirements of laboratories outlined in the federal Safe Drinking Water Act (SDWA). The SDWA is the federal law that protects public drinking water supplies by granting the United States Environmental Protection Agency (EPA) the authority to establish minimum water quality standards to protect drinking water supplies and requires all owners or operators of public *water* systems to comply with the health-related water quality standards. Under the SDWA, laboratories performing drinking

water analyses for compliance monitoring must be certified by the EPA or an authorized state-run laboratory certification program (i.e. California ELAP). The proposed regulations continue fulfillment of the state-run certification program requirements.

VIII. DOCUMENTS RELIED UPON

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20. Environmental Laboratory Technical Advisory Committee. (2016, July). Agenda Item #6. Laboratory Accreditation Standards {video file}. Retrieved from https://www.waterboards.ca.gov/drinking_water/certlic/labs/eltac_meetings.html.

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22. United States Environmental Protection Agency. (2017, May 14). Memorandum: Drinking Water Program Oversight.

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26. Environmental Laboratory Consulting Services, LLC. Email Correspondence with T. McAninch on July 21, 2018.

27. A2LA. Email Correspondence with C. Gunner on June 13, 2019.

28. Florida Department of Health, Laboratory Certification Program. Email correspondence with V. Soto Contreras on November 15, 2018.

29. New York Department of Environmental Protection, Laboratory Certification Program. Email correspondence with V. Pretti on July 27, 2018.