
State Water Resources Control Board

NOTICE OF PROPOSED RULEMAKING

TITLE 22. SOCIAL SECURITY DIVISION 4. ENVIRONMENTAL HEALTH CHAPTER 19 (Certification of Environmental Laboratories)

NOTICE IS HEREBY GIVEN that the State Water Resources Control Board (State Water Board) proposes to amend, adopt, or repeal the Environmental Laboratory Accreditation Program (ELAP) regulations described below after considering all comments, objections, and recommendations regarding the proposed action.

SUMMARY OF PROPOSED REGULATORY ACTION

The State Water Board proposes to amend California Code of Regulations, Title 22, Division 2, Chapter 19, to update requirements and standards for accreditation of environmental testing laboratories. These proposed amendments are administrative and technical in nature and make the necessary improvements needed to operate a fully functional and effective Environmental Laboratory Accreditation Program.

PUBLIC HEARING

The State Water Board will hold an Administrative Procedure Act (APA) public hearing during a Board workshop to receive written and oral comments regarding the proposed regulations. The hearing will include a presentation by State Water Board staff on the proposed regulations. During the comment period, the public will be allowed three minutes to provide oral comments, unless additional time is approved. While a quorum of the State Water Board may be present, this hearing is for the public to provide comments in accordance with the APA, and the State Water Board will take no formal action.

The public hearing will be held as detailed below.

Wednesday, December 18, 2019 – 9:30 a.m.
Joe Serna Jr. CalEPA Headquarters Building
1001 I Street, Second Floor
Sacramento, CA 95814

E. JOAQUIN ESQUIVEL, CHAIR | EILEEN SOBECK, EXECUTIVE DIRECTOR

1001 I Street, Sacramento, CA 95814 | Mailing Address: P.O. Box 100, Sacramento, CA 95812-0100 | www.waterboards.ca.gov

The State Water Board will consider adoption of the proposed ELAP regulations at the Board's March 17, 2020 State Water Board meeting. The location and start time of the Board meeting are provided below:

Tuesday, March 17, 2020 – 9:30 a.m.
Joe Serna Jr. CalEPA Headquarters Building
1001 I Street, Second Floor
Sacramento, CA 95814

Additional information on Board meetings, hearings, and workshops is available on the [State Water Board's Meeting Information webpage](#).

SPECIAL ACCOMMODATION REQUEST

Consistent with California Government Code Section 7296.2, special accommodation or language needs may be provided, including any of the following:

- An interpreter to be available at the hearing;
- Documents made available in an alternate format or another language;
- A disability-related reasonable accommodation.

To request these special accommodations or language needs, please contact the Moisés Moreno-Rivera at (916) 341-5261 as soon as possible, but no later than 10 business days before the scheduled Board hearing. TTY/TDD/Speech to Speech users may dial 711 for the California Relay Service.

SI NECESITA ARREGLOS ESPECIALES

Conforme a la Sección 7296.2, del Código del Gobierno de California, los siguientes servicios o arreglos especiales pueden ser solicitados:

- Servicio de intérprete durante la audiencia;
- Documentos en otro idioma o en un formato alterno;
- Arreglos razonables relacionados a una discapacidad.

Para solicitar estas adaptaciones especiales o servicios de idioma, puede contactar a Moisés Moreno-Rivera al (916) 341-5261 lo más pronto posible y a más tardar 10 días hábiles antes de la fecha de la audiencia de la Junta (Board). Los usuarios del Sistema TTY/TDD/Voz-a-Voz pueden marcar el 7-1-1 para utilizar el California Relay Service.

WRITTEN COMMENT PERIOD

Any interested person, or their authorized representative, may submit written comments relevant to the proposed regulatory action to the Clerk of the State Water Board. Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Clerk to the State Water Board by **12:00 noon on Friday, December 20, 2019**, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Note that comments previously submitted about the preliminary drafts of the proposed regulatory action will not be part of the rulemaking record. Outstanding comments about the proposed regulatory action must be resubmitted during the written comment period to be included in the rulemaking record.

You may submit written comments via any of the following:

- Electronic mail (email): commentletters@waterboards.ca.gov

- U.S. Postal Service:

Ms. Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
P.O. Box 100, Sacramento, CA 95812-2000

- Hand Delivery:

Ms. Jeanine Townsend, Clerk to the Board
State Water Resources Control Board
1001 I Street, 24th Floor, Sacramento, CA 95814

Persons delivering comments must check in with lobby security and have them contact Ms. Jeanine Townsend at (916) 341-5600

Also, please indicate in the subject line and/or on the cover page of submittals:

“Comments – Proposed Environmental Laboratory Accreditation Program Regulations.”

All comments should include the author’s name and U.S. Postal Service mailing address or email in order for the State Water Board to provide any notices that may be required in the future.

Due to limitations of the email system, emails larger than 15 megabytes (MB) may be rejected and will not be delivered and received by the State Water Board. Therefore, emails larger than 15 MB should be submitted in several separate emails or another form of delivery should be used.

The State Water Board requests but does not require that written comments sent by mail or hand-delivered be submitted in triplicate.

The State Water Board requests but does not require that reports or articles in excess of 25 pages be submitted in conjunction with the comments, that the commentator provide a summary of the report or article and describe the reason for which the report or article is being submitted or is relevant to the proposed regulation.

Please note that under the California Public Records Act (Gov. Code, § 6250 et seq.), your written and oral comments, attachments, and associated contact information (e.g., your address, phone, email, etc.) become part of the public record and can be released to the public upon request.

AUTHORITY AND REFERENCE

Pursuant to Health and Safety Code Sections 100829 and 100830, the State Water Board is authorized to adopt the subject regulations. This action is proposed to implement, interpret, and make specific Health and Safety Code Sections 100825-100830, 100837-100845, 100850, 100852, 100860.1, 100865-100872, 100880, 100886, 100895, 100905-100915.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Background and Summary of Existing Relevant Regulations:

In 1988, the California Environmental Laboratory Improvement Act (ELIA) became law and established ELAP to evaluate and provide accreditation to environmental testing laboratories in California. In 1994, the Environmental Laboratory Accreditation Act (Health and Safety Code, Section 100825-10090), and California Code of Regulations, Title 22, Division 4, Chapter 19 were codified to provide the authority and structure of a laboratory accreditation program to standardize and accredit laboratories that analyze environmental regulatory samples and provide data used for important human health and environmental decision making in California. Furthermore, the statutes for state regulatory agencies, such as the State Water Board, the Department of Toxics Substance Control, and the Department of Public Health, require that any analysis of material required by their programs be conducted by a laboratory accredited by ELAP.

Pursuant to Health and Safety Code 100825, only those laboratories that chose to perform analyses on environmental samples for regulatory purposes are subject to regulations adopted under the California Code of Regulations. Therefore, participation in ELAP is voluntary and is a business decision for a laboratory.

Policy Statement Overview and Summary of Proposed Regulatory Action:

Problem Statement:

The current regulations were established in 1994. Over time, the requirements for operation of the accreditation program have become outdated, and criteria for determining the competency of a laboratory performing environmental testing has not kept up with the fundamental elements of accreditation standards. Examples of fundamental elements that are lacking in the current regulations include quality system

requirements, ethics and integrity policy requirements, data traceability requirements, method validation requirements, sample handling policies, and enforcement. The inadequate requirements in the current regulations have resulted in an ineffective accreditation program and a laboratory community that operates without effective regulatory oversight.

Furthermore, the lack of specificity and detail in the current regulations has impacted ELAP's ability to consistently assess the quality and competency of laboratories. Similarly, differing interpretation of the current regulations has created an unequal playing field where laboratories operate to different standards and can gain an unfair business advantage over other laboratories. This 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.

Objective (Goal):

The broad objective of the proposed regulations is to modernize the accreditation program within the authority granted by the Environmental Laboratory Accreditation Act. The proposed regulations include:

- Updates to the administrative process for operating an accreditation program.
- Modification or elimination of outdated requirements.
- Replacement of existing accreditation standards with a standard that results in data of known and documented quality that state agencies can rely on to make regulatory and policy decisions that affect public health and the environment. To achieve this goal, ELAP is proposing to incorporate by reference into the regulations the nationally recognized, consensus-based 2016 TNI Standard – Revision 2.1, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016 TNI Standard), with two exceptions.

Benefits:

The benefits of the proposed regulations are discussed below.

Benefits to the Laboratories

- Reduces misinterpretation and confusion by clearly defining administrative and technical requirements.
- Promotes elevated performance by specifying the managerial and technical activities that can affect the quality of results.
- Allows for flexibility in the implementation of the standards and accommodates operation and management of laboratories of all sizes and scopes.

- Provides clarification on the types of activities and conditions that lead to enforcement.
- Promotes a fair business environment, where all laboratories are held to the same standards.

Benefits to the State Regulatory Agencies:

- Ensures laboratories produce data of known and documented quality by adopting essential quality system elements.
- Consistency of results across laboratories by standardizing laboratory activities and practices.
- Improved confidence that the data produced has been sufficiently scrutinized through appropriate quality assurance measures before being released by the laboratory.
- Greater legal defensibility of data by having supported documentation for traceability, such that the history of samples and associated data is easily retraceable.
- Accommodates needs of state agencies that rely on ELAP accredited laboratories by allowing ELAP greater flexibility to change what analytical methods are offered for accreditation.

Benefits to the Accreditation Program:

- Allows ELAP to efficiently and effectively help laboratories navigate and interpret the regulations by providing clarity and specificity to requirements of the program.
- Eliminates the need for ELAP to dedicate resources to maintaining the relevance and pertinence of the accreditation standards, and instead relies on Expert Committees of TNI, with representative members from the national laboratory community, to improve the TNI Standard based on best professional practices in the industry. ELAP would still be required to adopt changes or updates to the 2016 TNI Standard approved by TNI Expert Committee into the regulations by the formal rulemaking process.
- Creates only one accreditation standard for all laboratories, which will simplify on-site laboratory assessments, fee structure, and employee training.
- Addresses resource challenges that ELAP faces by allowing laboratories to contract with third-party laboratory assessment firms to satisfy the onsite assessment requirement of the accreditation program.
- The specificity of the proposed regulations will help with enforcement against noncompliant laboratories.

Evaluation of Consistency or Compatibility with Existing State Regulations:

The State Water Board evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations and has determined that no other state regulations address the same subject matter and that the proposed regulations are consistent and compatible with other existing state regulations.

FORMS INCORPORATED BY REFERENCE

The proposed regulation incorporates by reference the 2016 TNI Standard, accreditation standards published by the NELAC Institute (TNI), a 501(c)(3) non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. TNI was established for the long-term management of the National Environmental Laboratory Accreditation Program (NELAP) and the continued development of accreditation standards. The organization is managed by a Board of Directors and is governed by organizational bylaws.

The standards produced by TNI are integrated documents containing language from relevant International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standards, and therefore, are copyright protected and provided through a license agreement. 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, TNI 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. The link to this document will remain active until public access to the document is no longer needed for the rulemaking process. To obtain a 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.

MANDATED BY FEDERAL LAW OR REGULATIONS

The proposed regulations are not federally mandated. However, the accreditation requirements of the proposed regulations align with requirements of the federal Safe Drinking Water Act (SDWA) (42 U.S.C. §300f-300j) and the National Primary Drinking Water Regulations (40 CFR §141) for laboratories that analyze drinking water for regulatory compliance. 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 fulfill the state-run certification program requirements.

OTHER STATUTORY REQUIREMENTS

Exemption from Peer Review

Health and Safety Code § 57004, mandates that proposed regulations be peer reviewed when the regulation includes a “scientific basis” or “scientific portions”. However, when certain circumstances exist, exemption is warranted. As stated in the *Unified California Environmental Protection Agency Policy and Guiding Principles for External Scientific Peer Review*, March 13, 1998 (Cal/EPA Guiding Principles) these circumstances include:

- A particular work product that has been peer reviewed with a known record by a recognized expert or expert body.
- Administrative standards and rules which are primarily management directives for which the underlying scientific principles, computer models, or decision tools have already been appropriately reviewed.

The State Water Board finds that the 2016 TNI Standards are consensus-based standards, developed in accordance with rigorous democratic procedures and the requirements of the federal Office of Management and Budget Circular A-119, and that circumstances exist to warrant exemption of peer review. The State Water Board further finds that the management and technical requirements in the 2016 TNI Standard have been appropriately reviewed and recognized by the United States Environmental Protection Agency as meeting requirements for regulatory compliance in the analysis of drinking water, wastewater, and hazardous waste. Therefore, the State Water Board finds that pursuant to CalEPA Guiding Principles the proposed regulations are categorically exempt from CalEPA requirements for peer review of regulations.

LOCAL MANDATE

The State Water Board has determined that the proposed regulations do not impose a mandate on local agencies or school districts, or a mandate that requires reimbursement pursuant to part 7 (commencing with section 17500) of the Government Code, division 4. Local agencies that have laboratories may incur costs to implement the new regulations; however, these costs are not the result of a “new program or higher level of service” within the meaning of Article XIII B, Section 6 of the California Constitution. The presumed costs apply generally to all individuals and entities that operate laboratories that analyze environmental samples for regulatory purposes in California and do not impose unique requirements on local governments (*County of Los Angeles v. State of California, et al.*, 43 Cal. App. 3d 46 (1987)). In addition, the local agencies can pass on the costs to the laboratory by increasing service charges or fees to the public. Therefore, no state reimbursement of these costs is required.

FISCAL IMPACT

The State Water Board has made the following determinations:

- The proposed regulations do not result in a cost to any local agency or school district that must be reimbursed in accordance with Government Code sections 17500 through 17630.
- The proposed regulations do not result in a cost or savings in Federal funding to the State.

Fiscal Effect on Local Government/Other Nondiscretionary Cost or Savings Imposed Upon Local Agencies

For 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. The State Water Board estimates that for public laboratories the total costs of the proposed regulation during the three-year implementation period could be \$17,268,908.00, and the cost for any 12-month period after full implementation could be \$9,448,908.00.

Fiscal Effect on State Government

The proposed regulations may have a fiscal effect on State government because of increased time that ELAP staff will dedicate to program tasks and core functions. At least initially, the on-site assessments will take longer as staff get familiar with the new accreditation standards. The 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 at an annual cost to the State of \$53,484.00.

The total annual cost of the regulation to the State government could be \$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.

HOUSING COSTS

The proposed regulations do not have an effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The State Water Board has done an economic impact assessment of the proposed regulations, as described below, and has determined that the proposed regulations may have a significant statewide adverse economic impact directly affecting environmental laboratories in California.

The proposed regulations make changes to California's state laboratory accreditation program and effects the requirements that the environmental testing laboratories must meet to analyze environmental samples for regulatory purposes in California. Laboratories that participate in the ELAP program must be compliant with the requirements of the 2016 TNI Standard, with two exceptions. The 2016 TNI Standard is a quality management system-based accreditation standard, which requires processes and procedures for the management of laboratory operations to assure the quality of the test results it generates.

Although the proposed regulations do not specifically require the purchase of new technology or laboratory equipment, hiring new personnel, or any additional investments to comply; to provide conservative estimates of potential costs, the economic assessment assumed that small laboratories (approximately 80% ELAP accredited laboratories) would hire a laboratory consultant to assist in implementation of the new requirements and 70% may employ one additional full-time person. Medium laboratories (approximately 10% ELAP accredited laboratories) were also assumed to hire a laboratory consultant to assist in implementation of the new requirements and 50% may employ one additional part-time employee. Large laboratories (approximately 10% ELAP accredited laboratories) were assumed to only hire a laboratory consultant to aid in the implementation of the 2016 TNI Standard.

In addition to the requirement to comply with the 2016 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.

The proposed regulations would not impact the ability of laboratories to compete with laboratories from other states, because all laboratories analyzing environmental samples for regulatory purposes in California would have to be accredited by ELAP and meet the proposed requirements. Furthermore, if environmental laboratories in California want to provide services to other states, then the proposed regulations would not apply because the laboratory would have to comply with that state's regulations, accreditation standards, and requirements. However, adopting the 2016 TNI Standard

would make it easier for California laboratories to meet the requirements of a state accreditation program that utilizes the TNI Standard, such as Oregon.

The State Water Board has considered proposed alternatives that would lessen any adverse economic impact on business and invites you to submit proposals. Submissions may include the following considerations:

- (I) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.
- (II) Consolidation or simplification of compliance and reporting requirements for businesses.
- (III) The use of performance standards rather than prescriptive standards.
- (IV) Exemption or partial exemption from the regulatory requirements for businesses.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The State Water Board estimates the cost for any 12-month period during the three-year implementation phase of the proposed regulations is \$14,031,206.53. The estimated cost for any 12-month period after full implementation of the proposed regulations is \$22,257,719.60. As noted above, these are conservative estimates that assume that small laboratories may hire a full-time employee and a laboratory consultant, that medium laboratories may hire a part-time employee and a laboratory consultant, and that large laboratories will only hire a laboratory consultant. Laboratories may, however, find less costly ways to comply.

Creation of Businesses

The State Water Board recognizes that to help successfully implement the proposed regulations, laboratories may choose to hire a laboratory consulting firm. Currently, there are three laboratory consulting firms in California and the proposed regulations are assumed to create an additional nine. These businesses are not prevalent in California because the current regulations limit their ability to prosper in California. However, the proposed regulations utilize the national consensus TNI standards, which laboratory accreditation consulting firms across numerous states support, and could spark the creation and growth of laboratory accreditation consultant businesses in California.

The proposed regulations also allow 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 the current state-specific accreditation standards. However, the national consensus TNI Standard is an accreditation standard that third-party assessment firms have experience assessing laboratories to. The State Water Board expects the size and untapped potential of the third-party assessor market in California could be inviting enough to create additional jobs in California.

Expansion of Businesses

The State Water Board assumes that any regulatory samples that are being analyzed by laboratories that are unable or unwilling to comply with the proposed regulations will still need to be analyzed and reported by an ELAP-accredited laboratory. Therefore, the State Water Board assumes laboratories that remain accredited would see an increase in business and revenues from the loss of accreditation or closure of some laboratories.

Creation of Jobs in California

The State Water Board estimates that the proposed regulations will create a total of 355 jobs. It is assumed that 332 jobs will be created in the environmental laboratory industry and 23 jobs will be created in supporting industries.

Elimination of Businesses

The State Water Board assumes that the proposed regulatory action may result in up to ten laboratory closures. Although, other state accreditation programs that converted their program's accreditation standards to the nationally recognized consensus-based TNI Standard observed that some laboratories closed, particularly the small ones, it is difficult for the State Water Board to know how many laboratory businesses will be eliminated because of the proposed regulations. Laboratories face pressures like heightened competition and pricing constraints, that can also result in closures. Additionally, a saturated laboratory industry in California has resulted in a number of laboratory consolidations and purchases. Therefore, the State Water Board is unable to determine if a closure is a result of a proposed regulation or because of current industry conditions.

Elimination of Jobs in California

The State Water Board assumes that there will 20 job positions eliminated by the proposed regulations, but there would be no net elimination of jobs because of the proposed regulations. This is because if the proposed regulations result in closures of laboratories, the regulatory samples that were being analyzed by those laboratories would still have to be analyzed by other ELAP-accredited laboratories. This resulting increase in business at labs that take on the business 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 picking up the additional sampling.

Benefits of the Regulation to the Health and Welfare of California

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.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The costs to implement and maintain compliance with the 2016 TNI Standard are assumed to comprise the main economic impacts a laboratory may experience from implementation of the proposed regulations. Although the proposed regulations do not specifically require the purchase of new technology or laboratory equipment, hiring new personnel, or any additional investments to comply, the State Water Board is assuming for the purposes of the economic impact assessment that laboratories will hire new personnel and/or a laboratory consulting firm to help with the implementation process. Based on those assumptions, the State Water Board estimates the cost to implement the proposed regulations for a typical laboratory ranges from \$40,000.00 to \$77,334.40.

BUSINESS REPORT

The proposed regulations require laboratories to comply with notification, reporting, and records retention requirements of state and federal agencies that data is being reported to. It is necessary that these reporting requirements apply to businesses, including laboratories, in order to protect the health, safety, and welfare of the people of the state.

SMALL BUSINESS

The proposed regulations will impact less than 500 small businesses. For the purposes of this analysis, the State Water Board considers laboratories that run less than 50 fields of accreditation to be “small businesses,” because it assumes that such laboratories are generally independently owned and operated, and not dominant in their field of operation.

It is difficult for the State Water Board to estimate the number of small laboratory closures that could result as a result of the proposed regulations because small laboratories are already especially vulnerable to other industry pressures that could induce closure or sale, independent of the proposed regulations. Although the TNI Standard can be implemented in any laboratory regardless of size or complexity, other state programs have suggested that smaller laboratories may need more time to implement the TNI Standard. ELAP is, therefore, proposing a three-year, staged implementation period to implement the regulations, and assistance to small laboratories to comply with the TNI requirements. Nonetheless, the State Water Board assumes a total of ten small laboratories will be unable or unwilling to comply with the proposed regulations and will voluntarily forgo ELAP accreditation. Some of those small laboratories may be in-house laboratories at drinking water and wastewater facilities that decide not to actually close, but to forgo ELAP accreditation and remain operational to analyze non-regulatory samples for day-to-day needs of the facility.

Because the State Water Board is concerned about small laboratory closure, it has initiated a Laboratory Mentorship Program. This program partners ELAP-accredited laboratories that have TNI accreditation with laboratories that service remote areas and

communities in the state where a laboratory closure may result in loss of service for that community. This mentorship program is helping laboratories with the implementation process and identifying needs of the laboratory to become compliant with the 2016 TNI Standard. Similarly, professional associations like the California Water Environment Association (CWEA) are sponsoring trainings for their small laboratory members. The CWEA training focuses on best practices for aligning with the 2016 TNI Standard and tools and resources for efficient implementation.

Therefore, although the regulations may have an impact on small businesses, the State Water Board plans to assist in compliance to reduce those impacts, as described above.

ALTERNATIVES STATEMENT

The State Water Board considered two alternative accreditation standards to incorporate into the proposed regulations: (1) a state-created accreditation standard, and (2) a modified version of an existing accreditation standard (the alternative accreditation standard developed by a Subcommittee of the Environmental Laboratory Technical Advisory Committee (ELTAC) is considered as a modified version of an existing standard). The State Water Board's reasoning for rejecting the alternatives is that they are less effective than the 2016 TNI Standard in carrying out the purpose and objectives for which the action is proposed, represent the status quo, and lack credibility.

The State Water Board engaged in a multi-year, stakeholder-involved process to evaluate the accreditation standard options and select the best accreditation standard for the program. All advisory committees involved in the selection process agreed that the selected accreditation standards should have quality system requirements. A quality system requires direct management and constant improvement of laboratory processes and procedures to ensure quality of the 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.

Quality system requirements are a new concept to ELAP and would be a new requirement for laboratories to comply with, so all alternative accreditation standards would result in similar challenges and costs to implement. Therefore, alternatives were assessed based on the effectiveness of the accreditation standard.

The alternative accreditation standard developed by a Subcommittee of ELTAC lacked the necessary quality system requirements to ensure that data produced by laboratories was of known and documented quality. Furthermore, the alternative only required that content of a quality system be included or referenced in a laboratory Quality Manual but does not provide the specificity and detailed criteria of each quality system requirement. Without the specificity and detailed criteria of each requirement, laboratories can interpret and implement these requirements differently, which disqualifies this alternative as a standard because it does not standardize laboratory activities and

practices. Additionally, the lack of specificity and detailed criteria of each requirement makes the alternative not auditable for compliance purposes, which is a fundamental problem with the current accreditation standard.

The alternative standard proposed by the ELTAC Subcommittee, which has not been reviewed or considered by the Environmental Protection Agency (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. TNI updates the TNI Standard through a consensus-based standard development program where expert committees, made up of national experts in the environmental laboratory community, develop and maintain the standards. The alternative accreditation standard developed by the ELTAC Subcommittee, would require ELAP to review and update the requirements independently, resulting in additional costs to the State Water Board. Furthermore, 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, has been widely effective and successful for other state programs in part because of the known and inclusive consensus-based standard development process.

CONSIDERATION OF ALTERNATIVES

The State Water Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The State Water Board invites interested persons to present alternatives to the proposed regulation during the public comment period.

AVAILABILITY OF TEXT OF PROPOSED REGULATIONS, INITIAL STATEMENT OF REASONS, AND THE RULEMAKING FILE

The State Water Board has prepared and is making available the proposed regulation text, which constitute the express terms of the proposed actions, and an Initial Statement of Reasons for the proposed regulatory action. The Initial Statement of Reasons includes the specific purpose for the regulations proposed for adoption, and the rationale for the State Water Board's determination that the adoption is reasonably necessary to carry out the purpose for which the regulations are proposed. All of the information upon which the proposed regulations are based, with the exception of the 2016 TNI Standards, is contained in the rulemaking file, which is available for inspection and copying throughout the rulemaking process. To inspect or copy the rulemaking file at the State Water Board office, contact Andrew Hamilton, identified below ("Contact Persons").

As noted above, because the standards produced by TNI are copyright protected and provided through a license agreement, these sections are incorporated by reference rather than set out in the regulations. The State Water Board has made the 2016 TNI Standard publicly available for viewing at 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. Refer to the “Forms Incorporated By Reference” section above for instructions to access a read-only, unlicensed version of the 2016 TNI Standard. Copies of the standard may also be purchased by contacting TNI's Executive Administrator, Suzanne Rachmaninoff, at suzanne.rachmaninoff@nelac-institute.org.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After holding the APA hearing and considering relevant comments received by 12:00 noon on December 20, 2019, the State Water Board is proposing to adopt the proposed regulations at its March 17, 2020 board meeting in Sacramento, CA. The specific room location will be set out in the State Water Board's agenda and will be made available to the public at least 10 days in advance. If the State Water Board makes modifications that are substantially related to the originally proposed text, the State Water Board will make the modified text – with changes clearly indicated – available to the public for at least 15 days before the March 17, 2020 board meeting. Any such modifications will also be posted on the State Water Board Web site. Please send request for copies of any modified regulations to the attention of the contact persons provided below (“Contact Persons”). The State Water Board will accept written comments on the modified regulation for 15 days after the date on which they were made available.

Updates to these proposed regulations may be received by subscribing to an e-mail notification list on the [State Water Board's e-mail subscriptions webpage](#)

Subscribe under General Interests, Environmental Laboratory Accreditation Program (ELAP).

AVAILABILITY OF FINAL STATEMENT OF REASONS

After the Water Board's adoption of the regulations, the State Water Board will make available the Final Statement of Reasons, which will include responses to comments submitted during the comment period. Copies may be requested from the contact person(s) named in this notice or may be accessed on the Web site address provided below (“Internet Access”).

INTERNET ACCESS

Copies of this Notice of Proposed Rulemaking, the Initial Statement of Reasons, and the text of the regulations may be found on the [ELAP's Regulations webpage](#)

Updates to the rulemaking file, including any modifications to the proposed regulatory text, comments on the regulations, and the final statement of reasons, will also be posted to the webpage.

Documents relating to this proposed action may also be found on [ELAP's Regulations webpage](#)

CONTACT PERSONS

Requests for copies of the proposed regulatory text, the initial statement of reasons, any subsequent modifications of the proposed regulatory text, timely submitted comments, the final statement of reasons, or other inquiries concerning the proposed action may be directed to:

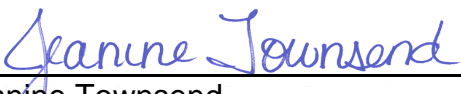
Jacob Oaxaca
Senior Environmental Scientist, Supervisor
State Water Resources Control Board
Environmental Laboratory Accreditation Program
1001 I Street, 17th Floor
Sacramento, CA 95814
Telephone: (916) 323-3433
Electronic mail address: jacob.oaxaca@waterboards.ca.gov

In the event Mr. Oaxaca is not available to respond to requests or inquiries, please contact:

Andrew Hamilton
Environmental Scientist
State Water Resources Control Board
Environmental Laboratory Accreditation Program
1001 I Street, 17th Floor
Sacramento, CA 95814
Telephone: (916) 323-3427
Electronic mail address: andrew.hamilton@waterboards.ca.gov

October 11, 2019

Date



Jeanine Townsend
Clerk to the Board