

**STATE WATER RESOURCES CONTROL BOARD
BOARD MEETING SESSION – DIVISION OF DRINKING WATER
MAY 5, 2020**

ITEM 8

SUBJECT

CONSIDERATION OF A RESOLUTION TO ADOPT PROPOSED ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (ELAP) REGULATIONS

DISCUSSION

State regulatory programs designated by the Legislature to protect public health and the environment rely on accurate and reliable environmental testing data to monitor the effectiveness of regulatory actions. Under the Environmental Laboratory Accreditation Act (Health & Saf. Code, div. 101, pt. 1, ch. 4, art. 3, §100825 et seq.), laboratories that perform environmental testing for regulatory purposes are required to be accredited by the State Water Resources Control Board (State Water Board) Environmental Laboratory Accreditation Program (ELAP). ELAP ensures that accredited laboratories can comply with an accreditation standard and demonstrate the capacity and competence to generate data of known and documented quality.

ELAP's current regulations, which were established in 1994, contain the requirements for operation of the accreditation program and the standards for determining the competency of a laboratory. These regulations are outdated and do not incorporate the fundamental elements of modernized accreditation standards. The inadequate requirements in the current regulations have resulted in an ineffective accreditation program and a laboratory community that operates without effective regulatory oversight. This jeopardizes the validity of the data produced by accredited laboratories and creates a lack of confidence in data used by the State regulatory agencies to make decisions regarding public health and the environment.

The broad objectives of the proposed regulations are to adopt a single accreditation standard that ensures quality data for all state regulatory agencies and to modernize the accreditation program within the authority granted by the Environmental Laboratory Accreditation Act. The proposed regulations include:

- Replacement of existing accreditation standards with 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.
- Detailed guidance on the accreditation process (initial/renewal/amendment application, timelines).
- Use of Third Party Assessment Agencies as a resource to conduct some onsite assessments.

State Water Board staff engaged in a multi-year, stakeholder-involved process to select an accreditation standard and develop the proposed regulation text. Focused stakeholder meetings were conducted from 2015 through 2019 and multiple preliminary drafts of the regulation text were released with suggested changes from the laboratory community incorporated into the proposed regulation text. Public workshops to present the preliminary drafts and solicit comments, were held in 2017 and 2019, respectively, with locations in Redding, Sacramento, San Francisco, Fresno, Los Angeles, and San Diego.

On October 11, 2019, the State Water Board published a notice of proposed rulemaking pursuant to the requirements of the California Administrative Procedure Act (APA). Public comments on the draft regulations were received during a 70-day public comment period, which ran from October 11, 2019 to December 20, 2019. On December 18, 2019, the State Water Board held an APA public hearing (during a Board Workshop). The purpose and intent of the public comment period and public hearing was to receive verbal and written comments from the public on the proposed regulations in accordance with the APA.

Following the conclusion of the public comment period State Water Board staff compiled and reviewed every verbal and written comment that was received during the comment period. Concurrently, staff met with various stakeholder groups that commented on the proposed regulations to have an open dialogue about the submitted comments. These meetings were used to clarify questions that remained regarding the proposed regulations and to discuss potential changes to the regulation text.

On January 17, 2020, State Water Board staff hosted a focused stakeholder forum with the authors of the alternative quality management system proposal. The purpose was to assist State Water Board Members Tam Doduc and Sean Maguire, in understanding the differences between the staff proposal and the alternative proposal.

Based on the comments and feedback received from stakeholders, State Water Board staff made changes to the proposed regulation text. On February 13, 2020, staff released the proposed regulation text for an additional 15-day public comment period which ended on February 28, 2020. The purpose and intent of the public comment period was to provide an opportunity for the public to review and comment on the changes.

State Water Board staff summarized the categories of comments received during the public comment periods and has provided draft responses to the State Water Board and the public. Final responses to all comments that were received during the public comment periods will be prepared and contained in the Final Statement of Reasons and submitted to the Office of Administrative Law as part of the regulations package.

The 2016 TNI Standard incorporated by reference into the proposed regulations contain relevant language from the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standards, which are copyright protected, and the 2016 TNI Standard is 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, 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.

All other elements of the regulatory package are posted on the program webpage at: https://www.waterboards.ca.gov/drinking_water/certlic/labs/elap_regulations.html.

POLICY ISSUE

Should the State Water Board adopt the proposed resolution and accompanying regulations?

FISCAL IMPACT

The Initial Statement of Reasons (ISOR) and the Economic and Fiscal Impact Analysis (Std. 399) contain evaluations of the economic impacts of the proposed regulations on California business enterprises and individuals. As part of the Std. 399, the State Water Board also evaluated the fiscal impacts to local and state government.

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, some laboratories may decide to hire new personnel and/or a laboratory consulting firm. Other laboratories may, however, find less costly ways to comply.

The proposed regulations could result in closures of laboratories that are unable or unwilling to implement the 2016 TNI Standard. However, 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.

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. Therefore, qualifying laboratories may incur costs for services provided by third-party assessment firms that are in excess of what they had to pay for such services under the existing regulations.

Because of the size of California's environmental laboratory industry, the proposed regulations represent an opportunity for expansion and growth of industries in the state that provide laboratory consultations and assessments. Reliance upon a national accreditation standard ensures that there are firms with the skills and knowledge available to assist laboratories with compliance; whereas, creation of a "California-only" standard would likely limit such opportunities to tap into those existing resources.

The State Water Board considers the economic impact of the proposed regulation on public laboratories that provide assessments for drinking water and wastewater treatment facilities as a fiscal impact to local and state governments. As noted above, the fiscal impacts on local governments will depend upon how the laboratory decides to implement the 2016 TNI Standard, including whether they decide to hire additional personnel. ELAP's experience with small, remote municipal laboratories during its mentorship program is that additional personnel are not required, as long as assistance with implementation is provided. In addition to the impact of the TNI Standard, some public laboratories may incur costs due to increased assessment fees. It is possible that an increase in operational costs for laboratories of public facilities could be passed on to rate payers. However, some public laboratories may forego accreditation and only run analyses for internal operational purposes, and instead send regulatory samples to an ELAP-accredited commercial laboratory.

The proposed regulations may have a fiscal effect on State government. The initial impact of the proposed regulation would have a relatively small effect on ELAP staffing resources, which could be accommodated through redistribution of existing staff. However, additional personnel or reallocation of resources may be needed for effective implementation and transitioning to the new accreditation standards.

The proposed regulations do not affect any federally funded state agency programs.

STATEWIDE IMPACT ON DATA QUALITY

Effective stewardship of the environment and protection of public health requires quality data to inform state agencies of the effectiveness of regulatory actions. Such data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or the toxicity of sediments in rivers. The regulatory agencies, who are the primary users of the data generated by the laboratories regulated by this proposal, require data to be accurate, consistent, comparable across laboratories, and generated using robust quality assurance requirements to ensure legal defensibility. The proposed regulations include a single laboratory accreditation standard that incorporates quality management requirements that standardize laboratory activities and practices to ensure that data produced is of known and documented quality that meets the regulatory agencies' needs. A single standard will help provide data of equal quality regardless of a laboratory's size, type, geographic location, or community's economic status.

In addition, the proposed regulations provide flexibility to ensure that analytical methods are available for regulatory purposes. Each agency, pursuant to its own particular statutes and regulations, identifies those particular monitoring requirements in its

permits, orders and other regulatory requirements. Under the proposed regulations, ELAP will be able to accredit laboratories for whatever fields of accreditation the state agencies determine that they need laboratories to be accredited for, as opposed to requiring ELAP to maintain and update a list of offerings in its regulations.

STAFF RECOMMENDATION

The State Water Board should adopt the proposed regulations.