

**STATE WATER RESOURCES CONTROL BOARD
BOARD MEETING SESSION – DIVISION OF DRINKING WATER
APRIL 7, 2020**

ITEM 6

SUBJECT

CONSIDERATION OF AN ORDER TO UPHOLD DENIAL OF ACCREDITATION RENEWAL AND IMPOSITION OF CIVIL LIABILITY FOR WESTERN ANALYTICAL LABORATORY IN CHINO, CALIFORNIA.

DISCUSSION

On May 9, 2019, the Environmental Laboratory Accreditation Program (ELAP) issued a notice revoking the certificate of accreditation of Western Analytical Laboratory (WAL) and denying WAL's application for renewal of accreditation, and issued a separate citation for civil penalties in the amount of \$137,841.60 for failure to comply with the Environmental Laboratory Accreditation Act (ELAA) and applicable regulations. The revocation notice was eventually withdrawn by ELAP because WAL's accreditation was expiring. WAL timely filed a Petition for Reconsideration on the denial of accreditation renewal and the issuance of the citation for civil penalties pursuant to Health and Safety Code section 116701. The State Water Board held a hearing on December 5, 2019 at the California Environmental Protection Agency headquarters in Sacramento to consider the matters.

The State Water Board received evidence and testimony from WAL and ELAP regarding the alleged violations prior to the hearing, and each party was awarded equal time to present their arguments at the hearing. After weighing and considering the evidence and arguments, the State Water Board has determined that because of the seriousness of the actions by WAL, the State Water Board is upholding the denial of accreditation renewal and is issuing an administrative civil liability for \$90,000. In light of the circumstances pertaining to this case, the State Water Board is extending WAL's interim accreditation 90 days from the date of adoption of this order to afford WAL a reasonable time to comply with the conditions for renewal of accreditation included in this Order, and remands the application process for renewal of accreditation to ELAP.

The 90-day period provided is to afford WAL time to correct deficiencies in its laboratory's quality assurance program, and may be extended upon demonstration of continuing progress towards compliance with one of the two paths to renewal accreditation, described below, and clear justification for the extension request, subject to approval of the Deputy Director of the Division of Drinking Water.

To renew accreditation following the 90-day period, WAL must reapply for accreditation with ELAP and pass an onsite assessment, demonstrating WAL has updated its quality assurance program to include policies and procedures that would prevent data

fabrication and reporting data from another source as its own. Such a program shall also ensure that work performed by WAL meets the needs of its clients, that samples analyzed for nonregulatory purposes are clearly identified by WAL and reported as such, and that data being submitted for a regulatory purpose be supported by the appropriate documentation, including chain of custody for all samples submitted to the laboratory. Additionally, the quality assurance program must include a data integrity and ethics training program for its employees that includes a clear policy prohibiting data manipulation and fabrication.

Alternatively, as volunteered by WAL in its “Supplemental Submission in Support of Petition for Reconsideration,” WAL could apply for renewal of accreditation through ELAP after it successfully implements and is accredited in the ISO/IEC 17025 laboratory standard, which is more rigorous than current regulatory requirements. WAL must also implement a data integrity and ethics training program for its employees that includes a clear policy prohibiting data manipulation and fabrication and is approved by ELAP. If WAL chooses this alternative, the State Water Board would reduce the fine by \$50,000, requiring payment of a civil liability of \$40,000.

ISSUE

Should the State Water Board adopt the order upholding denial of accreditation renewal and imposition of civil liability for Western Analytical Laboratories?

FISCAL IMPACT TO LABORATORY

The proposed Order upholds the imposition of civil liability for WAL. A civil liability of either \$90,000 or \$40,000 will be imposed depending on the path to reaccreditation that WAL selects.

If WAL selects the path to reaccreditation that includes seeking accreditation to the ISO/IEC 17025 laboratory standard, then the laboratory may decide to hire a consultant to help implement the laboratory standard. The cost of a consultant will depend on the amount of time needed for the laboratory to implement the laboratory standard and the distance of travel for the consultant. Additionally, the laboratory would pay an accreditation body that accredits to ISO/IEC 17025 to assess the laboratory and grant the accreditation. The additional costs associated with this path to reaccreditation is the reason for the discounted civil liability.

FISCAL IMPACT TO THE STATE

If WAL seeks reaccreditation, the proposed order requires WAL to submit a new application, accreditation fees and pass an onsite assessment. This is the normal process of accreditation for laboratories participating in the accreditation program, and would be covered by the accreditation fees paid by WAL. The onsite assessment would not be completed by ELAP if WAL decides to seek accreditation to ISO/IEC 17025.

IMPACT TO DATA QUALITY

Data generated by environmental laboratories inform state regulatory agencies of the effectiveness of regulatory actions and are drivers of decision made to protect the environmental and safeguard human health. These data may include the concentration of chemical contaminants in drinking water, identification of harmful bacteria at beaches, or the toxicity of sediments in rivers. Regulatory agencies require the data to be accurate, consistent, comparable across laboratories, and generated using robust quality assurance requirements to ensure legal defensibility. The proposed Order imposes requirements on Western Analytical Laboratory to implement more robust quality assurance practices in the laboratory before reaccreditation can be offered in an effort to ensure that data produced by WAL is of known and documented quality that meets the needs of state regulatory agencies.

STAFF RECOMMENDATION

Staff recommends that the State Water Board adopt the proposed order.