

**STATE OF CALIFORNIA
STATE WATER RESOURCES CONTROL BOARD**

ORDER DW 2020-0001

In the Matter of Review of
Orders Issued by the Environmental Laboratory Accreditation Program to
Western Analytical Laboratory for Denial of Accreditation Renewal and
Administrative Civil Liability

**ORDER UPHOLDING DENIAL OF ACCREDITATION RENEWAL AND
IMPOSITION OF CIVIL LIABILITY**

BY THE BOARD:

In this order, the State Water Resources Control Board (State Water Board) reviews two orders issued through the Environmental Laboratory Accreditation Program (ELAP)¹ for failure to comply with the Environmental Laboratories Accreditation Act (ELAA) (Health & Saf. Code, § 100825 et. seq) and the applicable regulations (Cal. Code Regs., tit. § 64801 et seq.), one denying Western Analytical Laboratory's (WAL's) application for accreditation renewal and the other for issuance of a citation for penalties in the amount of \$137,841.60. For the reasons discussed herein, the State Water Board upholds the

¹ The orders were signed by Christine Sotelo, Chief of ELAP. She was assisted in the matter by members of ELAP's Program Development, Research and Enforcement Unit, including Jacob Oaxaca, Naeem Ahmad, and Christopher Hand. Nickolaus Knight from the State Water Board's Office of Enforcement provided legal advice to the Prosecution Team. Robert Brownwood was added to the Prosecution Team on November 25, 2019. Andrew Hamilton, who is also works in ELAP as a Senior Environmental Scientist, advised the hearing officer, Sean Maguire, along with Kim Niemeyer, who is from the State Water Board's Office of Chief Counsel. To ensure a fair hearing, the State Water Board staff and attorney that issued the denial of accreditation and citation have been separated from the hearing team, and ex parte communications by the parties with the hearing team was prohibited.

denial of accreditation renewal and reduces the civil liability to \$90,000, with additional conditions as described.

1.0 INTRODUCTION

On May 9, 2019, ELAP issued a notice revoking WAL's certificate of accreditation² 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 ELAA and the applicable regulations. WAL timely filed a Petition for Reconsideration pursuant to Health and Safety Code section 116701.³ 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, 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

² Health and Safety code section 100910 requires that prior to revocation a notice be provided to the laboratory, providing an opportunity to request a hearing on the revocation. Therefore, although the notice identified the accreditation was revoked, the revocation never went into effect. Although WAL requested a hearing, no hearing was held because its accreditation was about to expire by law. Because of that, ELAP withdrew the notice of revocation on May 28, 2019. (Exhibit 3, May 28, 2019 email from N. Knight re Notice of Revocation Motion to Dismiss/Withdraw.)

³ All references are to the California Health and Safety Code, unless otherwise noted.

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. To renew accreditation following the 90-day period, WAL must reapply for accreditation with ELAP and pass an onsite assessment, that demonstrates 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.⁴ WAL must also implement a data integrity and ethics training program for its employees that includes a

⁴ Note that after accreditation to the ISO/IEC 17025 standard, WAL would still need to submit an application to ELAP and pay fees, but ELAP would not need to perform an onsite assessment.

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 \$40,000.⁵

2.0 FACTUAL BACKGROUND

On April 30, 2018, ELAP received a referral from the San Diego Regional Water Quality Control Board (San Diego Regional Board) regarding the operation of a non-ELAP accredited auxiliary laboratory at the Skyline Ranch Country Club Wastewater Treatment Facility (Skyline) in Valley Center, CA. The San Diego Regional Board made the referral based on violations of Skyline's Waste Discharge Requirements (WDR) (Order No. R9-2005-0258 and addenda) observed during an inspection of Skyline's wastewater treatment facility. (Ex. 2, attachment 1, "San Diego Regional Boards NOV and Summary of Inspection.")

The San Diego Regional Board provided ELAP with documents, including a June 1, 2018 letter from Dr. Alon Lebel of Invirotreat, Skyline's consultant, alleging that WAL set up an auxiliary laboratory at Skyline's facility in order to conduct the total coliform testing required in Skyline's WDR. (*Id.*) Provided with Invirotreat's letter were copies of laboratory reports prepared by WAL with total coliform results for Skyline's samples with a header listing WAL's ELAP accreditation number, a footer note stating that the laboratory was ELAP accredited, the order number assigned to Skyline's WDR, and a statement at the bottom of the report that samples were analyzed using the

⁵ With approval from the State Board, WAL may choose an alternative accreditation standard with equivalent quality management system requirements (e.g. 2016 TNI Standard).

analytical method “SM 9221 B” (Standard Method 9221 B from Standard Methods for Examination of Water and Wastewater). (*Id.*)

Pursuant to section 100865, ELAP conducted an onsite inspection of WAL’s laboratory on June 20, 2018. During the inspection, ELAP identified irregularities with data that was being submitted for regulatory compliance with Skyline’s WDR issued by the San Diego Regional Water Board. Specifically, ELAP alleged that WAL reported total coliform data for samples that it had not received or analyzed but relied upon unsupported data sheets created and filled out by Skyline staff. (Ex. 2, attachment 2, including raw data sheets from Skyline, lab reports generated by WAL using raw data sheets, and sample log.) Additionally, ELAP contends that WAL was operating a non-accredited laboratory at the discharger’s wastewater treatment facility to analyze samples for regulatory compliance purposes. (Ex. 1, p. 2, Order Issuing Citation.)

Following the inspection, the parties were involved in numerous settlement negotiations but were unable to reach an agreement.⁶ On May 9, 2019, ELAP sent WAL two orders, one revoking WAL’s accreditation to analyze environmental samples for regulatory purposes pursuant to Health and Safety Code section 100905 and denying WAL’s

⁶ Almost a year passed between the inspection by ELAP in June 2018 and issuance of the citation and notice of revocation and denial of renewal accreditation in May 2019. According to WAL, it was advised on September 6, 2018 that ELAP was contemplating an enforcement action based on the June 2018 inspection. The parties met on October 9, 2018 in Sacramento. Pursuant to that meeting, WAL provided additional documentation to ELAP on October 26, 2018, but did not receive any response until February 15, 2019. WAL replied to ELAP on March 22, 2019, providing additional information and materials, to which ELAP responded on April 2, 2019. WAL requested another opportunity to discuss and resolve the matter, but instead was issued the citation and notice of revocation and denial of renewal accreditation on May 9, 2019. (Ex. 7, p. 2, July 12, 2019 email from W. Carter, regarding Request for Hearing, and Stay/Interim Accreditation Pending Hearing.)

application for renewal accreditation pursuant to section 100850 subdivision (b). (Ex. 2, Notice of Revocation and Denial of Renewal Application.) Under section 100910, subdivision (a), a laboratory has an opportunity to request a hearing within twenty days of receipt of a notice of revocation. ELAP's second order issued a citation for \$137,841.60 in civil penalties, which was petitionable pursuant to section 100880(f). (Ex. 1, Order Issuing Citation.) The basis for the three actions (revocation, denial of the renewal application, and issuance of the citation) was the same alleged conduct that was discovered in June 2018.

On May 14, 2019, WAL requested a hearing on the revocation. However, because WAL's current accreditation was set to expire by operation of law on June 30, 2019, it was decided that ELAP would withdraw the revocation proceeding, allow WAL's current accreditation to expire by operation of law, and deny the renewal application. (Ex.3, May 28, 2019 email from N. Knight.) On June 10, 2019, WAL filed a petition for reconsideration of the denial and the citation, including a request for a stay. (Ex. 4, Petition for Reconsideration.) Several temporary stays were issued, and on July 25, 2019, the State Water Board Executive Officer, Eileen Sobeck, issued a letter continuing WAL's interim accreditation until the hearing had been held and the State Water Board had issued a decision. (Ex. 5, July 21, 2019 letter from E. Sobeck issuing stay; Ex. 8, July 19, 2019 letter from E. Sobeck issuing stay; and Ex. 9, July 25, 2019 letter from E. Sobeck issuing stay.)

3.0 HEARING PROCESS

On December 5, 2019, the State Water Board held an adjudicative hearing pursuant to Government Code section 11400, *et seq.*, and the State Water Board's regulations.

Board member Sean Maguire was the hearing officer, assisted by Kimberly Niemeyer, from the State Water Board's Office of Chief Counsel, and Andrew Hamilton, a Senior Environmental Scientist from ELAP. The functions of Board staff who acted in a prosecutorial role by presenting evidence for consideration to the State Water Board (Prosecution Team) were separated from the Board staff who advised the State Water Board. All parties observed a prohibition on *ex parte* communications.

The parties to the proceeding were the ELAP Prosecution Team and WAL. A hearing notice was issued to the parties on October 21, 2019, setting out deadlines for submitting testimony, prehearing briefs, and other evidence ahead of the hearing. Five issues were identified in the hearing notice for the parties to address:

- 1) Did WAL's creation of reports for Skyline with coliform sampling results violate the ELAA?
- 2) Was WAL operating a laboratory at Skyline?
- 3) Was the issuance of citation to WAL for a civil liability in the amount of \$137,841.60 appropriate?
- 4) Was the denial of WAL's application for renewal accreditation appropriate?
- 5) Has WAL implemented corrective actions to address problems?

On October 14, 2019, the parties submitted legal arguments, witness statements and other documents for the State Water Board's consideration, and rebuttal evidence was submitted November 4, 2019. At the hearing, the parties were each given one hour to make opening statements, present their evidence and arguments, cross-examine each other's witnesses, and make closing arguments. In addition, the hearing officer and his advisors also asked questions of the parties. The State Water Board has considered all of the evidence in the hearing record and bases the findings and conclusions herein upon that evidence.

4.0 LEGAL AUTHORITY

Under the ELAA, laboratories that perform analyses on any combination of environmental samples for regulatory purposes must obtain a certificate of accreditation (Health & Saf. Code, § 100825, subdivision (b).) To obtain accreditation, a laboratory is required to submit an application, submit passing performance testing requirements for the fields of testing for which the laboratory is seeking accreditation, pass an onsite assessment, and pay applicable fees. (Health & Saf. Code, §§ 100850, 100861, 100872.) In addition to denying accreditation for failing to meet minimum requirements, ELAP may deny or revoke accreditation where the laboratory is not in compliance with any other provision of the ELAA or regulations adopted thereunder. (Health & Saf. Code, § 100850.)

In addition to the ability to deny accreditation, the State Water Board also has the authority to take enforcement against laboratories that do not comply with the requirements of the ELAA. Enforcement includes issuing an order directing compliance, revoking or suspending a lab's accreditation, or issuing a citation that includes civil

penalties. (Health & Saf. Code §§ 100875, 100880, 100905.) The issuance of a citation and denials of accreditation may be petitioned for reconsideration under section 116701. (*Id.*)

5.0 ALLEGED VIOLATIONS

According to the citation and the denial of accreditation (Ex 1 and Ex 2), basis for the alleged violations and the statutory and regulatory basis for the decisions are as follows:

- WAL is not receiving or analyzing samples from Skyline, but instead using unsupported data sheets created without scientific measurement of determination to produce analytical reports to demonstrate compliance with a regulatory permit. Furthermore, the raw data sheets for samples dated April 1, 2015 to April 30, 2018 contained prefilled analytical results. Generating reports to represent sample results which were not completed is fabrication of data and is a violation of sections 100850(b)(4) and (5), 100890 and 100895.
- WAL established a non-ELAP accredited auxiliary laboratory at Skyline for the purposes of performing analyses of environmental samples for regulatory purposes. Failure to obtain accreditation for an auxiliary laboratory performing analyses environmental samples is a violation of sections 100825(b) and 100890.
- WAL held itself out to its clients as having been accredited for Standard Method (SM) 9221B, as all reports state “ELAP Accredited Laboratory” and “Samples analyzed using SM 9221B.” Misrepresentation of accreditation is a violation of sections 100825(b), 100890 and 100895.

- Mr. Conti (WAL's laboratory director) knew or should have known that Skyline was submitting WAL laboratory reports for regulatory purposes, as the permit number was identified with "PERMIT NO.: R9-2005-0258 Addendum 1" on every report issued. Mr. Conti stated during the inspection on June 20, 2018 that the permit number was entered into the Laboratory Information Management System (LIMS) which then transferred the permit number into the report automatically. However, Mr. Conti initially made false statements to ELAP inspectors at the time of the site inspection, by stating he was unaware the data were being used for regulatory purposes. Making these false statements is a violation of sections 100890, 100895 and 100905.
- Skyline sample documentation between April 29, 2013 to April 30, 2018 lacked basic data integrity information such as: analysis time and date, quality control checks, incubation temperature and time. Furthermore, the raw data sheets for samples dated April 1, 2015 to April 30, 2018 contained prefilled analytical results. Properly documented samples are an essential element of data integrity. Data sheets without supported documentation or records compromises the reliability and validity of analytical data and is a violation of Title 22 of the California Code of Regulations (CCR), section 64815, subdivision (a).⁷
- WAL was unable to provide documentation and records pertaining to the training it provided to staff operating the auxiliary laboratory at Skyline including but not limited to a Standard Operating Procedure for Standard Method 9221B and

⁷ All references to the California Code of Regulations (CCR) are to Title 22, unless otherwise noted.

training attendance records. Implementing a staff training program is the responsibility of the Laboratory Director and a critical element of WAL's quality assurance program. Failure to maintain records of the implementation of the laboratories [sic] quality assurance program is a violation of CCR section 64815, subdivision (b).

- The date of expiration for various laboratory standards and chemicals were not recorded or were unverifiable due to the absence of a logbook or the ability to produce a certificate of analysis. Failure to maintain records for the implementation of the laboratory's quality assurance program is a violation of CCR section 64815, subdivision (d).
- ELAP inspectors observed laboratory staff wearing shorts and open laboratory coats while performing laboratory work, handling samples and handling chemicals. Additionally, WAL stored expired standards and chemicals with unexpired standards and chemicals. These practices have the potential to increase contamination of the samples or results. Failure to design, arrange and operate the laboratory in a way to minimize the potential of sample contamination is a violation of CCR section 64813, subdivision (a).

6.0 OBJECTIONS RAISED AT THE HEARING

At the hearing, WAL requested that the witnesses be excluded during the examination of the other witnesses. (Hearing Transcript at p. 10, lines 11-17.) This request was denied, as all of the witnesses' testimony had already been made available to the parties, and it is the State Water Board's practice to not exclude witnesses from the

hearing room. (Hearing Transcript at p. 13, lines 7-12.) WAL also objected to the written testimony submitted by the Prosecution Team, arguing that had not been submitted under penalty of perjury. (Hearing Transcript at p. 11, lines 7-12.) This objection was also overruled, as the witnesses swore to the truth of their testimony at the hearing and were available for cross-examination. (Hearing Transcript at p. 13, lines 13-17.)

Prior to and at the hearing, WAL's attorney also expressed that he planned to object to evidence based on hearsay. (WAL's Rebuttal to Prosecution Team's Legal and Technical Analysis in Support of Citation and Denial of Accreditation, p. 24-26.) At the hearing, the objections were noted and taken under submission. (Hearing Transcript, p. 9, lines 20-24.) Those objections will be addressed during the discussion of the evidence, below. In addition, WAL objected to Jacob Oaxaca's summary of the Prosecution Team's testimony at the hearing, arguing that Mr. Oaxaca was making conclusions and not providing evidence. (Hearing Transcript at p. 28-29, lines 16-3.) After review of the transcript, the State Water Board agrees that several of Mr. Oaxaca's statements during his testimony were legal conclusions and strikes the last two paragraphs of Mr. Oaxaca's testimony on p. 28 of the transcript before the objection by Mr. Carter. Similarly, on page 32 of the hearing transcript, the State Water Board strikes the statement "Again, WAL fabricated the data," as being a conclusory statement. The objection as to whether the statements about Method 9221B calls for an expert opinion is, however, overruled. (Hearing Transcript at p. 33, lines 8-10.) Mr. Oaxaca, Mr. Hand and Mr. Naeem's professional background and experience submitted with their written testimony established the qualifications necessary to

discuss whether only performing the confirmation phase of the testing was a deviation from Standard Method 9221 B, and WAL had the opportunity to cross-examine these witnesses on the issue.

7.0 DISCUSSION

Although there are a number of violations alleged by the Prosecution Team, the State Water Board focused the parties on five issues:

- 1) Did WAL's creation of reports for Skyline with coliform sampling results violate the ELAA?
- 2) Was WAL operating a laboratory at Skyline?
- 3) Was the issuance of citation to WAL for a civil liability in the amount of \$137,841.60 appropriate?
- 4) Was the denial of WAL's application for renewal accreditation appropriate?
- 5) Has WAL implemented corrective actions to address problems?

An analysis of these issues are discussed below.

7.1 WAL's creation of reports for Skyline with data that was not derived from their laboratory facility was a violation of the ELAA.

Each month from approximately April 2008 to April 2018, laboratory reports with total coliform results for samples collected from Skyline were sent to the San Diego Regional Board by Invirotreat.⁸ All laboratory reports from March 2014 to April 2018 were signed

⁸ Beginning July 2018, Skyline used EnviroMatrix Analytical, Inc to perform its coliform sampling. (PT Ex. 3, Testimony of C. Hand, attachment 3, "Quarterly Monitoring Report for July-Sept 2018.")

by Gregory Conti, WAL's Laboratory Director. As defined in the regulations, the laboratory director "is the person responsible for the quality of reported data." (Cal. Code Regs., tit. 22, § 64801, subdivision (f).) However, neither Mr. Conti nor WAL were responsible for the data quality because the analysis of these samples was not performed by WAL, but by Skyline personnel. Without any information on which to base the veracity of the results, WAL took the raw data results from Skyline on a monthly basis, compared the results provided to a look up table⁹ within the analytical method to estimate the total coliform concentrations in the samples, and prepared reports for Invirotreat. (Transcript at p. 115, lines 6-16.) Each laboratory report contained a header with WAL's laboratory information and ELAP accreditation number. (Ex. 2, attachment 2, laboratory reports prepared by WAL.) The laboratory reports also identified Skyline as the customer and listed the permit number of Skyline's WDR.¹⁰ (*Id.*) At the bottom of the reports there was a note that stated, "Samples analyzed using SM 9221B", an analytical method that was not included on WAL's certificate of accreditation. (*Id.*) These reports were subsequently submitted to the San Diego Regional Board by Invirotreat for compliance with Skyline's WDR. (Ex. 2, attachment 1, Skyline's Annual and Second Semi-Annual Monitoring for 2017 (including coliform results reports prepared by WAL.)) These reports falsely represented that the analysis was done by WAL, and that WAL was accredited for SM 9221B, which it is not. Making false representations in any record or report or other document submitted, maintained or

⁹ Table 9221: III in Standard Method 9221 C.

¹⁰ WAL claims that the permit number appeared on all reports generated for Skyline projects because it was based off a template in their laboratory integrated management system (LIMS). (Ex. 4, at p. 28, lines 9-23, Petition for Reconsideration; Hearing Transcript, p. 113, lines 13-23.)

used for purposes of compliance is a violation of the ELAA. (Health & Saf. Code §§ 100890, 100895.)

7.1.1 Argument that Had No Knowledge of Regulatory Use is not Reasonable or Believable

In the arguments and declarations submitted by WAL, it is alleged that Mr. Conti had no idea that the laboratory reports with total coliform results were being submitted to the San Diego Regional Board for regulatory purposes, despite the permit number being listed on the laboratory reports and his signature to signify approval of data.¹¹ Instead, “WAL believed that Dr. Lebel, as the engineering consultant for Skyline, had designed and was implementing a process quality control arrangement for ensuring that Skyline’s treatment system was operating effectively.” (Ex. 4, p. 8, lines 11-13, Petition for Reconsideration.) This argument, however, does not seem reasonable or believable. First, for total coliform testing results to serve as an “internal process control” for ensuring the treatment plant was operating effectively, the results would need to be reported as soon as the analysis was complete. Total coliforms are used as an indicator of contamination from biological pathogens in water sources and are tested to determine the adequacy of water treatment and the integrity of a distribution system. Therefore, the presence or absence of total coliform provides invaluable information for determining whether a treatment process is properly functioning. If the testing was

¹¹ Mr. Conti stated that he did not think the reports he was preparing would be mistaken for being an accredited report because they did not include information such as “analysts and times completed and times analyzed,” which are things he indicated would be on reports for accredited work. (Hearing Transcript at p. 119.) However, the reports prepared by WAL for accredited laboratory work look identical to the unaccredited testing done for coliform, and neither contain the name of the analysts or the times completed or analyzed. (See Ex. 2, App. 1.)

actually being done for internal process quality control, the operator of the treatment facility would have required the results as soon as possible to identify if the plant was operating properly. However, raw data was only submitted to WAL on a monthly basis, so the reporting of the final total coliform concentration in this context could not serve as an internal process control. Therefore, Mr. Conti's assumption that this the testing was being done for "internal process control" and not for a regulatory purpose seems questionable.

Second, as described at the hearing, WAL was not doing much more than transcribing the numbers sent to it by Skyline onto a document that looked very similar to those reports that WAL created for submission to the regional board for regulatory purposes. Although WAL's briefing documents suggest that WAL was performing "calculations" on the raw data, there were no calculations being done. (Hearing Transcript at p. 115, lines 9-21.) WAL was using the raw results sent by Skyline to look up total coliform concentrations in the lookup table, Table 9221:III. This is something that Skyline personnel could easily do and did not require any advanced knowledge or calculations. (*Id.*) No real explanation was offered for why WAL would be asked to create reports using raw data sent to it by Skyline that looked identical to those that were created for regulatory purposes. In fact, during the hearing, laboratory director Gregory Conti was asked if performing this monthly report for Invirotreat seemed "strange". His response was, "In retrospect, certainly, but Invirotreat used to have a lot of unusual testing and requests so, I mean, I wasn't that surprised by it." (Transcript Hearing at p. 115-116, lines 22-6.) Because WAL was analyzing other samples from Skyline for chemical parameters and reporting the data to comply with Skyline's WDR, it seems logical that

WAL would have at least asked Dr. Lebel about whether the data for total coliform was also being reported to the regional board.

7.1.2 “Knowing” Requirement Met by Knowledge of Prior Lab Director

In his briefing documents and in his closing argument at the hearing, Mr. Carter, the attorney for WAL, argued that it is not sufficient that “maybe they could have done better,” and instead he argues that there had to be a “knowing” false statement. (Ex. 4, p. 22; WAL’s Supplemental Submission at p. 19; Hearing Transcript at p. p. 150, lines 11-22.) Health and Safety Code sections 100890 and 100895 allow for fines to be imposed for “knowingly” making “false statements or representations in any application, record, report, or other document submitted, maintained, or used for the purposes of compliance with [ELAA].” As a general rule, an institution or entity acts knowingly, or deliberately, based on the knowledge of deliberate conduct of those authorized to act on its behalf. (*People v. Forest E Olson, Inc.* (1982) 137 Cal. App. 3d 137, 139-40.) Therefore, because a corporation can be held responsible for knowing information dispersed among its employees, it is not only relevant what Mr. Conti knew, but also what Mr. Zimmer and Mr. Knight knew.

In his letter to the San Diego Regional Water Board, Dr. Lebel stated that Skyline Ranch Country Club contracted with WAL to set up a satellite facility at the facility because of the short hold times for coliform testing. (Ex. 2, Att. 1.) Although Mr. Conti may not have been aware of the purpose for the testing, Dr. Lebel testified that “it was known that [the data] would be used for regulatory submission. This was part of our permit. And ...that’s why the satellite lab was set up...This was the understanding from the start.” (Transcript from Hearing at p. 129-130, lines 24-10.) Mr. Zimmer trained the Skyline

employees one time on how to conduct the testing, leaving a binder with directions for future reference. (Hearing Transcript, p. 137-138, lines 25-10.) A system was created whereby the Skyline employees would send the raw data sheets to WAL, which would then put the numbers into a report, and that report was sent to Invirotreat, who would then send the report to the San Diego Regional Board as part of its quarterly monitoring report. These reports, however, falsely represented that the analysis was done by WAL, and that WAL was accredited for SM 9221B, which it is not.

7.1.2 Reports Prepared by WAL Were Not Supported by Data Meeting Basic Quality Requirements

ELAP alleged WAL had reported total coliform results without the full and necessary data to utilize the lookup table, Table SM 9221B: III. ELAP noted several sample dates where the raw data sheets from Skyline had results of the 24-hour examination for a presumptive-positive reaction but lacked the results of the 48-hour examination required to complete the presumptive phase of the analysis. ELAP alleged that when it compared sample dates to the same dates on WAL's laboratory reports, a total coliform result was sometimes reported, even though there was no evidence of additional data submitted to WAL. (PT Ex. 3, "Testimony of Christopher Hand," pp. 8-9.) WAL claims that this discrepancy was because Skyline reported the raw data sheets in between analysis on certain sample dates, but the following months raw data sheets would capture the missing information. (WAL Ex. F2, p. 7, line 20 – p. 8, line 28.) Upon analysis of the data, the State Water Board has determined that although this explanation holds true for some months (e.g. 08/16), it is not always the case. (Ex. 2, Raw Data Files, 2016-08.pdf, p. 1.) There are at least several examples where the following months' data sheets also did not contain the data necessary to complete the

presumptive phase (e.g. 06/16, 07/16). (*Id.*) Identification of even one instance where a final result is reported without the necessary information is considered data

manipulation and is in violation of the ELAA. (Health & Saf. Code § 100890, 100895.)

In addition to there being missing data, WAL was not accredited in, or familiar with analysis using method SM 9221B (multiple tube fermentation method), and therefore, did not possess the minimum competency to evaluate the data and create reports for the reporting of that data.¹² For example, WAL was not ensuring that the data that it was incorporating into its report met the minimum quality control requirements for the method. (WAL Ex. N, p. 1, SM 9221, noting that production of valid results requires strict adherence to quality control procedures, which are outlined in Section 9020.)

Even if one could argue that it was consistent with the ELAA for Skyline to run the analysis and provide the results to WAL for inclusion in a report, WAL was not being provided assurance that data it received from Skyline met the minimum requirements required by the method. In fact, the information that was provided to WAL was not consistent with the method requirements, therefore the data should have been rejected.

For example, some of the data sheets submitted to WAL had pre-filled “NA” in the confirmation phase section. (PT Ex. 3, Attachment 6, Hearing Ex. 2.) Instead of rejecting that data because it was not consistent with the method requirements,

Greg Conti incorporated that raw data into his report, stating in his declaration that it

¹² During ELAP’s onsite investigation and interview with WAL staff, it was revealed that WAL lacked the necessary incubators, glassware, and media to analyze samples by SM 9221B. Ms. Kristina Trinh, WAL’s chemist, stated that the laboratory only uses IDEXX products for microbiology testing, a brand consistent with enzyme substrate methods and not multiple tube fermentation methods used in SM 9221B. (Ex. 2, of Ex 2, “ELAP Inspection Report” at p. 3.)

was his understanding that Skyline was assuming the worst-case scenario by not performing the confirmation phase of the method. (WAL Ex. F2, "Second Supplemental Declaration of G. Conti," at p. 9, lines paragraph 29.) This, however, is inconsistent with the requirements for running the analysis pursuant to SM 9221B. Under this method, the presumptive phase is first run, and if a presence of total coliform is detected, then the analysis must proceed to the confirmation phase. (WAL Ex. N, p. 3, SM 9221B, "Confirmed Phase.") The pre-filled "NA" represents a predetermination of the outcome of the analysis and is not consistent with the method. Although the State Water Board is not necessarily agreeing with the Prosecution Team that the pre-filling "NA" is data fabrication, at the very minimum, it demonstrates that WAL was preparing reports with data that were not generated consistent with the method, and is evidence that WAL was not competent in the method and knowledgeable of method requirements. Creating reports using data created outside the laboratory, based upon an analysis that the laboratory is neither accredited for nor has the competency to perform, using data that obviously didn't meet the minimum requirements of the method itself, is contrary to the ELAA and highlights the need for WAL to incorporate into its practices a quality management system.

7.2 Evidence Does Not Support Argument that WAL was Running an Auxiliary Laboratory

At the hearing, the Prosecution Team called Dr. Lebel, Skyline's consultant who is the project engineer for its recycled water plant and who prepares and submits the monitoring reports to the regional water board on behalf of Skyline. Dr. Lebel was asked to authenticate the letter he sent to the San Diego Regional Board on June 1, 2018, in which he states that the laboratory at Skyline was established by WAL

and was WAL's auxiliary laboratory.¹³ Although WAL's previous owner may have set up the laboratory, there was not sufficient evidence to support that the laboratory at Skyline was auxiliary to WAL. An auxiliary laboratory is defined in section 6480, subdivision (b) of the regulations, as a stationary place that:

- 1) Is operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination; and
- 2) Performs analyses in one or more of the same Fields of Testing as the laboratory to which it is auxiliary, and
- 3) Is under the supervision of the same Laboratory Director as the laboratory to which it is auxiliary, and
- 4) Only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and
- 5) Is located such that the transport of samples to the auxiliary laboratory does not affect the quality of the analytical results.

Although Mr. Lebel testified that this laboratory was auxiliary to WAL, his testimony did not establish the required elements, and in fact it was clear that the laboratory was not operated or under the supervision of WAL.¹⁴ Although WAL's previous owner may have

¹³ At the hearing, WAL's attorney, Mr. Carter, objected to the letter from Skyline's counsel, Kutak Rock, from being admitted into evidence as it is hearsay. (Hearing Transcript at p. 73-74, lines, 22-7.) That objection is sustained. However, the June 1, 2018 letter from Invirotreat to the Regional Water Board, which makes that same statement that WAL set up a satellite lab at Skyline in 2008, is allowed into evidence because Mr. Lebel was present at the hearing to authenticate the letter and was available for cross-examination.

¹⁴ WAL objects to including into evidence the July 19, 2019 letter from Kutak Rock LLP, which was an exhibit attached to Mr. Hand's testimony, arguing that it is hearsay. This objection is overruled. In hearings conducted by the State Water Board most of the

set up the laboratory at some point in time for Skyline and its consultant, Invirotreat, there was no evidence that anyone from WAL continued to operate or supervise the laboratory's operation. Testimony of Dr. Lebel established that no one from WAL had been back to the laboratory since the laboratory was set up in 2008. (Hearing Transcript at pp. 48-49, lines 1-22; p. 135, line 2-19.) Although WAL continued to send supplies to the laboratory, no one from WAL was either helping to operate or supervise the laboratory. Unfortunately, it does not appear that *anyone* was overseeing the operation of the laboratory at Skyline. For example, at the hearing, WAL questioned Mr. Oaxaca about the training identified on the quarterly report submitted to the Regional Water Board. Although several individuals were identified as being trained by Mr. Lebel, those individuals were being trained in the operation of the plant, and not in how to run the coliform samples analyses.¹⁵

technical rules of evidence do not apply, including the hearsay rule. Government Code section 11513, which governs hearings conducted by the Board, provides in relevant part: "Any relevant evidence shall be admitted if it is the sort of evidence on which responsible persons are accustomed to rely in the conduct of serious affairs, regardless of the existence of any common law or statutory rule which might make improper the admission of the evidence over objection in civil actions. Hearsay evidence may be used for the purpose of supplementing or explaining other evidence but over timely objection shall not be sufficient to support a finding unless it would be admissible over objection in civil actions."

¹⁵ WAL objected at the hearing to the question of Mr. Oaxaca about whether it was possible that the people identified on the report were being trained to run the wastewater plant as being speculative (Hearing Transcript at p. 63.) It was later established, however, during the cross examination of Dr. Lebel during rebuttal that the training was on operating the facility. (Hearing Transcript at p. 134, lines 17-20.)

7.3 The Amount of the Civil Liability Should be Reduced to Reflect Costs Incurred

As noted in the civil liability sent to WAL, the total maximum for the potential liability could have been in excess of millions of dollars.¹⁶ Just for the five years that Mr. Conti was the laboratory director, ELAP estimated that the total potential liability was \$1,504,000. Instead, however, ELAP used its discretion to issue a civil liability in the amount of \$137,841.60, which it stated represented “three times the estimated economic benefit of non-compliance” for the approximately four years of reports signed by Mr. Conti. (Ex. 1 at p. 3-4; “Prosecution Team Legal and Technical Analysis in Support of the Citation and Denial of Accreditation,” at p. 12.)

In reviewing the evidence submitted by the parties, it is not clear that ELAP considered the costs of the contract when assessing the economic benefit of the contract. Although WAL was paid \$900 for the monthly testing, not all of this was income for the laboratory. We received testimony from WAL that of the \$114,500 billed during the ten years of work, approximately \$53,593 were costs for glass tubes and test media sent to WAL. (WAL Supplemental Submission at p. 17-18.) This means that the laboratory made approximately \$60,000 or \$6,000 per year from the contract.¹⁷ Focusing, as the

¹⁶ In the civil liability and the denial of accreditation, there were no allegations presented that WAL had other clients that it was bending the rules for. In addition, WAL stated in its petition and its supplemental pleadings that Skyline Ranch was just one of 1,900 clients. (Ex. 4, “Petition for Reconsideration” at p. 5, line 16.). The \$6,000 per year that WAL received from the work it did for Skyline was less than one-percent of its total annual income of \$911,474. (Ex. 4, “Petition for Reconsideration” at p. 36, line 15.)

¹⁷ At the hearing, Mr. Conti testified that over the course of 10 years, the profit varied greatly, and at the end the cost of the media was \$729 per month, which would have been less than \$200 per month in profit. (Hearing Transcript at pp. 90-91, lines 15-11.) No documentation was submitted to the State Water Board regarding the actual costs of the testing media.

Prosecution Team did, on just the five years of reports signed by Mr. Conti, the total economic benefit would be approximately \$30,000.

Currently, there are no regulations that detail how the ELAP should assess civil liability. Although the Prosecution Team suggested basing the civil liability on three times the economic benefit, it is unclear what State Water Board precedent this is based upon. The State Water Board's "Water Quality Enforcement Policy," which is not directly applicable to civil actions brought under the ELAA, suggests that the civil liability be set at least ten percent above the economic benefit derived. (State Water Board Water Quality Enforcement Policy, October 2017, at p. 22.) Nonetheless, it is important that when the State Water Board set a liability, it does so at an amount that disincentivizes violating the law. Here, if the total liability was set at three times the total economic benefit of the contract over those five years, as suggested by the Prosecution Team, that amount would be \$90,000.

WAL is being given the option to implement the ISO/IEC 17025 laboratory standard with an ethics/data integrity program in lieu of implementing the quality assurance requirements in the current regulations. If WAL chose this alternative, the State Water Board would reduce the fine by \$50,000, requiring payment of a civil liability of \$40,000. The rationale for this is that the ISO/IEC 17025 standard has more rigorous and detailed requirements than what is currently required for quality assurances in the current regulations. (C.f. Cal. Code Regs., tit. 22, § 64815.) Allowing implementation of requirements that go above and beyond what is currently required in exchange for a reduction in a civil liability is something that the State Water Board already allows in its

regulation of water quality violations. (State Water Board's "Water Quality Enforcement Policy," October 5, 2017, p. 31.)

7.4 Denial of WAL's Application is Appropriate

Section 100850 requires ELAP to deny accreditation to a laboratory when it finds that that laboratory is "not in compliance with any other provision of [the statutes] or regulations..." (Health & Saf. Code, § 100850(d).) The evidence supports the finding that WAL was not in compliance with the ELAA statutes and applicable regulations, and therefore denial of accreditation is appropriate until WAL makes changes to its quality assurance program to ensure that the problems identified do not happen again. This included WAL relying upon unsupported data sheets to produce reports that were used to demonstrate compliance with a regulatory permit and accepting data that did not meet the minimum requirements of the method itself. Although it argues that it didn't know its reports were being relied upon for a regulatory purpose, that argument is belied by the way the reports were prepared to identify Skyline as the client, identify the permit number that the report was being prepared for, identifying WAL as an ELAP accredited laboratory, and identifying that the analysis was run pursuant to SM 9221B. Relying on information created outside the laboratory to prepare reports, based upon an analysis that the laboratory is neither accredited for nor has the competency to perform, using data that obviously didn't meet the minimum requirements of the method itself, is contrary to the ELAA. At minimum, WAL did not "have a quality assurance program in place to assure the reliability and validity of the analytical data" that it produced, which is a violation of section 64815(a) of the regulations.

7.5 WAL Has Not Yet Implemented Necessary Changes

At the hearing, WAL identified that although it had made some changes to its laboratory practices, it had not yet begun to incorporate a quality assurance system, such as ISO/IEC 17025, which it had proposed to do in its “Rebuttal to Prosecution Team’s Legal and Technical Analysis.”¹⁸ (Transcript at p. 122, line 14 - p.125, line 8.)

8.0 CONCLUSIONS

8.1 ACCREDITATION IS DENIED

There was a lot of blame to go around as to how WAL ended up creating reports that were used by Skyline to demonstrate compliance with its permit that were based on data that WAL neither collected nor had an understanding of, and were analyzed using a method that WAL was neither accredited for nor had the competency to run. At a minimum, however, it was clear that WAL lacked a quality management system to detect and prevent these issues from occurring. In order to be reaccredited, WAL must submit a new application and fees, and pass an onsite assessment that evaluates the policies and procedures of WAL’s quality assurance program. WAL’s quality assurance program must include standard operating procedures for intaking new work that ensures WAL understands the needs of its clients and the purpose of the reported data, as well as, a standard operating procedure for how work for nonregulatory purposes will be clearly identified and reported to the client. If raw data are being submitted to the

¹⁸ Corrective actions WAL had made in response to the allegations included removing from its reports its identification as an ELAP accredited lab, including its accreditation number, and “for tests that were not accredited in or they’re non-regulatory,” ...[flagging those] so they couldn’t be misinterpreted or misused.” (Transcript at p. 122, lines 15-21.)

laboratory, there must also be a standard procedure to ensure that the data being submitted are 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 prohibition on data manipulation and fabrication.

8.2 STAY REMAINS IN PLACE FOR ADDITIONAL 90 DAYS

The current stay will remain in place for an additional 90 days from the date of this order, allowing the WAL time to obtain reaccreditation.

8.3 CIVIL LIABILITY OF \$90,000 IS UPHELD

The evidence submitted in writing and at the hearing supports issuance of a civil liability to the laboratory of \$90,000.

8.4 CIVIL LIABILITY IS REDUCED IF WAL IMPLEMENTS ISO/IEC 17025

WAL has the option of becoming accredited in the ISO/IEC 17025 laboratory standard and implementing a data integrity and ethics training program.¹⁹ 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.

¹⁹ With approval from the State Board, WAL may choose an alternative accreditation standard with equivalent quality management system requirements (e.g. 2016 TNI Standard).

ORDER

IT IS HEREBY ORDERED

- A. The State Water Board ORDERS that, pursuant to the ELAA and applicable regulations, WAL is denied renewal accreditation until it either:
- a. Updates its quality assurance program, including an ethics and data integrity program, passes an onsite assessment, passes proficiency testing requirements, and reapplies and pays fees to ELAP for renewal accreditation; OR
 - b. Demonstrates it is accredited to ISO/IEC 17025, implements a data integrity and ethics training program, passes proficiency testing requirements, and reapplies and pays fees to ELAP for renewal accreditation.
 - c. The current stay on WAL's accreditation is extended 90-days from the date of this order, to allow WAL time to become reaccredited. WAL may request a further extension of the stay upon demonstration of continuing progress towards compliance with one of the two aforementioned paths to renewal accreditation and clear justification for the extension request, subject to approval of the Deputy Director of the Division of Drinking Water.
 - d. If WAL chooses to adhere to current regulations, WAL's quality assurance program must be amended to include:

- i. Standard operating procedures for intaking new work that ensures WAL understands the needs of its clients and the purpose of the reported data;
 - ii. Standard operating procedures that address how work for nonregulatory purposes will be clearly identified and reported to the client.
 - iii. Standard operating procedures to ensure that if raw data is submitted to WAL for analysis that it is supported by the appropriate documentation, including chain of custody for all samples submitted to the laboratory.
 - iv. A data integrity and ethics training program for employees that includes a clear prohibition on data manipulation and fabrication.
- e. If WAL decides to pursue ISO/IEC 17025 accreditation:
- i. Accreditation must be offered through a third-party accreditation body that operates in accordance with ISO 17011, Conformity Assessment – General Requirements for Accreditation Bodies.
 - ii. In addition to being accredited to ISO/IEC 17025, WAL must implement data integrity and ethics training program for employees that is approved by ELAP and includes a clear prohibition on data manipulation and fabrication.

- B. The State Water Board ORDERS that WAL must pay an administrative liability of \$90,000, or if it implements ISO/IEC 17025, \$40,000.
- a. \$10,000 is due immediately.
 - b. Remainder is due before accreditation is provided, unless other arrangements are worked out with the State Water Board.

CERTIFICATION

The undersigned, Clerk to the Board, does hereby certify that the foregoing is a full, true and correct copy of an order duly and regularly adopted at a meeting of the State Water Resources Control Board held on April 7, 2020.

AYE: Chair E. Joaquin Esquivel
Vice Chair Dorene D'Adamo
Board Member Tam M. Doduc
Board Member Sean Maguire
Board Member Laurel Firestone

NAY: None

ABSENT: None

ABSTAIN: None



Jeanine Townsend
Clerk to the Board