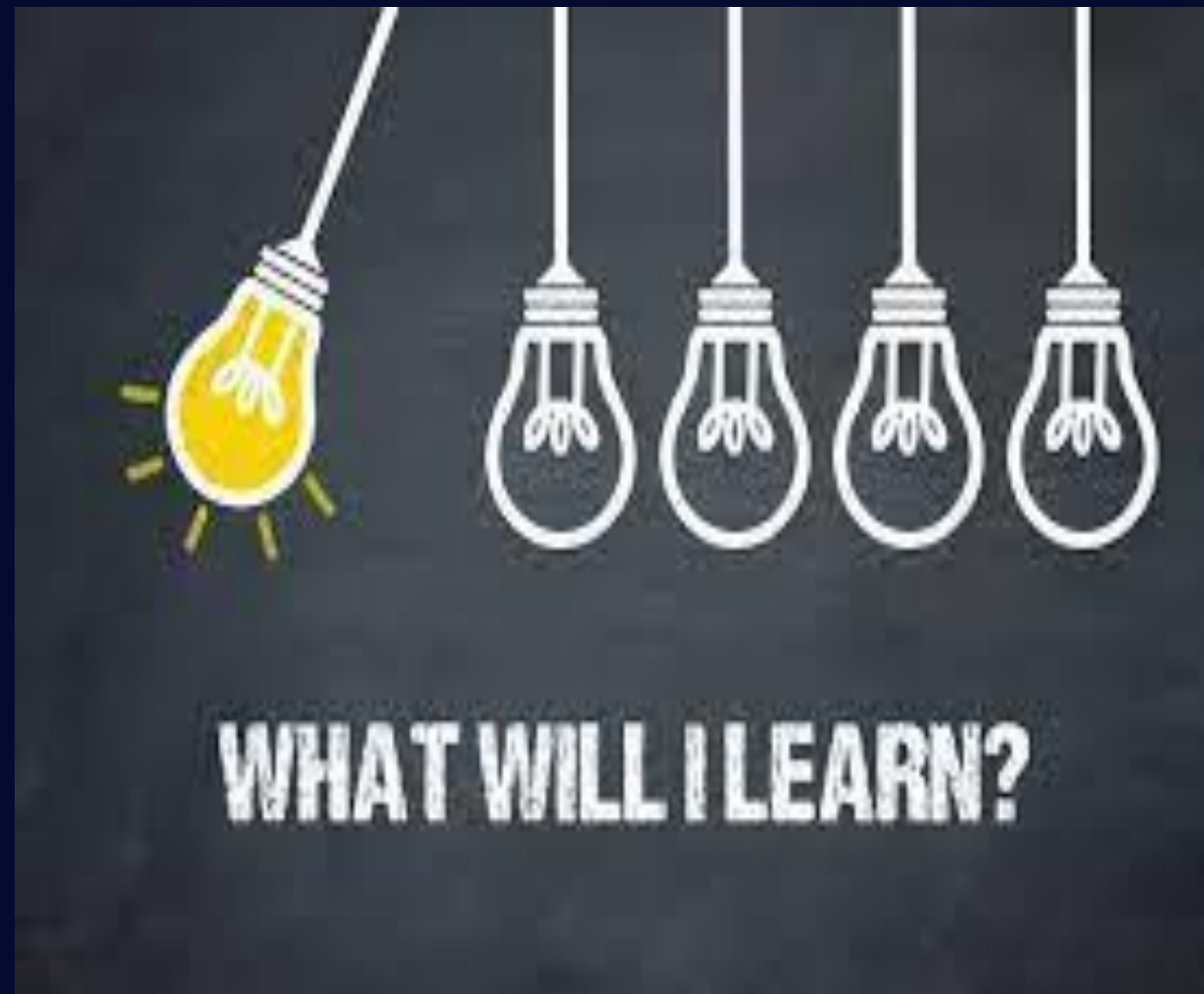


ELAP Enforcement Considerations for Wastewater Laboratories

Alexandria Turner
ELAP Enforcement Unit Supervisor



Learning Objectives



- Overview of the ELAP enforcement unit
- Enforcement trends with Wastewater labs
- Case study examples
- How to report an issue or concern

ELAP- Separation of Function

ELAP Administration

CA ELAP

- ELAP provides evaluation and accreditation of environmental testing laboratories to ensure the quality of analytical data used for regulatory purposes to meet the requirements of the State's drinking water, wastewater, shellfish, food, and hazardous waste programs.
- ELAP is part of the Division of Drinking Water at the State Water Resources Control Board and is overseen by Program Manager Christine Sotelo.
- ELAP's staff and functions are divided between three locations - Sacramento, Glendale, and Richmond.

ELAP Enforcement

- Enforcement is a critical component in creating the deterrence needed to encourage the regulated community to anticipate, identify, and correct violations.
- Role is to ensure that violations of statutes and regulations result in firm, fair, and consistent enforcement.
- Act independently of administrative actions
- Enforces legal compliance for accredited laboratories by pursuing administrative and criminal actions against laboratories performing egregious violations against the Environmental Laboratory Accreditation Act and applicable regulations.

MEET THE EXPERTS



Environmental Laboratory Accreditation Program (ELAP) Enforcement Unit

Established 2015



Conducted over 100 investigations to date



**Uncovered a wide spectrum of
laboratory violations**

Alexandria Turner



Naeem Ahmad



Katlin Bloom



Jennifer McClarren



Leann Castle



Karen Black





- ✓ Over 50 years combined laboratory experience
- ✓ Degrees in Biology, Chemistry, Environmental Sciences
- ✓ Experience with advance analytical instruments
- ✓ Experience with complicated multi agency enforcement cases
- ✓ Experience with regulation development



SUMMARY OF FINDINGS

Violations and Improper Practices

- Notice of Violations
- Suspensions
- Revocations
- Citations

Lab Fraud

- Criminal conviction
- Debarment

Dry Labbing

- Suspension
- Citations

Enforcement Trends with Wastewater Labs



1. Outdated or missing documentation
2. Repeat findings
3. Potential for undue influence
4. Unqualified/untrained staff
5. Data not reported on time
6. Lack of Data and Integrity training

1. Outdated or Missing Documentation

Regulatory Requirement

- **Section 64802.05. Quality Systems.**
 - SOPs must be updated annually or whenever there is a change in method or technology
 - Training records are required for all staff and should include DOC and any additional training in the lab
 - QAM needs to be reviewed annually or whenever organizational or instrumentation changes occur

Examples

- SOPs have a revision date of 2017
- Missing training records
- Outdated quality assurance manual
- Missing PT records

2. Repeat Findings

Regulatory Requirement

- CCR § 64802.20 (i)
 - If a subsequent on-site assessment, either announced or unannounced, reveals that a laboratory failed to take the corrective action(s) specified in a corrective action plan, then ELAP will take action to deny, suspend, or revoke accreditation for the Field(s) of Accreditation affected by failure to take corrective action CCR § 64802.20 (i).

Examples

- CAR not complete or performed prior to a subsequent inspection

Repeat Finding – 
Failure To Take Corrective Action

3. Undue Influence



Regulatory Requirement

- 2016 The NELAC Institute (TNI) Standard: Section 4.1.5(b) (2016 TNI V1M2 Rev.2.1)
 - have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

Examples

- Fear of authority
- Intimidating work environment
- Pressure from management to:
 - meet deadlines
 - Provide clean data by any means
 - Looking for certain results

ELAP Case Study of Undue Influence



- Received a referral from a regional board
- Sent an Order for Information
- Conducted a site visit
- Findings:
 - Undue influence from the operations management
 - Method deviations
 - Lack of training policies and records
- Enforcement Action:
 - Notice of violation and order to correct

4. Unqualified/Untrained staff



Regulatory Requirement

- CCR § 64812(a)(b)- Lab personnel requirements
- 2016 The NELAC Institute (TNI) Standard: Section 1.6 (2016 TNI V1M2 Rev.2.1)
 - Initial demonstration of capability
 - Ongoing demonstration of capability

Examples

- Staff with no DOCs performing analysis
- New hires
- Operators
- Unqualified technical managers

Death



Walkerton E. Coli Outbreak

Contaminated drinking water after heavy rainfall, near a cattle ranch, lead to manure entering an aquifer of a nearby well.

Unqualified water operators, who testified they were not familiar with drinking water standards



- Contamination of municipal water by bacterial pathogens in Walkerton
- 7 deaths
- 2300 ILL

5. Data Not Reported on Time

Regulatory Requirement

- CCR § 64814- Notification, Reporting and Control of Records
 - (h) A laboratory shall report to clients:
 - (1) In accordance with 2016 TNI Standard – Revision 2.1, Volume 1, Module 2, Section 5.10; or
 - (2) In accordance with the request for analysis, the full and complete results of all requested contaminants and pollutants from the analyses of the sample or components thereof.

Examples

- Received referrals from regulators that sample data was not reported on time

6. Importance of Ethics and Data Integrity in Environmental Testing labs

- Water, wastewater, and public health laboratories all face public health consequences when laboratory personnel do not act ethically
- Lives are at stake if lab staff do not perform their jobs with integrity
- Data integrity is a focal point of environmental laboratory quality assurance/quality control (QA/QC) programs, ensuring regulatory compliance
- Help produce reliable and defensible data
- Unintentional uncontrolled data integrity practices can quickly evolve into unethical practices

Regulatory Requirement

2016 The NELAC Institute (TNI) Standard:

- Section 5.2.7 (2016 TNI V1M2 Rev.2.1)
- “Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees”.
- “Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in detailed investigation that could lead to very serious consequences including immediate termination, debarment, or civil/criminal prosecution”.

CA Environmental Laboratory Accreditation Program :

- Section 64802.05. Quality Systems.
- "(a) Comply with quality system requirements in accordance with 2016 TNI Standard Revision 2.1, Volume 1:
 - (1) Module 2, with the following exceptions:
 - (A) Module 2, Section 4.1.7.2(f) - Technical Manager Qualifications; and
 - (B) ▪ Module 2, Section 5.2.6 - Technical Manager Requirements;" "(b)
- Develop and implement a quality assurance program."

Failed Public TRUST



Iowa Sues Sioux City for Cheating on Wastewater Reports

Sioux City mislead state of Iowa officials regarding water pollution test results for 3 years (2012-2015)



- City treatment management discovered the treatment facility was not working properly, but did not disclose to the state, instead submitted fraudulent tests.
- State seeking to permanently prevent the city from operating the treatment facility

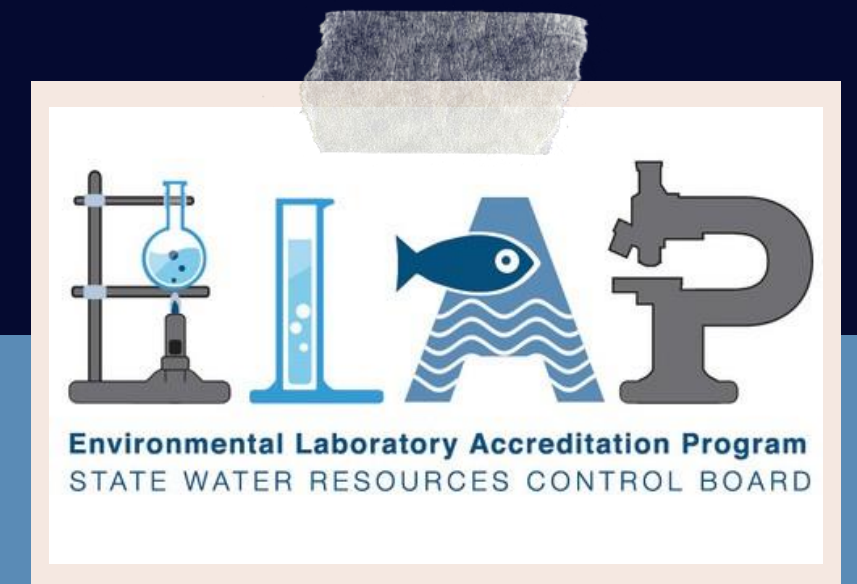
How to report an issue?



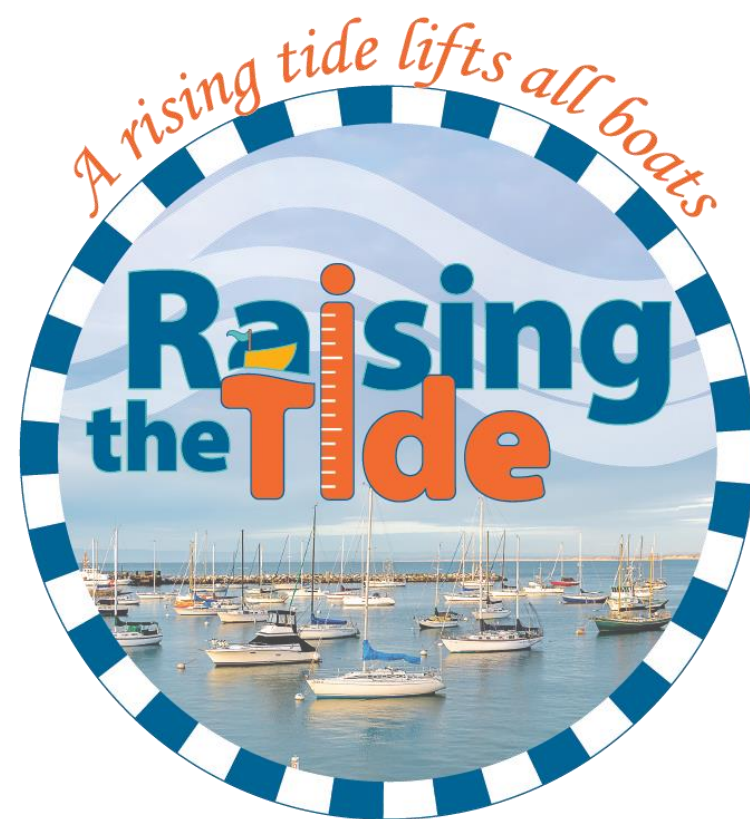
1
MANAGER/
SUPERVISOR



2
QA DEPARTMENT/
TECHNICAL
MANAGER



3
REGULATORY
AGENCY



2022 ELAP Conference featuring CSEA



- **View the 2022 ELAP Conference YouTube videos**

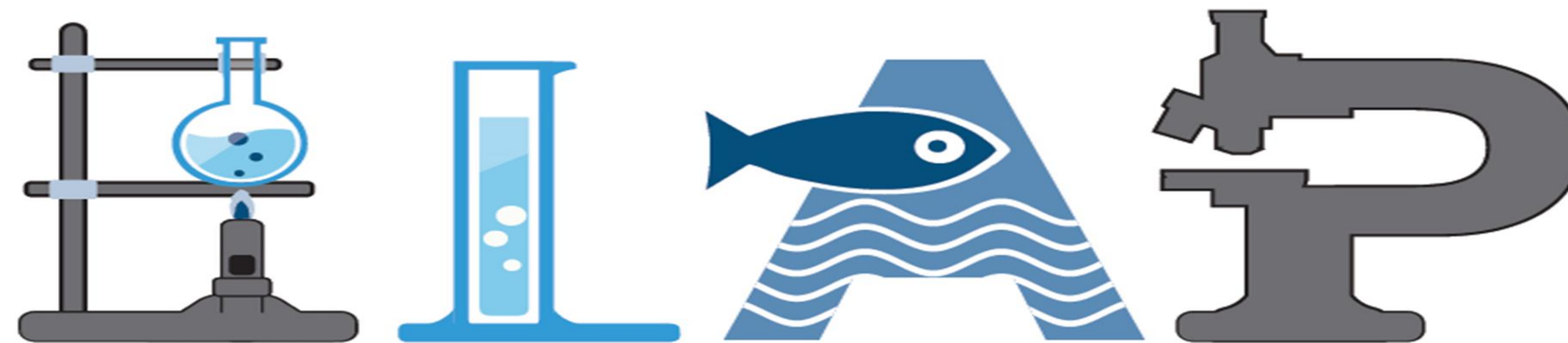
May 31st : Set Sail With Laboratory Essentials – [Now available on the ELAP YouTube Channel](#)

June 1st : Optimize Your Laboratory – [Now available on the ELAP YouTube Channel](#)

June 2nd : Laboratory Ethics and Integrity – [Now available on the ELAP YouTube Channel](#)

June 3rd : TNI Documentation Workshop - The Final Voyage – [Now available on the ELAP YouTube Channel](#)





Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

Alexandria Turner
ELAP- Senior ES Supervisor
Alexandria.Turner@waterboards.ca.gov
elapca_technical@waterboards.ca.gov

elapca@waterboards.ca.gov