Observations from California's On-Site Assessment Unit

Maria Friedman
State Water Resources Control Board
California Environmental Laboratory
Accreditation Program

Environmental Laboratory Accreditation Program
STATE WATER RESOURCES CONTROL BOARD

CALIFORNIA
Water Boards

Introduction

- Joined the California Environmental Laboratory Accreditation Program team in 2016
- Manage the Assessment Unit
- This presentation represents my observations

Introduction

- CA ELAP accredits over 600 in-state and 100 out-of-state laboratories; approximately 55% are privately owned, 45% are public (government-operated, including federal state, and municipal labs)
- Assess compliance to California regulations and EPA approved methods
- California regulations do not include QMS

About This Presentation

- Observations do not necessarily represent what might be found nationwide or at labs under different regulations
- Presentation will not include any discussions on corrective actions (i.e., how will or how can the findings be addressed)

OBSERVATIONS

Training

Training

- Does not have initial DOC for all analysts performing analysis
- Does not have ongoing DOC for all analysts performing analysis

Traceability

Traceability

Chain of Custody

- Does not have COC procedures
- Sampler's name not recorded on COC
- Sample type not clearly defined in COC (e.g., DW or WW)

Quality Assurance / Quality Control

Quality Assurance / Quality Control

Records

- Does not affix label to thermometers that were calibrated
- Does not record weights used to calibrate balance
- Does not record which support equipment was used for a particular measurement
- Does not have records of thermometer calibration

Quality Assurance / Quality Control

Records

- Does not document the temperature and the date/time in/out of samples placed in ovens or incubators
- Does not record the preparation of reagents, standards, or samples
- Working standards not traceable to primary source

Quality Assurance / Quality Control

Standards/Reagents

- Standards prepared and stored beyond recommended storage time
- Lab using expired (or unknown when they expire or no recorded expiration) standards, reagents, cultures, comparator, detergent, media

Quality Assurance / Quality Control

QA Manual

- Does not review and update, if necessary
- Missing information on some quality system elements
- Not signed
- Organizational structure not defined

Quality Assurance / Quality Control

LFB/LFBD (LCS/LCSD, BS/BSD)

- Does not run LFB/LFBD
- Uses incorrect LFB/LFBD standard
- Applies incorrect acceptance criteria
- Does not vary LFB/LFBD concentration, where required
- Uses incorrect formulation and concentration, where defined

Quality Assurance / Quality Control

LFM/LFMD (MS/MSD)

- Does not run LFM/LFMD, where required
- Does not run LFM/LFMD at prescribed frequency
- Does not always include needed analytes to be spiked

Quality Assurance / Quality Control

LRB (Method Blank)

- Does not run LRB per batch
- Does not prepare LRB the same manner as samples, where needed (e.g., digested or extracted)

Quality Assurance / Quality Control

SOPs

- Does not have SOP
- Incomplete SOP (e.g., missing QC elements, calibration info, calculations, etc.)
- Missing procedural steps
- Does not have authorized signature

Quality Assurance / Quality Control

Sample Duplicates

- Does not run sample duplicates, where needed
- Does not run sample duplicates at the correct frequency
- Uses incorrect acceptance criteria, where defined

Quality Assurance / Quality Control

MDLs

- Does not conduct MDL studies
- RLs lower than MDLs
- Does not follow MDL procedures, where defined
- Does not prepare MDL sample the same way client samples are prepared (e.g., not digested)

Quality Assurance / Quality Control

Microbiology

- Does not monitor variability in analysts capability in counting total coliform colonies
- Does not monitor if liquid media had been reduced to more than 10% of its original volume due to evaporation
- Does not store broth media in loose-cap tubes at proper temperature
- Does not conduct sterility test of the commercially available (pre-filled) dilution water bottles

Quality Assurance / Quality Control

Microbiology

- Does not conduct microbiological water suitability tests
- Does not check sample bottles for sterility
- Does not conduct sterility check for commercially- or laboratory-prepared media (e.g., Colilert or SimPlate media)
- Does not check sample bottles for autofluorescence
- Does not monitor bacterial density (air in workplace)

Quality Assurance / Quality Control

Microbiology

- Does not check sample bottles for volume accuracy at the 100-mL mark
- Support Equipment (timing device) issues
  - Does not calibrate or does not record the calibration of timing device (stop watch) against national timing service or certification
  - Does not check the autoclave timing device against a certified stop watch

Quality Assurance / Quality Control

Microbiology

- Does not test for the quality of reagent water used
  - No check for conductivity prior to each use (for those without in-line or without resistivity indicator light)
  - No check for total organic carbon
  - No check for total chlorine residual
  - No check for HPC
  - No check for heavy metals

Quality Assurance / Quality Control

Microbiology

- Does not check the efficacy of dechlorinating agent in sample bottles

Instrumentation

Instrumentation

Laboratory Equipment

- Does not perform instrument maintenance
- Does not keep or does not have instrument or support equipment maintenance records

Instrumentation
Calibration

- Does not include a calibration blank in the calibration curve, where needed
- Does not bracket the batch with an end check, where needed
- Always using quadratic fit without first trying simpler curve types
- Does not use at least 6 points for quadratic calibration curves

Instrumentation
Calibration

- Using incorrect acceptance criteria
- Does not run calibration blank after every 10 samples
- Does not calibrate or have no records available for review of the calibration of support equipment (e.g., DO meter, turbidity meter, in-line conductivity meter, pH meter)
- Does not use or does not have second-source standards

Support Equipment

Support Equipment

Pipets and Volume Dispensers

- Not verifying accuracy of pipets delivering volumes of 10mL or less

Support Equipment

Balance & Weight Sets

- No record of weight sets used
- Reference weights not calibrated or re-certified every 5 years
- Balance does not have sensitivity of at least 0.1g for a load of 150g
- Balance not calibrated but being used

Support Equipment

Thermometers

- Does not verify workability of working thermometers
- Does not have correct graduation or increments for intended use
- Uses expired or un-calibrated NIST or working thermometers

Support Equipment

Thermometers

- Does not have maximum registering thermometer in autoclave to check if sterilization temperature is reached
- Does not use total immersion thermometer for monitoring water bath

Analysis/Prep

Analysis/Prep

Procedural, Micro

- Does not monitor weight loss <15% of the HPC plates (plated media agar) during 48-hour incubation

Analysis/Prep

Procedural, pH

- Does not record pH meter slope
- Does not run pH calibration verification (calibrating at two points and verifying at pH in between)
- Does not use a flat-head probe to check pH of solid agar media
- Does not measure or verify sample pH before, during, or after analysis, when required

Analysis/Prep

Temperature Issues

- Reads temperature from equipment LED display instead of from thermometer inside incubator
- Correction factors not applied to measurements of temperature
- Does not consistently monitor or does not monitor at all the temperature of support equipment (e.g., refrigerators, freezers, ovens)
- Does not record temperature with conductivity measurement

Analysis/Prep

Temperature Issues

- Does not record water bath or incubator temperature twice a day at least 4 hours apart
- Does not monitor or record temperature during sample prep or when needed like at sample receipt
- Does not report temperature at which pH was measured

Analysis/Prep

Procedural, Inorganics

- Does not calculate the difference between high and low values for test replicates to show compliance with <30% requirement for BOD samples
- Does not have low-level conductivity standard or not determining cell constant
- For TCLP, does not use a minimum sample amount of 100g

Analysis/Prep

Procedural, Inorganics

- For titrimetric methods, does not record volume of titrant used to allow reprocessing of data to verify calculated results
- For metals, sample digestion based on elapsed time instead of sample volume reduction
- Does not add nutrients directly to BOD bottle when sample exceeds 67% of total volume

Analysis/Prep

Procedural, Inorganics

- For solids
  - does not use correct sample volume to yield minimum 2.5 mg residue
  - Does not verify and record constant mass of dried residue, not repeating drying cycle

CONCLUSIONS

Common Issues

- Procedural
- Calibration
- QA/QC microbiology
- COC
- MDL Compliance
- Thermometer

Thank you!

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