# PRELIMINARY OBSERVATIONS FROM CALIFORNIA SUPPORT

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NV5

# MANY THANKS

- Christine Sotelo Environmental Program Manager ELAP-Our Leader
- Kate McCarthy, Communications Manager
- Our TEAM approximately 350 yr env/assessor experience:

| | | |
|---|---|---|
| Chris Gunning | Calista Daigle | Dixie Marlin |
| Nile Luedtke | Paul LeBlanc | Jeanne Mensingh |
| Marlene Moore | Halley Dunn | Richard Sheibley |
| Kathi Gumpper | Tessa Landry | Lori Beeler |
| John Gumpper | Angie Alden | |
| | | |

# PRESENTATION

- Tasks and status
- What do we audit to?
- Assessment consistency
- Challenges
- Issues common to all ABs
- Findings

# TASKS – STATUS AS OF JUNE 30, 2018

- Training Assessors
  - Provided 6 courses with curriculum and materials –Training Completed:
    - TNI ELAP
    - Organic
    - Micro
    - Metals
    - Inorganic
    - Radiochemistry
  - Thanks to Pace Labs for providing data to work with during classes

# TASKS – STATUS AS OF JUNE 30, 2018

- Training continued
  - Training for Labs:  Multiple One-day Public Workshops to explain TNI 2016 across the state
  - Second training for assessors scheduled in September 2018 for TNI 2016

# TASKS – STATUS AS OF JUNE 30, 2018

- Document development
  - Review of ELAP SOPS and QA Manual
  - Developed 28 checklists for most used methods & CA regulations
  - Developed on site assessment observation form based on current CA regs
- On-site assessment of DW Labs
  - Completed – 76
  - Scheduled/Confirmed – 19
  - Reports and CAPs mixed status, some complete and some in progress
  - Labs that dropped or cancelled – 12
  - Approximately 380 total labs will be assessed over 3 yr

# WHAT DO WE AUDIT TO?

- We audit to the CA regulations and method requirements. Currently, ELAP is not TNI but is working to promote the use of TNI 'lite' in its regulations
- We audit to the state regulations and the method requirements
  - Standard Methods (SM) quality control sections (e.g.,1020, 3020, 9020…) provide specific details for various methods.
  - Per EPA's 2017 MUR: If a laboratory is using a method from "Standard Methods for the Examination of Water and Wastes", they would refer to the appropriate section of Standard Methods for QA/QC requirements.

# ASSESSMENT CONSISTENCY

- Mentoring CA assessors
- Making lists of all the findings and citations, and categorizing them for all of our assessors to use (e.g. document control, records, annual support QC, etc.)
- We get together for regular phone calls to reach consensus
- We ask ELAP questions with documented responses.
- ELAP has provided helpful interpretations to questions.

# CONSISTENCY: CLARIFICATION FROM ELAP

- To cite or not when a practice is performed correctly but not included in the quality system (i.e. QAM, SOP, forms, work instructions, etc.)
  - ELAP Response: Definitely cite - either under the method or 64815b or 64815d. Requirements must be documented or compliance will not be a consistent practice across the lab. Requirements can be defined in the quality manual, SOPs, work instructions, or any other media or means the lab chooses.
- Is the lab required to have proof of degrees/license (CWEA or AWWA certification)
  - ELAP Response: Agree – okay to cite. It is not good enough to accept when lab says they have the degrees or certifications. They must show supporting docs at least one time. Requirement is in regulations. For license, show the latest, as these expire.

# CONSISTENCY: CLARIFICATION FROM ELAP

- Must labs report positive total coliform and/or E. coli results directly to the department?

  1. Their bacterial monitoring report has to be submitted directly to the department (64819.a.1).
     - How do laboratories comply with this?
     - Labs say only one person can upload? Not feasible

  2. Positive results for E.coli, total coliform, and fecal coliform need to be reported to the designated contact person for the water supplier within 24 hours and records of the communication maintained(64819.a.2.a).

# CONSISTENCY: CLARIFICATION FROM ELAP

- Lab uses certificates of analysis from vendor for evidence of sterility, volume accuracy of containers or digestion tubes, media pH…
  - Per ELAP guidance, certificates from the vendor cannot be substituted for in-house verification unless they include the specific batch related raw data for the test performed at the vendor's facility.

# CHALLENGES

- Few SHALLs, many ‘shoulds’
- The current California regulations are not as specific as the TNI standard.
- Example:
  - TNI standard specific micro criteria, but these criteria cannot currently be used for citing lab deficiencies.
  - SM has various revisions of section 9020 currently approved through EPA. Revisions have different QC criteria.
  - Per CA ELAP guidance, labs must use methods from SM 22nd edition
  - Scope interpretation: Example – scope indicate standard methods but on-site, the lab is using HACH™ or Colilert™.
  - If the lab scope: 4500-Cl G runs HACH
  - Scope indicates Colilert but the lab is running Colilert-24 and Colilert-18

# CHALLENGES

- To distill or not to distill SM4500-F B,C-1997?
- Can lab be accredited without distillation capability?
  - lab must show evidence that distillation is not necessary (however means the lab chooses). If lab does not have equipment for the distillation, then they must not have 4500-F B (distillation) in their cert.
  - Lab can retain 4500-F C (ISE analysis) but must show evidence that no distillation will be required of samples – note that distillation is mentioned in part C and is needed for high TDS and when fluoborates are present, so to meet part C, the evidence that no distillation is needed must be provided or documented.

# CHALLENGES

- Overfilling 100ml micro sample bottles, beyond 1” or to the point that the sample cannot be properly shaken
- Regulation that establishes the requirement:
- 40 CFR § 141.852.a.1
- 22 CCR § 64815.b

# CHALLENGES

- Getting lab documents well in advance
- SWTR and LT2 – (enumeration required) CFR 141 requires transport temperature <10C, unless collected <2 hr and then document true temperature at time of receipt.
- Do you measure every bottle (IR GUN) or measure a temp. blank that may have been in cooler longer than all the samples?

# ISSUES COMMON TO ALL ABS

- Labs CANNOT use the package insert/instructions as their SOP or as the basis of their SOP.
  - Footnote 1 following the table in 141.852.a.5: “The methods listed are the only online versions that may be used. For vendor methods, the date of the method listed in paragraph (c) of this section is the date/version of the approved method. The methods listed are the only versions that may be used for compliance with this rule. Laboratories should be careful to use only the approved versions of the methods, as product package inserts may not be the same as the approved versions of the methods.”
  - Package inserts for SimPlate, Colilert do not always include all of the required steps and/or QC.

# ISSUES COMMON TO ALL ABS

- The laboratory does not verify the titrant normality of the 0.02N H2SO4 when containers have been opened for one month.
  - Labs are not verifying titrants: Requirement: SM2020 2010 B.2.b: Verify standardized titration reagents by periodically re-standardizing. Method parameters in Part 2000 that are determined using standardized titration reagents are acidity, alkalinity, and hardness. Typically, the standardized reagents are stable for several months when sealed to avoid evaporation and stored properly. Re-standardize reagents once a month or when improper storage occurs.

# ISSUES COMMON TO ALL ABS

- Do we accept certificates of analysis for titrant standardization? Does RM accredited certificate to Guide 34 or ISO 17034 matter?
  - Per SM titrants must be standardized by the lab at least monthly
- Do we accept certificates of analysis for sterility?
- Do we accept volume verification certificates of analysis (e.g., digestion tubes for metals, most common example or pipette volumes for micro)
- AB=Accrediting Bodies

# ISSUES COMMON TO ALL ABS

- Scope changes
- Additions:
  - Some states require application before change/audit
  - Some do not
  - Timeline for approval before the audit
  - Added cost / time on site
- Deletions
  - Requested on site, line out on scope, sign and date by lab
  - NOTE: Most states use the date of the deletion request as the date the method/analyte is no longer accredited.
- Most scopes do not list the version of the methods—only way to know is to get the SOP; many SOPS may not state specific methods' editions or year of approval
- Errors ?

# SCOPE CHANGES CA

- We compare the spreadsheet list of methods to the pdf scope in the file sent by CAELAP to us
- Send pre-assessment notification that states the lab must be sure all methods applied for are in the agenda for DW or in their CA application
- We can't add time when we booked many back to back audits
- Labs in enforcement take added time to assess—very important to have this knowledge to have more assessment time

# ISSUES COMMON TO ALL ABS

- Does lab need to be accredited/certified for support tests? pH, conductivity etc.
  - Response: if the result is not reported to the client no.
- Demonstrations of capability are new and often labs are shocked when asked.
  - For SM use 1020 where it is required
  - Use the EPA method if it is stated as such
- Must labs in CA use SM9020-2005 or can they use any EPADW approved SM 9020 version?

# FINDINGS

- Lack of documented traceability  - who did it, when did they do it, what did they use?
- Corrective action responses do not include all of the requirements listed.
- SOPs are not nearly detailed enough and/or include (or reference) enough information.  In some cases, the SOP is just the instructions that came with SimPlate (for example) or a copy of the published method.
- Document control and/or annual review of the documents is basically non-existent.

# FINDINGS

- Small labs do not know how to deal with independent audits.
- Labs have dread and fear about meeting TNI requirements.
- Labs do not know the ‘rules’ regarding DW – methods cannot be modified.
- General QA – labs do not understand how to establish QA system, QA manual & SOPs.
- Do not calibrate or verify calibration
- Do not implement QC and calibration per the methods.

# FINDINGS

- Three findings related to facility contamination
  - The laboratory checks the residual chlorine level by dipping a chlorine test strip into the sample.
  - Labs do not wipe and treat bench tops with a disinfectant before and after use.
  - The floor in the Metals laboratory is degraded to the point where concrete gravel is abundant below the analysts chair adjacent to the ICPMS.

# FINDINGS

- No records available for the education of the Lab Director.
  - BS
  - 3 yr related laboratory experience
  - Utility owned water/wastewater California Water Pollution Control Association or California-Nevada Section of the American water works association - level depends other fields of testing.
- 25 findings to date related to definition of roles and responsibilities

# SUMMARY

- Progress in consistency, having scheduled audits, findings based on requirements
- Gaining more consistency in audits
  - Mentor
  - Findings based on requirement, not assessor opinion
  - Improved scope management
  - More PT review by CAELAP
  - ELAP providing interpretation, communicated to all assessors
  - Phone calls to get on the same page