



STATUS OF CALIFORNIA TRAINING AND AUDIT SUPPORT

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PRESENTATION

- Team Qualifications
- Purpose of contract and status
- Findings from assessments
- Observations

QUALIFICATIONS

- Our TEAM has approximately 325 years of assessment experience
- Marlene Moore trained hundreds of environmental assessors
- Ten staff audit over 30 labs/yr and have for 20-40 yrs
- Technical expertise, communication skill, audit EPA, FDA, USGS

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	*Assessors

PURPOSE OF CONTRACT AND STATUS

- Training
- Assist in developing requirements
- Assess drinking water laboratories

- Status as of Sept. 30, 2018
- Training Assessors- Provided 7 courses with curriculum and materials
 - Organic
 - Micro
 - Metals
 - Inorganic
 - Radiochemistry
 - Two assessor training classes
- Training for Labs - Multiple One-day Public Workshops to explain TNI 2016 across the state

ASSIST IN DEVELOPING REQUIREMENTS

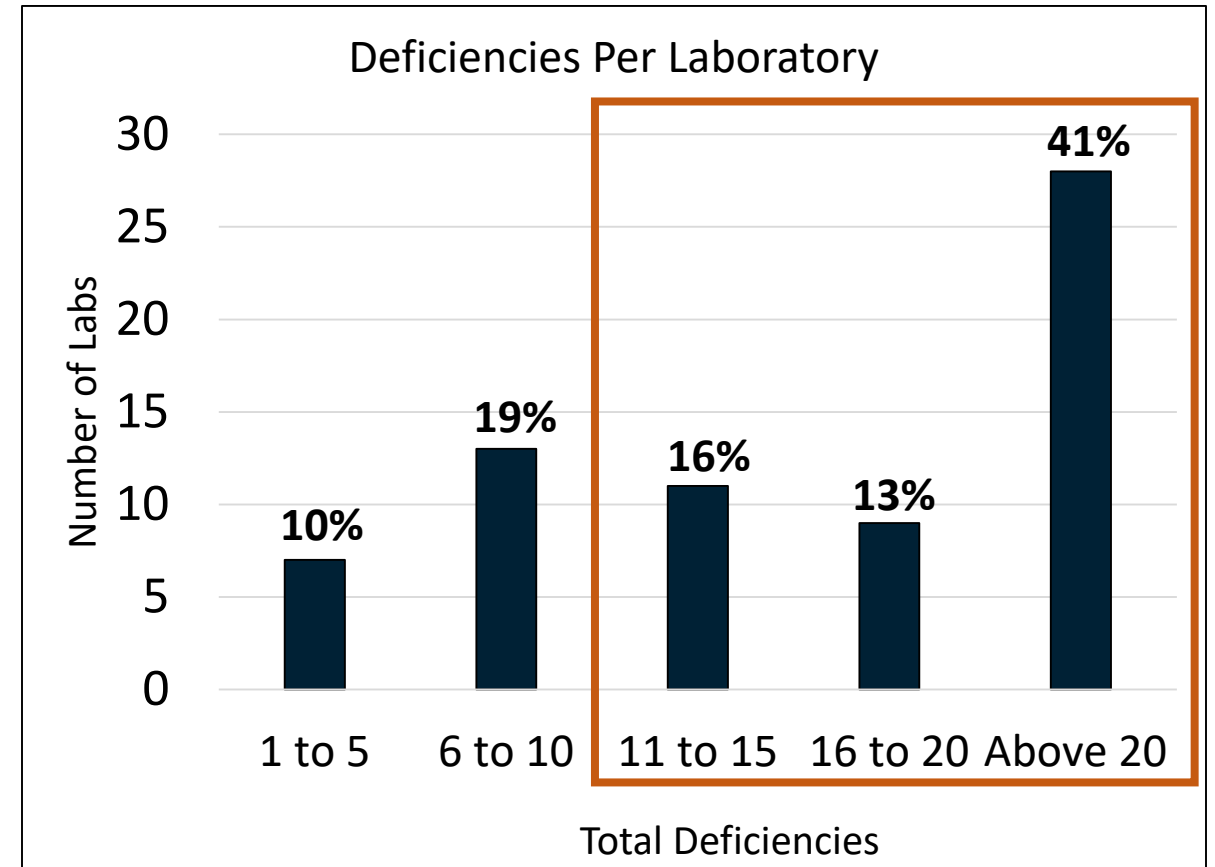
- Reviewed ELAP operational procedures, PT review procedures, quality system
- Generated 28 general technical checklists
- Advise on laboratory requirements
- Developed on site assessment observation form based on current CA regs

ASSESS CA DW LABORATORIES

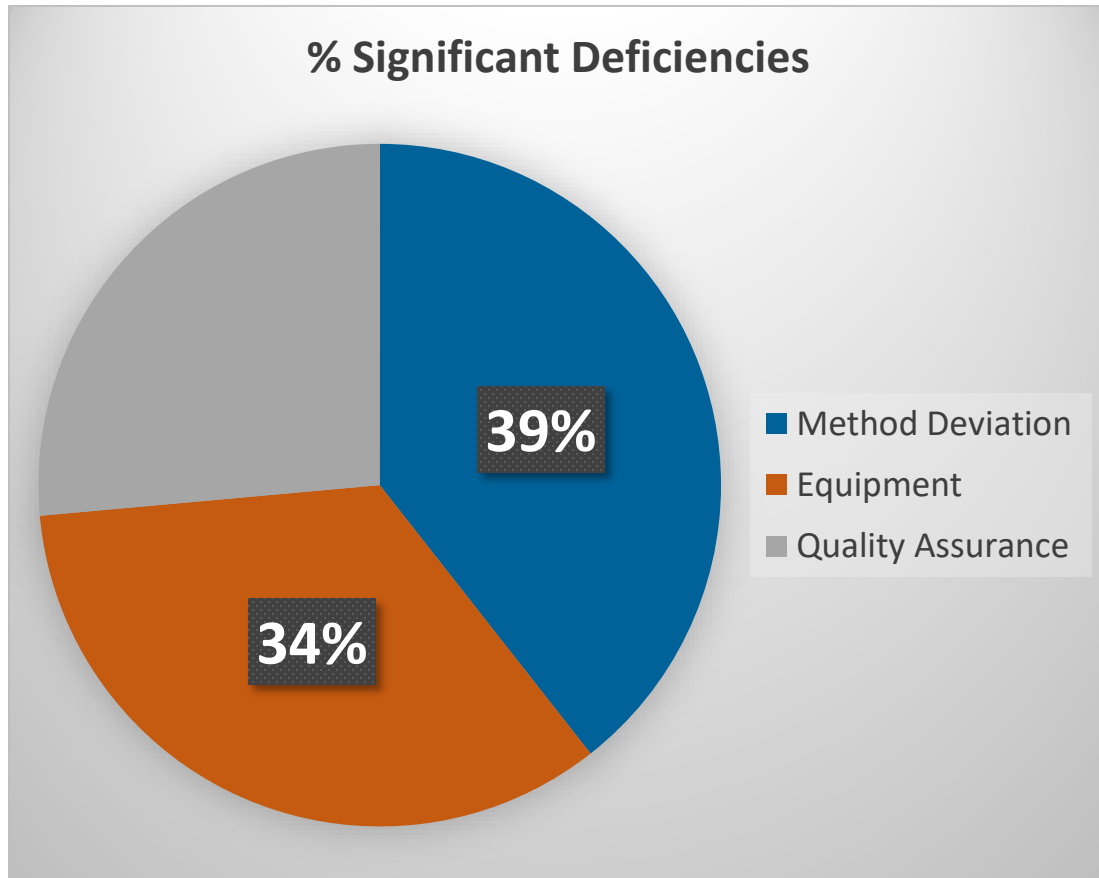
- On-site assessment of DW Labs
 - Completed – 88
 - Scheduled/Confirmed – 20
 - Reports and CAPs mixed status, some complete and some in progress
 - Labs that dropped or cancelled – 13
 - Approximately 320 total labs will be assessed over 3 yr
 - By end of calendar year completed 1/3 of drinking water labs

DEFICIENCIES FROM ASSESSMENTS

- Looked at data from the first 68 assessments (21% of CA DW labs)
- A “deficiency” is a failure to comply with regulations or published methods
- Many had a large number of deficiencies
 - Once the number is above 20, data are typically impacted
- The number per lab has reached 70!



SEVERITY OF DEFICIENCIES



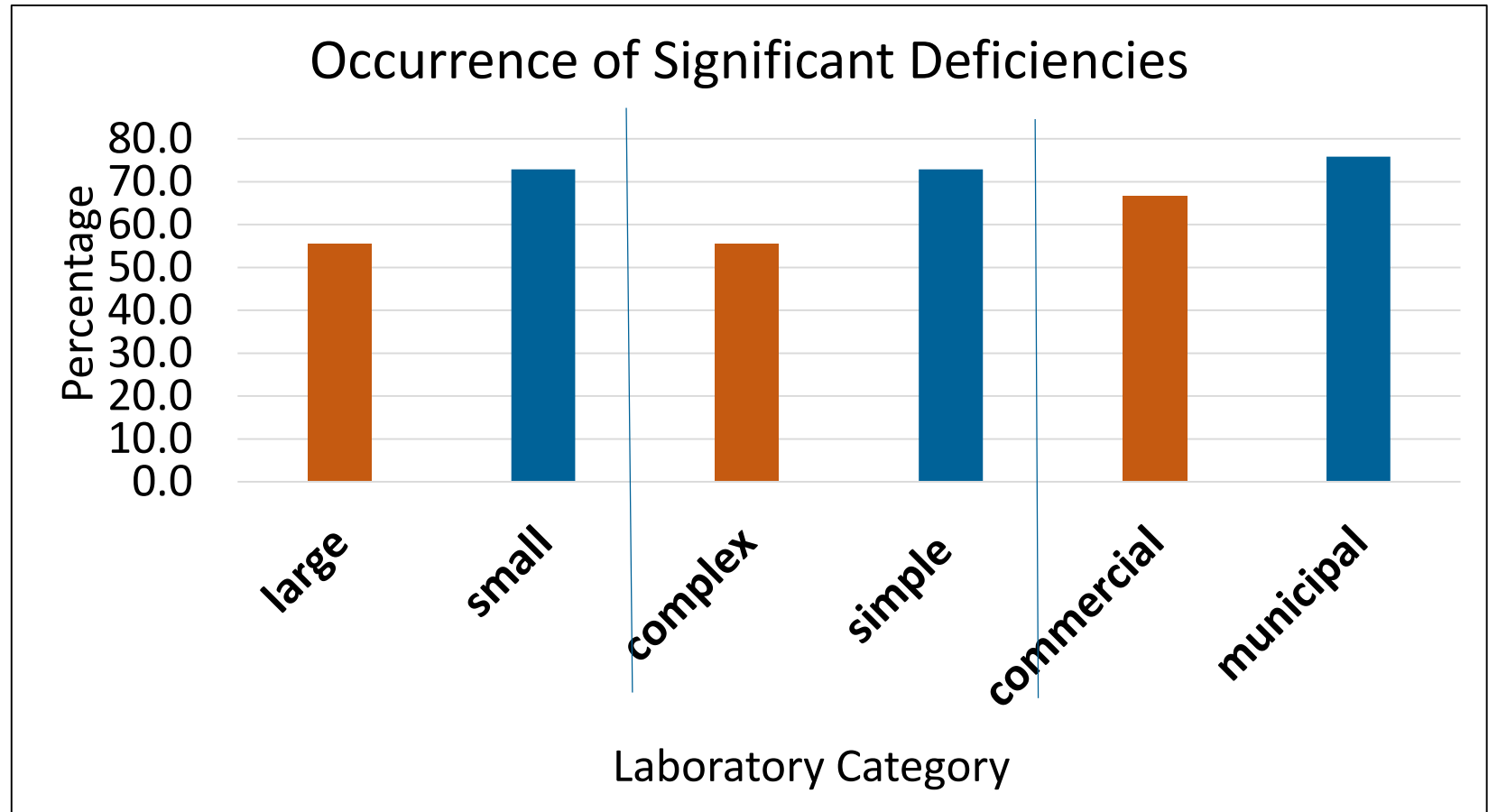
- The labs with a large number of deficiencies have deficiencies that are significant in nature
 - 39.4% are related to method deviations (labs do not implement QC per the method requirements)
 - 34.2% are related to improper use of laboratory equipment (labs do not calibrate or verify calibration)
 - The rest are quality assurance related
- Multiple significant deficiencies indicate a laboratory is not meeting minimum competency levels
- Method related items are not new to the laboratories

EXAMPLES OF DEFICIENCIES

- Significant
 - No lab director, no one in charge, no notice to ELAP
 - Using LIMS with many incorrect calibration and QC limits, questionable data
 - Incorrect calculations
 - No method blanks, no duplicates or QC
 - Using expired media/standards
- More serious
 - Analyzing cyanide and do not know how to calibrate
 - Floors of gravel while analyzing metals; micro rooms dirty with no disinfectant
 - Insufficient volume used for micro testing – potential false negatives
 - Published methods have options for tests; lab does not know what they do
 - Manipulate proficiency test results

PERVASIVENESS OF DEFICIENCIES

- Problems do not change based on size or type of laboratory (small/large, municipal/commercial, simple/complex)
- Labs in California are trailing the national industry



DEFICIENCIES FROM ASSESSMENTS

- Quality Assurance deficiencies make up 25% of all deficiencies
 - Labs do not understand how to establish QA system, QA manual & SOPs
- Small labs have three times more QA-related deficiencies than other laboratory subgroups
- Without systems, deficiencies are not corrected long term

- Culture must change
 - Small labs do not know how to deal with audits
 - Some labs believe they should be audited into compliance
- Labs do not know the ‘rules’ regarding DW
 - Methods cannot be modified
- Labs have dread and fear about meeting requirements
- Labs do not know how to set up processes to ensure long term success
- Most laboratories want to comply

THANK YOU

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