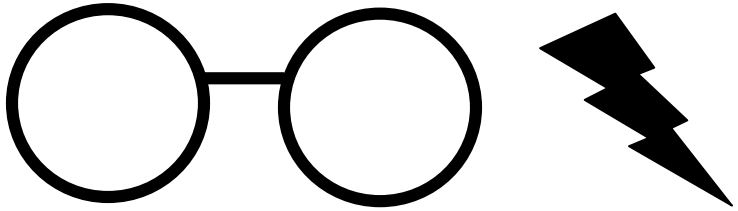


Fantastic Findings and How to Avoid Them

Travis Bartholomew, Program Manager

Oregon Health Authority

OREGON ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
Public Health Division

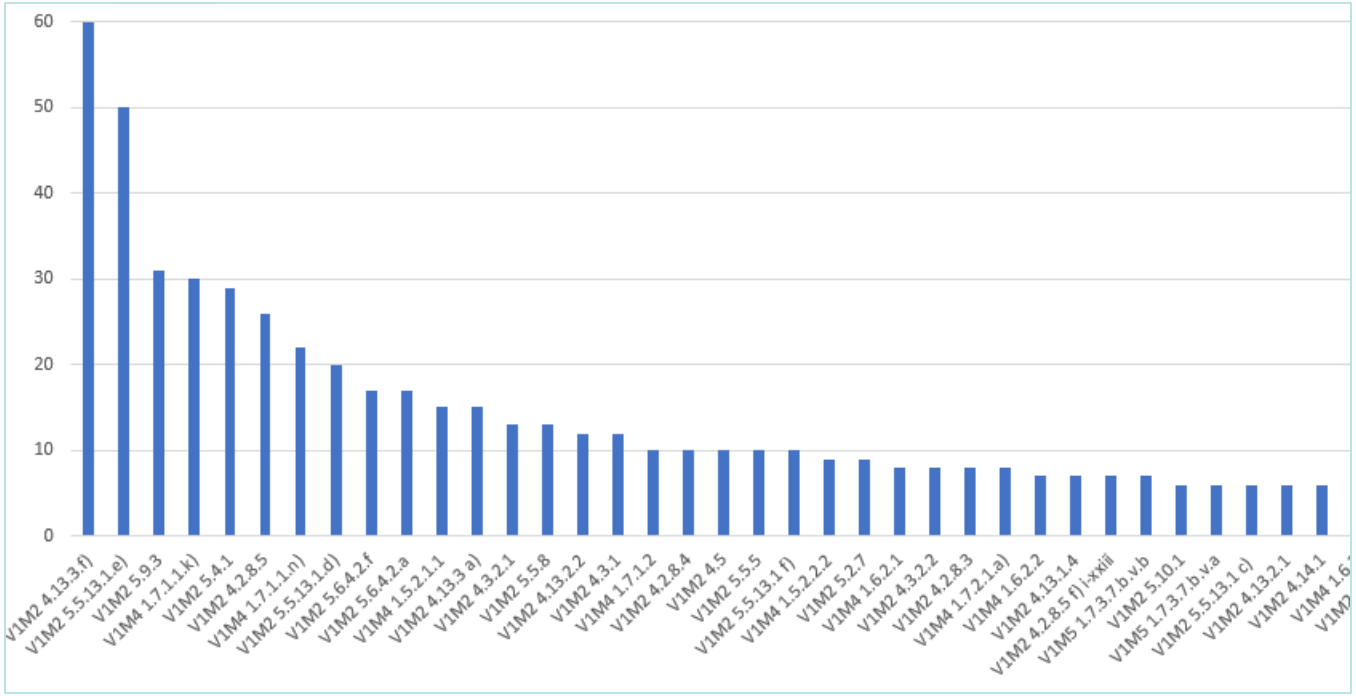
Disclaimer

WARNING! The content of this presentation should not be construed as advice or counsel. The opinions expressed in this presentation do not represent the official positions of ORELAP or the Oregon Health Authority. ORELAP staff may not offer consulting services to laboratories. The presenter makes no claims as to whether implementing any of the ideas discussed during this presentation will guarantee compliance to the 2016 TNI Standard or Oregon Administrative Rules. Any laboratory Quality Assurance Officer attempting to use the content of this presentation to get out of a finding will be given even more findings ☺

Common themes in findings

- Policies/procedures not in line with the 2016 TNI Standard.
- Record-keeping.
- Poor analyst understanding/training.
- Modifications to test methods.
- Forgetfulness (COVID brain fog?)

Most commonly used standard references in 2023



Most commonly used standard references in 2023

- V1M2 4.13.3.f: Records and record-keeping
- V1M2 5.5.13.1.e: Volumetrics calibration/verification
- V1M2 5.9.3: Essential quality control
- V1M4 1.7.1.1.k: Relative error
- V1M2 5.4.1: Using appropriate methods
- V1M2 4.2.8.5: SOPs
- V1M4 1.7.1.1.n: ICV from a second source
- V1M2 5.5.13.1.d: Thermometers calibration/verification

Three kinds of findings

- Known issues, should not be occurring with moderate oversight
  - Pipet not checked quarterly despite an SOP and form being available
  - ICV not a second source, despite this being lab-wide policy
- Known issues, difficult to stop 100% of the time even with tight oversight
  - Scribbling out errors
  - Forgetting to check the box saying you checked for chlorine residual
- Unknown issues
  - Not following reference method requirements
  - Unaware of TNI requirement

There are three certainties in life

1. Death
2. Taxes
3. An assessor WILL find a non Class A graduated cylinder in your laboratory if they look hard enough.

Analytical records and traceability

- This is the single greatest issue identified during ORELAP onsite assessments.
- Because of the complexity of environmental testing, the amount of variables, pieces of information, activities, conditions, times, temperatures, persons, reagents, it can seem like an impossible task to record all the pertinent information.
- Read V1M2 4.13.3.f, there are 19 subpoints under this one standard reference, that's 1 more than under 4.2.8.4 for quality manual contents, and only 4 less than SOP topics under 4.2.8.5.f
- This can prove to be a never-ending task. pH test strips now frequently come with the manufacturer's lot number printed on the package, you need to record this, too!

Analytical records and traceability

How can you possibly keep up?

Strategies:

1. Ask the analyst to itemize a list of every tangible thing they interact with during the test (e.g., supplies, equipment, sample fractions, timers, tools, etc.)
2. Shadow the analyst while they walk through every phase of the analysis, then ask yourself, what do we need to record in order to reconstruct what the analyst just did five years from now?
3. Review a data package with the analyst, and quiz them on the steps you know to be required in the method and SOP. How long did you leave it in the oven? How do I know?

How do I prevent repeat findings?

- Use your internal audits to review past ORELAP findings.
- Use your annual management reviews to review past corrective actions and determine if the issue is really solved.
- Put controls in place to prevent recurrence, too many times labs settle with retraining the analyst, but how will that help the next analyst doing that job?
- Add an item to your data review checklist.
- Create tracking documents to track the frequency of required tasks, make sure these are communicated to all staff and prominently located.
- Look for examples of a finding in other departments.

Final Tips for Success

- You must become familiar with the 2016 TNI Standard. You should be able to apply your working knowledge of the requirements to any process in the laboratory.

- The best team leads, QAOs, technical directors are out walking the floor. Don’t stay cooped up in your office.

- Seek buy-in from your employees and make change a collaborative effort.

Questions?