



Valley Water

Clean Water • Healthy Environment • Flood Protection

ELAP Accreditation- Third-Party On-Site Assessment Experience

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Outline

- Planning Process
- Scheduling
- Preparing for the assessment
- Assessment Process
- Findings and Corrective Action Plans
- Lessons Learned and Useful tips
- Next Steps: The TNI 2016 Standard



Valley Water Laboratory

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- Valley Water operates two accredited labs.
 - One main lab, and
 - One satellite lab.
- Accredited for:
 - 7 FOA Tables
 - 42 test methods
- Instrumentation used includes LCMSMS, GCMS, ICPMS, ICP-OES, ICMS, IC, UV/Vis, etc.



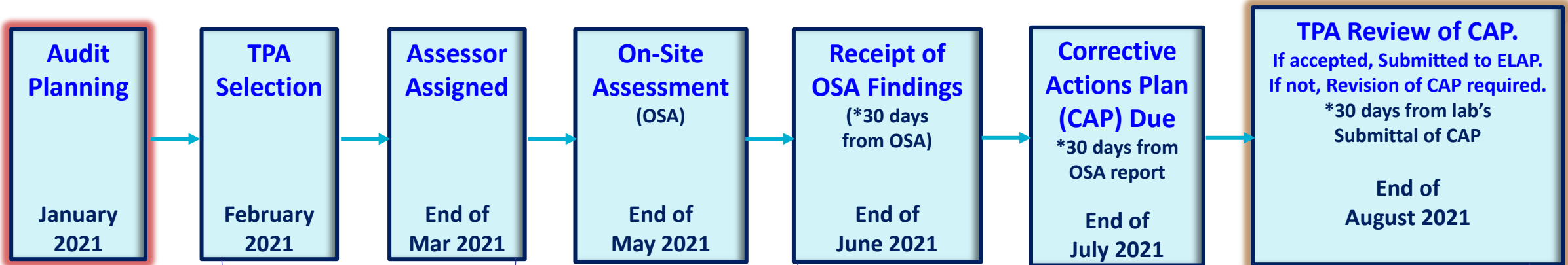
Valley Water's Planning Process for OSA

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- Developing an Assessment timeline
 - Alignment with the accreditation cycle
 - Lab Projects/Schedule Conflicts
 - Sophisticated technology use==> Plan for TPA
- Some factors to consider when selecting TPA:
 - Lab's review of cost, performance, experience with CA regulations, etc.
 - Virtual or on-site (DW assessments are on-site)
 - Number of days for OSA based on accredited methods
 - TPA availability aligned with assessment timeline and lab schedule
- The OSA for Valley Water Lab in May 2021 was for CA ELAP Regulations.
 - OSA planned for four days to cover both labs.

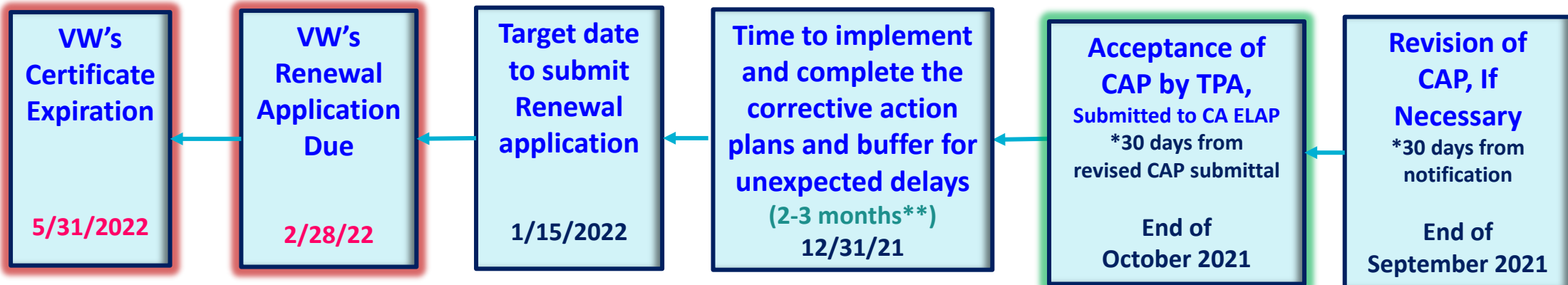


Valley Water Lab's Planning Process for OSA



Contracting process timeline may vary from lab to lab.

*May vary for each TPA



**Valley Water Lab's Planning Target.
Will vary from lab to lab.

*May vary for each TPA

Preparing for the Assessment

- Provide requested documents to the assessor by due date.
- Become familiar with the portal or online file structure that the TPA uses.
- Announce the assessment date(s) to staff for scheduling purposes.
- Request assessment outline/schedule from the assessor.
- Review Quality Manual or other related documents to ensure all regulatory requirements are included.
- Prepare an overview of the organization and laboratory function.
- Prepare current org chart with employee names to share with the assessor.
- Set up work area for the assessor, and make a plan of how the audit will be conducted.

Assessment Process

Opening Meeting – An Important Step:

- Provide overview of the organization and logistics of the OSA
- Discuss any schedule/time adjustments
- Health and safety considerations, COVID-19 related protocols, etc.
- Discuss processes covered by overall organizational function, such as purchasing, accounting, recruitment, shipping and receiving, etc.
- Inform assessor of the lab's preference of either a daily debrief or a summary of findings at the end of the assessment.



Assessment Process

Review of the Key Elements of Laboratory Quality Management System include, but are not limited to:

- Quality Manual
- Training/IDOCs/DOCs
- Data Integrity and Ethics
- Document Control
- Control of Data
- Corrective/Preventive Actions
- Management Review
- Internal Audit Program
- Suppliers/Subcontracting
- Requests, Tenders, and Contracts
- Proficiency Testing Program
- Reporting Results
- Sampling/Sample Receiving
- Measurement Traceability

Assessment Process

Review of methods included in scope:

- Not significantly different compared to prior ELAP Assessments
- Review of SOPs for any regulatory requirements, such as notifications of positive total coliform or E.Coli results.
- The assessor may select to review similar technologies together.



Closing Meeting and Further Steps

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- Final assessment report may or may not be provided at the close-out meeting, however, assessment debrief will be.
- Assessment debrief is an important step to review and discuss findings. Discuss any disagreements, and address any findings already addressed by the closing meeting.
- Final report may be received 30 days or sooner after the OSA. May vary by TPA.
- Lab has 30 days to submit a Corrective Action **Plan** (CAP) to the TPA.
- TPA has 30 days (May vary by TPA) to review the CAP. They can either accept or request revision(s)
- Lab has 30 days to submit revised CAP.
- TPA has 30 days to review the revised CAP. May vary by TPA.
- If accepted, TPA submits the CAP to CA ELAP and closes out the assessment.
- Lab ensures that the CAP is followed and the due dates met.
- Subsequent assessments may include review of CAP and follow up action(s).

Some Key Tips to Prepare for OSA:

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- Include requirements of the regulations in Quality Manual or other related document, such as:
 - Initiating corrective action when a PT result is out of acceptance criteria
 - Regulatory notifications and data reporting
 - Record retention schedule
 - Process for invalidating a sample result
 - Technical Manager qualifications
 - Process when technical manager is not available for durations specified in regulations
- Reporting of PT results – Ensure that report matches exactly how the method is listed on the FOA table.
- Have pre-determined annual internal audit plan and records that it is being followed
- Have a functional corrective/preventive action system in place and ensure proper closure and follow up.
- Conduct management reviews and documenting outcomes.
- Determine linear calibration range when method specifies it, even if routine analysis does not extend to that range.
- For drinking water, ensure that all requirements of the method are addressed.

Note: This just a very brief snapshot of what can be written as a finding, if not followed.

Preparing for TNI Implementation

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- Valley Water implemented a 3-phased approach:

Phase I Big Rocks

In 2018, Technical Manager and QA Officer performed a prelim gap assessment to the TNI Standard and identified five key areas to focus on, one was internal audit program to review elements of quality management system.

Phase II It takes a Team!

In 2019-2020, Technical Manager and QA Officer performed prelim internal audits of the quality management system using the TNI checklist, and all analysts performed audits of analytical methods to start learning the TNI requirements.

Phase III Are We There Yet?

In Sept. 2021, Valley Water requested a gap assessment by a third-party assessor to review laboratory processes for compliance with the TNI Standard and identify areas of improvement.



Preparing for TNI Implementation

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- Valley Water's next OSA will be in Spring/Summer 2023 and will include TNI Standard Requirements
- Some lessons learned from our journey so far (To Be Continued..)
 - It takes time to plan and implement new processes.
 - Expect that not every change will go smoothly the first time.
 - Many LIMS systems have features that can help with the TNI Implementation.
 - Ensure that the new processes or updates, when made, are known to all levels of staff.



QUESTIONS

