



Staying Afloat Following a Regulatory Inspection

DATE: July 29th, 2025 PRESENTED BY: Keri Bishop, CHOP
Hazardous Waste Program Manager, Oregon Health & Science University

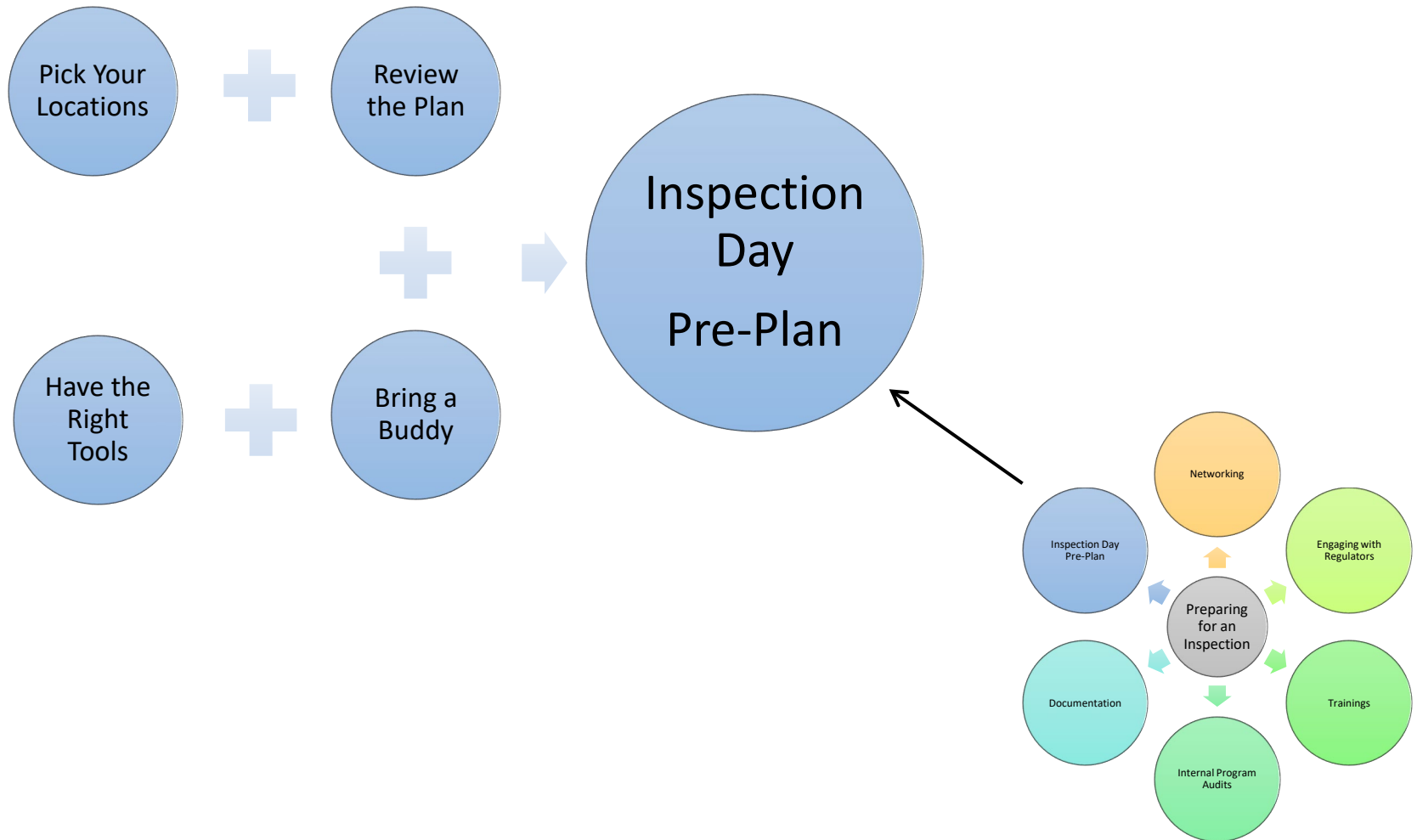


Before the Inspection...

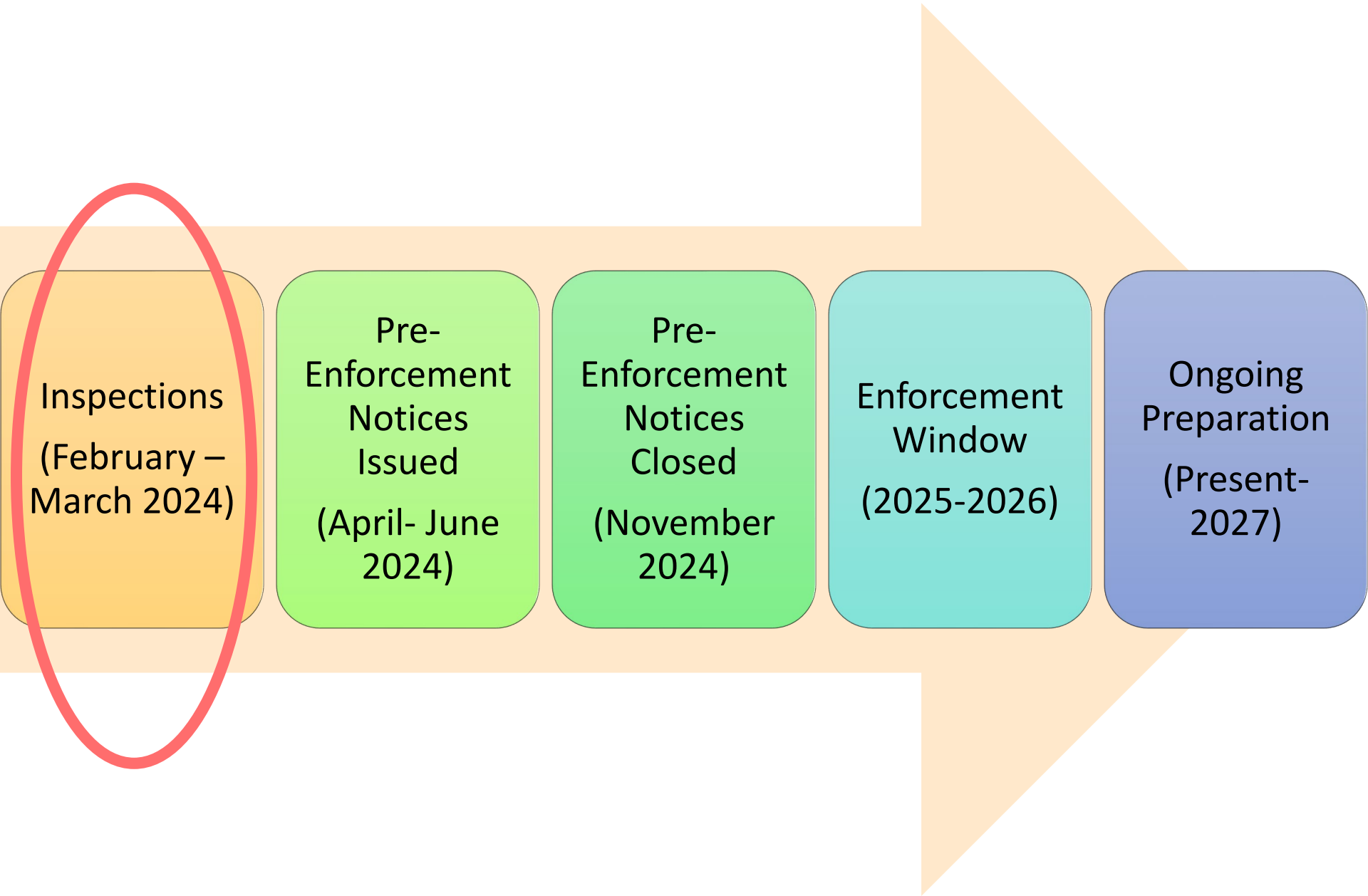




Before the Inspection...



The 5 Steps of the Post-Inspection Process



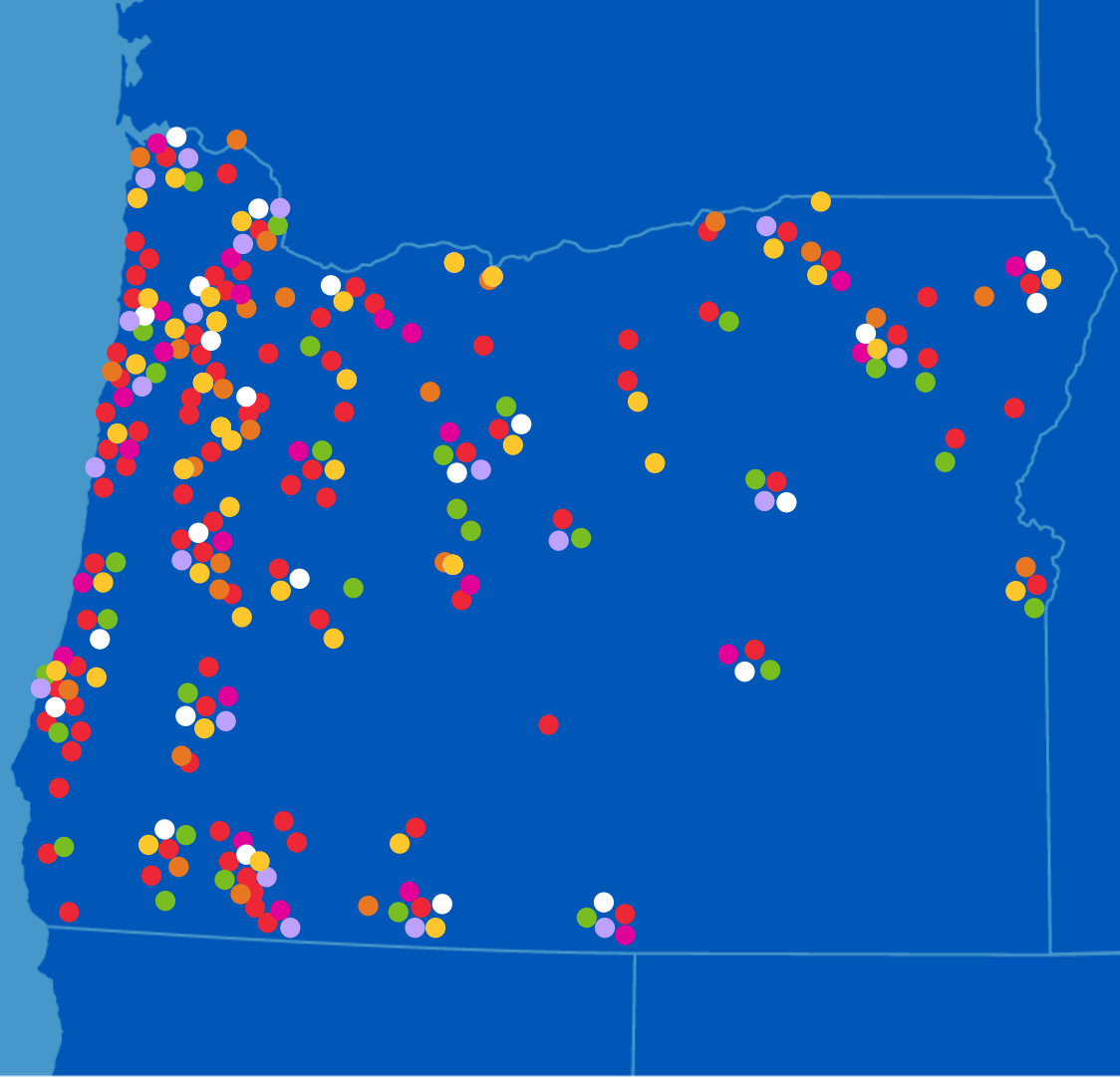


A Little Bit About OHSU...

Statewide collaborations

- Clinical practices
- Research
- Residency training sites*
- Student rotations or clerkships
- CME
- Oregon Rural Practice-based Network
- Telemedicine network

*Includes existing and planned sites
for residencies in coming years



Where Healing, Teaching, and Discovery Come Together

The Inspections



Fig. 1: "OHSU Feasibility Study" Salazar Architect Inc., 9 Oct. 2012, <https://www.salazarch.com/design-all/ohsu-planning-studies>. Accessed 06 June. 2025.





The Inspections

Date	Location	Inspection Duration
February 29, 2024	OHSU Marquam Hill Campus	Regulators On-Site - 4hrs
March 21, 2024	OHSU Schnitzer Campus	Regulators On-Site- 1.5hrs.
March 21, 2024	OHSU CHH Complex Campus	Regulators On-Site- 1.5hrs
March- April 2024	Electronic Inspection	20hrs Total

Total EHS FTE Time Spent on Inspections- 34hrs
Over 60 Emails



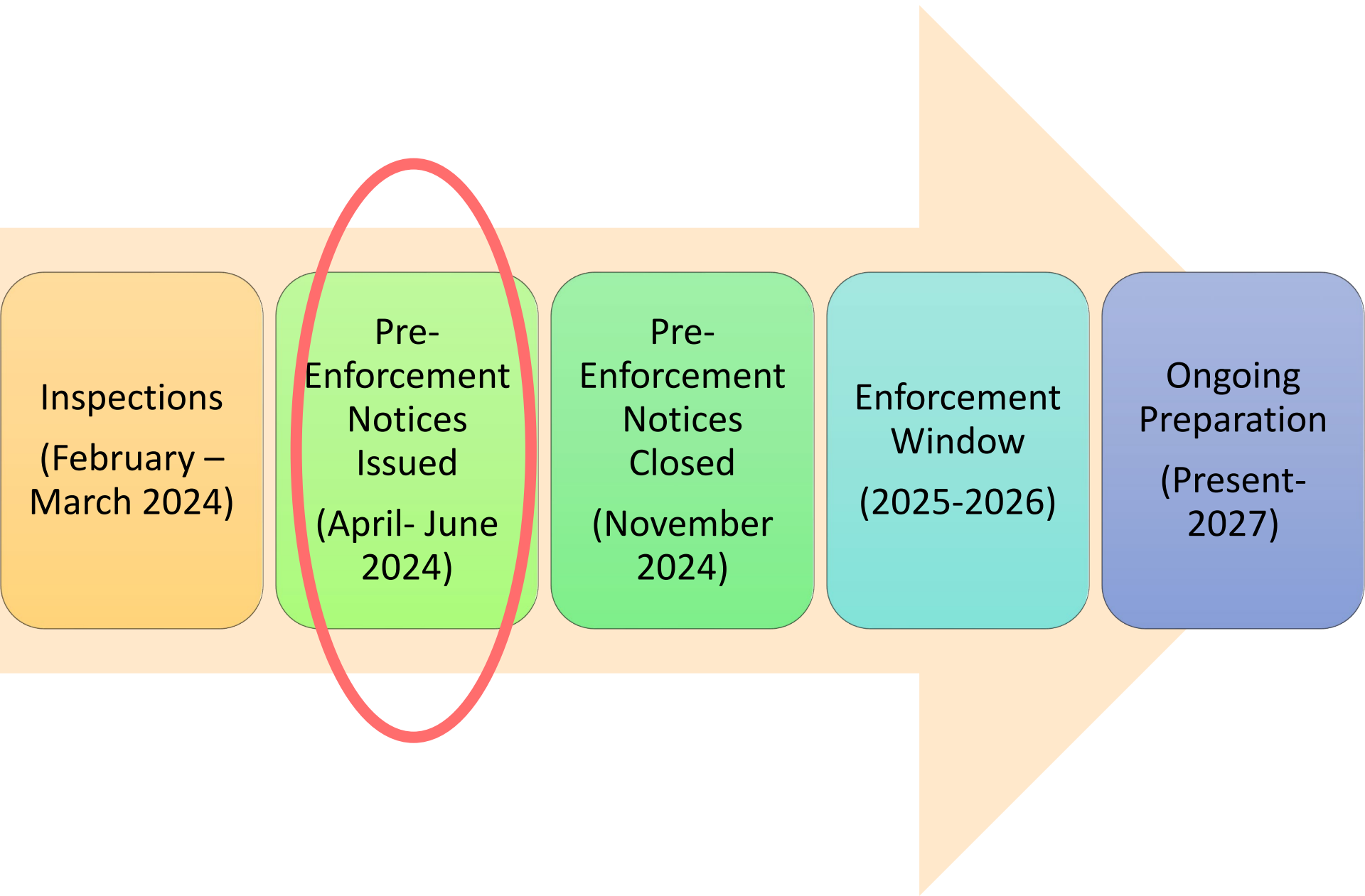
The Inspections: Lessons Learned

- Pre-Plan for Inspection Day
- Know Your Audience and Only Offer What is Asked
- Be Aware of Scope Creep
- Sort Your Emails

▼ Inbox	7
After Birds	3
▼ DEQ Communications	23
CHH Complex	
Legal	4
Marquam Hill	
Schnitzer	
Haz. Waste Forum	9
HW Prgm Questions	10



The 5 Steps of the Post-Inspection Process





Pre-Enforcement Notices Issued

Date	Location	Type of Pre-Enforcement Notice	Number of Violations
April 10, 2024	OHSU Marquam Hill Campus	Pre-Enforcement Notice	12
May 13, 2024	OHSU Marquam Hill	Amended Pre-Enforcement Notice	15
May 21, 2024	OHSU Schnitzer Campus	Warning Letter- Opportunity to Correct	11
June 14, 2024	OHSU CHH Complex Campus	Pre-Enforcement Notice	10

Total Violations- 36
Unique Violations- 14

Pre-Enforcement Notices Issued: A Timeline

April

- **1st** PEN Issued
- Clarification on Violations Requested

May

- **Amended and 2nd** PENs Issued
- Use of Technical Assistance Denied

June

- **3rd** PEN Issued
- **1st** Corrective Action Due Date
- OHSU engages Government Relations Team and Legal Counsel

July

- **2nd** Corrective Action Due Date
- 24 of 36 Corrective Actions Accepted

August

- Virtual Meeting with DEQ; Both Legal Teams are Present
- Extension Given for Remaining 12 Corrective Actions

September

- Update and Complete PENS

October

- **3rd** Corrective Action Due Date

Pre-Enforcement Notices Issued: Request for Clarification

April

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- Clarification on Violations Requested

May

- Amended and 2nd PENs Issued
- Use of Technical Assistance Denied





Pre-Enforcement Notices Issued: Engaged Legal Representation

June
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[RCRA Online](#), [McCoy and Associates Website](#),

and the Forum are your Friends!



Pre-Enforcement Notices Issued: Resolution of Corrective Actions

❑ Average of 60% FTE Time over 6 months

❑ 600+ FTE Hours

❑ 225+ Email Exchanges

❑ 50+ Meetings

❑ Back Burner- Documentation

September

- Update and Complete PENS

October

- **3rd** Corrective Action Due Date



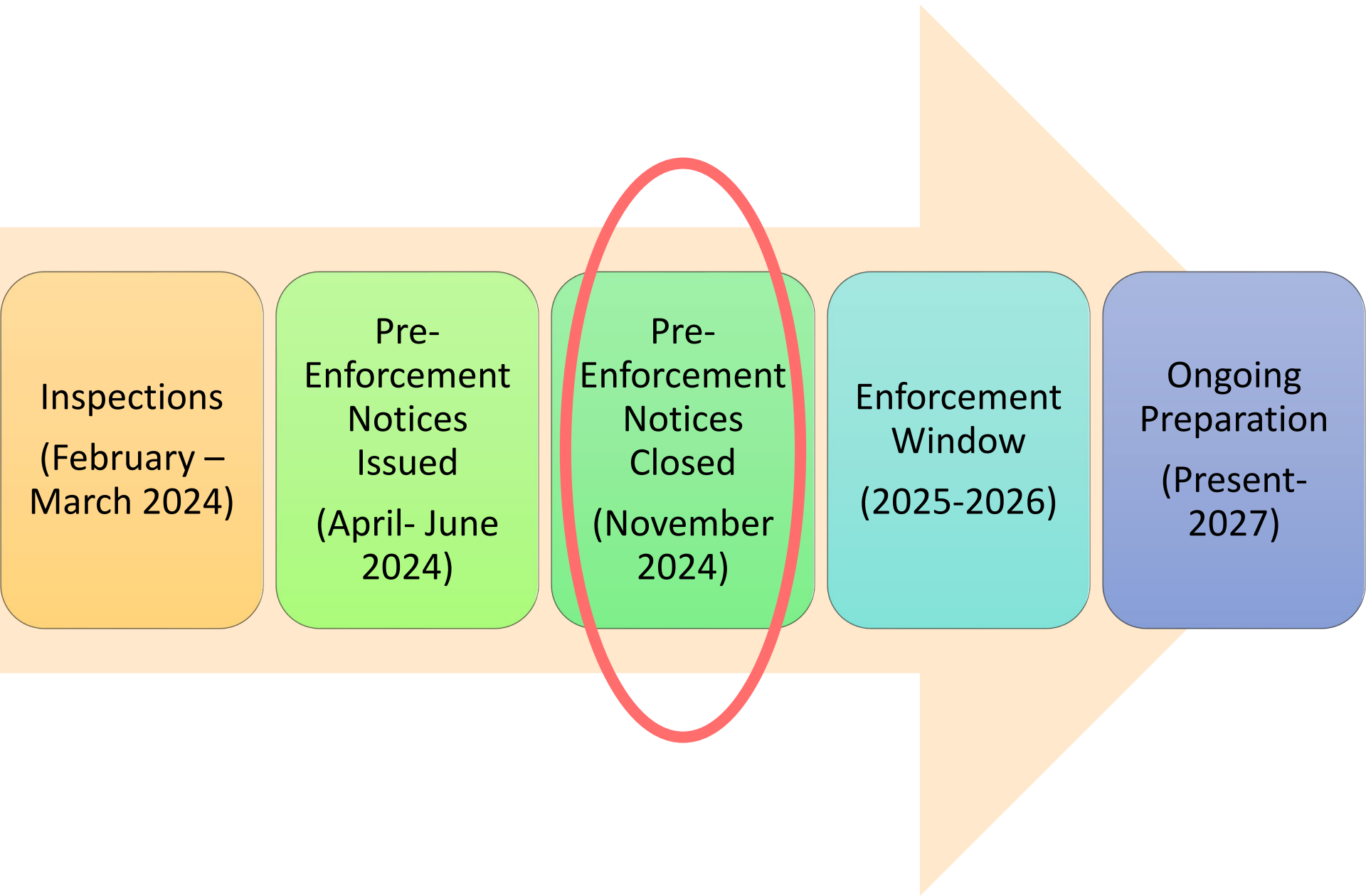


Pre-Enforcement Notices Issued: Lessons Learned

- The Inspection does not Stop until Corrective Actions are Resolved
- Pursue Additional Conversations with Regulators When Needed
- Do Your Own Research
- Format Your Corrective Actions
- Know Your Bandwidth



The 5 Steps of the Post-Inspection Process



Pre-Enforcement Notices Closed: What's Next?



1. Organize Corrective Actions
2. Communication/Engagement
3. Implementation

Pre-Enforcement Notices Closed: Organize Corrective Actions

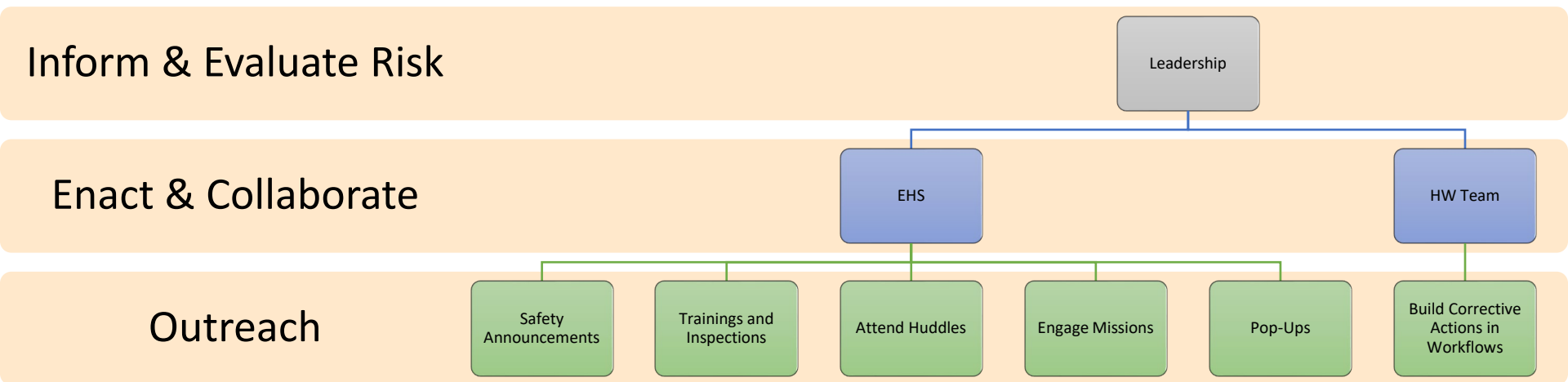
For Leadership

Current List of DEQ Action Item Status- July 2025

NO.	ACTION ITEM	Current Status	NEXT STEPS	Owner
11	Discuss Updating Online HC HW Training	Incomplete		EPT Mngr.
12	Discuss taking over ITG UW	Incomplete	ITG does not have a reliable UW Vendor- EHS to follow up with ITG	EPT Mngr.
13	Where is the Temptell Ultra Waste going on MH and the Clinics	Incomplete	Keri to meet with Pharmacy	HW Prgm Mngr.
14	Crossings Campus (including the Marquam Buildings), Logistics, ITG and SOD in SciShield	Incomplete	ay to request all supplies and give update by end of July 202	EPT Mngr.
15	Implement an annual SAA audit process – to spot check generators compliance with the regulations.	In Progress	Inspection Form has been created for all HC Units/Clinics (Sentact) and Lab Spaces (SciShield). Facilities Inspection Form still needs to be created/Anticipate Inspections beginning for HC Units/Clinics and Lab Spaces in Q1FY26/Unsure how to inspect Clinical Lab Spaces	HW Prgm. Mngr/EHS Team
16	Pharm + Ars- Labels- Begun the process of notifying the label vendor and our logistics department of this change. Once the new labels have arrived on site, EHS will dispose of the legacy labels.	In Progress	This was completed in July of 2024, and then Label Vendor/Logistics reverted back to the old HWP Label. This needs to be addressed. / Arsenic Label needs to be updated	HW Prgm. Mngr
17	Unknowns SOP	In Progress	Part of the Larger SOP Project- HWD SOP has been started but needs to be completed. This SOP is the #1 Priority for the SOP Project and will need to be sent to DEQ once completed	HW Prgm. Mngr
18	Laboratory Cleanout SOP	In Progress	Part of the Larger Hazwaste Pickup SOP Project- Both the internal and external SOPs have been started. Ideally they are both out for review by the end of CY25	HW Prgm. Mngr
19	Update Cobas Labels	In Progress	Team needs to Double Check if all Labels have been Updated	VD Action Item
20	Update "Hazardous Waste -Pending Determination" Containers to "Characterisic Profile Containers"	Completed	West Campus and Schnitzer Campus- Completed; Marquam Hill and CHH Complex- Incomplete; Crossings Campus- Pending Campus Opening and Labs added to SciShield	HW Prgm. Mngr
21	Create Campus Characteristic Profiles in SciShield	Completed	Not part of DEQ Inspection, but Crossings Campus needs to be done as soon as those labs are in SciShield	HW Prgm. Mngr
22	Update Core Lab Labels	Completed		HW Team



Pre-Enforcement Notices Closed: Communication/Engagement



Communicate Early and Often to Keep Momentum



Pre-Enforcement Notices Closed: Implementation

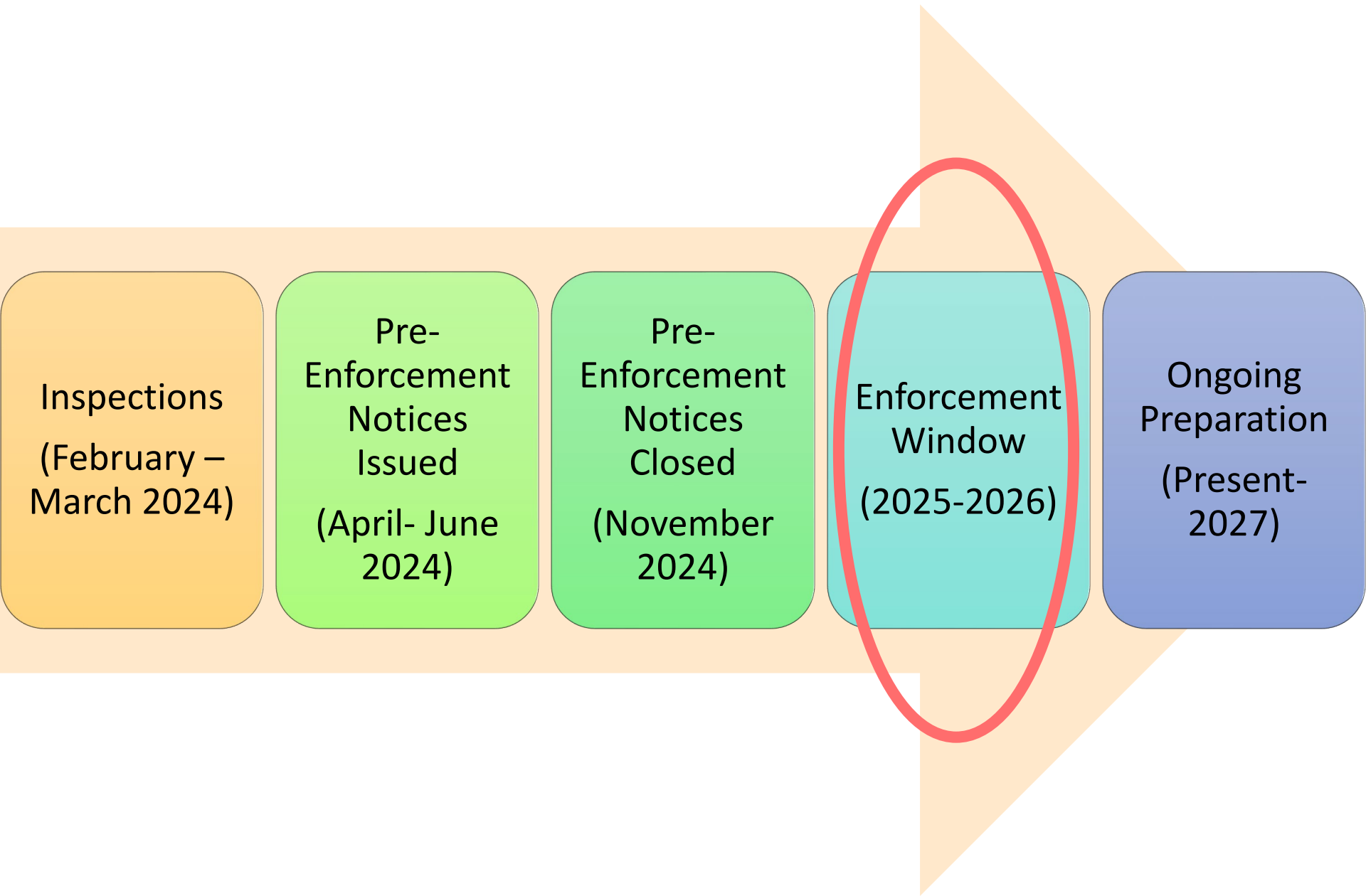
- ☐ Build Simple Corrective Actions into HW Team Workflows (and Don't forget about the Backburner!)
- ☐ Provide Options along with a Pros and Cons list to Leadership for the More Complex Corrective Actions
- ☐ Request Input from Mission Leadership when Systematic Changes Affect their Departments
- ☐ Collaborate with EHS Colleagues When Possible
- ☐ Outreach- Outreach- Outreach!
- ☐ Keep Leadership Informed of Progress



Pre-Enforcement Notices Closed: Lessons Learned

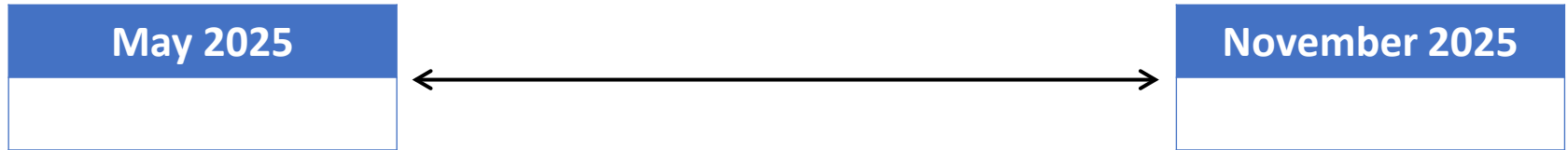
- Time Management
 - ☐ 30 FTE Hours
 - ☐ 25 Email Exchanges
 - ☐ 5 Meetings
- Organize Corrective Actions
 - ☐ Phone a Friend
 - ☐ Integrate into Current Workflows
 - ☐ Planning is Essential
- Make a Plan for the Backburner
- Communicate Early and Often

The 5 Steps of the Post-Inspection Process





Enforcement



\$40,000

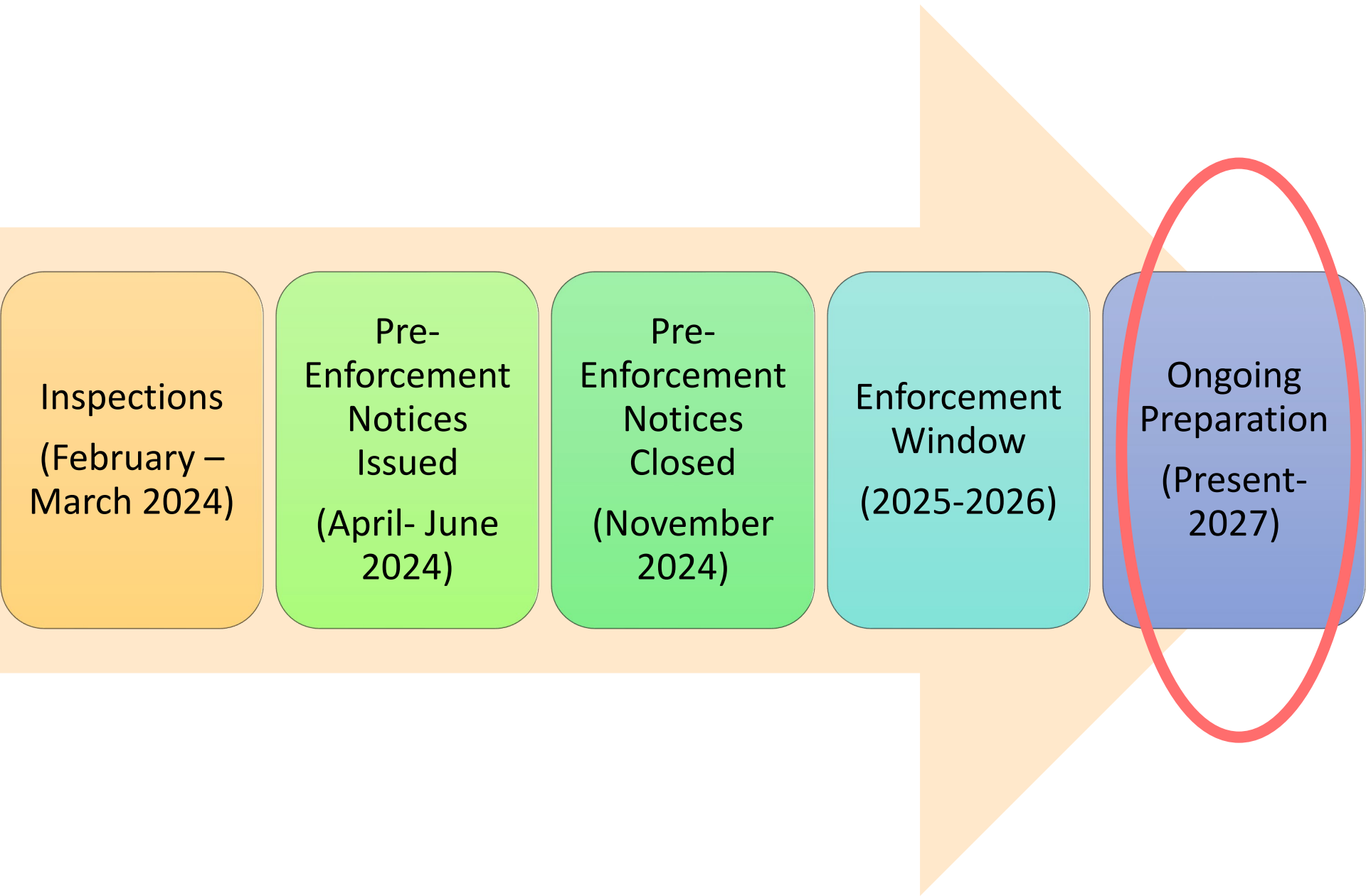


\$400,000

Lesson Learned- Money Talks

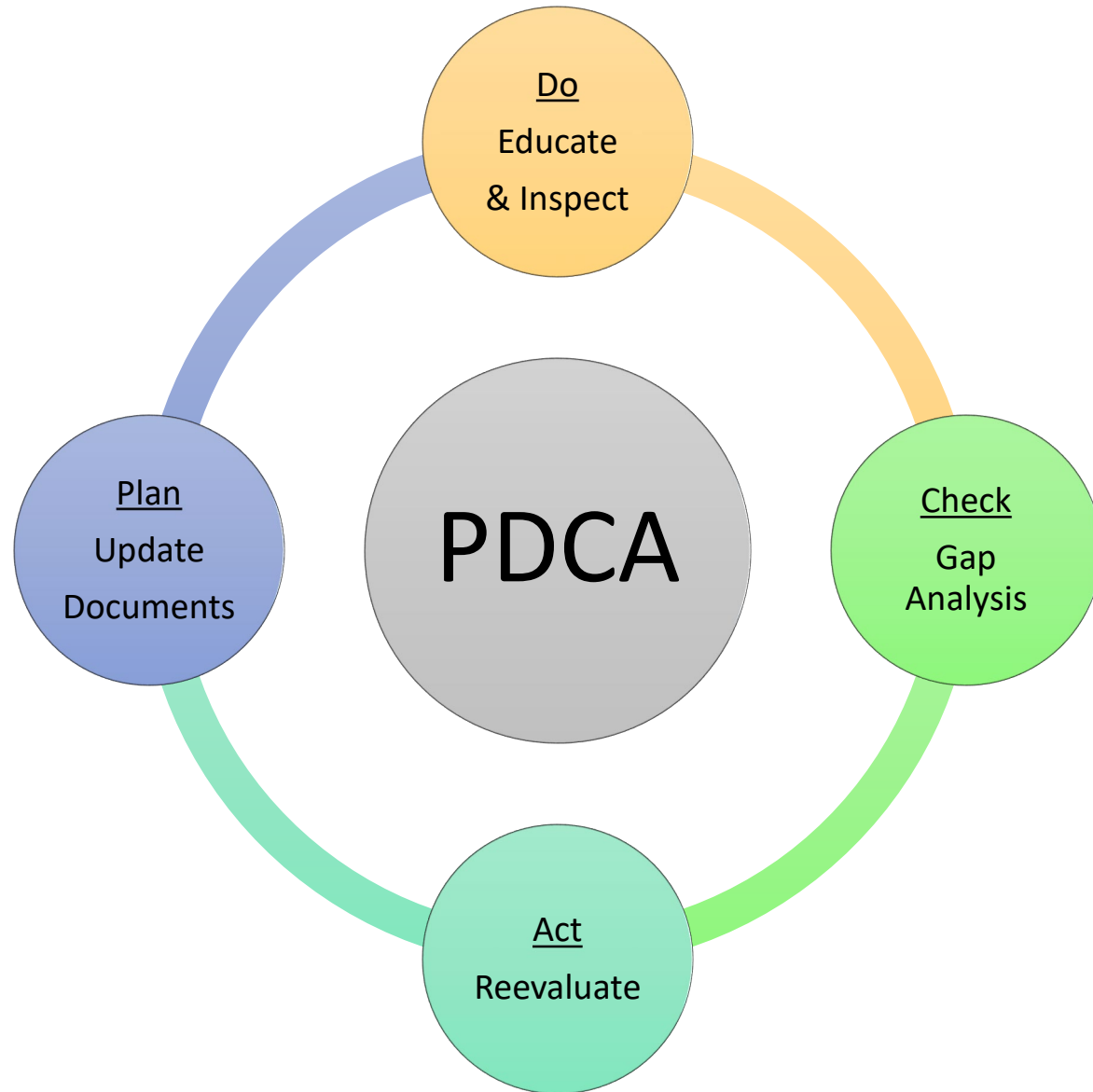


The 5 Steps of the Post-Inspection Process





Ongoing Preparation





Key Takeaways

Preplan for Inspection Day-
Bring a Buddy and a
Sharpie!

Invite Additional
Conversations If Needed

Sort Your Emails

Know Your Bandwidth

Do Your Own Research

Leadership Engagement –
Frame Communications
through a “Risk-Based”
Lens



QUESTIONS



Thank You