

Issues Management Training



PRESENTED BY

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Welcome to Issues Management Training

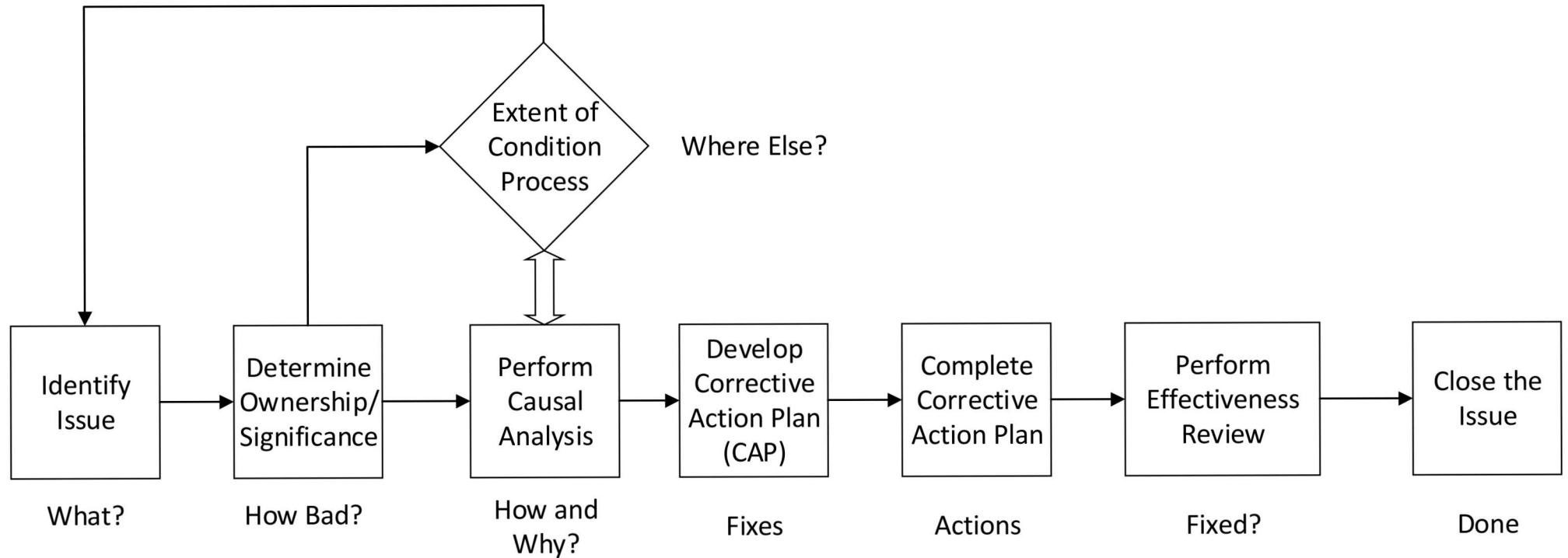
Agenda

- Introductions
- Why you are here?
 - Select AIS users
 - In an assurance role
 - Interested in being an early adopter of Sage
- What you will learn
 - Issues Management Process Overview
 - End-to-End Walkthroughs of Issues Management in Sage
- What happens next
 - September 30 – Soft Launch for Risk Management and Issues Management Modules
 - Assessment module build out
 - April 2, FY19– Sage Go Live- and what happens to AIS
 - What happens to Active Records



Issues Management Process Flow

Source of Issues
Include but not
limited to:
Events
Assessments
Occurrences
Noncompliances
Customer
feedback
Non conforming
Audits
Extent of condition



Definitions

➤ What is Issues Management

- Issue Management is the process by which Issues are identified, managed, tracked and evaluated through resolution to prevent recurrence.

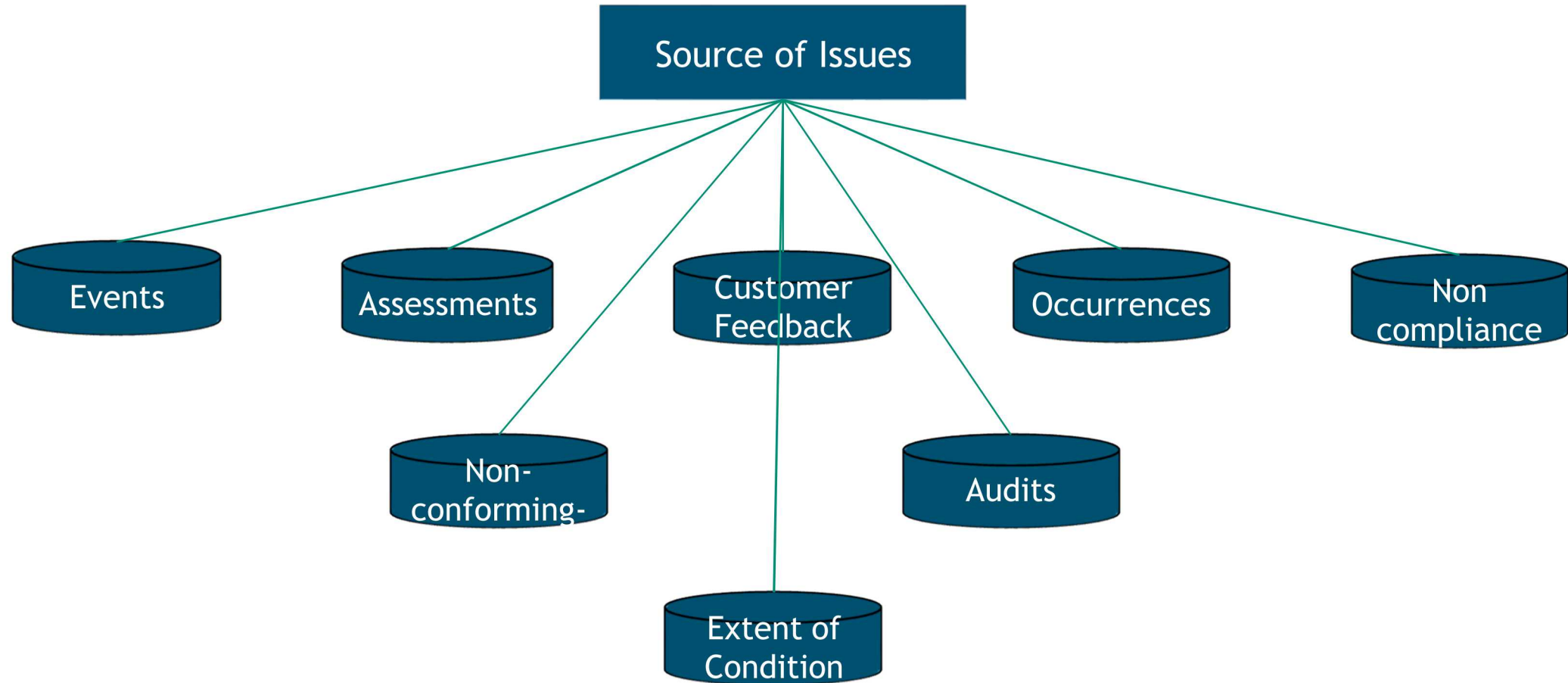
➤ What is an Issue

- An issue is an emerging or current Problem (deviations from desired, specified, or required state or performance) and its undesired consequences.

➤ Why is Identifying and Managing Issues Important

- Provide a safe and secure workplace
- Meet scope of work requirements with the highest level of quality and cost efficiency
- Meet milestone commitments
- Meet U.S. national security needs

Where Can Issues Come From?



Issues Management Process

Identify an Issue	An issue can occur in any environment: production, R&D, Security, Safety, etc. Issue is a deviation from the desired outcome and should be addressed systematically. Once an Issue has been identified, open a record in Sage and follow the Issues Management process to address the issue.
Determine the Significance Level	Identify the Significance of the Issue. Consider whether the Issue impacts multiple organizations.
Determine the Extent of Condition	Determine whether the same Issue or condition exists elsewhere. If yes, take the Extent of Condition into consideration when determining the root cause and the corrective actions.

Issues Management Process-Continue

Perform Causal Analysis	Conduct causal analysis to identify and understand the causes (both individual and organizational) that contributed to the Issue. Once the causes are identified, then the Issue can be corrected and prevented from reoccurring through appropriate corrective actions.
Develop Corrective Actions	Determine the appropriate corrective actions to correct the issue and prevent recurrence.
Perform Effectiveness Review	Perform effectiveness review by conducting verification to ensure the product, service, system, etc. meets its intended purpose. Also conduct Validation to determine whether the Issue has been eliminated and whether the corrective action achieves its planned results of the process, service, system, etc.
Close the Issue	Once a successful Validation has occurred, close the Issue in Sage.

What is an Issue

WHAT IS AN ISSUE

- Safety incident
- Security incident
- Gap in meeting compliance and/or regulatory requirement
- Material or part that does not meet specification
- Findings from internal or external assessments/audits
- Deviation in product or services
- Customer issue
- Testing failure
- Prototype failure
- Equipment failure

WHAT IS NOT AN ISSUE

- Conflict between employees
- Employee personal problems
- Individual Job Performance
- Management problems
- Cultural problems
- Lack of office space

Determine Significance Level

- Once Issue is identified, **Responsible Manager** determines Significance Level to describe the severity level of the Issue.

Category of Issue	Low Significance	Moderate Significance	High Significance
Environmental Safety & Health	<ul style="list-style-type: none"> Non-Occurrence trackable events (NOTES) and OSHA recordable injuries that are not reportable Conditions identified where cause and needed action are known and potential impact to workers or environment is acceptable with action, or Near miss of impact to a worker or environment contained within a single facility 	<ul style="list-style-type: none"> Occurrence report level “I” or “L”, or Conditions identified that impact the safety of personnel or the environment and the causes are not readily apparent and needed actions require further analysis to determine Near miss to co-located (multiple) workers or impact to the environment in multiple facilities contained onsite 	<ul style="list-style-type: none"> Occurrence report level “H”, or Formal DOE initiated investigations, or Near miss with impacts to the general public or environment extending offsite
Security	<ul style="list-style-type: none"> Security Incident Management Program (SIMP) designated “Low Risk” event Other security conditions identified where cause and needed action are known and security impacts are acceptable with action 	<ul style="list-style-type: none"> Security Incident Management Program (SIMP) designated “Medium Risk” event Other security conditions that if left unresolved could result in a security event/breach (potential for recurrence) 	<ul style="list-style-type: none"> Security Incident Management Program (SIMP) designated “High Risk” event Other security conditions that if left unresolved could result in a serious security event/breach (high probability of recurrence)

Issue Significance	Timeline				Qualified Causal Analyst (QCA)	Extent of Condition Evaluation (Minimum)	Corrective action Verification	Corrective Action Validation
	Determine Significance (From Discovery Date)	Complete Causal Analysis (From Discovery)	Develop CAP (Days from Discovery)	Validation Assessment				
Occurrence Reporting(ORPS)								
High	ORT Tool	55 Business days	55 calendar days	Qualified Lead Assessor	Corp. Sr QCA	Lab Wide or Intra Division	Required	Required
Low	ORT Tool	14 Business days	21 Calendar days	Issue Owner or Appointee	Issue Owner or Appointee	Local	Required	Recommended
Informational	ORT Tool	14 Business days	21 Calendar days	Issue Owner or Appointee	Issue Owner or Appointee	Local	Required	Optimal
NOTE	ORT Tool	14 Business days	21 Calendar days	Issue Owner or Appointee	Issue Owner or Appointee	Local	Required	Optimal
SIMP								
CAT A	SIMP Tool	30 calendar days	As needed	Qualified Lead Assessor	Corp. Sr QCA	Lab Wide or Intra Division	Required	Required
CAT B	SIMP Tool	As required	As needed	Issue Owner or Appointee	Issue Owner or Appointee	Local	Required	Recommended
Internal Audit								
High	1 day	30 Business days	90 Calendar days	Qualified Lead Assessor	Corp. Sr QCA	Lab Wide or Intra Division	Required	Required
Moderate	1 day	30 Business days	60 Calendar days	Qualified Lead Assessor	QCA	Lab Wide or Intra Division	Required	Recommended
Low	1 day	14 Business days	21 Calendar days	Issue Owner or Appointee	Issue Owner or Appointee	Local	Required	Optimal
Other								
High	1 day	30 Business days	90 Calendar days	Qualified Lead Assessor	Corp. Sr QCA	Lab Wide or Intra Division	Required	Required
Moderate	1 day	30 Business days	60 Calendar days	Qualified Lead Assessor	QCA	Lab Wide or Intra Division	Required	Recommended
Low	1 day	14 Business Days	21 Calendar days	Issue Owner or Appointee	Issue Owner or Appointee	Local	Required	Optimal
Problem and Process Improvement								
Find and Fix	See LOS – Problem Solving and Continuous Improvement			Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Mgmt Surveillance								

Perform Causal Analysis

Why Causal

Identify why the Issue occurred

- The factors that resulted the Issue
- The magnitude of the Issue
- The location of the Issue
- The timing of the harmful outcomes of one or more past events
- Determine what behaviors, actions, or conditions leading to the cause of the Issue

When Causal is Needed

Significance Levels

- Lower than Low - Find and Fix. No Causal required
- Low - Use the “Five Why” method to determine causes. If Apparent Cause, or likely cause, then document the cause(s)
- Moderate - Use a **qualified Causal Analyst** to facilitate a Causal
- High - Use a **qualified Senior Causal Analyst** to facilitate a Causal. Use at least two causal analysis methods to determine cause(s)

Causal Methods

- Five Whys
- Failure Modes and Effects Analysis (FMEA)
- Timeline Analysis
- Change Analysis
- Barrier Analysis
- Cause Mapping
- Causal Factor Analysis
- Kepner-Tregoe Analytical Troubleshooting
- Human Performance Improvement (HPI) Analysis

Extent of Condition

- Determine if same Issue or condition exists elsewhere
- Examples of Extent of Condition
 - Same equipment in other areas

Develop Corrective Action Plan (CAP)

Implement Compensatory measure to correct the immediate issue

Define corrective actions to correct and prevent the causal factors

Define corrective actions to address the results of Extent of Condition

Determine the consequence of the risk if it occurs

Define actions to verify corrective action effectiveness and resolution of the issue

Define actions to validate the corrective action(s) have eliminated the issue

Review CAP with Stakeholders

Implement Corrective Action Plan

- Implement all corrective actions
- Ensure corrective action eliminates the cause(s) of existing Issue
- Ensure the corrective action eliminates the cause of a potential Issue, defect, or other undesirable situation to prevent occurrence
- Attach evidence of completed corrective actions
- Review the closure evidence for each action for completeness
- If there are any changes in corrective action, document the change

ESCALATE



Conduct Effectiveness Review

➤ Verification

- Evaluate if corrective actions have been completed as intended

➤ Validation

- Conduct Validation Assessment per plan
 - Observe work
 - Inspect Changes to equipment or facility
 - Assess whether the cause still exists
 - Chart Performance from problem identification to current time
 - Review records/data for occurrence of similar problems since last corrective action
 - Run a test to challenge the process
 - Interview managers and workers for consistency and correctness in their understanding of changes
- Validation must be conducted **between 90-360 days** after all corrective actions have been implemented

Close the Issue

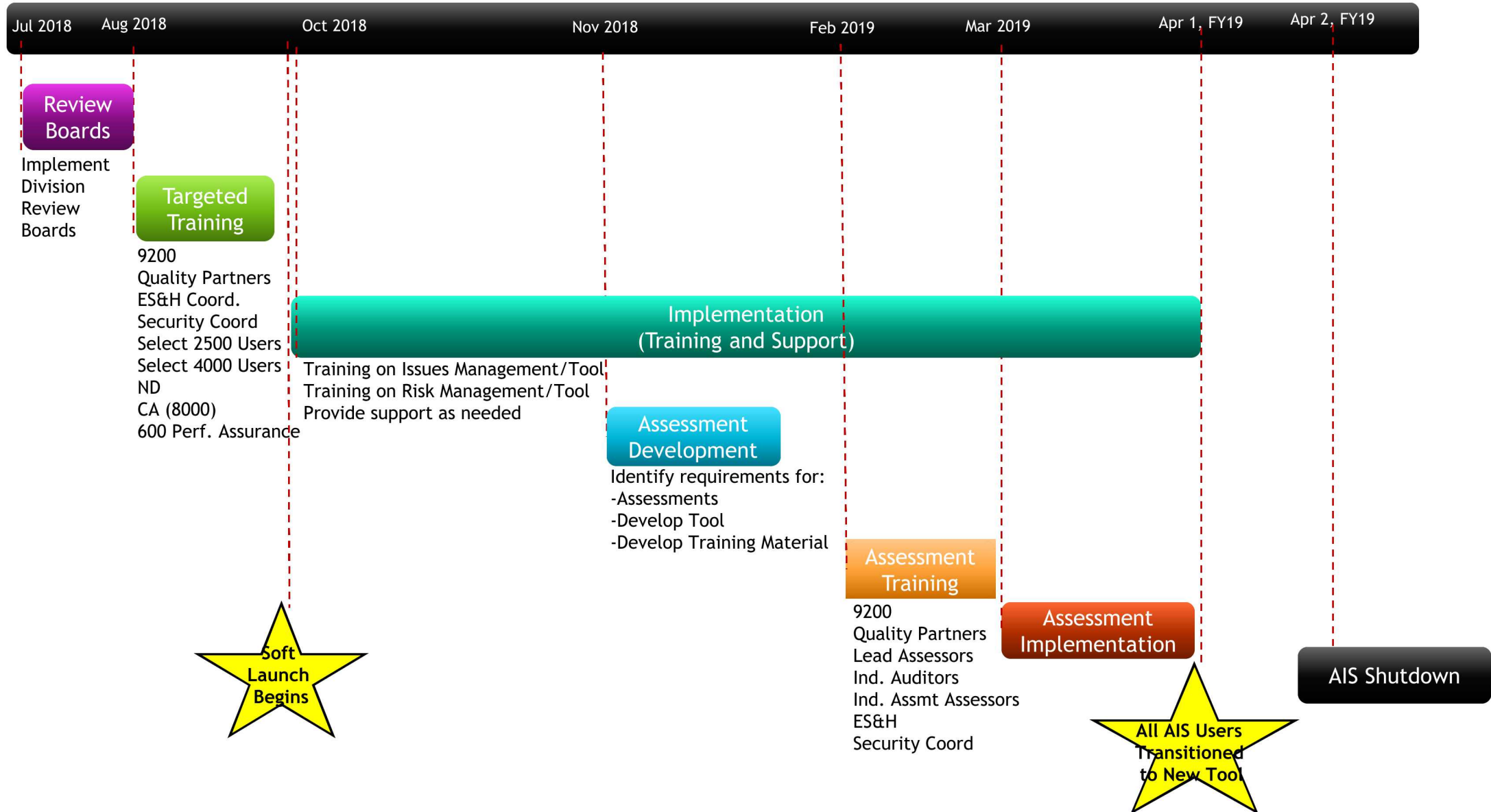
- Issue Owner and Responsible Manager review ALL information in Sage
 - Review closure of evidence
 - Close the record in Sage
- Monitor the Issue for a period of time through Assessments or performance metrics to ensure corrective actions are effective



Issues Management Improvement Activities

- Single process and tool
- Escalation process and criteria defined to request for support/guidance in managing the Issue
- Able to provide performance metrics (types of issues and systemic issues)
- Reports
 - Systemic Issues
 - Report by Categories by Organization
 - Aging Corrective Actions
 - Escalated Issues
 - Other reports as needed (based on feedback from the IM Working Group)

Implementation Timeline



Questions?