Closed-Loop Systems for Quality Management in an Environmental Laboratory

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Outline

1. Changes in an Environmental Lab
2. Opportunities and Challenges
3. Systematic Planning
4. Management of Change
5. Closed-loop Systems
6. Summary

Changes in an Environmental Lab

Regulatory

- Regulations
- Standards
- MCLs/DLs, etc.
- New/Updated Methods
- Guidance Documents
- Reporting Requirements

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Changes in an Environmental Lab

Operational

- Management
- Business Strategy
- Stakeholders
- Personnel
- Budget
- Supply Chain

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Changes in an Environmental Lab

Customer Driven

- Scope
- Methods
- Volume of Work
- Type of Work
- Notifications
- Reporting Requirements

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Changes in an Environmental Lab

Innovation

- LIMS
- Software
- Equipment
- Ideas
- Machine Learning
- Artificial Intelligence

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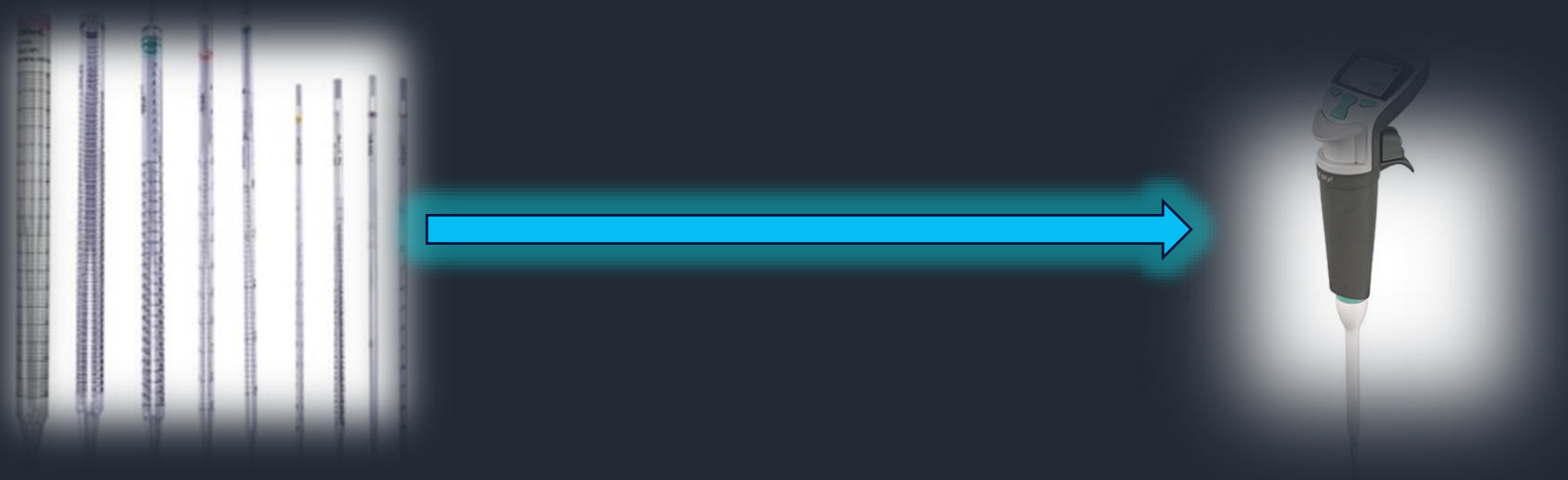
Example: Innovation in a Lab



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Example: Innovation in an Environmental Lab

In an Accredited Environmental Lab using an established Quality Management System, what steps are needed to adopt such change?

Planning for Change

- Where are we now?
- Where are we going?
- How do we get there?

Planning for Change

- Where are we now?
- Where are we going?
- How do we get there?

Planning for Change

- Where are we now?
  - Check current reality
    - Resources
    - Workload
    - Level of Service
    - Risk Analysis

Planning for Change

Strategic Approach

- Big Picture
- Goals and Objectives
- Risk Analysis
- Key Process Indicators
- Resource Allocation

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Systematic Approach

- Plan for Execution
- Technical Processes
- Communication
- Data Analytics
- Improvement Opportunities

Planning for Change

- Strategy: Begin with the end in mind

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Planning for Change

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Planning for Change

Begin with the end in mind

Match initiatives with current reality

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Prepare for the change: share the plan with internal and external stakeholders, as applicable

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Evaluate Stakeholder Feedback: Negative and Positive

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Planning for Change

Begin with the end in mind

Match initiatives with current reality

Prepare for the change: share the plan with internal and external stakeholders, as applicable

Implement the change

Evaluate Stakeholder Feedback: Negative and Positive

Review progress and analyze results

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Planning for Change

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Identifying Loops and Challenges

- Quality Management System in an environmental lab is:
  - A complex, structured framework
  - Quality elements in one process are linked to another

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Identifying Loops and Challenges

- Quality Management System in an environmental lab is:
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  - Quality elements in one process are linked to another

- Operational challenge in implementing change:
  - Incorporating change while routine work is being completed.

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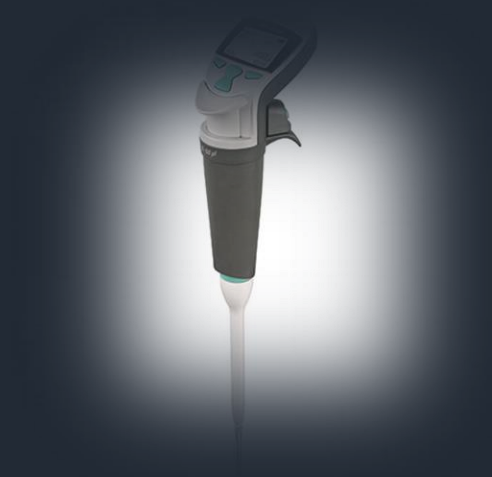
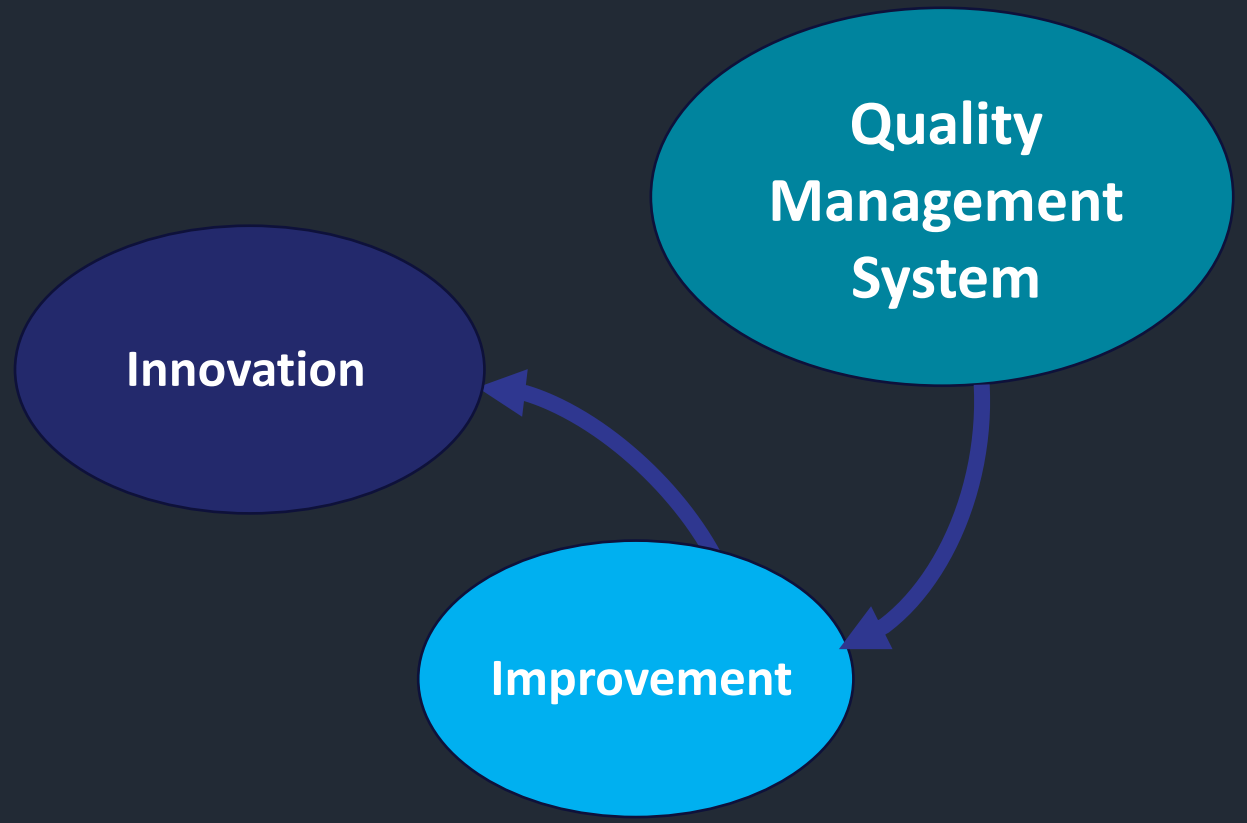
Identifying Loops

- A robust Quality Management System contains many loops
- Let’s review the process for implementing a change to a new type of pipet..



Closed-Loop System - Improvement



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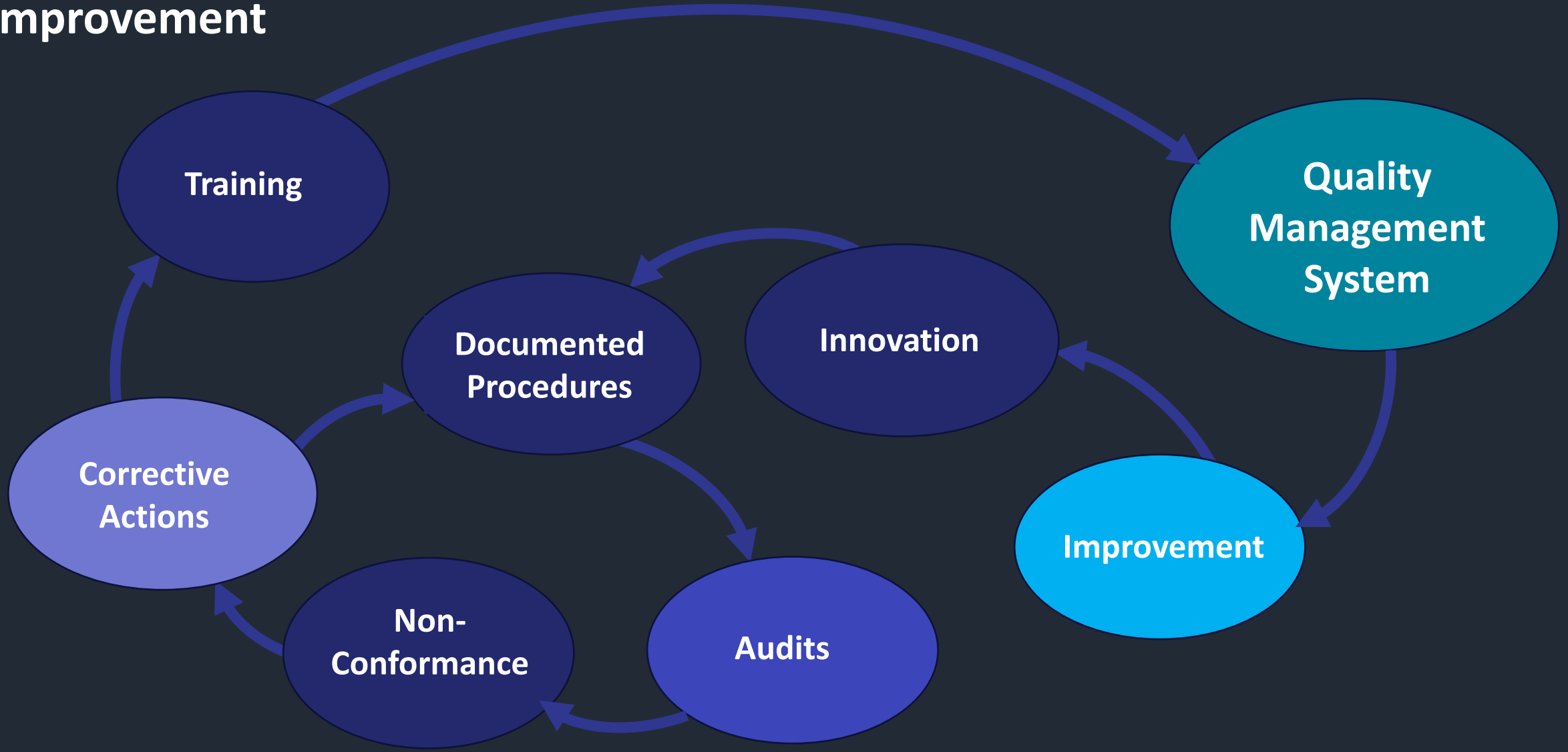
*Example of a closed-loop process

Closed-Loop System - Improvement



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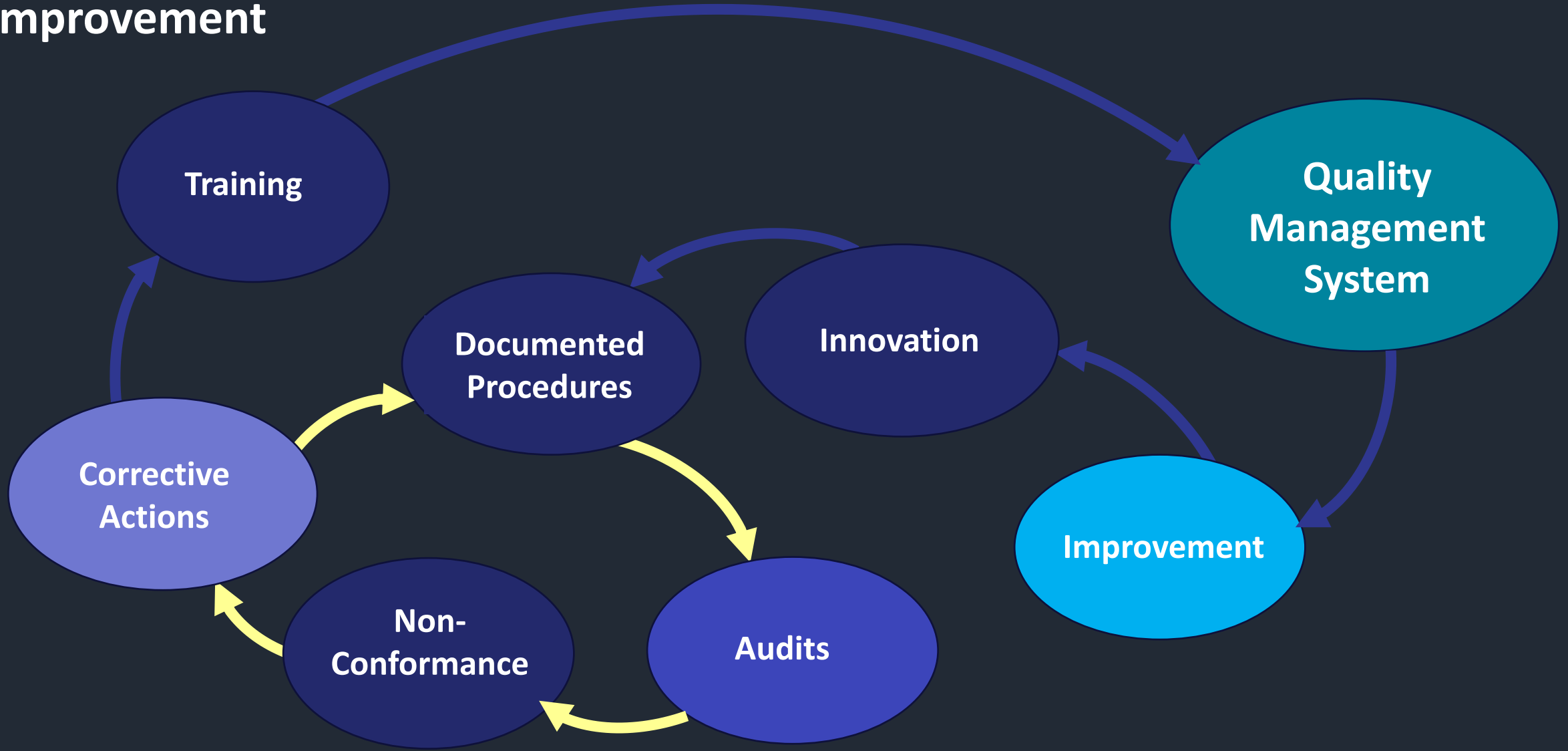

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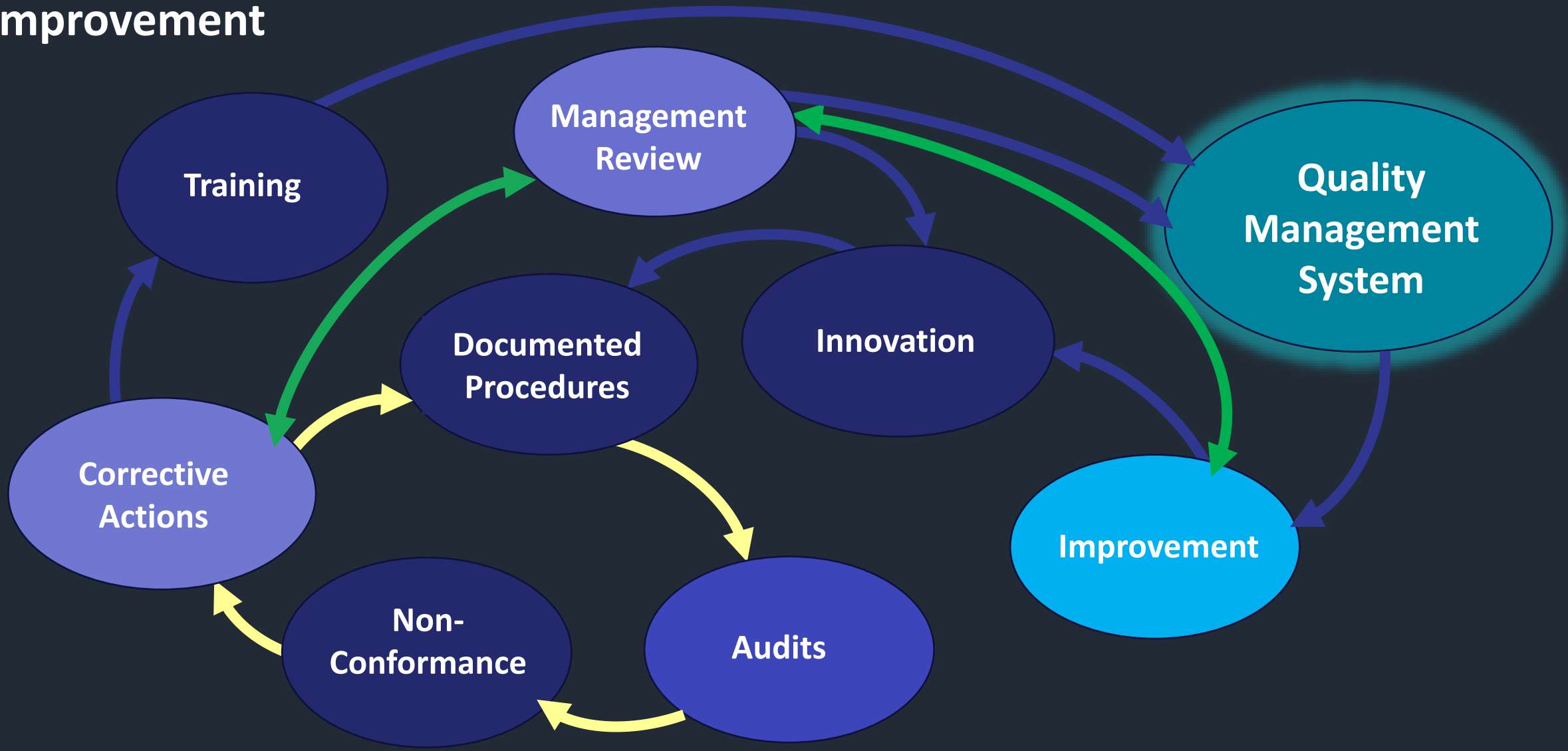

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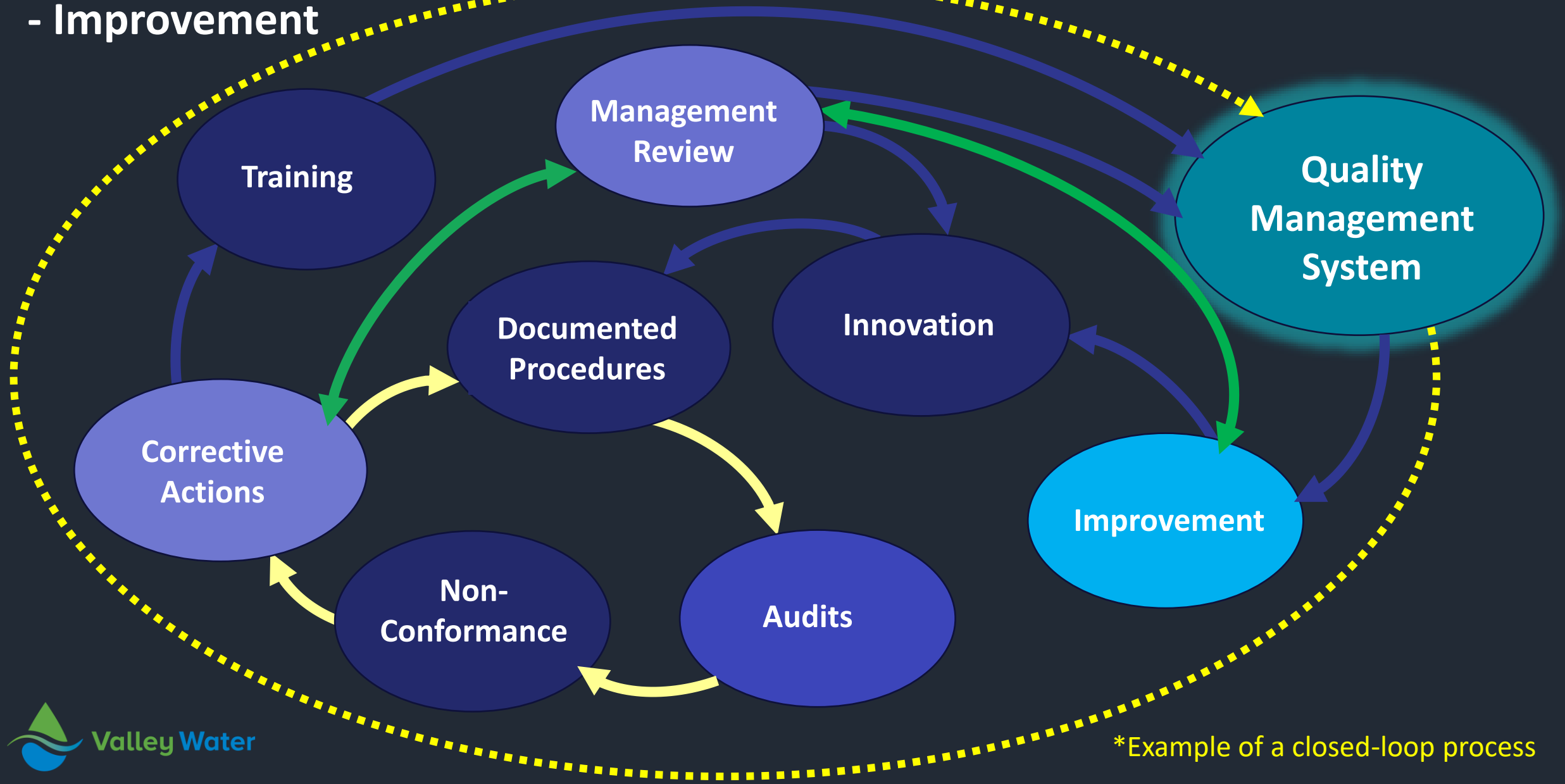

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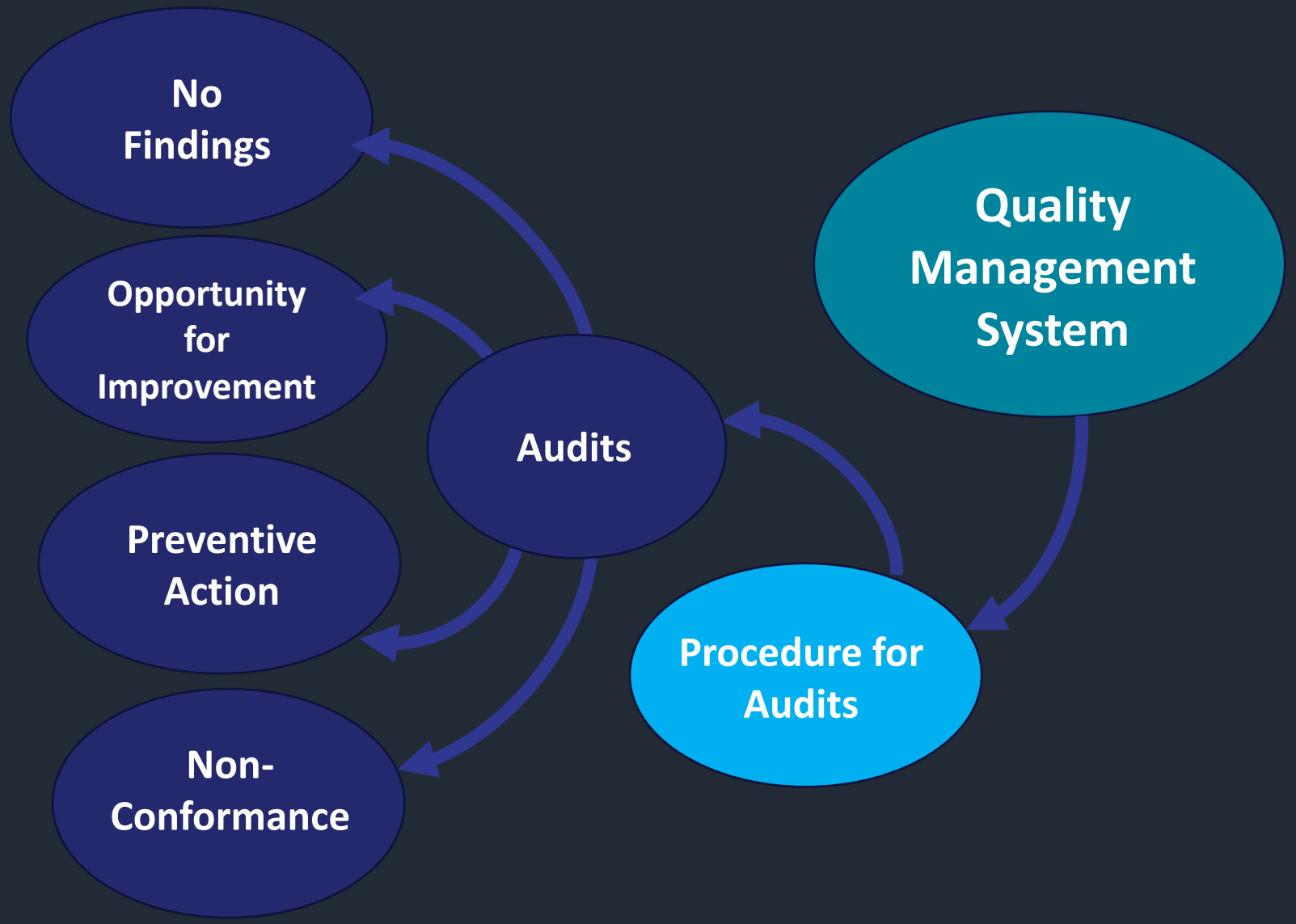
Closed Loop System - Audits

Scenario from audit process… Let’s review

Closed-Loop System - Audits



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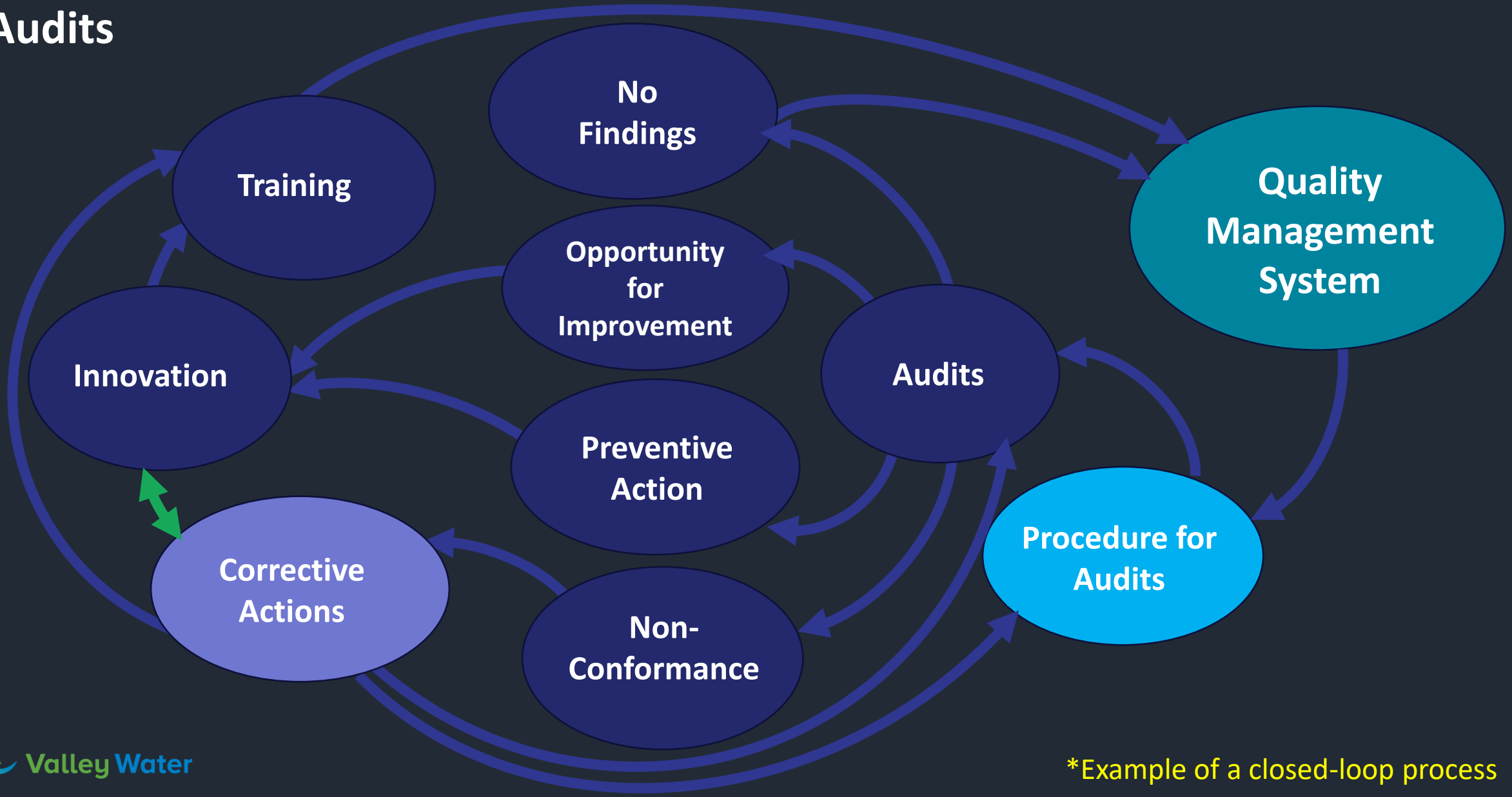
Closed-Loop System - Audits



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*Example of a closed-loop process

Closed Loop System - Audits

Scenario from an internal audit:

"…..Review time of revised standard operating procedures can be reduced if there was a way to compare the previous version with the revised copy."

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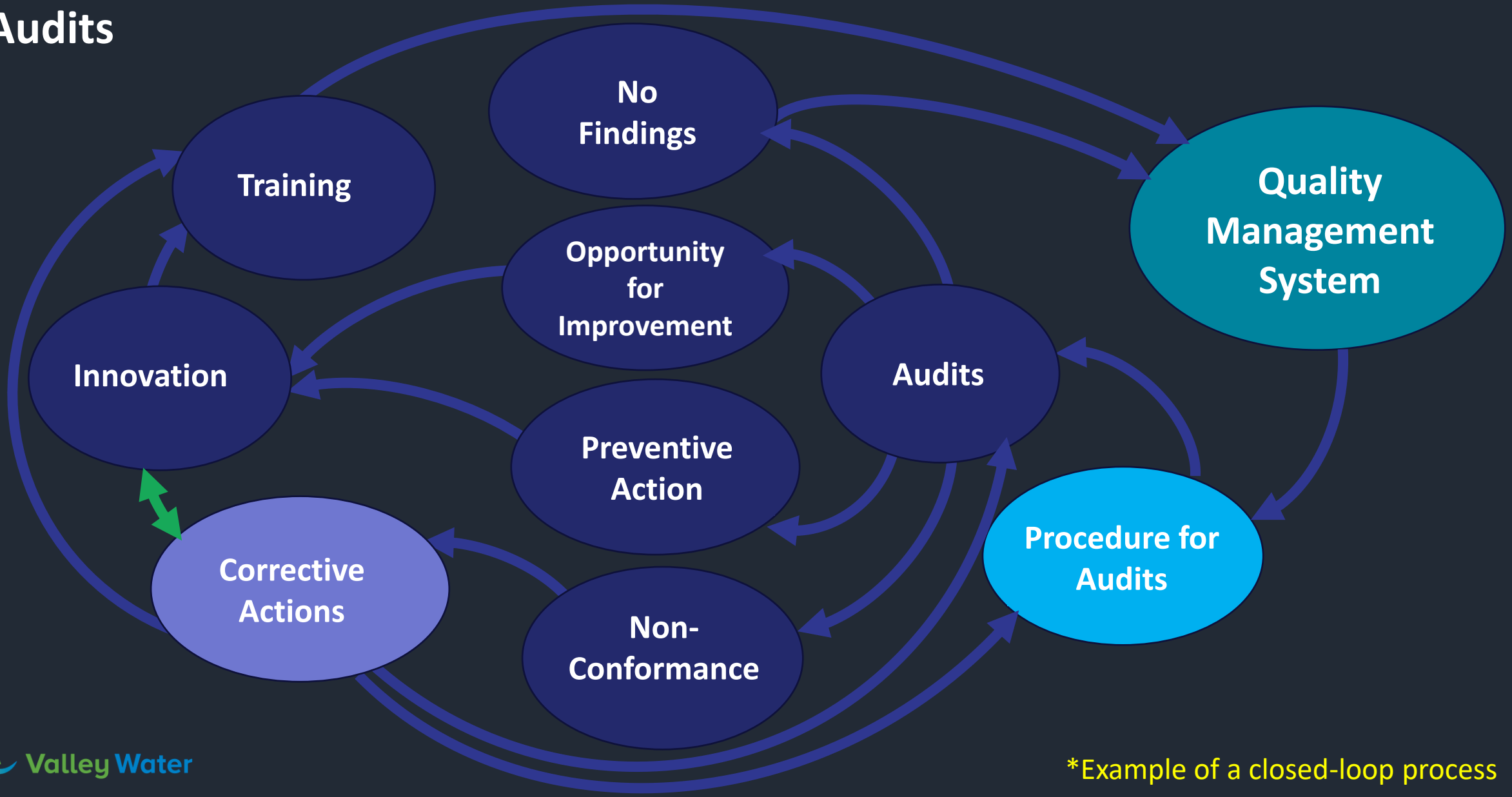
Closed-Loop System - Audits



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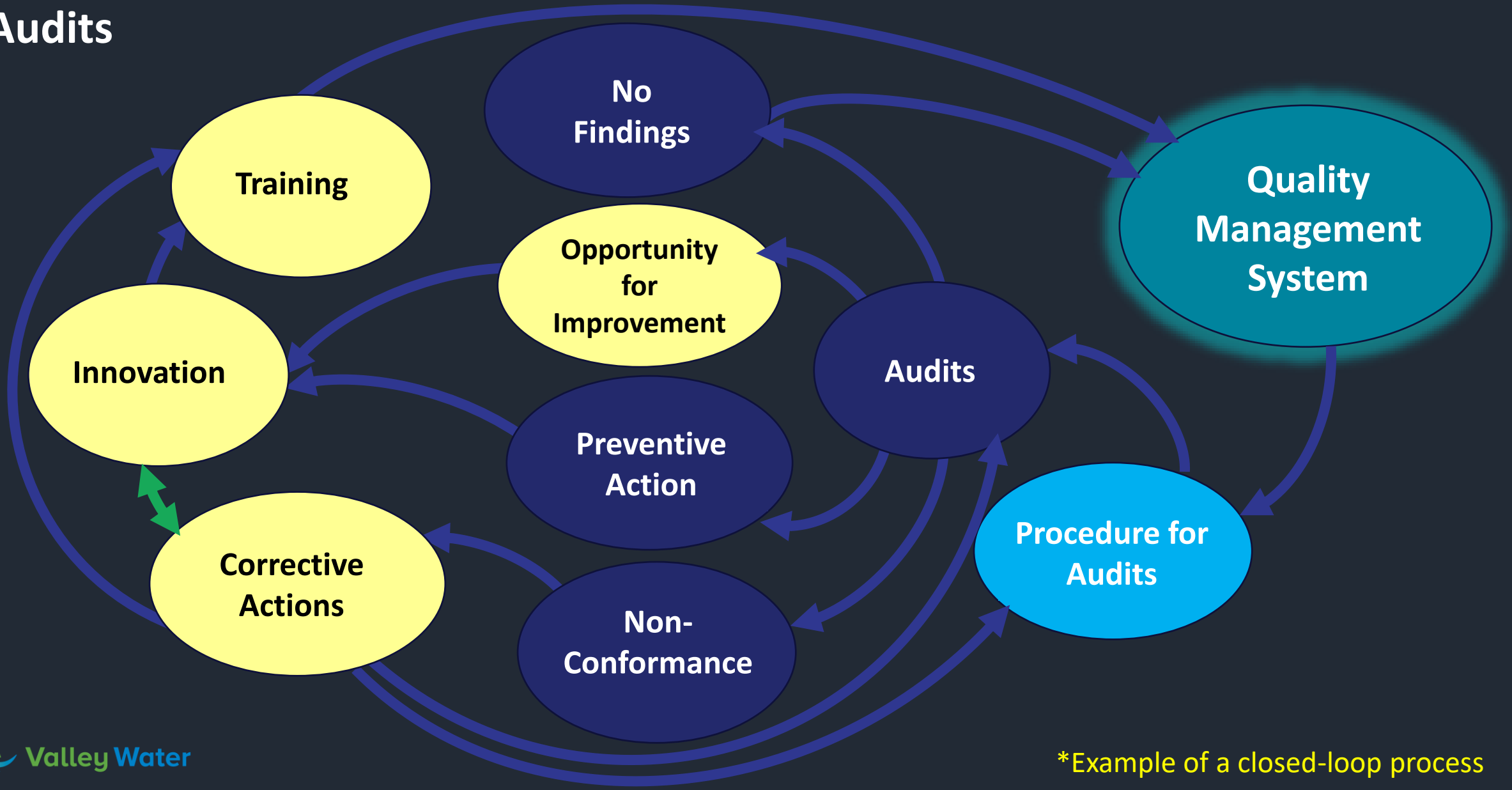

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Closed-Loop System - Audits

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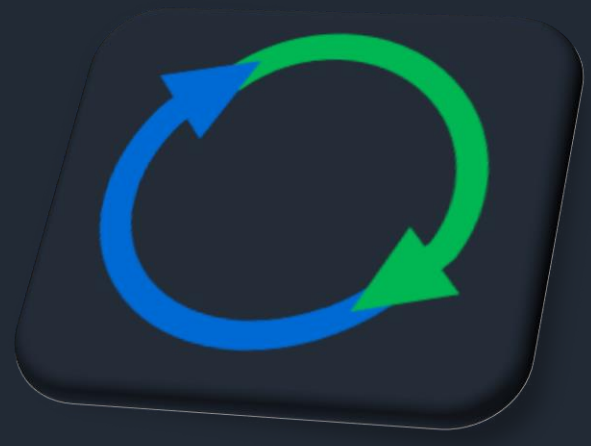
*Example of a closed-loop process

Summary

- Closed loop quality management provides:
  - Improved quality
  - Increased efficiency
  - Consistency
  - Fewer non-conformances
  - Continual improvement
  - Clear direction with staff
  - Conformance with regulatory requirements



Conclusion

- Systematic planning helps to:
  - Identify interconnectivity of processes
  - Set clear expectations
  - Ensure informed decision-making
  - Achieve efficiency and cost savings
  - Attain higher rate of success
  - Improve documentation
  - Promote teamwork and inclusivity
  - Establish culture of continual improvement

Systematic planning establishes a framework that is synchronous and sustainable.

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QUESTIONS