How to Perform an Internal Audit

Presented by Erin Hohman

Internal Audits

- Review of policies and procedures to identify any inconsistencies and to ensure the lab has quality systems in place, follows good laboratory practices, and generates quality data
- Evaluation of all steps in the path of workflow to identify any problems throughout the entire process

Internal Audits

- Ensure that lab has documented procedures and is following them
- Ensure that lab procedures meet regulatory requirements
- Increase staff awareness of QA requirements and identify areas where additional training is needed

Internal Audits

- Evaluate performance and determine if there are areas that can be improved
- Help the lab prepare for the accreditation process
- Allow the lab to find and correct any deviations before an external audit

Internal Audits

- Prepare
- Conduct
- Summarize
- Correct
- Evaluate

How to Prepare for an Internal Audit

Determine Audit Frequency

- Should be included in the lab QA manual
- Typically recommended that internal audits be performed at least once per year
- More frequent audits may be needed if
  - New staff, equipment, or methods are employed
  - There are perceived risks to data quality
  - Lab receives customer complaints

Define the Audit Purpose

- Meet regulatory or customer requirements
- Prepare for accreditation or external audit
- Respond to a complaint or issue
- Respond to an accident or injury

Define the Audit Scope

- Processes and SOPs
- Staff competence and training
- Equipment
- Environment
- Handling of Samples
- Quality control and verification of results
- Recordkeeping and reporting practices
- Safety

Define the Audit Scope

- Scope of audit may be determined by resource limitations
- Determine which areas are the most critical or highest risk by reviewing any previous audit results and corrective actions

Determine Audit Resources

- How many people are available or needed to perform the audit
- How much time is available to dedicate to the audit
- Is there room in the budget to hire an auditor if needed

Select the Audit Team

- Determine what special skills or knowledge might be needed to efficiently and effectively handle the scope of the audit
- Make sure auditors have a good understanding of the lab's quality system, standard operating procedures, and processes

Select the Audit Team

- Ensure that auditors are objective, able to pay attention to details, and able to communicate effectively
- Auditors need to be independent of the area being audited

Develop Written Checklists

- Develop a technical understanding of areas to be audited
- Review established policies and standards
  - ISO requirements
  - EPA requirements
  - Specific EPA or Standard Method methods

Develop Written Checklists

- Should be easy to use and include areas for recording comments
- Typically focus on specific tests or processes and address all areas of the quality system for that test or process

Written Checklists

- Should have a cover page which includes
  - Auditor's name
  - Auditor's signature
  - Date of audit
  - Date audit is completed

Sample Refrigerators		Compliance		
Criteria	Requirement	Y	N	N/A
Temperature recordkeeping	• Temperature log (thermometer accurate to 0.5°C)			
Temperature Calibration/ Documentation	• Thermometer calibrated annually with NIST traceable thermometer			
	• Thermometer labeled with calibration date and correction factor			
Other	• Thermometer held in water bath			
	• Refrigerator temperature ≤6°C			
	• Do not store solvents, food, or beverages			
Comments:				

Balances					
Criteria	Requirement	Compliance			Comments
		Y	N	N/A	
Calibration	• Serviced and recalibrated annually by manufacturer or comparable company				
Calibration Verification	• Performed at least once each day the balance is used				
	• Performed using NIST Class S or ASTM/ANSI Class 1 weights				
	• Weights are within acceptance limits				
Other	• Balance is kept clean, and air movement and vibrations are kept to a minimum				
	• Log book is maintained				

Chlorine					
Criteria	Requirement	Compliance			Comments
		Y	N	N/A	
Training	• Each approved analyst has read the SOP				
	• Each approved analyst has performed an IDOC				
	• Each approved analyst is able to perform a calibration				
Reagents/ Standards	• Correct reagents/standards are being used				
	• Reagents/standards properly labeled				
	• Reagents/standards are within expiration date				
Calibration	• Meter is calibrated quarterly				
	• Calibration has a range of 5 points				
	• Calibration is recorded in the instrument logbook				

Checklist Resources

- OEPA Laboratory Manual for Chemical Analyses of Public Drinking Water
  - https://epa.ohio.gov/portals/28/documents/labcert/CHEMMAN%202014_final.pdf
- USEPA Manual for the Certification of Laboratories Analyzing Drinking Water
  - https://www.epa.gov/dwlabcert/laboratory-certification-manual-drinking-water
- General Lab Criteria Form
  - https://www.epa.ohio.gov/dsw/permits/General_Lab_Criteria_Inspection_Forms

Audit Preparation

- Let everyone involved in the audit know what areas will be audited and provide a tentative schedule
  - Allows staff to make sure they will be available to participate in the audit
  - Allows staff to work out any logistics and acquire any needed documents in advance

How to Conduct an Internal Audit

Audit Process

- Remain objective
  - Purpose of the audit is to identify areas that need to be approved not “catch someone in the act”
- Remain honest
  - There is no benefit to the lab if the employee or auditor omits information or disregards a nonconformance

Audit Process

- Perform an initial evaluation of documents including training records, data/bench sheets, SOPs, MDL studies, instrument logbooks, and temperature logs

Audit Process

- Perform direct observations of the staff doing specific tasks
- Ask open ended questions
  - Ask staff to explain what they're doing or why they're doing steps in a certain order
  - Note any questions that the employee is not able to answer
- Record any questions that come up that aren't on the audit checklist

Audit Process

- Document any discrepancies or possible issues on the checklists
  - Be as specific as possible to help make corrective actions easier
  - Discuss issues with staff as they're identified so they have an opportunity to clear up any confusion or locate additional records that are missing
- Document any good lab practices that should be praised

Sample Refrigerators		Compliance		
Criteria	Requirement	Y	N	N/A
Temperature recordkeeping	• Temperature log (thermometer accurate to 0.5°C)	√		
Temperature Calibration/ Documentation	• Thermometer calibrated annually with NIST traceable thermometer	√		
	• Thermometer labeled with calibration date and correction factor	√		
Other	• Thermometer held in water bath	√		
	• Refrigerator temperature ≤6°C		√	
	• Do not store solvents, food, or beverages	√		
Comments: Thermometer in fridge read 9°C.				

Sample Refrigerators		Compliance		
Criteria	Requirement	Y	N	N/A
Temperature recordkeeping	• Temperature log (thermometer accurate to 0.5°C)	√		
Temperature Calibration/ Documentation	• Thermometer calibrated annually with NIST traceable thermometer	√		
	• Thermometer labeled with calibration date and correction factor	√		
Other	• Thermometer held in water bath	√		
	• Refrigerator temperature ≤6°C	√	X	ELH 5/10/21
	• Do not store solvents, food, or beverages	√		
Comments: Thermometer in fridge read 9°C. Fridge door was left open while samples were being put away right before the temperature was checked. The fridge door was shut, and the temperature was read 15 minutes later. The temperature had returned to ≤6°C.				

How to Summarize Audit Findings

Audit Summary

- Review checklists to make sure all areas have been completed
- Determine if additional information or questioning is needed

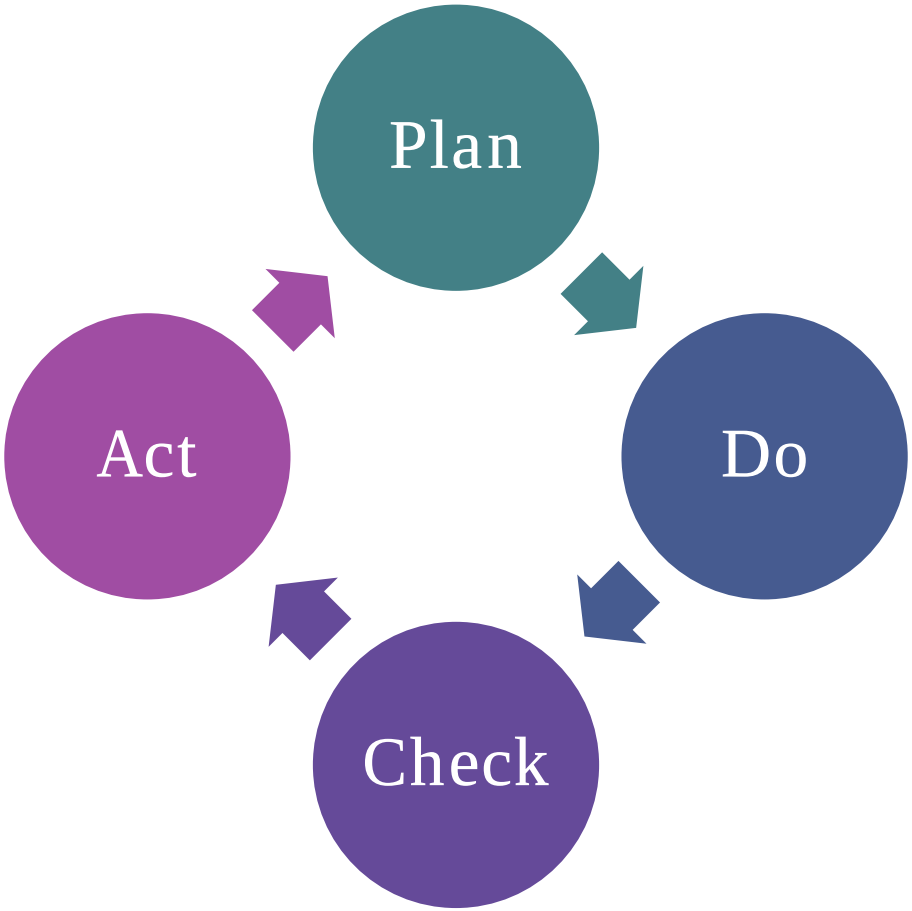
Audit Summary

- Make a list of all the deviations noted during the audit
- Group similar findings together to identify systemic problems
- Rank issues by risk severity to know where to focus improvement efforts first

Audit Summary

- Summarize audit findings in a written report
- Share with QA manager and/or senior management
- Review findings with lab staff
  - Explain what deviations occurred
  - Provide positive feedback

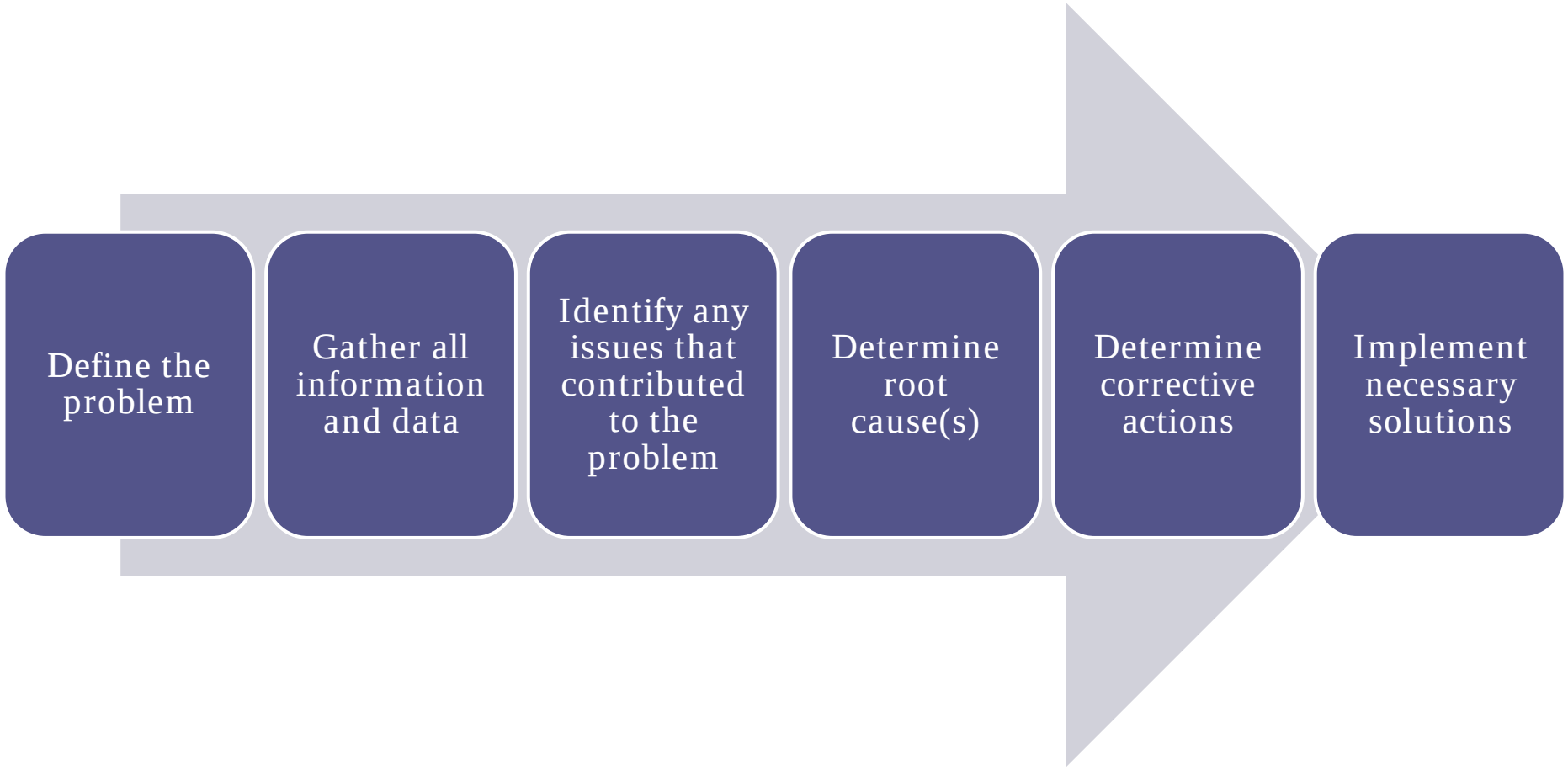
How to Correct Deviations



Corrective Actions

- Any deviations identified in the audit should be assigned a corrective action
- Assign each corrective action to a designated person and determine an expected date of completion
- Designate who will be responsible for making sure the plan is successfully implemented

Corrective Actions



Corrective Actions

- Perform a root cause analysis for each deviation to identify why the issue happened and determine how best to correct it and keep it from happening again

Root Cause Analysis

- List all possible causes of the deviation
- Distinguish between root causes and causal factors
- Test each possible root cause to find which one is the most likely

5 Whys

- Determine the root cause by repeatedly asking “Why?”
  - Ask why the problem happened and record the answer
  - If the answer doesn’t identify the root cause, then ask “Why?” again
  - Continue the process until the root cause is identified

Problem: The thermometer in the TDS oven isn't labeled

Why?
- It hasn't been calibrated

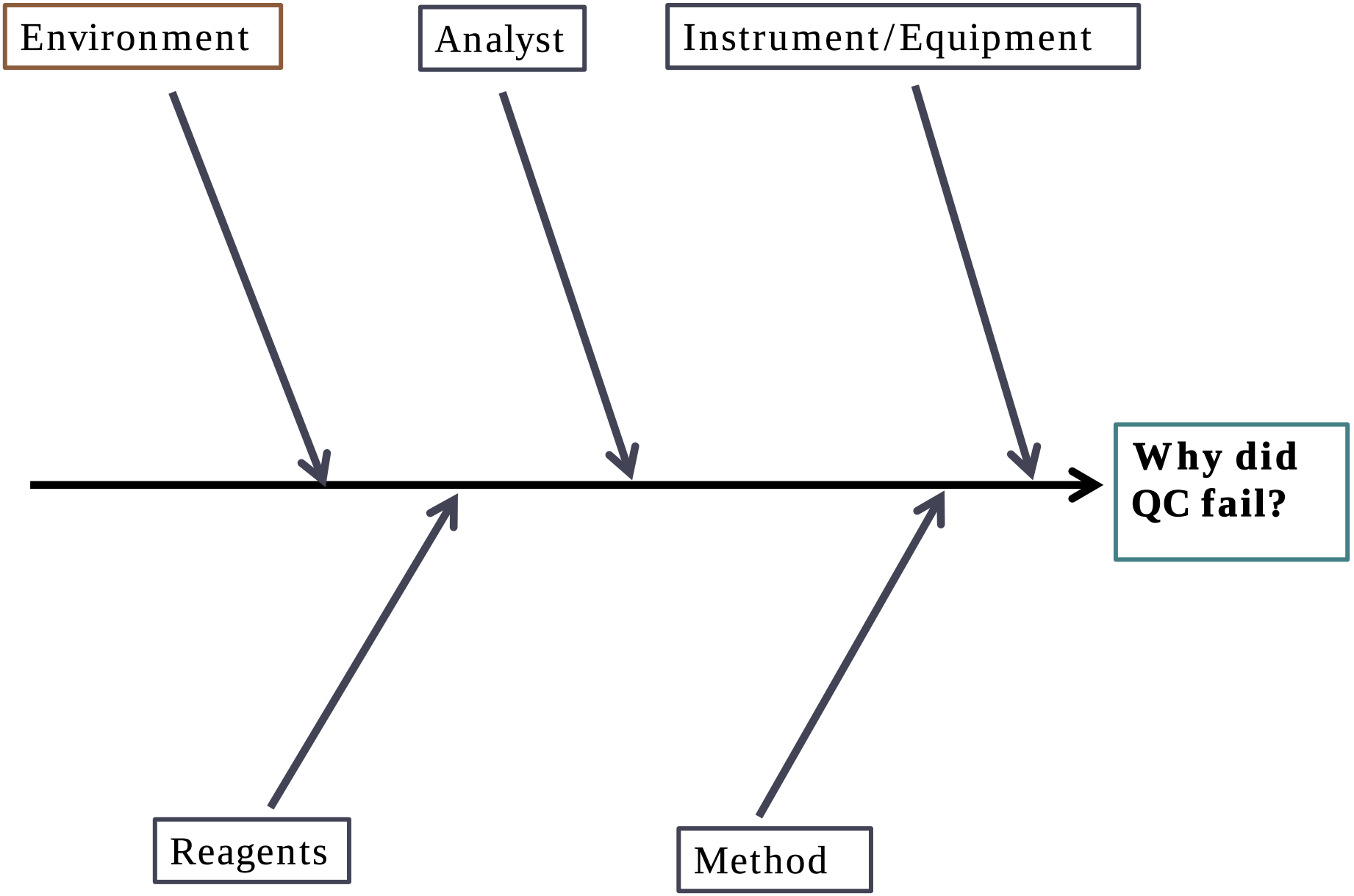
Why?
- It wasn't on the list of thermometers to be calibrated

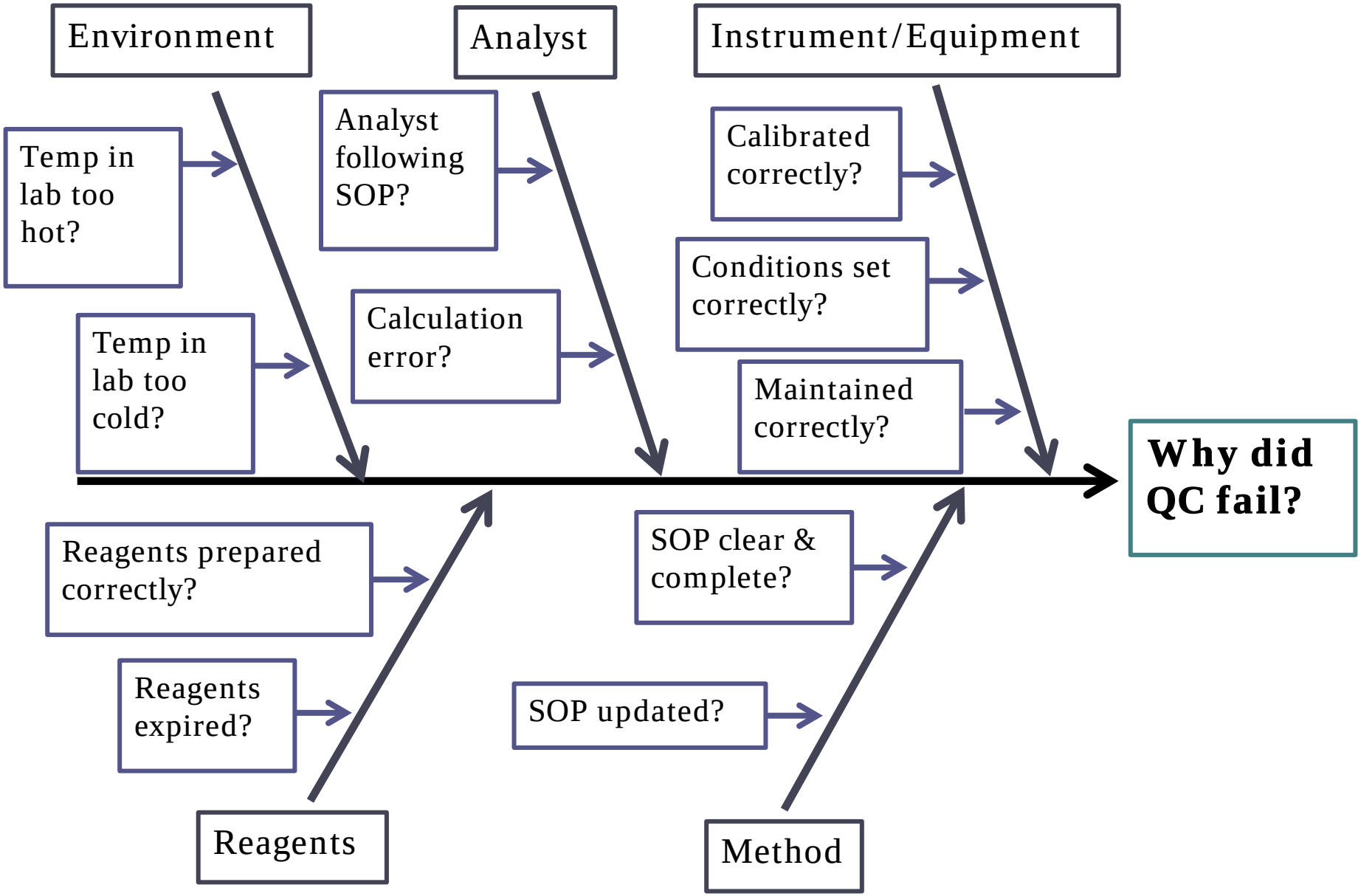
Why?
- QA manager wasn't notified that the old thermometer had broken and was replaced with a new one

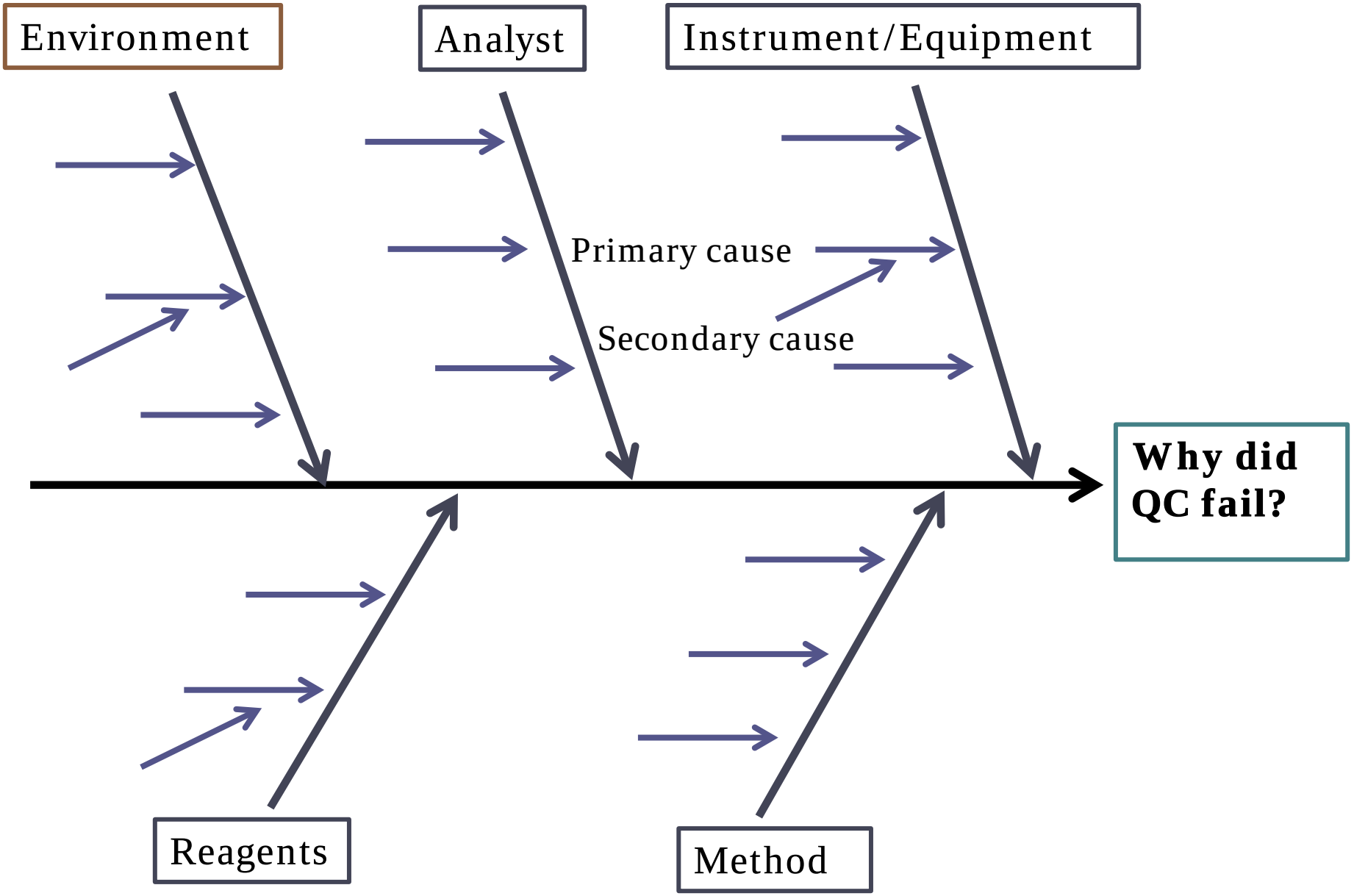
Why?
- Analyst did not know that the QA manager needed to be notified

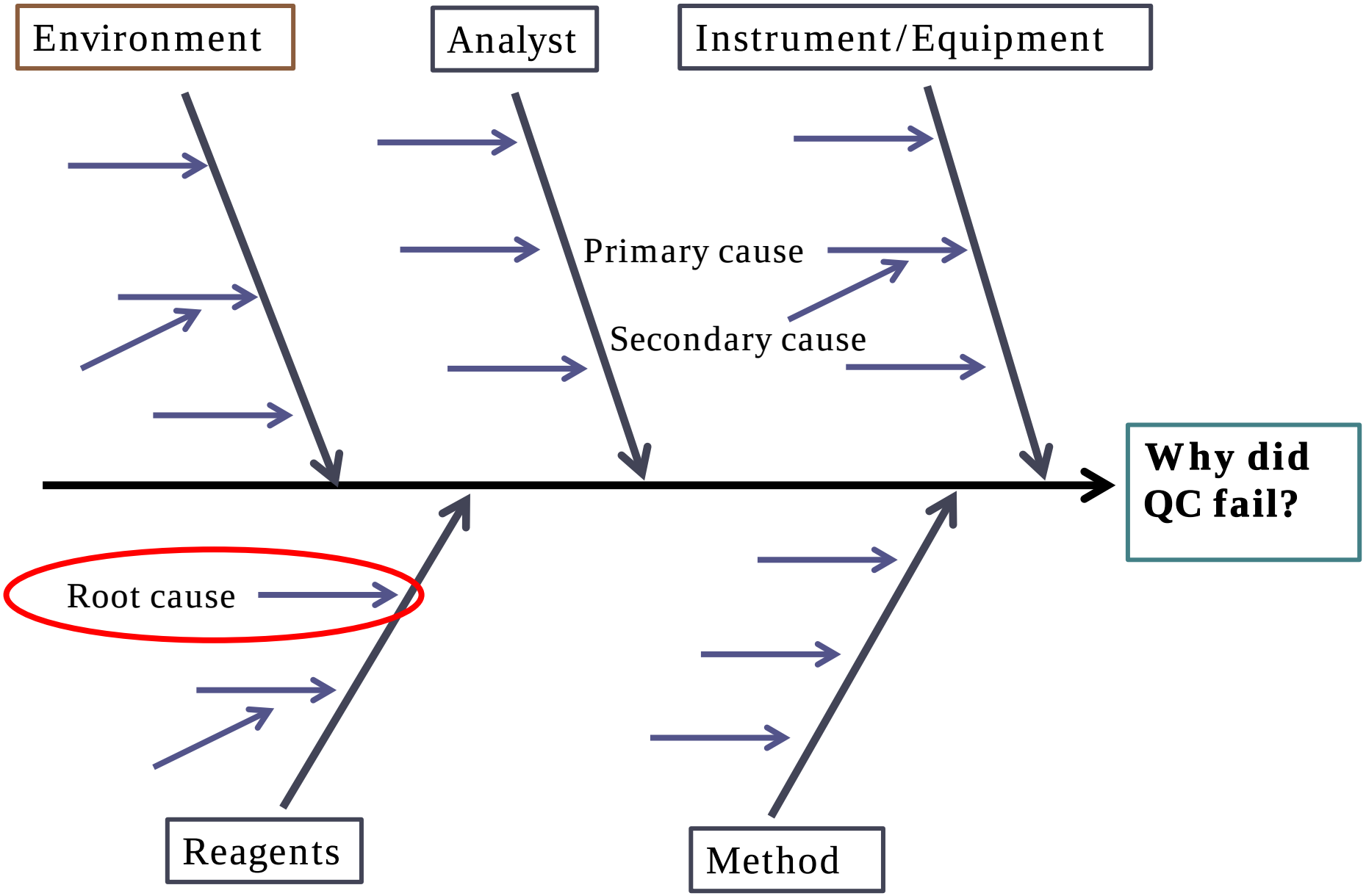
Fishbone Diagram

- Visually map cause and effect to help identify possible root causes
- Follow branched paths to potential causes until you find the correct one


Environment
Analyst
Instrument/Equipment
Why did QC fail?
Reagents
Method


Environment
Analyst
Instrument/Equipment
Temp in lab too hot?
Temp in lab too cold?
Analyst following SOP?
Calculation error?
Calibrated correctly?
Conditions set correctly?
Maintained correctly?
Why did QC fail?
Reagents prepared correctly?
Reagents expired?
Reagents
SOP clear & complete?
SOP updated?
Method


Environment
Analyst
Instrument/Equipment
Primary cause
Secondary cause
Why did QC fail?
Reagents
Method


Environment
Analyst
Instrument/Equipment
Primary cause
Secondary cause
Why did QC fail?
Root cause
Reagents
Method

Corrective Actions

- Once root causes are identified, recommend an appropriate corrective action
- Implement the decided upon action and check to see if it's effective
- Continue to monitor over time

Corrective Actions

- Keep written documentation for each corrective action
- Document should
  - Describe the deviation
  - Describe the root cause
  - Outline the plan to correct the deviation
  - Describe if it was effective and how it was measured

Corrective Action No. 2021-03

Date Initiated: 03/08/21

Corrective Action Assigned to: Analyst 1, Analyst 2, Lab Manager

Completion Due Date: 3/19/2021

	Signature	Date
Analyst 1		
Analyst 2		
Lab Manager		

Corrective Action 2021-03 Description

Failed PT for Turbidity

Turbidity by EPA method 180.1
Assigned Value = 289 NTU
Reported Value = 335 NTU
Acceptance Range 246 - 333 NTU

Corrective Action 2021-03 Procedures

1	Analysts and Lab Manager to meet to discuss corrective action
2	Analyst 1 to review procedures and follow root cause diagram to determine why the PT standard failed and was reported as unacceptable.
3	Lab Manager to order a Rapid Return Standard
4	Analyst 1 to analyze Rapid Return PT and Lab Manager to report to Phenova.
5	Lab Manager to report completed Corrective Action and supporting documentation.

Corrective Action 2021-03 Actions Taken

Based on the root cause analysis (see attached) it was determined that the turbidity PT result was reported high due to dirty glassware. One of the three tubes used to measure turbidity is discolored and scratched. When tested with lab DI water, this tube read 10 NTU higher than the rest. We were unable to remove the discoloration by washing the tube. Lab manager ordered new tubes and a rapid return PT. The PT was analyzed using the new tubes, and the result was graded as acceptable.

Action Closed(QA): _____ Date: _____

How to Evaluate Audit Success

Evaluate the Audit

- The success of an internal audit will depend on
  - Adequate preparation
  - Precise performance
  - Detailed documentation
  - Productive follow up
  - Commitment of lab leadership to implement and sustain corrective actions

Evaluate the Audit

- Auditors should request feedback on the audit process
- Auditors should review the checklists to determine if any items are missing or should be removed
- Determine if changes need to be made to the audit team for next time

Evaluate the Audit

- Auditors should compare results with previous audits if possible to determine if there's been improvement

Contact Information

- Erin Hohman
  - 740-389-5991
  - erin.hohman@alloway.com
  - www.alloway.com

Alloway®
Your Resource for Defensible Data

Questions?