QA/QC Requirements in Environmental Laboratories

Presented by: Erin Hohman

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Quality Management

- **Quality is everyone's business**
- **Quality requires commitment**
- **Essential to all laboratory testing processes**
  - Ensures that the data generated is accurate and precise
  - Provides customers, regulators, and the community with confidence regarding test results

Quality Assurance

- **A broad plan for maintaining quality in all aspects of the laboratory**
  - Planning
  - Quality control
  - Quality assessment
  - Reporting
  - Quality improvement
- **Pro-active and process-oriented**

Quality Control

- Only one part of quality assurance
- The specific steps taken to ensure that the quality assurance methods are functional and the data is valid
- Reactive and product-oriented

QA vs. QC

	Quality Assurance	Quality Control
Employee Training	Staff are properly trained in lab procedures.	• Complete training checklist. • Read & understand SOPs. • Perform Initial Demonstration of Capability.
Equipment	All equipment is calibrated using controlled standard solutions.	• Set limits on calibration results. • Establish corrective actions for failed calibrations.
SOPs	Staff are following Standard Operating Procedures for each task.	• Provide a SOP for every procedure. • Make sure they're well organized and clearly written. • Make SOPs available to all employees. • Keep SOPs as controlled documents.

Certifications & Accreditations

- **State Agencies**
  - Drinking water
  - Waste water
  - Bacteriological and chemical
  - VAP
- **A2LA**
- **NELAP**
- **Industrial Programs**
- **ISO**

Quality Systems Requirements

- **ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories**
  - General requirements
  - Structural requirements
  - Resource requirements
  - Process requirements
  - Management system requirements

Quality Systems Requirements

- Quality system
- Defined laboratory purpose
- Personnel
- Physical facility
- Equipment and reference materials
- Measurement traceability and calibration
- Test methods and standard operation procedures
- Sample handling, sample acceptance policy, and sample receipt
- Records
- Laboratory report format and contents

Quality Systems Requirements

- Subcontracting
- Outside support services and supplies
- Complaints
- Internal audits
- Instrument calibration
- Methods documentation
- Demonstration of capability
- Documentation and labeling of standards and reagents
- Statistical controls
- Document controls

Quality Systems Requirements

- **Quality Assurance Manual**
  - Addresses every QA/QC requirement and process for the lab
    - Sampling
    - Sample receipt
    - Analysis
    - Reporting
- **Quality Assurance Officer**
  - Investigates and sets the standards for quality, health, and safety in the lab
  - Ensures that lab practices and data comply with quality standards

Training

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Training

- **Key to producing quality work**
- **Training should be:**
  - Structured
  - Consistent
  - Documented
  - Ongoing

Training

- **Ethics**
  - Ethical behavior and ethical issues that may occur in the laboratory
  - Expectations of employees and management
  - Process for reporting unethical behavior
  - Possible impacts of and punishments for unethical behavior

Training

- **General Laboratory Practices**
  - Laboratory safety
  - QA/QC manual
  - Standard Operating Procedures
  - Logbook use
  - Glassware cleaning and preparation
  - Pipet use

Training

Sample Handling

- Sample bottle preparation
- Preservation
- Holding times
- Sample log-in
- Chain of custody
- Sample retention and disposal

Training

- **Analytical Methods**
  - Read and understand SOPs
  - Training performed by an experienced analyst
  - Demonstrate proficiency (IDOC/ODOC)
    - Analyze a “blind” test sample
    - Analyze 4 control samples and meet set accuracy (%R) and precision (%RSD) limits

Training

- **Data Handling**
  - Bench sheets
  - Data sheets
  - Standard curves
  - Manual integrations
  - Logbooks
  - QC data

Training

- **Documentation**
  - Checklist
  - Training logs
    - Activity
    - Date
    - Trainer
  - SOP documentation forms
  - IDOC/ODOC forms

Field Training

Employee Name: John Doe

	Date Trained	Trainer Initials	IDOC Performed	Form to QA
pH measurement	3/15/19	ELH	3/18/19	3/18/19
Chlorine measurements	3/15/19	ELH		

	Read SOP	Completed Form	Form to QA
010 Field Sampler Cleaning	3/11/19	3/11/19	3/18/19
012 Grab Sampling	3/5/19	3/5/19	3/18/19
013 Field Safety Management	3/11/19	3/11/19	3/18/19
1669 Low Level Hg Sampling			
4500 H+B pH	3/15/19		
4501 Chlorine			

Trainee: _____ Date: _____

Supervisor Review: _____ Date: _____

Form 5617-4

Document Control

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Documentation

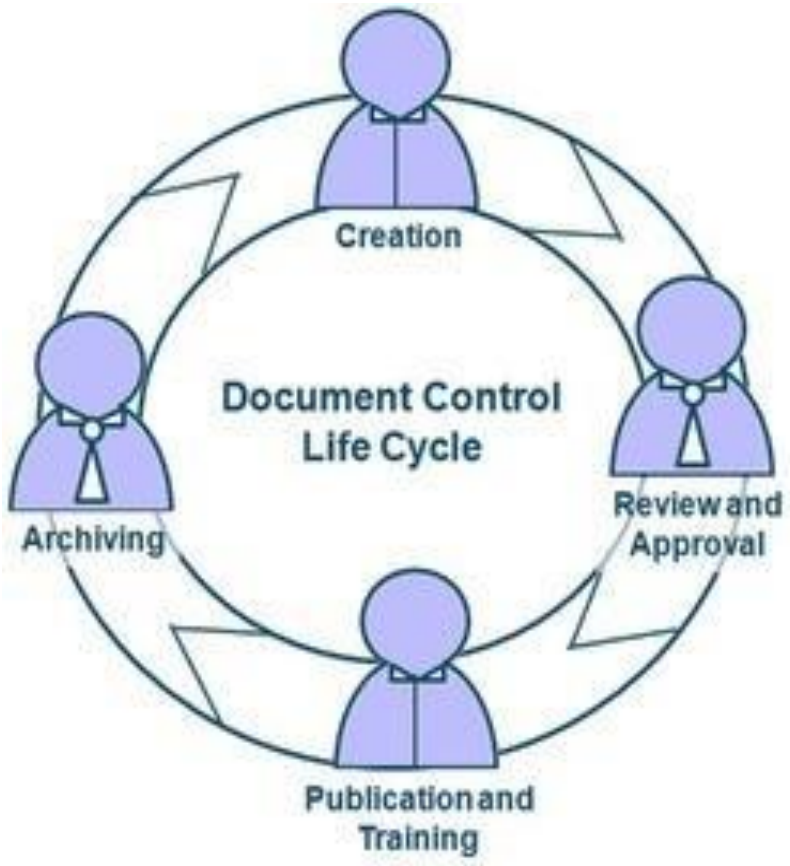
- **Quality assurance depends on documentation to:**
  - Demonstrate that quality control operations are being carried out
  - Assure accountability of data – safeguard against sample mix-up
  - Demonstrate that reasonable precautions were taken against falsification of data
  - Ensure traceability and reproducibility of the reported data

Documentation

- **All major processes/procedures must be documented**
- **Should be able to reconstruct events by establishing how, what, where, when, and who**
  - Test method used
  - Raw data collected and final result reported
  - Quality control data obtained when the sample was analyzed
  - Instrument used and its condition
  - Analysis time and date
  - Analyst who ran the test
- **Document information immediately**

Document Control

- Ensures that there is only one version of each document in use
- Prevents unauthorized changes to documents, procedures, or calculations
- Important for all plant operations – not just the laboratory



Document Control

- **Types of documents to control:**
  - Manuals
  - Standard Operating Procedures (SOPs)
  - Forms
  - Logs and Logbooks
  - Equipment print-outs
  - Job descriptions
  - Training records

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STANDARD OPERATING PROCEDURES FOR METHOD 200.7 Rev 4.4

Originator:		**Date:**
Section Supervisor:		**Date:**
QA Manager		**Date:**

FAS Standardization	
Cr^{+6} Normality	
Vol Cr^{+6} (mL)	
Vol FAS (mL)	
FAS Normality	

Batch	
Analyst	
Date	
Sample Date	
PQL (AA)	

Sample	Sample Vol (mL)	Vol FAS (mL)	Blank - Sample	COD (mg/L)
Blank				
LCS				
RAW				

New Employee Checklist

Form 201-0

Employee Name: _____

	Date Trained	Trained By
Organization/Supervisor		
Explain use of time clock		
Explain lunch/break policy		
Explain Food/Drink Policy		
Sign Job Description		
Sign Initial Log Book		
Explain Phone System		
Issue Key		

Document Control

- Establishes a quick reference

SOP Number	SOP Title	Author	Current Revision
120.1	Conductivity	Marcy Bolek	0
130.2	Hardness, Total Titrimetric	John Hoffman	2
160.1	Solids, Total Dissolved	Norm Huff	1

Document Control

- Establishes a time frame

Revision Number	Revision Date	Revision Approved by	Reason SOP Revised
0	January 3, 2002	Marcy Bolek	New SOP
1	August 7, 2004	Marcy Bolek	Added distillation step prior to ion analysis
2	November 1, 2007	Marcy Bolek	Check preservation prior to distillation

Logbooks

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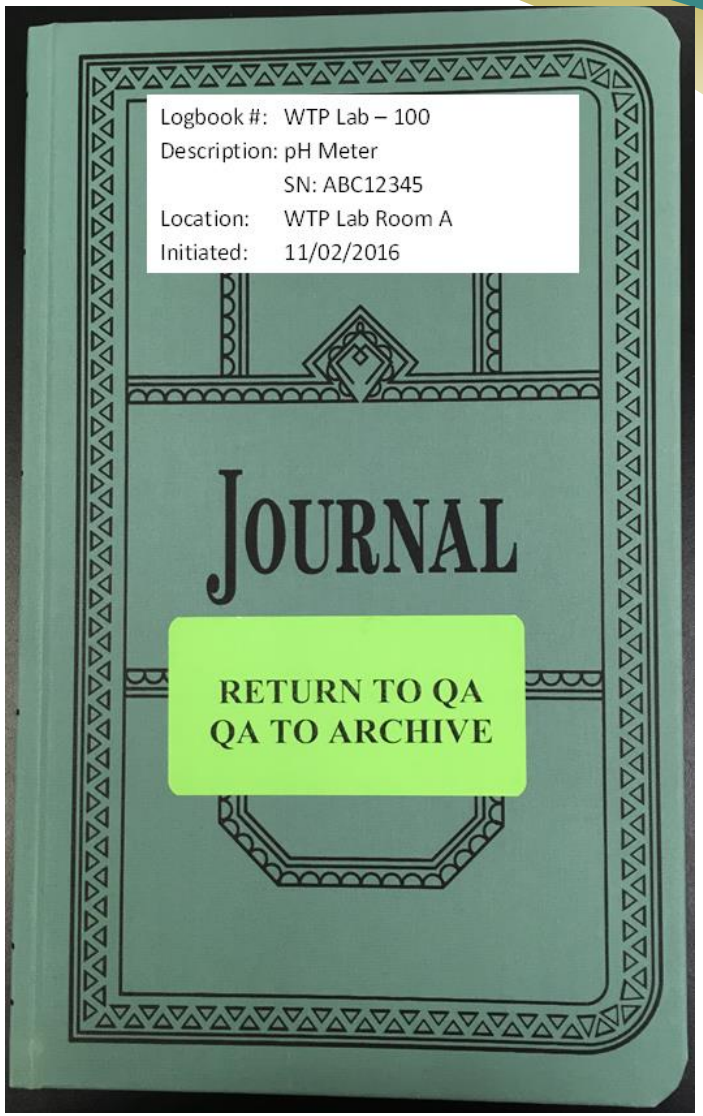
Logbooks

- **Types of Logbooks:**
  - Reagents
  - Instruments
  - Samples
  - Waste
  - Safety



Logbooks

- **Numbered pages**
- **Assigned logbook number**
- **Entries in permanent ink**
- **Error corrections**
  - Single line through the entry
  - Correct information
  - Initials and date

Standards & Reagents

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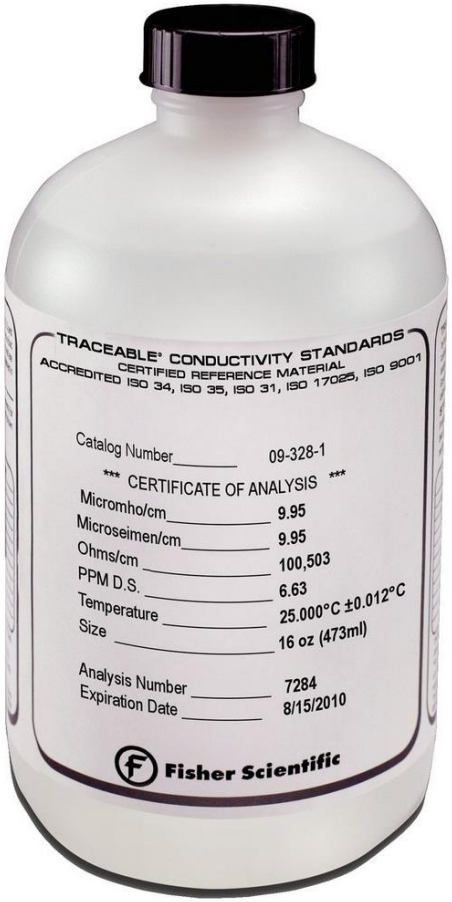
Standards & Reagents

- **Procedures for consumable materials used in laboratory**
  - Purchase
  - Reception
  - Storage
- **Records**
  - Manufacturer/Vendor
  - Certificate of Analysis
  - Date of receipt
  - Expiration date

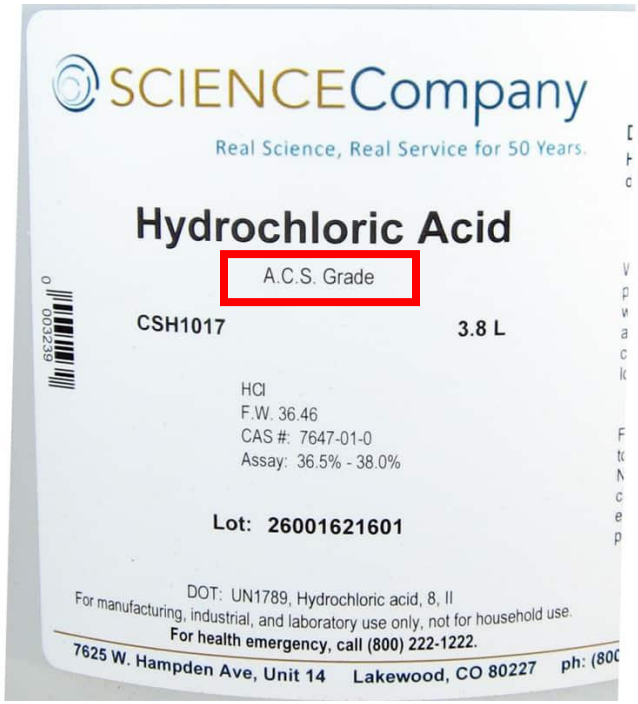


Standards & Reagents

- **Records shall be maintained on reagent and standard preparations**
  - Traceable to:
    - Purchased stocks
    - Method of preparation
    - Date of preparation
    - Expiration date
    - Preparer
- **Prepared standards and reagents must bear a unique identifier and expiration date, and be linked to the above information and records**

Reagents

- **Reagents available in various grades**
  - Highest purity
    - Analytical Reagent Grade
    - Spectral Grade
    - HPLC Grade
  - Good purity
    - ACS Grade
  - Low purity
    - Laboratory grade
    - Technical grade

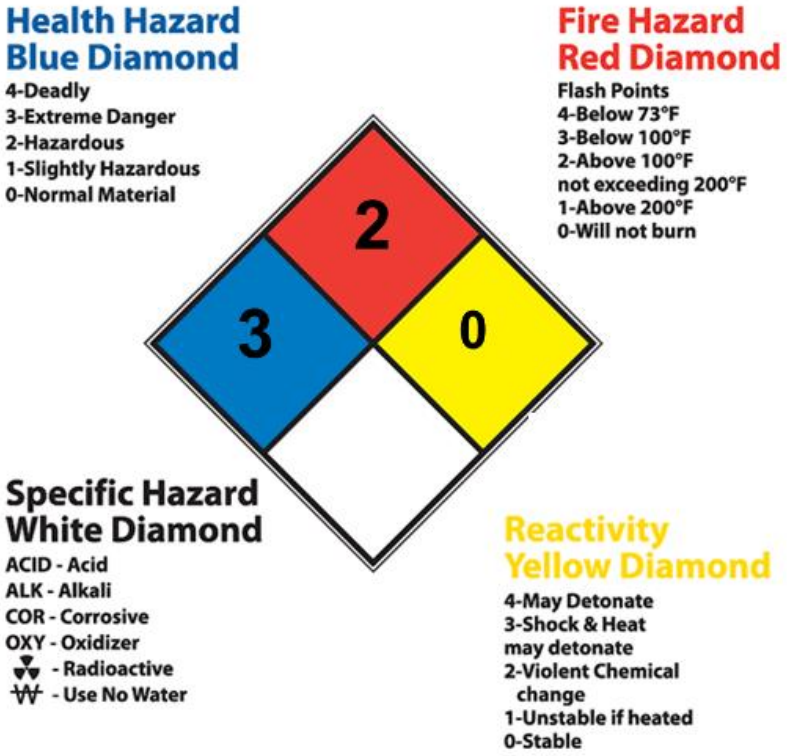


Reagents

- **Reagent receipt logbook**
  - Name of reagent
  - Control number
  - Date of receipt
  - Supplier and catalog number
  - Manufacturer and lot number
  - Expiration date

Reagents

- **Storage**
  - Consult label for proper storage
    - Refrigeration
    - Flammable reagents
    - Compatibility
- **Labeling**
  - Control number
  - Date of receipt
  - Date of opening and initials



Prepared Reagents

- **Reagent preparation logbook**
  - List of reagent preparation instructions
  - Standard methods and approved methods
  - Numbered pages and numbered lines
- **Daily preparation logbook**
  - Name of reagent
  - Date of preparation
  - Expiration date
  - Analyst
  - Stock reagent control number

Prepared Reagents

- **Labeling**
  - Preprinted self-adhesive labels
  - Name of reagent
  - Date of preparation
  - Expiration date
  - Analyst
  - Logbook page number and line number

Reagent Labels

Name:_____

_____

Preparation Date:_____

Expiration:_____**Initials:**_____

Page No._____**Line No.**_____

Use:_____

Methodology

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Analytical Methodology

- **Standard Method**
  - Method approved by a standard-setting organization, such as ASTM
- **Official Method**
  - Method specified by a government agency or professional society responsible for regulatory activities, such as EPA or FDA
- **Standard methods can become official methods if adopted by the regulatory agency**

Analytical Methodology

- **All analytical methods used in the laboratory must be:**
  - Written down
  - Kept in the laboratory
  - Accessible to all personnel

Method Validation

- **Any new or majorly modified methods need to be validated before samples are analyzed**
  - To demonstrate appropriateness
  - To gather data on accuracy and precision

Method Validation

- **Types of testing to be done on methods:**
  - Control samples (amount of analyte is known)
  - Reagent blanks
  - Duplicates
  - Spikes
- **Method should be tested by an experienced analyst**
- **Control samples should span the entire expected range of the method**

Standard Operating Procedures

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Standard Operating Procedures

- **Highly detailed description of how the laboratory performs a method**
  - The SOP is not the same as the actual method
- **Each procedure performed by the laboratory should have a specific SOP**
- **A good SOP facilitates the training of analysts and helps assure data quality**

Standard Operating Procedures

- **Operational SOPs**
  - Sample receiving
  - Equipment calibration
  - Quality assurance activities
  - Training
  - Corrective actions
  - Document control
- **Procedural SOPs**
  - pH
  - Chlorine
  - Metals
  - Nitrate
  - Phosphate
  - E. coli
  - VOCs

Standard Operating Procedures

- **SOPs need to:**
  - Be accessible
  - Be organized
    - Format
    - Filing
    - Numbering
  - Indicate the effective date
  - Have a revision number
  - Have approval signatures

SOP Format

City of _____ Revision 0 Effective Date: 01/10/2008
SOP # 101 Title: Document Format, Approval, Distribution, and Control

Approvals:

(Title # 1):		Date:
(Title # 2):		Date:
(Title # 3):		Date:

- 1.0 Scope and Application
- 2.0 Summary of Method
- 3.0 Definitions
- 4.0 Numbering of Documents
- 5.0 SOP Format
- 6.0 Approvals, Distribution and Control of SOPs
- 7.0 Approvals, Distribution and Control of Forms
- 8.0 Retention of Records
- 9.0 Revision History

If not signed this is an uncontrolled copy of a date sensitive document and may not be current after xx/xx/xxxx (today's date)

SOP Format

- Test Method(s)
- Applicable Matrix
- Method Detection Limit
- Scope & Application
- Summary of Method
- Definitions
- Interferences
- Safety
- Equipment & Supplies
- Reagents & Standards
- Sample Collection, Preservation, Storage, & Shipment
- Quality Control
- Calibration & Standardization
- Analysis Procedure
- Calculations

SOP Format

- Method Performance
- Data Assessment & Acceptance Criteria for QC Measures
- Method Specific Corrective Actions
- Contingencies for Out-of-Control or Unacceptable Data
- Pollution Prevention
- Waste Management
- References
- Additional Information
- Revision History

Data Verification

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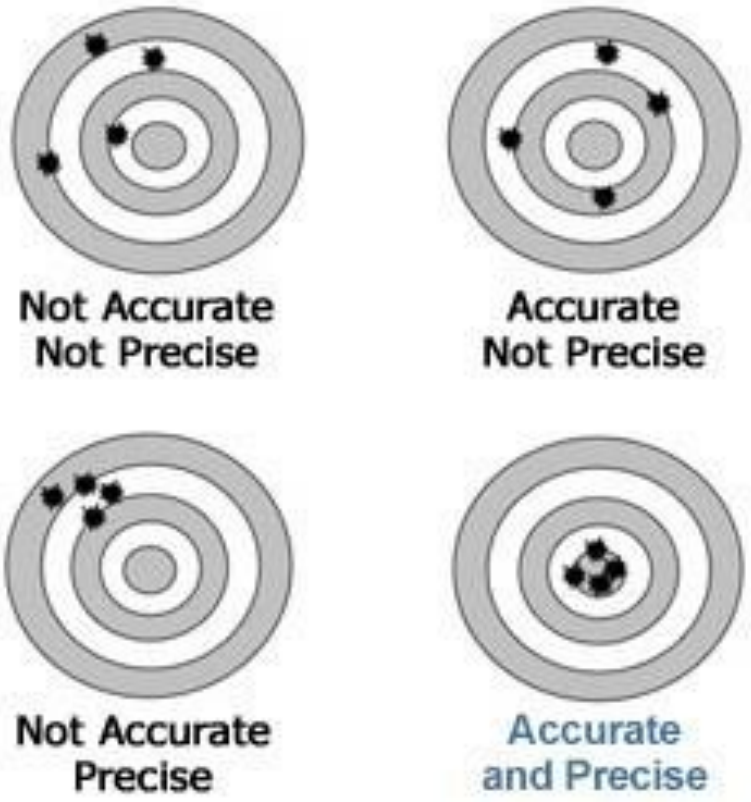
Data Verification

- **Data verification is the process of evaluating:**
  - the completeness,
  - correctness,
  - and conformance/compliance
- **Against**
  - the method,
  - procedural,
  - or contractual requirements.

Data Verification

- **Accuracy**
  - Control samples
  - Blanks
  - Matrix spikes
- **Precision**
  - Duplicates
  - Matrix spike/matrix spike duplicates



Data Verification

- **Performed during data collection and after data analysis**
- **Involves:**
  - Field data and sample collection
  - Laboratory data
- **Performed by personnel involved with:**
  - Collection of samples
  - Data
  - Generation of data
  - External verifier

Data Verification

- **Primary Review**
  - Analyst reviews all of the data and QC results
  - Analyst calculates sample results and enters results into the data system
  - Analyst gives analytical run to the appropriate supervisor
- **Secondary Review**
  - Supervisor reviews the run and data entry
  - Supervisor approves the data for reporting or has the analyst reanalyze the samples

Data Verification

Final Review

- Authorized manager reviews and signs the completed report and releases the data to the client or regulatory agency

Data Verification

- **Data reviewers should check if:**
  - COC is complete
  - Sample preservation and hold times meet requirements
  - Instrument calibration meets requirements
  - QC standards are analyzed and meet requirements
  - Data is calculated correctly
  - Data is reported correctly
  - Data makes sense

Data Verification

- **Data reviewers need to know:**
  - Analytical method procedures
  - QC acceptance limits
  - Required reporting levels
  - Project documentation requirements
- **Sources for data verifiers include:**
  - Quality Assurance Plan (QAP)
  - Sampling protocols
  - SOPs

Data Verification Records

- **Certification Statement**
  - Certifies that data has been verified
  - Signed by responsible person in laboratory or by responsible person from external verifier
- **Case Narrative**
  - Overall summary of the verified data
  - Documents technical non-compliance issues
- **Data Package**
  - Summary of QC data
  - Copies of raw data

Corrective Actions

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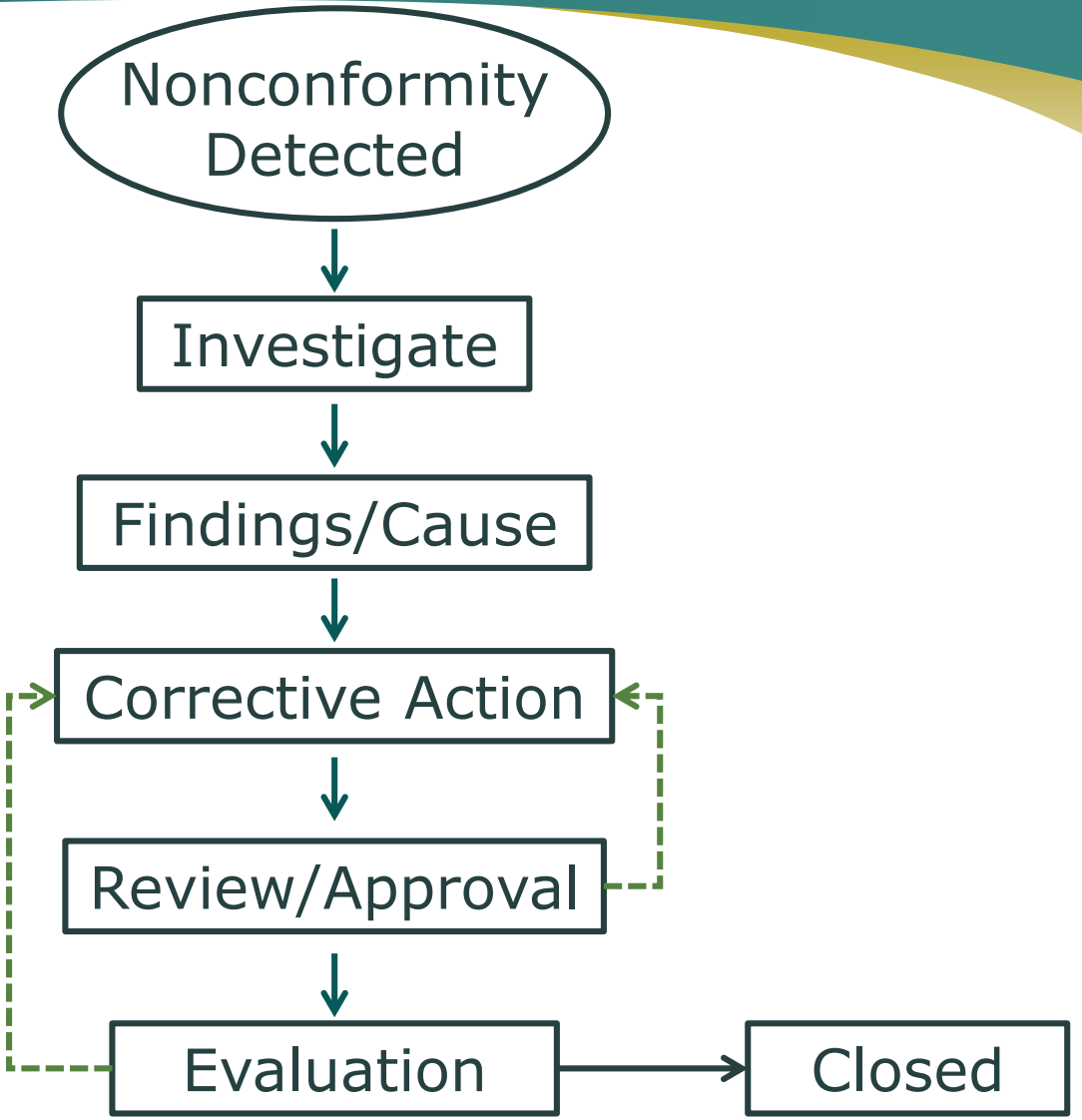
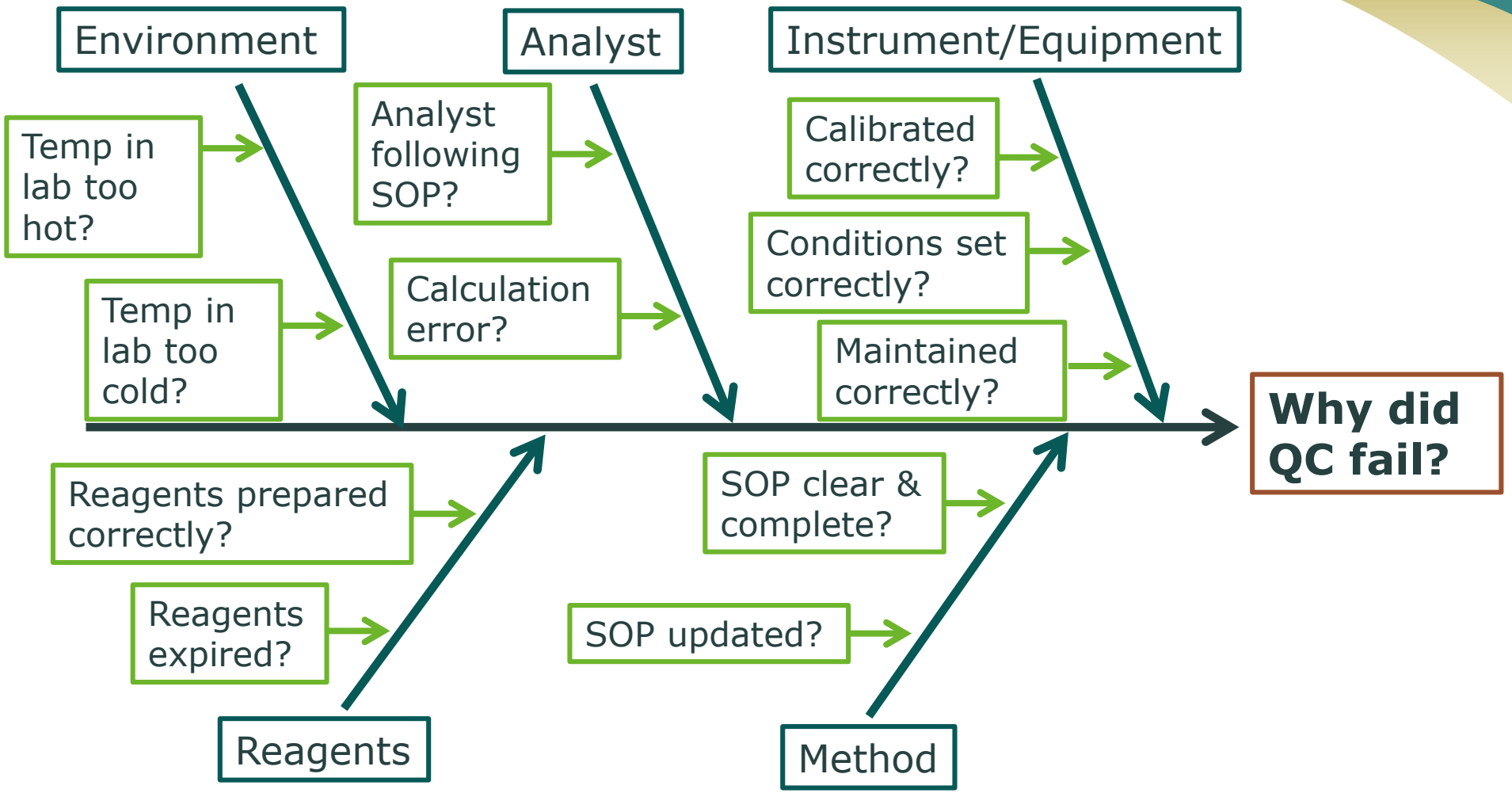
Corrective Actions

- **Corrective action may be needed in response to:**
  - Out-of-Control data
    - A point outside of the control limits
  - Complaints
  - Audit or PT study results

Corrective Actions



Root Cause Analysis



Corrective Actions

- **Designate who is responsible for:**
  - Creating a corrective action plan
  - Implementing the plan
  - Ensuring the plan is successfully implemented
- **Set a deadline for implementation and closing of the corrective action**
- **Document the corrective action(s)**

Corrective Actions

REPORT OF CORRECTIVE ACTION

Date of Analysis:_____
Submitted by:_____
Analyst:_____
Date:_____
Parameter: _____
Out of Control Description:

Corrective Action:

The correction action required was taken on

_____(Date)

_____ (analyst signature)

Internal Audits

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Internal Audits

- Ensure that lab is following documented procedures
- Ensure that lab is meeting regulatory requirements
- Evaluate performance and determine if there are areas that can be improved
- Allow lab to find and correct any deviations before an external audit

Internal Audits

- Should occur regularly and be conducted by the QA Officer, senior management, or an outsourced auditor
- Results must be documented and kept on file

Internal Audits

- Identify areas or methods to be audited
- Meet with personnel
- Evaluate method or procedure
- Evaluate quality control checks
- Evaluate any evidence of inappropriate actions
- Complete audit checklist and discuss findings with management
- Issue corrective actions
- Conduct a follow-up audit to ensure deficiencies have been addressed

Internal Audit Checklist

Requirement	Compliance			Notes
	Y	N	N/A	
Lab shall establish, implement, & maintain a quality system appropriate to the scope of its activities.				
Lab shall document policies, systems, programs, & procedures.				
All documents issued to lab personnel are reviewed & approved by authorized personnel prior to use.				
All records shall be held secure & in confidence.				
Observations, data, & calculations shall be recorded at the time they're made & shall be identifiable to the specific task.				

Thank You !

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