KEY ELEMENTS OF A QUALITY MANAGEMENT PROGRAM

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Shealy Consulting, LLC

FORMAL QUALITY MANAGEMENT PROGRAMS

SIXSIGMA

ISO International Organization for Standardization

ACCREDITED IN ACCORDANCE WITH nelac

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SIX SIGMA

Six Sigma is a disciplined, data-driven approach and methodology for eliminating defects (driving toward six standard deviations between the mean and the nearest specification limit) in any process – from manufacturing to service.

To achieve Six Sigma, a process must not produce more than 3.4 defects per million opportunities (1/294,118 data points generated). A Six Sigma defect/error is defined as anything outside of specifications.

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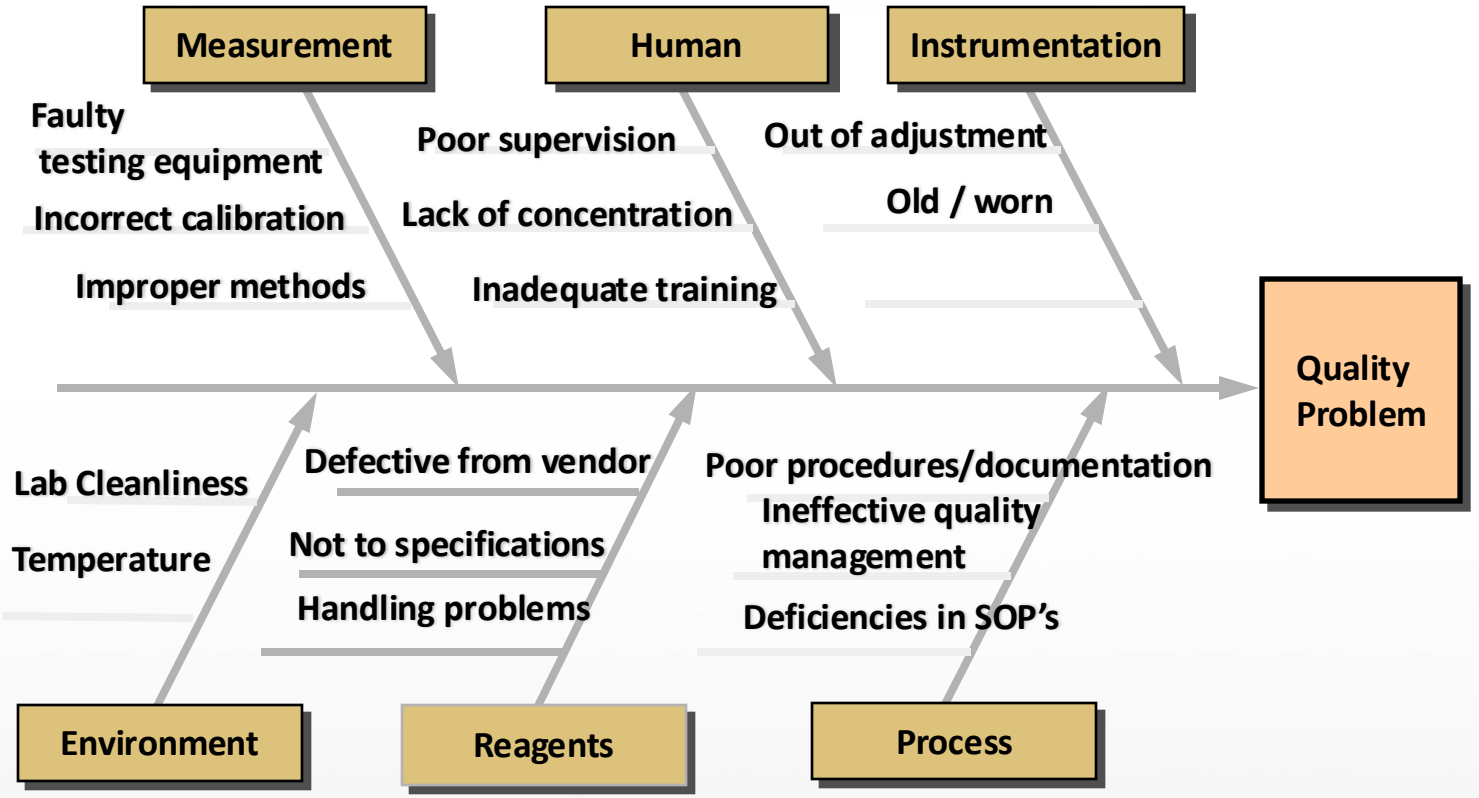
NELAC (National Environmental Laboratory Accreditation Conference)

An US program that provides evaluation and accreditation of environmental testing laboratories to ensure the quality of analytical data used for regulatory purposes to meet the requirements of the United State's drinking water, wastewater, shellfish, food, and hazardous waste programs.

QUALITY FACTORS



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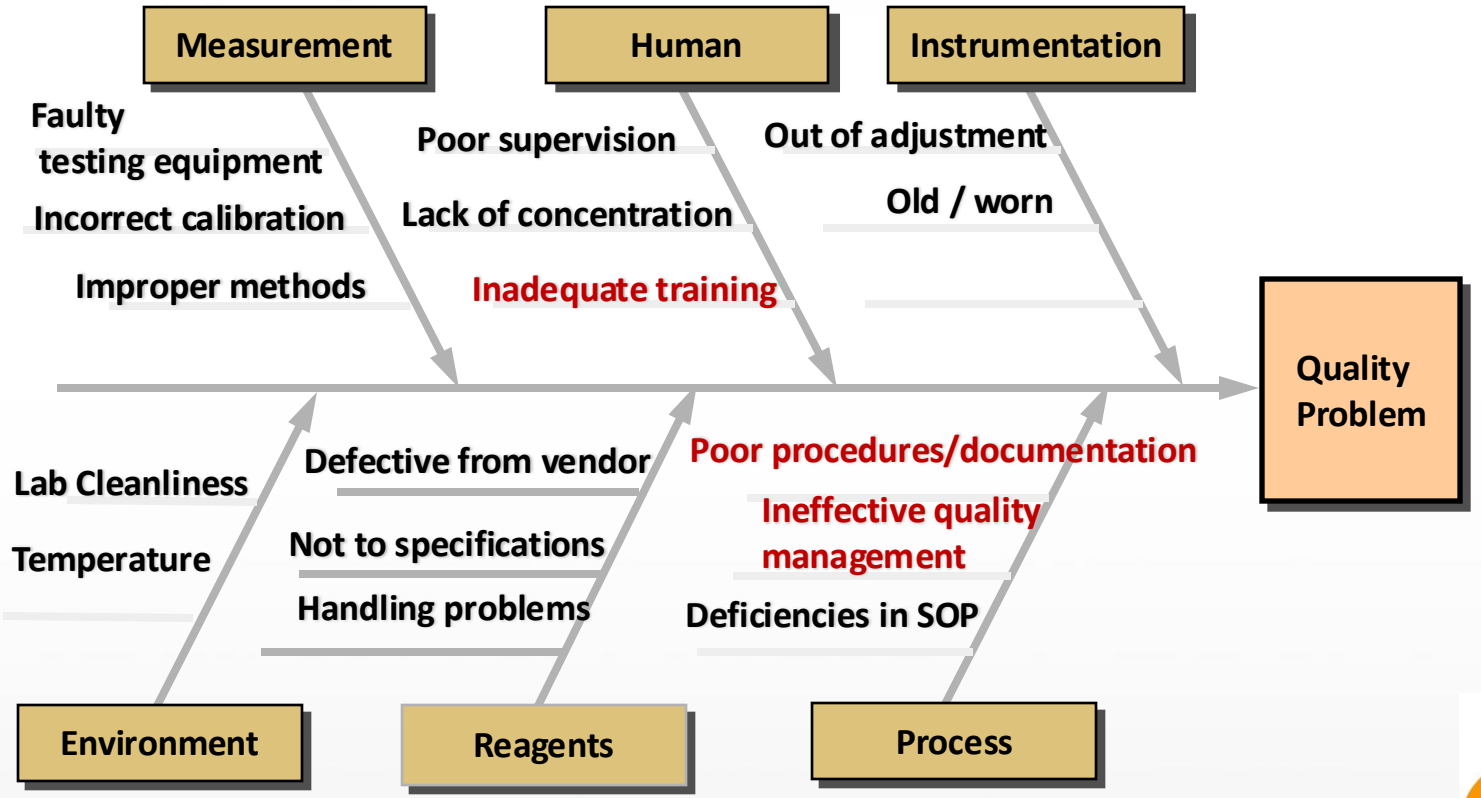
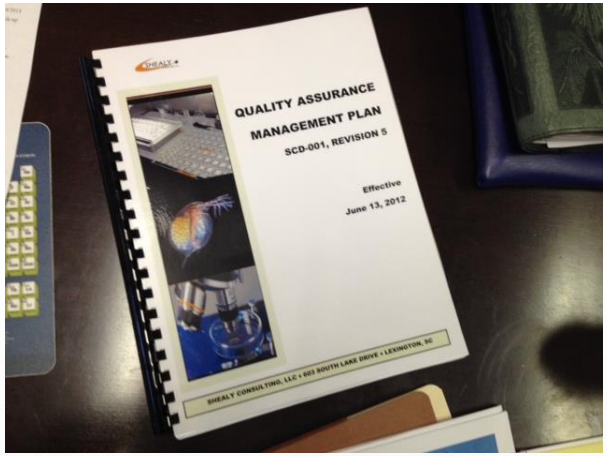


IN YOUR LABORATORY

Do you have a FORMAL program to manage the quality of your data?

Do You have a QAMP?

If not you are required to!



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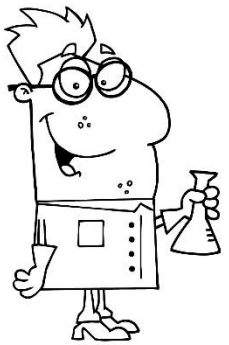
GOAL OF A QMS



- **The goal of the QMS is to consistently produce data of traceable quality that would be defensible in a court of law. Consistent adherence to this plan will reduce the variability due to controllable conditions and analyst error.**

KEY ELEMENTS OF A QUALITY MANAGEMENT PROGRAM

1. **STANDARD OPERATING PROCEDURES**
2. **PERSONNEL TRAINING**
3. **DOCUMENTATION**
4. **ON-GOING QUALITY ASSESSMENT**

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1 STANDARD OPERATING PROCEDURES

Definition

A set of written instructions that document a routine activity followed by an organization

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STANDARD OPERATING PROCEDURES

A good SOP should:

- Provide all the information necessary a task
- Should be a stand alone document
- Should provide quality information
- Should included references to relevant documents
- Should include a list of revisions to track edit history
- Should include a signature log for all personnel
- All sop's in an organization should have the same structure

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STANDARD OPERATING PROCEDURES

DONT'S

DON’T generalize in a technical procedure.
DON’T assume that the reader knows the process.
DON’T refer to a method or analysis for most of the procedure steps.
DON’T ramble on about unnecessary things. Be concise.

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STANDARD OPERATING PROCEDURES

Shealy structure – 18 sections

1. Purpose
2. Summary of method
3. Definitions
4. Interferences
5. Safety
6. Equipment and supplies
7. Reagents and standards
8. Sample collection, preservation and storage
9. Quality control
10. Calibration and standardization
11. Procedure
12. Data analysis and calculations
13. Method performance
14. Corrective actions and contingencies for out-of-control and unacceptable data
15. Pollution prevention
16. Waste management
17. References
18. Miscellaneous

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STANDARD OPERATING PROCEDURES

In following the NELAC standard you will need to have the following SOP's that address issues specific to the QMS

- Document Requirements
- Document Control
- Nonconformance and Corrective Actions
- Records Management
- Report Generation, Assembly, and Review
- Report Revision
- Development of Control Charts
- Annual Internal Audit
- Client Complaints

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1 STANDARD OPERATING PROCEDURES

"The devil is in the details"

The best technology can not make up for poor or non-existent set of instructions on how to use it.

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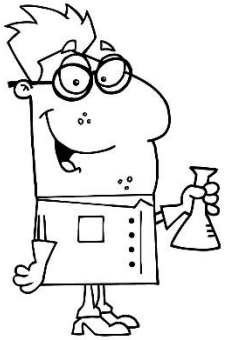
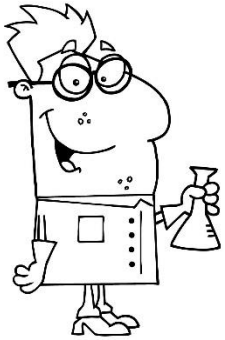


2 PERSONNEL TRAINING

All personnel should understand and sign an ethics policy and a comprehensive safety plan

2 PERSONNEL TRAINING



Training Records Should Include:

- General Laboratory checklist
- Analyses specific checklist
- Demonstration of Capability Certification Statement
- Initials and Signature Documentation
- On-going Training Attendance
- Initial Documentation of Capability (IDOC)
- Continuing Documentation of Capability (CDOC)
- Ethics Policy Agreement
- Job Responsibilities Checklist

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GENERAL TOXICOLOGY LABORATORY TRAINING CHECKLIST

TOPIC	TRAINEE SIGNATURE	TRAINER SIGNATURE	DATE
Comprehensive Safety Management Plan Review (SCD-002)			
Emergency Contact Information			
Evacuation Procedure			
Building Security			
Time Clock Usage			
Telephone Usage			
Personal Protection Equipment Overview			
Job Description Explanation			
General Laboratory Chore Responsibilities and Courtesy			
Initials/ Signature Sheet			
Data Integrity/ Ethics Training			
Logbook Protocols			
Documentation Process/ Error Correction			
Computer (Network)			
EPA Manuals / SOP Location			
Location of Supplies and Chemicals			
MSDS Location			
Open Date/ Expiry Date on Reagents and Standards			
Balance Usage and Calibration Documentation			
Chemical Inventory			
Procurement of Materials			
Glassware Cleaning, Care and Storage			
Sample Receiving / Chain-of-Custody Procedures			
Temperature Gun			
TRC Meter Calibration (IDOC is required)			
Temperature with Capillary Thermometer			
D.O. Meter Calibration, Documentation and Operation			
pH Meter Calibration, Documentation and Operation (IDOC is required)			
Reference Toxicant Reagent Preparation (&Lab Reagents)			
Preparation of dilution cups and testing paperwork			
Test Solution Preparation			
Fish Culture Feeding			
Algae Preparation and Algae Cell Count			
YCT Batch Preparation			
EPA Water Preparation			
Salt Water Preparation			
Non-Conformance Memos			

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General Toxicology Laboratory Training Checklist (Continued)

TOPIC	TRAINEE SIGNATURE	TRAINER SIGNATURE	DATE
Outside Organism Log-In			
Hardness Analysis (IDOC is required)			
Alkalinity Analysis (IDOC is required)			
Salinity and Conductivity Documentation, Calibration and Operation (IDOC is required)			
C. dubia Brood (In-house Culture) Board Maintenance			
P. promelas In-house Culture Maintenance			
Chronic Toxicity Testing with *Ceriodaphnia dubia*			
Acute Toxicity Testing with *Ceriodaphnia dubia*			
Chronic Toxicity Testing with *Pimephales promelas*			
Acute Toxicity Testing with *Pimephales promelas*			
Chronic Toxicity Testing with *Mysidopsis bahia*			
Sample Disposal and Documentation			
Level 1 Review			
Level 2 Review			
Statistical Analysis			
Report Production			

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Specific Toxicology Laboratory Training Checklist

	Initial Qualification					Renewal Qualification						
	IDOC 1	IDOC 2	IDOC 3	IDOC 4	SOP							
Test Date												
Test Material												

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OFFICIAL INITIALS AND SIGNATURE

Employee Name: _____ Date: _____

Name (print)	Signature

Initials (print)	Signature

Approved By: _____ Date:_____

Elizabeth Thompson, Quality Manager

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ON-GOING TRAINING ATTENDANCE

DATE	CATEGORY	TITLE	TRAINER	EMPLOYEE SIGNATURE

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DOCUMENTATION

Documentation Policies

- All analytical instrument operational records are maintained in bound logbooks.
- These logbooks are controlled, and if they are spiral bound they are ‘locked’ with a metal closure that is numbered.
- Logbooks that are taken out of use are archived. The archived logbook must be labeled with initial and final use dates.

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DOCUMENTATION

Documentation Policies

- Data that is recorded on bench sheets or in logbooks must be recorded at the time the observation is made.
- All raw data is retained in the client's file with the final report
- Bench data has no skipped spaces and is recorded in black ink
- All laboratory logbooks are reviewed monthly and this review is documented in the first page of the logbook

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DOCUMENTATION

Data Review

Good idea to have multiple levels of review!

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3 DOCUMENTATION

Data Review

All data generated during toxicity testing receive three levels of review.

Level 1

The analyst conducts a Level 1 review upon termination of a toxicity test.

Level 2

A Level 2 review is conducted after the test has been statistically analyzed and the final report has been prepared.

Level 3

A Level 3 review is conducted by the laboratory signatory. The Level 3 review is a general review of the test and final report prior to the release of information.

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3 DOCUMENTATION

Data Review

LEVEL I:
CONTROL VALIDATION:
Control with 3 broods at 60%____ OR at 80%_____
Mean ≥ 15 offspring per **surviving** female_____
Mortality ≤ 20% _____
ADDITION VERIFICATION:
Verify that 4th broods NOT included in analyses.____
Initials of 1st addition/ mean calculation: _____
Initials of 2nd addition/ mean calculation: _____
Data input requirements met?_____
All sample holding times met?____
Sample information correct (see COC)?____
LEVEL I by: _____

	LEVEL II:	
1) Stats input correct?	Yes	No
2) Is % Inhibition reasonable?	Yes	No
3) Does test pass at CTC?	Yes	No
4) If test failed, has client been notified?	Yes	No
5) Date of notification:		
6) Is DMR attachment correct?	Yes	No
7) Is the report cover sheet correct?	Yes	No
8)Is dilution series 0.5 or greater?	Yes	No
9) If there are any protocol deviations, are they discussed in the Case Narrative?	Yes	No

LEVEL II by: _____

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3 DOCUMENTATION

Reporting

- Title and test type
- Sample collection information and unique ID number assigned during sample receipt
- Test dates
- Identification of method used
- Page numbers, including total number of pages in the report
- Summary of data and statistical analysis
- Final test result (includes %inhibition or pass/fail)
- Shealy contact name and phone number
- A case narrative stating that all results were in compliance with procedures, or provides information about non-conforming data or test conditions
- Copies of all statistical analysis reports
- Report for the most recent Reference Toxicant test
- Chain-of-custody form copies
- DMR reports, if requested by the client.
- Statement regarding NELAC Accreditation

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4 ON-GOING QUALITY ASSESSMENT

Nonconformance Events

- Sample Receipt Nonconformance
- Quality Control Nonconformance
- Laboratory Nonconformance
- System Nonconformance

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4 ON-GOING QUALITY ASSESSMENT

System Nonconformance

A system nonconformance is a reoccurring or “non-isolated” deviation from laboratory policies or procedures.

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4 ON-GOING QUALITY ASSESSMENT

Corrective Actions

If a trend in nonconformance is identified, a Corrective Action form (SCF-QS-515) will document the investigation and the solution implemented

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4 ON-GOING QUALITY ASSESSMENT

Quality Assessment Audits and Responses

Audits of the laboratory are conducted internally and by external agencies such as certifying bodies or clients. Audits include the following:

- Internal audits are conducted annually by an employee who does not assist in the daily testing and operation of the laboratory.
- DMR/QA and PT studies are conducted yearly to verify the laboratory's ability to accurately conduct test procedures.
- External audits by SC DHEC, USEPA, US DOE and NELAC are conducted on a regular basis.

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4 ON-GOING QUALITY ASSESSMENT

Corrective Actions

If a trend in nonconformance is identified, a Corrective Action form (SCF-QS-515) will document the investigation and the solution implemented

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GOAL OF ANY QUALITY MANAGEMENT SYSTEM

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DATA INTEGRITY

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