



# Standards in Existing Regulations

Explicit & Implicit QMS Requirements

# Current Regulations

- ELAP has Quality Management System requirements in Title 22
- Each program/agency that requires ELAP certification has additional guidance for Quality Management Systems
- Guidance documents are not explicitly referenced in Title 22, prompting ambiguity regarding the degree of their enforcement

# Title 22

## **QMS Requirements:**

- Laboratory Organization And Personnel Responsibilities
- Quality Assurance Objectives For Measurement Data
- Sampling Procedures
- Custody, Handling, And Disposal Of Samples
- Calibration Procedures And Frequency
- Analytical Procedures
- Acquisition And Reduction, Validation And Reporting Of Data
- Internal Quality Control Checks
- Performance And System Audits
- Preventive Maintenance
- Assessment Of Precision And Accuracy
- Corrective Action
- Quality Assurance Reports

# Title 22

## Technical Standard

- Quality assurance and quality control practices must be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods.
- Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method.
- Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.

# Drinking Water Cert Manual, 5th ed.

## QMS Requirements:

- Laboratory organization and lines of responsibility, including QA managers
- Training records and documentation that laboratory personnel have demonstrated proficiency for the methods they perform.
- Process used to identify clients' data quality objectives
- SOPs with dates of last revision
- Field sampling procedures
- Laboratory sample receipt and handling procedures ~ chain-of-custody procedures
- Instrument calibration procedures
- Data reduction, validation, reporting and verification
- Quality Control
- Internal and external system and data quality audits and inter laboratory comparisons
- Preventive maintenance procedures and schedules
- Corrective Action contingencies
- Record keeping procedures
- Sample rejection policy
- Control charts

# Drinking Water Cert Manual, 5<sup>th</sup> ed.

## Technical Standards

Detailed Requirements for the following disciplines:

- Chemistry
- Microbiology
- Radiochemistry
- Sample Collection

# NPDES Compliance Inspection Manual

## QMS Requirements:

- Sample handling procedures
- Approved analytical procedures ~ SOPs
- Initial Demonstration of Capability
- Records of reagent preparation, instrument calibration and maintenance, incubator temperature, and purchase of supplies
- QC checks are on materials, supplies, equipment, instrument calibration and maintenance, facilities, analyses, and standard solutions
- Documentation of any EPA-approved deviation from specified test procedures
- Standard and specific procedures for cleaning glassware and containers
- Standard operating procedures for daily operation of instruments and equipment
- Documentation of standards sources, traceable to a national standard
- Analysis run logs or instrument run logs
- Written troubleshooting procedures
- Documentation on equipment maintenance and service checks and schedules
- Control charts
- Corrective actions
- Procedures for correction of data entry errors

# RCRA SW-846 Chapter 1, update 5

## QMS Requirements (as applicable per each client's QAPP)

- Data Quality Objectives
- Sample Custody SOP
- Sample Collection SOP
- Analytical Method SOP, including subsampling, sample preparation/cleanup, calibration, QC, and analysis
- Reagent/Standard Preparation and Traceability SOP
- Equipment Calibration and Maintenance SOP
- Corrective Action SOP
- Data Reduction SOP
- Data Reporting SOP
- Records Management SOP
- Waste Disposal SOP
- Internal QA Audits
- Data verification/validation
- Control Charts ~ “Data Quality Assessment”



# NSSP Guide for the Control of Molluscan Shellfish, 2015 rev.

## QMS Requirements:

- Organization and management structure of the laboratory
- Laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised
- Procedures and methods used to analyze samples ~ SOPs
- Quality control measures, their frequency and tolerance limits, for determining equipment performance
- Maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration
- Internal assessment and participation in a recognized annual proficiency test program (FDA, NELEOM, etc.)
- Corrective action for any deficiencies found in the laboratory quality assurance program, laboratory operations, and laboratory performance

# Conclusion

- If current QMS requirements are deemed insufficient, add more QMS requirements to ELAP regulations, such as a requirement for Data Integrity and Ethics training.
- To make the QMS stipulations found in supporting guidance documents mandatory requirements, explicitly cite them in the ELAP regulations.