



# Have You Defined A Fence Line for Your Quality System?

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# What is a Quality System?

A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services.

The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required Quality Assurance and Quality Control activities.

TNI V1M2-2016 Section 3.0 Terms and Definitions

# What is a Laboratory?

## Laboratory

body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

ISO 17025:2017 Section 3 Terms and definitions

# What is the Scope of a Quality System?

“This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel.”

ISO 17025:2017 Section 1 Scope

# What is a Fence Line?

The area and associated activities in which an organization chooses to implement its Management System. Examples include a department, a division or a specific operation.

# Structural Requirements

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.\*

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.\*

ISO 17025:2017 Section 5 Structural requirements

\*Also found in ISO 17025:2005 Section 4 Management requirements



## Fence Line



# Quality Manual

- The quality system shall be documented in the laboratory's quality manual and related quality documentation and shall be referenced in the quality manual.
- 4.2.8.3 The quality manual shall contain:
  - .....
  - d) identification of all major organizational units that are to be covered by this quality manual
  - .....





# Example Laboratory Organizations

There are many types of laboratory organizations for which TNI and ISO 17025 standards could apply.

## Municipal

Water /Wastewater  
Stormwater  
Field Sample  
Collection  
Regulatory and  
Process Control  
activities  
Fixed Labs

## Private

Consulting Firms  
Industrial Labs  
University  
Research Labs  
Field Sample  
Collection  
Pilot Plants  
Fixed & Mobile  
Labs

## Commercial

Field Sample  
Collection  
Calibration  
Organizations  
Regulatory  
Science  
Emergency  
Response  
Client Methods

## FSMO\*

Field Sample  
Collection  
Stationary Air  
Monitoring  
Air Stack Testing  
Pretreatment  
Programs

\* Field Sampling and Monitoring Organization

# What is covered by the Quality Management System (QMS)

## Process Control Testing

Turbidity, Chlorine residual,  
pH

## Regulatory Compliance

Total coliform, BOD, THM

## Troubleshooting

Leak testing  
Material identification such as  
tank residue

## Sample Collection

Grab  
Composite

## Special Projects

Pilot Labs  
Distribution studies

# What is covered by the Quality Management System (QMS)

## Process Control Testing

Turbidity, Chlorine residual,  
pH

## Regulatory Compliance

Air testing, water testing,  
tissue testing

## Emergency Response

Field testing

## Sample Collection

Grab  
Composite  
Mold, Tissue

## Special Projects

Research testing  
Pilot labs

# What is covered by the Quality Management System (QMS)

## Calibration Activities

Thermometers, Calibers  
In-network

## Routine Testing Projects

SDWA, CWA, CAA, RCRA

## Emergency Response

TICs

## Sample Collection

Grab  
Composite  
Mold, Tissue

## Special Projects

Research testing  
Client Product Testing w/  
Client Methods

SDWA-Safe Drinking Water Act  
CWA – Clean Water Act  
CAA Clean Air Act  
RCRA – Resource Recovery &  
Conservation Act  
TICs – Tentively Identified Compounds

# What is covered by the Quality Management System (QMS)

## Basic Field Testing

Turbidity, Chlorine residual,  
pH

## Advanced Field Testing

FTIR (Carbonyl Sulfide)  
NDIR (NOX)

## Emergency Response

Field testing

## Basic Sample Collection

Grab  
Composite  
Mold, Tissue

## Advanced Sample Collection

Isokinetic  
Non-Isokinetic

## Example Situations for Discussion

### University Lab

Lab is accredited for some drinking water and wastewater analysis. It performs research for water quality issues such as for Lead and Copper Rule.

Should the operation of instruments and sample collection as part of the research projects fall under the lab's Quality Management System?

### Municipal Lab

A municipal drinking water lab is accredited for microbial testing of drinking water.

The lab analyzes drinking water samples for nitrate/nitrite and HPC as part of its nitrification monitoring program.

Should the laboratory activities related to the nitrate, nitrite and HPC testing be part of the Quality Management System?

### Commercial Lab

A commercial laboratory focuses on environmental testing. An industrial organization has contracted with the laboratory to perform product testing. The industry will provide the equipment and standard operating procedures.

Should the product testing fall under the commercial laboratory's Quality Management System?



# Risks

What are the risks if the fence line is not well defined?



## Client Expectations

Clients assume that your Quality Management System covers all components of the lab unless exceptions are clearly stated. Could result in loss of client trust.



## Assumed Exceptions

Staff may assume that the Quality System does not apply to perceived exceptions such as non-accredited methods, special projects or client methods.

Lab may assume no exceptions resulting in delays and additional costs.



## Level of Effort

Lab may spend extra effort where it is not needed resulting in additional costs.

Lab may not spend the effort needed resulting in lost traceability, documentation and defensibility.

# Benefits

A well-defined fence line for a Quality System can promote flexibility, greater understanding of expectations, advance customer outcomes and promote sustainable practices.

## Client Needs & Expectations

- Review of client Quality Assurance Project Plans.
- Use of customer provided methods and equipment.

## Eliminate Assumptions

- Can provide for a tiered approach to client needs.
- Account for special services.

## Level of Effort

- Level of effort appropriate to situation.
- Improved efficiency and traceability.

## For Consideration

# QUALITY SYSTEM ≠ ACCREDITATION

You do not need to be accredited or plan to be accredited to implement a Quality System.

Accreditation does require a Quality System.

# References

- ISO/IEC 17025:2005: *General Requirements for the Competence of Testing and Calibration Laboratories*
- ISO/IEC 17025:2017: *General Requirements for the Competence of Testing and Calibration Laboratories*
- TNI 2016 Environmental Laboratory Sector Standard Volume 1: *Management and Technical Requirements for Laboratories Performing Environmental Analysis.*
- TNI 2014 Field Sampling and Measurement Organization Sector Volume 1: *General Requirements for Field Sampling and Measurement Organizations*



**THANK YOU**

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