Implementing a Quality Management System in an Environmental Laboratory

By Ilona Taunton, TNI and Paul Junio, Northern Lake Services

July 20, 2018

A Quality Management System (QMS), also called a Quality System or Management System, describes the manner in which you, as a laboratory, manage your operations to assure the quality of the test results you generate.

This QMS is organized, defined, and documented through your Quality Manual and various policies and procedures. The QMS must describe your objectives and principles relative to quality and must address:

Quality System, Management System, or Quality Management System

The 1990 version of ISO/IEC 17025 used the term Quality System to describe the process by which a laboratory manages its operations to "assure the quality of the test results it generates." By the time the second edition was published in 2005, this term was changed to Management System, although the phrase quality management system also appeared in this version. The NELAC Institute started using Quality System in 1994, and to date has not made the transition to Management System. As a transitional step, this document uses the term Quality Management System.

- How your objectives and principles will be achieved through written policies and procedures;
- How your laboratory is organized including work processes;
- How each individual is accountable for their assigned activities and responsibilities as it relates to generating quality data;
- How you expect policies and procedures to be implemented; and
- How you will evaluate the effectiveness of your system.

The QMS is the framework under which you will plan, implement, and assess work performed by your laboratory and the Quality Assurance (QA) and Quality Control (QC) activities that are necessary to meet your stated objectives.

A QMS is important for two reasons:

1. The QMS (which is outlined in the Quality Manual) serves as a guide to the laboratory in implementing the processes and procedures intended to provide data of known and documented quality.

2. A well thought out QMS provides clients with an understanding of how your laboratory intends to produce and document the data from samples that are submitted for analysis and adds a significant level of confidence in your laboratory's reported results.

A Quality Management System (QMS) does not ensure nothing goes wrong. It tells you what to do when it does, and it helps to prevent it from happening in the future.

Terminology and a Lesson in Hierarchy

To develop your QMS, you must understand the difference between a Quality System, Quality Assurance, and Quality Control. These terms are intimately related, but represent very different processes. Definitions for each of these terms are found in the TNI Environmental Laboratory Standard (EL-V1M2, Section 3), but the relationship is often unclear as many use these terms interchangeably.

> *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 (QA) and quality control (QC) activities.*
>
> *Quality Assurance: An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.*
>
> *Quality Control: The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.*

As a summary, these three terms form a hierarchical system in which the Quality System or QMS is the umbrella under which all activities are performed. It is a management system that is designed to ensure data of known and documented quality and describes all activities related to providing a quality work product:

- Policies, Procedures
- Organizational Responsibilities & Accountability
- Assessment

The description of these activities and policies is found in the Quality Manual (QA Manual, Quality Assurance Plan, however named).

Quality Assurance are those management activities that implement the policies and oversee the implementation of the Plan:

- Planning, including developing policies and procedures;
- Implementing policies by writing procedures to be used to accomplish the goals outlined in the policies;
- Insuring that all procedures are being followed as written;
- Assessing how well the procedures and policies are followed;
- Assessing how well the implemented processes work;
- Establishing a mechanism for addressing failures in processes, procedures or technical work; and
- Looking for and implementing procedures that will enhance the laboratory's ability to produce data of known and documented quality.

Quality Control are usually technical activities that monitor how well the processes are working but is not limited to the testing. Quality controls:

- Measure performance of a process, and
- Verify that performance measures meet specified limits.

In this sense, a Quality Control measure could be related to accuracy of data transcription, ordering and/or receiving supplies, etc.

Note: As a cautionary note, you may use other sources (laboratories, consultants, workshops, etc.) to develop your quality system, but make sure that it becomes *your* management system. Since the QMS is described in detail in your quality manual, you must be sure that you are performing what is written, regardless of whether it is "extra" or "not required" for accreditation. When you write it into your Manual, it becomes *your requirement*.