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IMPLEMENTATION OF AN EPA COMPLIANCE-RELATED QA PROGRAM WITHIN THE NQA-1 CRITERIA

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IMPLEMENTATION OF AN EPA COMPLIANCE-RELATED QA PROGRAM WITHIN THE NQA-1 CRITERIA, S.L. English, Pacific Northwest Laboratory,(a) Richland, Washington

The spirit of "detente" is not restricted to the United States and the Soviet Union. Within the federal government there is a new era of increased mutual involvement and cooperation between the U.S. Department of Energy (DOE) and the Environmental Protection Agency (EPA) for the protection of the health and safety of the general public and environment. With the increased interaction between DOE, EPA, and state agencies concerning hazardous waste, analytical laboratories must reevaluate their quality assurance (QA) programs. In accordance with DOE Order 5700.1A, Pacific Northwest Laboratory (PNL) initially implemented a QA program using appropriate requirements from the voluntary consensus standard ANSI/ASME NQA-1. Increased interaction with the EPA has dictated the need to consider the QA requirements for analytical activities associated with the Resource Conservation and Recovery Act (RCRA), which are addressed in Chapter 1 of the EPA document, *Test Methods for Evaluating Solid Waste* (SW-846). PNL has determined that the RCRA QA requirements can easily fit within the NQA-1 structure. Both programs have benefits to offer the analytical laboratory.

The EPA document, SW-846, focuses on field sampling and laboratory analyses and gives a more direct approach to QA and the essential quality control (QC) that helps demonstrate the validity of the analytical results. SW-846 is currently undergoing some changes, which were presented for public comment in the *Federal Register* on January 23, 1989 (54 FR 3212).

The proposed revisions to SW-846 include Section 1.1, which is a general discussion of the necessity of a QA program within a laboratory. The QA program is the overall system within which the technically specific QC activities can be defined, implemented, and monitored. Although Section 1.1 is not intended as a regulatory requirement in the proposed changes, it is essential that a laboratory have an established QA/QC program. Section 1.1 identifies some of the essential elements of a QA program by referring to another EPA document, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (QAMS-005/80), which provides information on elements that should be included in a QA plan.

As a generality, EPA prefers to see the QA plans in the recommended format. If your QA system is flexible, prepare the analytical laboratory QA plan in the QAMS-005/80 format. But also take into consideration all of the additional elements identified in NQA-1. Supplement the sixteen elements of QAMS-005/80 with those pertinent NQA-1 topics, such as training, procurement control, document control, nonconformance reports, and records control, that contribute to a better overall program.

In SW-846, EPA provides some very detailed instructions on the appropriate QC that must be performed but very little help on the QA aspects. NQA-1,

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including the appendices and supplements, is an excellent source of details to be considered for a more complete system. For example, NQA-1, Supplement 10S-1, Supplementary Requirements for Inspection, defines a more systematic approach to QC rather than just individual actions of running a QC sample. Some of the relevant items presented are qualification of personnel; designation of mandatory hold points, such as when control values exceed +/- 3 standard deviations; a documented plan for how the QC is to be implemented; a rational for the frequency of verification samples; inspections and resolution of nonconformances including reinspection or retest as appropriate; and identification of minimum records. Another example is the extensive information NQA-1 provides for establishing an auditing program. NQA-1 provides guidance for qualification of personnel, preparation, conduct, documentation, reporting, follow-up, and close-out of an audit.

An easy way to see the commonality and the individual strengths of the EPA (SW-846/QAMS-005/80) and the DOE (NQA-1) systems is to compare the identified elements. In addition to a title page and a table of contents, the EPA suggests the laboratory consider the elements underlined below. Included with each EPA heading is additional information as to where a similar NQA-1 element can be found.

PROJECT DESCRIPTION. This is a QAMS-005/80 specific requirement. Understanding the goals and activities associated with incoming samples provides a possible opportunity for the laboratory to contribute suggestions for a better final product, e.g., an improvement in sampling technique that provides a better sample to the lab, another recognized analytical technique that provides better results for complex matrix samples, a method with greater sensitivity. Having a defined scope for the analytical laboratory activities will emphasize the idea that the goal is to produce results that are reproducible and defendable, not necessarily research and development.

PROJECT ORGANIZATION AND RESPONSIBILITY. It is essential that people understand their responsibilities and the lines of communication. In NQA-1, the equivalent of this requirement is addressed in Basic Requirement 1, Organization. There is an interesting distinction between NQA-1 and QAMS in that NQA-1 requires QA to be independent from cost and schedule considerations. In the EPA arena, the QA representative may be a direct participant in the analytical process. The EPA places a heavy emphasis on the QC responsibilities.

QA OBJECTIVES FOR MEASUREMENT DATA. The EPA addresses QA objectives for measurement data in terms of accuracy, precision, and completeness. The real objective is to define acceptable operating parameters/acceptance criteria to control a process that will produce a final product that will meet the client's needs. In NQA-1, this is equivalent to specifying design input for the NQA-1 Basic Requirement 3 for Design Control or the specification of acceptance criteria in the NQA-1 Basic Requirement 11 for Test Control.

SAMPLING PROCEDURES. Both entities, the EPA and DOE, see it as essential that there should always be written instructions for the performance of routine activities. This aids in consistency of job performance between

personnel. The NQA-1 equivalent for this topic is the Basic Requirement 5 for Instructions, Procedures, and Drawings.

SAMPLE CUSTODY. The general EPA activities performed for sample custody are identification, tracking, and some special storage. These topics are covered in a combination of two basic requirements of NQA-1: Basic Requirement 8 for Identification and Control of Items and Basic Requirement 14 for Handling, Storage, and Shipping. In the EPA arena, sample custody may be needed for legal purposes. This is something not usually covered under NQA-1 activities, but it can be by a simple expansion of the general requirements.

CALIBRATION PROCEDURES AND FREQUENCY. Calibration of measurement instruments is essential for establishing the validity of any measurement data. This topic is addressed in the NQA-1 Basic Requirement 12 for Control of Measuring and Test Equipment and Basic Requirement 5 for Instructions, Procedures, and Drawings.

ANALYTICAL PROCEDURES. The EPA document QAMS-005/80 recognizes that sampling procedures, calibration procedures, and analytical procedures may all be addressed together. This could be within the same procedure or the same section of the QA plan. The NQA-1 Basic Requirement 5 for Instructions, Procedures, and Drawings establishes the requirement for these same procedures and allows the same flexibility on how to address the topics.

DATA REDUCTION, VALIDATION, AND REPORTING. EPA and NQA-1 both require that test results be documented and their conformance with acceptance criteria be evaluated. Basic Requirement 11 for Test Control is where the equivalent NQA-1 requirement is located.

INTERNAL QUALITY CONTROL CHECKS. This involves technically specific activities that provide assurance of the validity of the results. Even though the words/activities are specific to analytical laboratories, they are still the same principles presented in NQA-1 Basic Requirement 10 for Inspection. EPA specifies a few of the QC activities to be performed and monitored.

PERFORMANCE AND SYSTEM AUDITS. EPA and NQA-1 both address system audits. NQA-1 addresses audits in Basic Requirement 18 but does not have an equivalent of the performance audits that EPA promotes.

PREVENTIVE MAINTENANCE. This is a QAMS-005/80 specific requirement, but this is a natural extension of NQA-1 Basic Requirement 12 for Control of Measuring and Test Equipment.

SPECIFIC ROUTINE PROCEDURES USED TO ASSESS DATA PRECISION, ACCURACY, AND COMPLETENESS. Determining and monitoring accuracy and precision, establishing control charts, and identifying statistical tests to help evaluate data are just some of the processes for validating analytical processes. These activities are equal to those presented in the NQA-1 Basic Requirement 10 for Inspection.

CORRECTIVE ACTION. QAMS-005/80 includes nonconforming data, analytical equipment operation, and audit findings under the topic of corrective action. These activities are covered in a multitude of NQA-1 basic requirements such as Basic Requirement 15 for Control of Nonconforming Items, Basic Requirement 12 for Control of Measuring and Test Equipment, and Basic Requirement 18 for Audits.

QUALITY ASSURANCE REPORTS TO MANAGEMENT. The EPA QAMS-005/80 asks for reports on technical QC issues such as data accuracy, precision, and completeness to be presented to management. As in NQA-1 Basic Requirements 16 and 18, reports from audits and other significant QA problems are reported to management.

These elements are the minimum of what EPA (SW-846/QAMS-005/80) identifies as essential elements in a QA plan. NQA-1 addresses many of the same elements but provides additional guidance. Other pertinent topics identified within NQA-1 that would be valuable additions are training, procurement control, document control, nonconformance reports, and records control. Those topics could easily be inserted at the end of the QAMS-005/80 elements.

In an analytical laboratory, there must be both the QA program for the control of the administrative system and verification of the performance of all activities, and the QC program for establishing the validity of the analytical processes being performed. RCRA, through SW-846 and QAMS-005/80, promotes a system that recognizes and emphasizes the QC. In NQA-1, the emphasis is on the administrative control systems. Both systems have many common elements, but each system contributes something unique. The incorporation of both sets of requirements presents a symbiotic relationship that provides a stronger overall QA program.