COMPARABILITY BETWEEN NQA-1 AND THE QA PROGRAMS FOR ANALYTICAL LABORATORIES WITHIN THE NUCLEAR INDUSTRY AND EPA HAZARDOUS WASTE LABORATORIES

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ABSTRACT

There is increasing cooperation between the Department of Energy (DOE), Department of Defense (DOD), and the Environmental Protection Agency (EPA) in the activities associated with monitoring and clean-up of hazardous wastes. Pacific Northwest Laboratory (PNL) examined the quality assurance/quality control programs that the EPA requires of the private sector when performing routine analyses of hazardous wastes to confirm how or if the requirements correspond with PNL's QA program based upon NQA-1.

The standard EPA quality assurance/quality control requirements for work associated with the Resource Conservation and Recovery Act (RCRA) are found in Chapter 1 of SW-846, "Test Methods for Evaluating Solid Waste Physical/Chemical Methods," and what is generally referred to as Good Laboratory Practice. The quality assurance/quality control requirements for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA/ Superfund) activities are documented in the EPA Statement of Work (SOW) in the competitive bid package.

This paper will present the similarities and differences between NQA-1 and the QA program identified in ASTM-C1009-83, "Establishing a QA Program for Analytical Chemistry Laboratories within the Nuclear Industry"; EPA QAMS-005/80, "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans," which is referenced in Statements of Work for CERCLA analytical activities; and Chapter 1 of SW-846, which is used in analyses of RCRA samples.

The EPA QA programs for hazardous waste analyses are easily encompassed within an already established NQA-1 QA program. A few new terms are introduced and there is an increased emphasis upon the QC/verification, but there are many of the same basic concepts in all the programs.

INTRODUCTION

Pacific Northwest Laboratory (PNL) is a national laboratory operated by Battelle Memorial Institute for the U.S. Department of Energy (DOE). PNL is required to have a QA program based upon NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, which was published by the American National Standards Institute (ANSI) and the American Society of Mechanical Engineers (ASME). NQA-1 was structured to address design, procurement, and construction activities for nuclear facilities. It has been a challenge to take the requirements for a nuclear facility and successfully apply them to a research and development organization. The analytical laboratories within PNL have an even more challenging situation. These laboratories receive samples from multiple projects, many of which require a QA program other than NQA-1. The Environmental Protection Agency (EPA) sponsors many of these projects. Where the quality assurance requirements are specified in the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), which was reauthorized by the Superfund Amendments Reauthorization Act (SARA), PNL must ensure that its QA program, established under NQA-1, is adequate and flexible enough to accommodate the variety of requirements of the various clients.

AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM)

Quality Assurance Program

One of the most directly applicable and useful documents in applying NQA-1 to the analytical laboratories at PNL was ASTM C 1009-83, the "Standard Guide for Establishing a Quality Assurance Program for Analytical Chemistry Laboratories Within the Nuclear Industry." Although the title specifies chemistry laboratories within the nuclear industry, the basic principles could apply to any analytical laboratory. Both systems describe QA as "all those planned and systematic actions necessary to provide adequate confidence...".

The ASTM Standard grouped the recommended practices into nine functions that are considered the basic elements of a QA program. These elements are:

1. Organization
2. Quality Assurance Program
3. Training and Qualification
4. Procedures
5. Laboratory Records
6. Control of Records
7. Control of Equipment and Materials
8. Control of Measurements
9. Deficiencies and Corrective Actions.

All of these elements are similar to the basic requirements (BRs) of NQA-1. Table I displays a matrix of the 18

NQA-1 basic requirements by number and title, and the relative degree to which the ASTM standard addresses each.

COMPARISON OF NQA-1, ASTM C 1009-83, and Basic Requirements 1, 2, 8, 10, 12, 13, 15, 17, and 18 of NQA-1 are equally addressed in ASTM C 1009-83. This paper will identify where the NQA-1 BRs are not addressed, or where there are supplemental requirements identified, in the ASTM standard C 1009. NQA-1 basic requirements are addressed in the ASTM QA program as described below:

NQA-1 BR 3: Design control in the strictest interpretation is not one of the identified ASTM recommended topics. But, there is a notation with Table XI.2 of C 1009 that recommends that design control practices should be considered when acquiring major equipment and facilities. The ASTM standard recommends provisions to assure data are valid, comparable, complete, representative and of known precision and accuracy.

NQA-1 BR 4 and 7: ASTM C 1009 does not formally approach the idea of controlling procurements, but a notation with Table XI.2 indicates procurement control should be used with major equipment and facilities.

NQA-1 BR 5 and 6: Procedures and document control are equally addressed within the ASTM standard and NQA-1. It is interesting to note the ASTM standard recommends an editorial review of documents in addition to a technical review.

NQA-1 BR 9: Although not specifically called out, the ASTM Standard C 1009 addresses control of processes similar to NQA-1. The tests are different but the concepts are the same. By a combination of qualification of personnel, use of approved procedures, and specification of quality control limits, the analytical process is controlled.

Quality control is an important issue within the analytical laboratory and could be included under at least four of the NQA-1 basic requirements. Process control, inspection, test control, and control of measuring and test equipment

TABLE I

Comparison of NQA-1, ASTM C 1009-83, and CERCLA SOW Quality Assurance Requirements

NQA-1 BASIC REQUIREMENT	ASTM C 1009-83	CERCLA SOW
1 ORGANIZATION	+	#
2 QA PROGRAM	+	+
3 DESIGN CONTROL	-	-
4 PROCUREMENT CONTROL	-	+
5 INSTRUCTIONS AND PROCEDURES	+	+
6 DOCUMENT CONTROL	+	+
7 CONTROL OF PURCHASED ITEMS AND SERVICES	-	#
8 IDENTIFICATION AND CONTROL OF ITEMS	+	+
9 CONTROL OF PROCESSES	+	+
10 INSPECTION	+	+
11 TEST CONTROL	#	#
12 MEASURING AND TEST EQUIPMENT	+	+
13 HANDLING, STORAGE AND SHIPPING	+	+
14 INSPECTION, TEST AND OPERATING STATUS	+	+
15 NONCONFORMING ITEMS	#	#
16 CORRECTIVE ACTION	#	#
17 QA RECORDS	+	#
18 AUDITS	+	#

Key

- \- No equivalent requirements.
- # Partially addressed.
- \+ Completely addressed.

all use quality control as an integral part of ensuring the integrity of resulting data.

NQA-1 BR 11: As shown on Table XI.2 in ASTM C 1009, ASTM does not have an identified principle of laboratory QA that corresponds to NQA-1 test control. Most test control is performed in conjunction with the sample planning and collection. Field blanks, duplicates, and unknowns provide evidence the samples are acceptable. Quality control is the essence of test control.

NQA-1 BR 14: Inspection, test, and operating status is addressed by ASTM with the recommendation to use a traveler. Recommended quality control charts serve as indicators of inspection and the proper operating status of equipment.

NQA-1 BR 16: Deficiencies and corrective actions are one of the elements of a laboratory QA program recommended by ASTM. NQA-1 and ASTM both recommend identification, evaluation, resolution, and records. NQA-1 specifies that there should be follow-up activities to verify implementation. This may be inherent in the ASTM standard, but it is not identified.

COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION AND LIABILITY ACT QUALITY ASSURANCE PROGRAM

Analytical data is one of the most commonly shared types of information between the environmental and nuclear communities. Data in these situations must meet the QA requirements of both the EPA and the DOE and U.S. Nuclear Regulatory Commission (NRC). There are differences in the QA programs of each that can be attributed to the needs of each industry.

The intent of NQA-1 is to ensure the integrity of a known final product. The EPA QA system must insure the integrity of production of data on an unknown. Even though these sound different, there are many basic activities that are common to both. NQA-1 provides the broad categories under which all activities can be encompassed, but in the CERCLA program the EPA provides a large amount of quality control requirements that are program specific. In the CERCLA program all routine analytical work is awarded, via a public bid process, to laboratories in the Contract Laboratory Program (CLP). The QA/QC requirements are identified in detail within the Statement of Work (SOW) for each contract (Table I). The QA requirements are similar between SOWs, but the quality control requirements are tailored to the type of analyses involved.

The USEPA Contract Laboratory Program Statement of Work for Organics Analysis, Multi-Media, Multi-Concentration, 2/88, has been used for comparison to the QA requirements of NQA-1. The SOW has two general sections that correlate to what is generally considered QA: Exhibit E Quality Assurance/Quality Control Requirements, and Exhibit F Chain-of-Custody, Document Control and Standard Operating Procedures. Within this document, EPA also has 54 pages of very technically specific quality control requirements.

The goals of the CLP QA program are to ensure that data of known quality and integrity are generated, and the loss of data due to out-of-control conditions is minimized. EPA asks for written standard operating procedures which describe the in-house procedures participating laboratories must employe to ensure that these goals are achieved. There are six major components that must be included. These are:

1. Organization and Personnel
2. Facilities and Equipment
3. Analytical Methodology
4. Sample Custody
5. Quality Control
6. Data Handling.

As each component is expounded upon in the SOW, many of the topics addressed in NQA-1 are covered. NQA-1 basic requirements that are either partially addressed, not addressed, or expanded upon in the CERCLA SOW QA program are described below:

NQA-1 BR 4, 5, 6, 8, 9, 10, 12, 13, and 14 are specifically addressed in the CLP.

NQA-1 BR 1: Where NQA-1 requires the identification of the organizational structure and functional responsibilities of all activities affecting quality, the CLP program requires only the structure and functional responsibilities of the QA organization.

NQA-1 BR 2: Training is addressed in a questionable manner. CLP states, "It is highly desirable that there be a training program for employees." In the NQA-1 arena where requirements are identified with "shall," it is hard to understand "it is highly desirable...." Experience has shown that EPA is looking for documented training. EPA recommends the system include "practice work" that could be equated to qualification of the analysts.

NQA-1 BR 3: CLP primarily addresses laboratory analyses and does not include any design control aspects.

NQA-1 BR 5: The CLP identifies a minimum of topics that should be addressed with documented procedures. Written procedures must address all major elements upon which the final quality of the work depends.

NQA-1 BR 6: Document control in the CLP is dedicated to technical procedures and all documents for a specified data case. The CLP document control includes those activities to put together an acceptable data package: preprinted data sheets, error correction procedure, cross checking data to assure consistency, document numbering and inventory, and shipping the final package. Some of these items would be included under the NQA-1 topic of records.

NQA-1 BR 7: The CLP specifically addresses control of purchased items but does not address services. It also asks for reagent inventory control.

NQA-1 BR 8: For identification and control of items the CLP requires a strict chain-of-custody system. This system is necessary for legal defensibility and may probably exceed what most laboratories are used to. There must be

specific procedures for sample identification, laboratory and sample security, and tracking of the sample.

NQA-1 BR 9: Control of process is addressed with the CLP procedures through training of personnel with "practice work."

NQA-1 BR 10: The extensive quality control that EPA requires is a form of inspection. The characteristic to be inspected and the methods to be employed are defined in the Statements of Work. Results from inspections must be documented and EPA requires an independent review. CLP recommends internal performance audits that are independent checks of the performance of the laboratory analysts.

NQA-1 BR 11: If test control is limited to verifying conformance of an "item" to specifications, then test control may not be within the analytical laboratory control. All samples are unknown and results cannot be directly inspected and termed nonconforming. It is the analytical process that must be controlled in order to evaluate the results. If the scope is broadened to include analytical processes, then all the quality control requirements serve as test controls.

NQA-1 BR 14: In the CLP, the topic of inspection, test, and operating status is partially addressed with the receipt inspection of samples. The quality control charts required by CLP could be used as operating status indicators.

NQA-1 BR 15: There are specific requirements for feedback and corrective action for analytical and sampling errors, or an out-of-control analytical system, and instructions on how to identify data that is outside the required parameters. But, this doesn't explicitly extend to nonconforming items such as reagents or equipment or procedural deviations.

NQA-1 BR 16: In the CLP, corrective action is required for an analytical system that is out of control. This doesn't necessarily extend to administrative systems.

NQA-1 BR 17: The CLP identifies extensive records requirements related to submitting a final data package or case file. It requires that a bench data, data handling, and laboratory notebook policy be addressed in procedures. CLP does not specify that there must be procedures for records maintenance and protection.

NQA-1 BR 18: The CLP does specify an audit program similar to the NQA-1 program. Planned and scheduled audits in accordance with procedures or checklists and follow-up are not required in the CLP as they are in NQA-1. However, the CLP does require an independent check of the performance of laboratory analysts to determine if prescribed procedures are closely followed. Performance audits under the CLP include quarterly analysis and evaluation of test samples with known values.

RESOURCE CONSERVATION AND RECOVERY ACT (RCRA) QUALITY ASSURANCE PROGRAMS

In its comparison of the NQA-1 QA program with the RCRA QA program, PNL went first to SW-846, "Test Methods for Evaluating Solid Waste Physical/Chemical Methods," Chapter 1, promulgated by the EPA as the cornerstone for the RCRA QA program. As a stand-alone program, SW-846 is weak. Six major components are discussed in SW-846:

1. Program Design
2. Organization and Responsibility
3. Performance and Systems Audits
4. Corrective Action
5. QA/QC Reporting to Management
6. Quality Control Program for the Analysis of RCRA Samples.

Through referencing EPA QAMS-004/80, "Guidelines and Specifications for Preparing Quality Assurance Program Plans," and QAMS-005/80, "Guidelines and Specifications for Preparing Quality Assurance Project Plans," the SW-846 QA program will address most of the concerns typically associated with an analytical laboratory QA program. The major components of QAMS-004/80 and QAMS-005/80 are shown in Table II.

QAMS-004/80 is aimed primarily at QA Program Plans for EPA regions or state authorities. For PNL's purposes, QAMS-005/80 for project plans was determined to be the more applicable document; however, elements of QAMS-004/80 do serve to fill in some gaps left by SW-846 and QAMS-005/80.

Table III displays a matrix of the 18 NQA-1 BRs by number and title, and the relative degree to which SW-846, Chapter 1, QAMS-004/80, and QAMS-005/80 address each.

NQA-1 basic requirements are either not addressed, partially addressed, or expanded upon in the RCRA QA programs described below:

NQA-1 BR 2: While both SW-846 and QAMS-004/80 discuss training, no specific references to training or qualification of staff exist in QAMS-005/80. For the most part, the training and qualification of personnel in SW-846 and the QAMS programs is based on academic considerations rather than qualification tests or certifications, as in NQA-1.

NQA-1 BR 3: Within the scope of this comparison, design is not addressed in SW-846 or the QAMS programs unless the definition of data quality objectives are considered as design elements. Also, QAMS-005/80 addresses reviews of network/sampling/analytical designs.

NQA-1 BR 4 and 7: Except for a discussion of the evaluation of subcontractors' QA/QC programs in SW-846, neither it, nor the QAMS programs address procurement controls or control of purchased items.

NQA-1 BR 6: Document control is neglected entirely in SW-846 and only discussed for quality assurance plans in the QAMS documents.

NQA-1 BR 8: SW-846 and EPA QAMS-005/80 add another wrinkle to Identification and Control of Items by introducing the concept of chain-of-custody. In addition to uniquely identifying items, in this case samples,

chain-of-custody provides an unbroken paper trail of who had possession of samples at all times.

The identification of items other than samples is not addressed in either SW-846 or the QAMS programs.

NQA-1 BR 9: PNL has interpreted Process Control as the performance of activities which affect quality in accordance with documented methods by trained and qualified individuals. As indicated previously under BR 2, QAMS-005/80 contains no specific reference to the training and qualification of staff.

NQA-1 BR 10: In contrast to inspecting a piece of hardware to verify that it meets the dimensions of the specification, data derived from analyzing unknowns cannot be inspected. Typically, no one knows what the answer should be. That is why the work is being done in the first place. To inspect data then, indirect techniques must be used. SW-846 and QAMS-005/80 address this through the use of quality control samples. QC samples are not provided for in NQA-1. Analyzing these samples along with the unknowns gives an indication of the quality of data being generated by a given analytical process. Under such a quality control program, sample blanks, duplicates, and blind standards are used at a specified frequency.

NQA-1 BR 12: In addition to the calibration controls described in NQA-1, SW-846 and the QAMS programs address periodic maintenance of instruments. Because data

TABLE II

Major Components of EPA QA Guidance Documents QAMS-004 and -005

QAMS004/80	QAMS005/80
1.0 Identification of the Office, Region, or Laboratory	1.0 Title Page with Provision for Approval Signatures
2.0 Introduction	2.0 Table of Contents
3.0 Quality Assurance Policy Statement	3.0 Project Description
4.0 Quality Assurance Management	4.0 Project Organization and Responsibility
	5.0 QA Objectives for Measurement Data in Terms of Precision, Accuracy, Representativeness, Completeness, and Comparability
5.0 Personnel Qualifications	6.0 Sampling Procedures
6.0 Facilities, Equipment, and Services	7.0 Sample Custody
7.0 Data Generation	8.0 Calibration Procedures and Frequency
8.0 Data Processing	9.0 Analytical Procedures
9.0 Data Quality Requirements	10.0 Data Reduction, Validation, and Reporting
10.0 Corrective Action	11.0 Internal Quality Control Checks and Frequency
11.0 Implementation Requirements and Schedules	12.0 Performance and System Audits
	13.0 Preventive Maintenance Procedures and Schedules
	14.0 Specific Routine Procedures to be Used to Assess DataPrecision, Accuracy, Representativeness, Completeness, andComparability (PARCC) of Specific Measurement Parameters Involved
	15.0 Corrective Action
	16.0 Quality Assurance Reports to Management

TABLE III

Comparison of NQA-1 and RCRA QA Requirements

NQA-1 BASIC REQUIREMENT	SW-846 CHAPTER 1	QAMS-004/80	QAMS-005/80
1 ORGANIZATION	+ *	+	+
2 QA PROGRAM	+	+	Ø
3 DESIGN CONTROL	–	–	Ø
4 PROCUREMENT CONTROL	Ø	Ø	–
5 INSTRUCTIONS AND PROCEDURES	+ *	+	+
6 DOCUMENT CONTROL	– *	Ø	Ø
7 CONTROL OF PURCHASED ITEMS AND SERVICES	Ø	Ø	–
8 IDENTIFICATION AND CONTROL OF ITEMS	Ø *	Ø	Ø
9 CONTROL OF PROCESSES	+ *	+	–
10 INSPECTION	+	+	+
11 TEST CONTROL	+	+	+
12 MEASURING AND TEST EQUIPMENT	+	+	+
13 HANDLING, STORAGE AND SHIPPING	+	Ø	+
14 INSPECTION, TEST AND OPERATING STATUS	Ø	–	Ø
15 NONCONFORMING ITEMS	–	–	–
16 CORRECTIVE ACTION	+	+	+
17 QA RECORDS	–	Ø	Ø
18 AUDITS	Ø	Ø	+

Key

– No equivalent requirements.
Ø Partially addressed.
\+ Completely addressed.
* Addressed, even partially, only by reference to QAMS-004/80 or QAMS-005/80.

quality is measured indirectly, the meticulous maintenance of instrumentation is paramount.

NQA-1 BR 13: The controls for handling, storage, and shipping contained in QAMS-004/80 are limited to environmental aspects of facilities and equipment and do not address samples.

NQA-1 BR 14: Inspection, test, and operating status controls are not addressed in QAMS-004/80. Neither SW-846 or QAMS 005/80 address the use of status indicators.

NQA-1 BR 15: The identification segregation and disposition of nonconforming items is not addressed in SW-846 or the QAMS programs.

NQA-1 BR 17: Retention and control of records is not touched upon in SW-846, and only discussed for the handling and retention of "data" in the QAMS programs.

NQA-1 BR 18: In addition to the system audits recognized by NQA-1, SW-846 and QAMS-005/80 introduce the concept of performance audits which may be visualized as challenging an analytical system with a known reference to verify proper performance. This could be thought of as an extension of the indirect data inspection method of quality control.

All other NQA-1 BRs are completely addressed by the three QA Programs.

SUMMARY

As a multi-faceted research and development organization, PNL has continually pioneered the application of NQA-1 to activities for which it was not originally designed. If you can look beyond the technical terminology and focus on the concepts behind each basic requirement, then you discover many of the same QA concerns in the ASTM, EPA, and NQA-1 programs. At PNL, the implementation of elements of the varied QA programs of ASTM, EPA and NQA-1 has produced an almost symbiotic relationship. Each QA program serves to supplement the gaps or weaknesses of the others. The basic requirements of NQA-1 supplemented with quality control and data quality considerations have been a sound basis for the analytical laboratory QA program at PNL.