FIFTEENTH ANNUAL ENERGY DIVISION CONFERENCE

CONFERENCE SESSION WM-6
A COMPARISON OF EPA AND NRC QUALITY ASSURANCE REQUIREMENTS

ENVIRONMENTAL VS NUCLEAR QUALITY ASSURANCE, COMPLIMENTARY OR CONFLICTING?

Dean W. Wolfe
Quality Assurance Manager, Oak Ridge Projects
Bechtel National, Inc.
P.O. Box 350
Oak Ridge, Tennessee 37831-0350

Abstract

With the growing application of quality assurance to shared environmental and nuclear areas of concern, there are increasing needs on individual projects to address both Nuclear and EPA quality assurance criteria. While they share many points in common, there are unique items addressed in the EPA criteria which are not addressed in the nuclear criteria and likewise, unique items addressed in the nuclear criteria not addressed in the EPA criteria. These differences can be attributed to the historical needs of each industry. This has resulted in misunderstanding between individuals from both areas, frustration in quality assurance program development and application, and questions being raised concerning the possibility of satisfying both in a single document. The objective of my paper is to examine and compare the Nuclear and EPA quality assurance criteria, highlight their differences, and, not only show how they are not in conflict, but, show that they are complimentary with each other, one providing guidance where the other does not.

INTRODUCTION

The most controversial issue in the nuclear industry in the last few years has been radioactive waste. This includes high-level, low-level, and mixed waste. Finding environmentally acceptable sites for disposal, and defending the suitability of those sites is paramount to the successful establishment of satisfactory disposal facilities. Significant attention has been given to site characterization. The need for consistent application of quality assurance is becoming increasingly recognized and urgent. The industry is under such close scrutiny, it can not afford any of the quality problems which have plagued the engineering, construction and operation of nuclear power plants. The political consequences are unacceptable. Nuclear quality assurance guidance documents have historically not provided complete specific quality assurance guidance for the performance of the scientific investigations involved in site characterization. While site investigations have been proceeding since the mid 1970s, these issues are just now beginning to be addressed.

Developing separately, quality assurance in environmental areas under the regulatory control of the Environmental Protection Agency (EPA), has established routine quality assurance techniques for the scientific investigations involved in environmental monitoring, sampling, and other activities. The investigations required for hazardous waste remediation has produced its own unique set of quality requirements. Because of the different historical needs of the EPA (vs NRC) the regulatory approach to quality assurance is different, the scope is different, and, while much of the same quality terminology is used by EPA, the meanings are sometimes subtly different.

Since existing nuclear quality assurance guidelines (ANSI/ASME NQA-1) do not specifically address the quality assurance and quality control requirements for site characterization, borrowing from the EPA guidelines, as was done with recent draft of ANSI/ASME NQA-3, is appropriate. On mixed waste projects, handling both radioactive and hazardous wastes, both regulatory agencies must be satisfied. Upon first impression, because of their differences, this appears difficult to do without utilizing two separate programs. However, on closer examination, the complementary aspects of the two approaches can be capitalized upon to produce an integrated quality assurance program.

QMS-05x only a discuss data reports

HISTORICAL PERSPECTIVE OF THE EVOLUTION OF QUALITY ASSURANCE GUIDANCE FOR SCIENTIFIC INVESTIGATIONS IN THE NUCLEAR INDUSTRY

In the mid 1970s, there was still a positive atmosphere around nuclear power. The oil price shock of 1973-74 had most of the industry in high gear to build power plants. The realities of the technical problems associated with the nuclear power industry and nuclear waste had only begun to be envisioned. A few plant cancellations had occurred but their significance had yet to be realized. The major problems, delays, policy changes and cancellations still lay in the future. The current quality assurance industry standard was ANSI N45.2 and its associated daughter standards. It provided acceptable interpretations for implementation of 10 CFR 50 Appendix B Quality Assurance requirements. The focus was design, procurement and construction of hardware. One daughter standard, ANSI N45.2.20, "Supplementary Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants" was in the draft stages of preparation (1973). This standard addressed the requirements for geological investigations, including soil sampling, borings, and geophysics. It did not address environmental sampling and monitoring. Many reasons can be hypothesized for this but a basic one is the considerable philosophical and physiological differences between the construction industry and the scientific community. There was no great urgency to issue the standard for nuclear industry use because most of the plants were already under construction. When this standard was finally issued in 1979, it did not get significant attention because there was no siting work proceeding and the issues surrounding site characterization had not fully surfaced. Shortly after that, ANSI/ASME NQA-1 replaced the ANSI N45.2 series with no equivalent subsurface quality assurance guidelines.

The disaster of Three Mile Island in 1979 combined with President Jimmy Carter's policy changes stopping the design and construction of fuel reprocessing facilities, ended the idealistic acceptance of nuclear power and created a politically troubled and problem plagued industry that no one wanted in their back yard. The public no longer trusted the industry (if it ever did) or the regulators. Now the problem of waste disposal was further complicated by the need to store spent fuel which might want to be recovered and reprocessed someday. Site selection became sensitive and political, every agency became involved and all research and investigations became subject to extreme scrutiny. The nuclear power plant design and construction industry had its infancy in a positive atmosphere with relatively straight

forward regulatory requirements. Its adolescence had clearly defined quality assurance standards through the ANSI N45.2 and regulatory interpretation (Regulatory Guides). There has been no such clear quality assurance guidance or regulatory stability for the scientific investigations involved in pre-site selection and characterization activities for waste repository facilities.

Regulatory and national standard guidance has not yet been firmly established with agreement from all concerned participants. Not until 1984 has there been any directly applicable interpretations of the necessary and prudent quality assurance measures to be applied to waste repository pre site selection and site characterization activities. Interpretations that have been issued have not been stable. The NRC and DOE have not always agreed and there has been debate on how much, if any, of a waste repository was "Safety Related" by nuclear power definitions. New definitions have been created. A review of guidelines and standards development proceeds as follows:

- Prior to 1979 -- ANSI N45.2 was the accepted quality assurance standard. It addressed design, procurement, and construction; all of which are not applicable to the scientific investigations and studies involved in pre-site selection and site characterization.

- 1979 -- ANSI N 45.2.20 was issued applicable to subsurface investigations for nuclear power plants. It was not applicable to waste repositories and guidance was limited to geological concerns surrounding the civil engineering requirements for foundation design. It did not include other environmental concerns such as ground water studies.

- 1979 -- ANSI/ASME NQA-1, 1979 was issued. NQA-1 was specifically applicable to Nuclear power plants. While replacing ANSI N45.2, it was oriented totally toward the hardware aspects of design, procurement, construction, operation and decommissioning and did not contain the sub-surface guidance of ANSI N45.2.20.

- 1983 -- ANSI/ASME NQA-1, 1983 was issued. Its applicability was expanded to include waste storage design, construction, operation and decommissioning. It was closer, but did not contain guidance for the scientific investigations required for repository pre-site characterization activities proceeding at the time.

- 1984 -- The NRC issued a guidance document in the form of the "NRC Review Plan for Site Characterization of

Waste Repositories". However, the activities proceeding in the burgeoning repository industry were difficult to classify as site characterization.

- 1985 -- The ANSI/ASME issued for comment in January, a draft supplement to ANSI/ASME NQA-1, Section 11S-2 "Supplemental Requirements for Investigative and Development Testing for Nuclear Waste Management" and the OCRWM issued "OCRWM QA Management Policies and Requirements". Finally there was specific guidance available to use on the work proceeding. Unfortunately, the draft supplement to NQA-1 met with considerable comment and went back to committee, not to re-emerge again until over a year and a half later in August 1986 for balloting. After balloting, it was killed and never issued.

- 1987 -- The first draft of ANSI/ASME NQA-3 "Quality Assurance Program Requirements for the collection of Scoentific and Technical Information for Site Characterization of High Level Nuclear Waste Repositories" was issued in July. It was the first standard to incorporate the kind of proven quality assurance and quality control techniques employed by the EPA. It borrows heavily from the environmental community. In February of 1988, a second draft was issued.

COMPARISON OF EPA AND NUCLEAR QUALITY ASSURANCE REQUIREMENTS

Contrary to the nuclear industry, rather than hardware quality, the EPA has focused on data quality. Rather than centralized quality regulatory requirements like 10CFR50, Appendix B and ANSI/ASME NQA-1, EPA quality assurance requirements are embedded in numerous regulations. Each of the quality assurance requirements documents has a slightly different focus and structure. While the NRC approach requires largely programmatic documents to be produced in a format convenient to the user and supplemented by implementing procedures, the EPA is prescriptive and requires procedural, quality control oriented documents fashioned in a format dictated by regulation and containing specific procedures. Areas such as design, procurement, document control and records are not highlighted in EPA quality assurance regulations but get separate attention in other specific documents (project management requirements, procurement regulations, etc). There are several EPA documents which specify Quality Assurance requirements. The two primary guidance documents are:

- Guidelines and Specifications for Preparing Quality Assurance Program Plans, QAMS-004/80

- Guidelines and Specifications for Preparing Quality Assurance Project plans, QAMS-005/80

Both of these documents are focused on data quality. QAMS-004/80 is targeted toward a local agency or state authority for overall administration of data collection efforts and requires implementation of QAMS-005/80 on a site specific basis. Normally contractors are required to prepare and submit for EPA approval, a site specific QA Project Plan. The criteria of each of these documents are listed in Table 1.

Neither of these documents satisfy all NQA-1 requirements, either singularly or together, and could not be used exclusively to satisfy nuclear quality assurance requirements. However, they have some things in common with NQA-1 and have guidance for activities not covered in NQA-1. The following discussion highlights the differences in guidance furnished by QAMS-005/80 and ANSI/ASME NQA-1. This discussion is centered around the quality assurance needs of scientific investigations required for nuclear waste site characterization and mixed waste site remedial investigations.

The scientific investigation is a distinctly different activity from the relatively production oriented aspects of the design and construction of a facility. In design and construction, we have great control over the whole process. We control temperatures, tolerances, and the rate at which things happen. Our design and construction activities are based upon specific plans, procedures, specifications and drawings. We heat-treat, weld, assemble and machine to achieve expected results within specified tolerances planned and documented in these plans, procedures, specifications and drawings. Unexpected, in process changes can be held down to a minimum based on our experience and degree of planning. Items can be inspected to verify conformance. If something does not meet requirements it is considered nonconforming and is scraped, reworked, repaired, or used-as-is under strict controls. This is not the case with a scientific investigation or research activity. First and foremost, we **expect the unexpected**. The initial direction of the investigation is planned but it is not uncommon to have unexpected results change the course of the activities. While the measurements we make can be specified as far as precision, accuracy, representativeness, completeness, and comparability, the data we obtain can not directly inspected or be termed nonconforming. We are discovering existing conditions which we have little or no control over. Repair, rework, or scrap have

no meaning with the production of data. All data is use-as-is. If something happens which is unexpected, we can not always stop and regroup. The data must be taken and evaluated later. It may be lost otherwise. Stop work has a different meaning. Because of the un-predictability of scientific research, procedures can not be as prescriptive, they must allow for the unexpected. Records and the quality of the measurement tools become the determinators of the quality of the work performed and its defensibility. Personnel qualifications may be less susceptible to test and certification (such as with NDE and welding), they are academic in nature. Maintenance of the measuring tools becomes a quality assurance criteria when measurement tools are to be left unattended. The avoidance of down time of these tools may determine if the desired data is obtained and its completeness.

It can be seen from examination of the criteria listings of Table 1 that the quality assurance criteria required by EPA stop short of being complete for the entire process of a scientific investigation. It focuses only upon data. It does not provide quality assurance guidance as to the evaluation and conclusions drawn from the data (ie: Peer Review) nor does it give guidance in several other areas which are applicable to a complete quality assurance program for a scientific investigation. Procurement, records and generic document control are among the criteria not addressed. ANSI/ASME NQA-1 must be referenced for establishment of a complete quality assurance program. However, since NQA-1 does not give guidance for these activities, the criteria of QAMS-005 may be added to NQA-1 to provide a more complete standard. The NQA-3 draft issued in July 1987 and updated in February 1988 incorporates applicable requirements for scientific investigations. It borrows from the EPA heavily. Since mixed waste and other DOE sponsored projects must satisfy both NQA-1 and QAMS-005/80, Table 2 presents a comparison between NQA-1 and QAMS-005/80 which may be useful. It is based upon the interpretation given by the draft NQA-3. NQA-3 incorporates data quality assurance criteria and controls which have no equal in NQA-1 into criteria 3, Design Control. Indicated by QAMS-005/80 criteria, they are as follows:

- Criteria 5.0 -- Objectives for data quality can be set based upon the specific activity being performed. They are limited by field conditions, the data being sought and technology. These are set in terms of Precision, Accuracy, Representativeness, Completeness, and Comparability (PARCC). This is similar to the setting of tolerances for a design.

- Criteria 6.0 -- Sampling procedures are required for direct inclusion in the EPA QAPP. It does not have a generic "Instructions, Procedures, and Drawings" requirement. Since sampling procedures are difficult to classify as a special process of test, the requirement is placed by ANSI/ASME NQA-3 in Criteria 3.

- Criteria 10.0 -- Data reduction, validation, and reporting. While data reduction controls can be interpreted as equivalent to calculation control for design, validation is unique to scientific data. Data is considered valid only if specific information about the data are known. Such information includes, who obtained the data, when, where, and how it was obtained, what procedures were used, the conditions under which it was obtained, the calibration status of the instruments, and, in the case of samples, what preservatives were used, who has handled the samples and where have the samples been. Data validation deliberately evaluates the quality of the data in terms of what is known about it.

- Criteria 11.0 -- Internal quality control checks. Since data cannot be inspected directly to determine its quality or conformance to requirements, an indirect method must be used. Quality control samples or checks are used to measure the quality of the sampling and analysis process, thus indicating the quality of the data obtained using the sampling and analysis process. Sample blanks, splits, duplicates, etc. are used at a planned frequency to accomplish this.

- Criteria 14.0 -- Specific routine procedures are used to assess data quality in conjunction with the quality control checks to determine data precision, accuracy and completeness.

The other criteria of QAMS-005/80 have equivalent requirements in NQA-1 and the subjects are discussed in NQA-3. However, the approach used in some of them is unique to data quality and deserves separate discussion.

- Criteria 7.0 -- Identification and control of items is taken one step further with chain-of-custody. Chain-of-custody procedures require that not only do samples have to be identified, their location and handling must be known from initial acquisition through eventual consumption or storage. This includes the logging of all activities which affect the sample through signature documentation of receipt, possession and release by all those persons handling the sample.

- Criteria 13.0 -- In addition to calibration, preventive maintenance is required for instrumentation which will be left unattended (such as air monitoring and well level monitoring instrumentation). Not only is the accuracy important to data collection and meeting project goals, the serviceability of the instruments becomes an essential aspect in obtaining complete data.

- Criteria 12.0 -- Audits are used similarly by the EPA to assess the status and adequacy of implementation of the quality assurance program (system audits). The EPA takes audits one step further into performance auditing. Similar to the technical audits conducted in nuclear arenas, performance audits are parallel activities conducted independently, to evaluate the adequacy of an activity. Examples are; introduction of a calibrated standards gas into a detector independent of the person performing calibration checks; a second analysis performed of a sample independently, and; the blind introduction of a known sample into an analysis stream.

CONCLUSIONS

While alone, EPA guidelines do not cover all the quality assurance concerns for a full scope program as required by the DOE and NRC, the nuclear industry needs to borrow from the EPA those proven quality assurance practices for scientific investigations. The quality assurance criteria of EPAs QAMS-005/80 provides appropriate controls required for the acquisition of data. Using the guidelines established by the draft ANSI/ASME NQA-3 to adopt the EPA approach to data quality assurance provides a well proven acceptable method of assuring the reliability of data obtained for scientific investigation. Currently, the draft NQA-3 is applicable only to scientific investigations conducted for high level nuclear waste repositories. Upon issuance consideration should be given to expanding its applicablity to any scientific investigation conducted in the nuclear power arena; experiments, low and high level waste repository site characterizations, etc.

When a specific project is required to satisfy both DOE and EPA quality assurance requirements (ANSI/ASME NQA-1 & QAMS-005/80), there are no incompatibilities. The Quality Assurance Project Plan required by the EPA, provides a procedural implementation mechanism for both the planning and procedures required by the DOE through NQA-1. If the quality assurance program prepared in accordance with NQA-1, requires the preparation of a "Quality Assurance Project Plan (QAPjP)" for

each site in accordance with the content requirements of QAMS-005/80, not only will the QAPjP satisfy the procedural implementation requirements of NQA-1, the NQA-1 quality assurance program will then comply with QAMS-004/80, for preparation of quality assurance program plans.

The controls required for scientific investigations are unique and not the same as those required for design, procurement and construction. While the draft ANSI/ASME NQA-3 has proceeded along these lines and provides such scientific investigation guidance mainly under design control, it is a force fit. Apparently this was done because the data may provide design criteria, not because the controls over data quality are the same as the controls over design. (Using this philosophy, we could group all quality assurance controls under one criteria called construction, because data provides a basis for design, design provides a basis for construction, procurement provides materials for construction, etc.). Controls required for design activities are different than those required for scientific investigations. Consideration by the NRC and DOE may be warrented to consider separate treatment of the controls required for scientific investigations by the creation of a 19th criteria and 10 CFR 50 Appendix B revision.

TABLE 1
Listing of QAMS-004 & 005 Criteria

QAMS-004/80		QAMS-005/80	
1.0	Identification of the Office, Region, or Laboratory Submitting QA Program Plan	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	Personnel Qualifications	5.0	QA Objectives for Measurement Data in Terms of Precision, Accuracy, Representativeness, Completeness, and Comparability
6.0	Facilities, Equipment, and Services	6.0	Sampling Procedures
7.0	Data Generation	7.0	Sample Custody
8.0	Data Processing	8.0	Calibration Procedures and Frequency
9.0	Data Quality Requirements	9.0	Analytical Procedures
10.0	Corrective Action	10.0	Data Reduction, Validation, and Reporting
11.0	Implementation Requirements and Schedules	11.0	Internal Quality Control Checks and Frequency
		12.0	Performance and System Audits
		13.0	Preventive Maintenance Procedures and Schedules
		14.0	Specific Routine Procedures to be Used to Assess Data Precision, Accuracy, Representativeness, Completeness, and Comparability (PARCC) of Specific Measurement Parameters Involved
		15.0	Corrective Action
		16.0	Quality Assurance Reports to Management

TABLE 2

A COMPARISON BETWEEN NQA-1 AND EPA QAMS 005/80

(Using The Guidance of The February 1988 Draft NQA-3)

ANSI / ASME NQA - 1	EPA QAMS 005 / 80
CRITERIA 1.0 --- ORGANIZATION	4.0 --- PROJECT ORGANIZATION AND RESPONSIBILITY
CRITERIA 2.0 --- QUALITY ASSURANCE PROGRAM	3.0 --- PROJECT DESCRIPTION 16.0 --- QUALITY ASSURANCE REPORTS TO MANAGEMENT
CRITERIA 3.0 --- DESIGN CONTROL (NQA-3 SUPPLEMENT 3SW-1) (Para.3)	5.0 --- QA OBJECTIVES FOR MEASUREMENT DATA IN TERMS OF PRECISION, ACCURACY, COMPLETENESS, REPRESENTATIVENESS AND COMPARABILITY
(Para. 4)	6.0 --- SAMPLING PROCEDURES
(Para. 4.1)	10.0 --- DATA REDUCTION, VALIDATION AND REPORTING
(Para. 4)	11.0 --- INTERNAL QUALITY CONTROL CHECKS AND FREQUENCY
(Para. 4)	14.0 --- SPECIFIC ROUTINE PROCEDURES TO BE USED TO ASSESS DATA PRECISION, ACCURACY AND COMPLETENESS OF SPECIFIC MEASUREMENT PARAMETERS INVOLVED
CRITERIA 4.0 --- PROCUREMENT DOCUMENT CONTROL	
CRITERIA 5.0 --- INSTRUCTIONS, PROCEDURES AND DRAWINGS	

(Continued)

TABLE 2
(Continued)

ANSI / ASME NQA - 1	EPA QAMS 005 / 80
CRITERIA 6.0 --- DOCUMENT CONTROL	1.0 --- TITLE PAGE WITH PROVISION FOR APPROVAL SIGNATURES 2.0 --- TABLE OF CONTENTS
CRITERIA 7.0 --- CONTROL OF PURCHASED ITEMS AND SERVICES	
CRITERIA 8.0 --- IDENTIFICATION AND CONTROL OF ITEMS (NQA-3 Para. 8.1)	7.0 --- SAMPLE CUSTODY
CRITERIA 9.0 --- CONTROL OF PROCESSES (NQA-3 Para. 9.2)	9.0 --- ANALYTICAL PROCEDURES
CRITERIA 10.0 --- INSPECTION	
CRITERIA 11.0 --- TEST CONTROL	
CRITERIA 12.0 --- CONTROL OF MEASURING AND TEST EQUIPMENT	8.0 --- CALIBRATION PROCEDURES AND FREQUENCY 13.0 --- PREVENTIVE MAINTENANCE PROCEDURES AND SCHEDULES
CRITERIA 13.0 --- HANDLING, STORAGE AND SHIPPING (NQA-3 Para. 13.2)	6.0 --- SAMPLING PROCEDURES
CRITERIA 14.0 --- INSPECTION, TEST AND OPERATING STATUS	
CRITERIA 15.0 --- CONTROL OF NON-CONFORMING ITEMS	
CRITERIA 16.0 --- CORRECTIVE ACTION	15.0 --- CORRECTIVE ACTION
CRITERIA 17.0 --- QUALITY ASSURANCE RECORDS	
CRITERIA 18.0 --- AUDITS	12.0 --- PERFORMANCE AND SYSTEM AUDITS AND FREQUENCY