WASTE MANAGEMENT R&D QUALITY ASSURANCE: AN ALTERNATIVE APPROACH*

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ABSTRACT

This paper summarizes the development and initial implementation of a Quality Assurance (QA) Program for technical activities associated with assessing compliance of an existing DOE nuclear waste site with applicable environmental regulations. The requirements for establishing the QA program are defined, along with the approach and emphasis used to develop the program. The structure of the program and the various levels of QA plans and procedures are briefly discussed. Initial implementation efforts are summarized. The QA program was developed by and for the project participants and was structured according to the major technical requirements of the project. The QA plans and procedures are written for the convenience and use of the technical staff and not merely to satisfy auditor expectations. Every effort was made to avoid an 18-point approach typical of many QA programs patterned after the dictates of the industry recognized "national consensus standards." Flexibility is emphasized due to the nature of the research and development activities associated with the technical program. Recommendations are provided for using this alternative approach to QA program development for similar technical efforts elsewhere.

BACKGROUND

Sandia National Laboratories (SNL) is currently supporting the Department of Energy (DOE), Nevada Operations, under the office of the Assistant Manager for Environment, Safety and Health, Health Physics and Defense Waste Division, Defense Waste Management Branch, in assessing the performance and compliance of an existing nuclear waste site at the Nevada Test Site. The Greater Confinement Disposal (GCD) site provides an alternative "intermediate-depth" disposal method for a variety of "orphan" wastes, including defense transuranic wastes that do not meet the acceptance criteria of the Waste Isolation Pilot Project (WIPP), low-level wastes that exceed the Class-C limits, and other orphan wastes. A technical program has evolved to address the technical and regulatory issues associated with assessing the performance of the GCD site and to develop a strategy for demonstrating compliance of the disposal concept with pertinent regulations.(1) Typical activities include site characterization and data acquisition efforts; source term analysis; a preliminary performance assessment to provide an initial basis for decisions regarding long-term analysis efforts that includes identification of critical models, input parameters, and the analytical computer codes needed to determine whether the site complies with environmental regulations; and the final performance assessment. The project participants include waste management experts from SNL, Reynolds Electrical & Engineering Company (REECo), Raytheon Services Nevada, and others.

DEFINITION OF QA REQUIREMENTS

In addition to the development of the technical program, planning efforts from the outset have included the identification of quality assurance (QA) requirements applicable to this research and development effort. The requirements then establish the approach for developing and implementing the GCD QA program. During Fiscal Year 1990 (October 1989 to September 1990), an analysis of the QA requirements for the GCD project was performed. All of the potentially applicable regulations and DOE Orders were reviewed for QA requirements. Various Environmental Protection Agency (EPA) regulations and QA documents were analyzed for aspects that might apply to the GCD project. The QA programs that were developed within SNL for the Yucca Mountain Project and the WIPP Project were also reviewed to gain an appreciation of what QA provisions have been useful and what to avoid with a program of the size and scope of the GCD project. The experience gained in developing and implementing QA programs for a variety of non-weapons research projects within SNL related to nuclear and waste management analyses and experimental efforts (Table I) was summarized. The national consensus standards for QA, such as the American Society of Mechanical Engineer's (ASME)

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TABLE I

Representative SNL Nuclear Waste QA Programs

Doc. No.	Title	Date
NUREG/CR 4369	Quality Assurance (QA) Plan for Computer Software Supporting the U.S. Nuclear Regulatory Commission's High-Level Waste Management Program	January 1986
SAND87-2254	High-Level Waste Management Code Maintenance and Quality Assurance	January 1988
LLW QA Plan	Quality Assurance Plan: Performance Assessment Methodology Development, LLW Disposal Safety Assessment	April 1989
QAP 6416-1	Quality Assurance Plan: Development of a Methodology for Performance Assessment of Nuclear Waste Isolation in Alternative Geologic Media	March 1989
QAP 6416-1A	Quality Assurance Procedure: FIN A-1266 Subtask 2.10, Development of a Computer Program for Simulating Groundwater Flow in Unsaturated Tuff	July 1989
QAP 6416-1B	Quality Assurance Procedure: FIN A-1266 Subtask 2.13, Preparation of Computer Programs for Implementing Mathematical Models of the Transport of Radionuclides in Unsaturated Welded Tuff	July 1989
QAP 6416-2	Quality Assurance Plan: FIN A-1165, Technical Assistance for Performance Assessment	March 1989

NQA-1,(2) ASME NQA-3,(3) and others, were also reviewed for applicability.

DOE Orders provide the primary basis for establishing the QA requirements for the GCD project. Specifically, DOE Order 5820.2A(4) provides policies, guidelines, and minimum requirements (including quality assurance) for managing radioactive and mixed waste facilities. Throughout, it references the requirements of DOE Order 5700.6B.(5) Both Orders endorse the use of the applicable requirements of NQA-1 and other appropriate national consensus standards. Both DOE/AL Order 5700.6B(6) and DOE/NV Order 5700.6B(7) specify "the judicious and selective application of appropriate requirements" of NQA-1. It was concluded that the final basis for the development of the GCD QA program must be based on NQA-1 guidance.

However, the DOE Orders provide considerable flexibility in the definition and selective application of the appropriate QA provisions based on a project-specific analysis. Traditionally, NQA-1 has served the needs of the nuclear industry well for the kinds of activities associated with commercial nuclear power plants. Though NQA-1 has gained acceptance as the "de facto" national consensus standard for QA in the nuclear industry, it has its shortcomings when applied to activities for which it was not originally intended (specifically activities associated with nuclear waste management research and development). In part due to past acceptance by auditors, utilities, and regulatory agencies, attempts have been made to force-fit NQA-1 provisions on projects (like the GCD project) that involve primarily analytical activities associated with nuclear waste site characterization and performance assessment. Among the major conclusions derived from the definition of GCD QA requirements is that the existing "standards" for QA in the nuclear industry (1) contain many elements that do not apply to the kind of technical efforts involved in the GCD project, and (2) are deficient in providing guidance for appropriate QA provisions for such things as site characterization and performance assessment analyses. Other standards, such as NQA-3 and the EPA QAMS documents,(8,9) do provide some guidance where NQA-1 is deficient or does not apply. Since no single QA standard provides an adequate basis for developing and implementing effective QA provisions for the GCD project, it became apparent that a QA program tailored to the project was required. The QA policy and approach for the GCD project QA program were developed based on this basic assessment.

APPROACH AND EMPHASIS FOR THE GCD QA PROGRAM

Similar to the approach taken at SNL over the past 6 years in other energy R&D programs, it was decided that a "reasoned" approach was needed to tailor (and structure) the QA program to the project, and not to NQA-1. It was considered important not to simply force-fit the QA requirements for the technical program around the "familiar" 18 quality criteria in NQA-1. Those criteria are familiar to QA professionals and auditors but are largely foreign and meaningless to the technical staff. Table II summarizes the primary differences between the GCD QA program and the typical emphasis encountered in typical nuclear project QA programs. The technical staff were involved in all phases of the development of the QA program and can claim a sense of ownership in the program provisions. It was considered imperative to keep the plans and procedures as simple, brief, concise, and clear as possible, and to avoid unnecessary QA provisions. The approach is success-oriented and emphasizes flexibility in planning and implementation. The structure of the program is modular and task-oriented, in order to be readily adaptable to the inevitable changes in direction and scope that the project will take. It is desired that the QA program be an integral part of project management as a management tool and resource to the project, and not just a policing function. Primary objectives of the program are to properly define and emphasize achievement of customer requirements and to ensure, and verify, adherence to good engineering and management practices. Emphasis is placed on project planning, "real-time" technical reviews, data quality, software QA, document control and records management, and QA surveillances. Less emphasis is placed on hardware-oriented activities such as nonconformance reporting, receiving inspection and other inspection activities, "special processes," and auditing. Finally, the policy for the overall QA management plan makes it clear that quality is the responsibility of all project participants, not the QA staff alone.

QA PLANS AND PROCEDURES

The overall basis for the GCD QA provisions is provided in the "Quality Assurance Management Plan (QAMP) for the Greater Confinement Disposal Compliance Assessment Program."(10) This plan is supported by "activity-level plans" (for continuing efforts that are not defined by specific tasks) for software and data base QA and document control and records management. All of these plans provide the basic requirements for a small number of brief implementing QA procedures (Table III) for certain general activities requiring more detailed guidance. These QA plans and procedures provide the framework and basis for the selective identification of QA requirements at the task-level. See Fig. 1. The QAMP requires the development and implementation of task-level QA plans to be written by each Task Leader as technical project tasks are defined and implemented each fiscal year. The Task QA Plans utilize the upper-tier QA plans and procedures as a shopping list of potentially applicable requirements and provide the final set of QA requirements for a given task, thereby providing the flexibility to easily adapt to changing customer requirements. As "living" controlled documents, the Task Plans are easily revised as technical scope or requirements change. Finally, technical plans and procedures are developed as required at the task level to implement specific technical activities called out in the task plans.

ACTIVITY-LEVEL QA PLANS

Software quality engineering practices are required of all GCD project software in order to achieve confidence in results generated with computer codes used in performance assessments of radioactive waste disposal. These results must be defensible, traceable, and reproducible. In order to achieve these goals, there are two primary requirements for quality software. The first requirement is a life-cycle approach to all phases of software (development, acquisition, modification, testing and verification, documentation, maintenance, and retirement). The degree of application of life cycle should be commensurate with the complexity and importance of each code to the GCD project analyses. The second requirement for quality software is Software Configuration Management (SCM) that establishes baselines for codes and tracks code modifications. The basic purpose of SCM is to be able to reproduce analysis results through identification of the code version used in analysis and to provide a system for reporting, correcting, and tracking software problems and improvements. The appropriateness of applying software to a specific physical process (validation) must be determined and documented by the analyst. Responsibilities are assigned for software activities, software quality reviews, software documentation reviews, and verification of adherence to plans via scheduled surveillances.

Emphasis in the areas of document control and records management is placed on the development and implementation of a reasonable set of plans and procedures to establish and maintain project-specific control of project documents and establishment of a records center dedicated to the project. The systems established are essentially responsive to the basic requirements of NQA-1 without unnecessarily burdening the technical staff with forms and long delays to enter and retrieve project documents and records. A limited set of critical project QA plans and procedures and technical plans, procedures, and other documents is handled as controlled documents. Significant responsibilities are placed on document authors and Task

TABLE II

Comparison of QA Programs

GCD QA Program	Traditional QA Programs
1. Content and format based on project technical activities.	1. Content and format patterned after NQA-1.
2. Flexibility emphasized, particularly for R&D activities.	2. Prescriptive and strict adherence to "standard" QA principles demanded.
3. Developed by the project staff for the project staff.	3. Developed by the QA organization for the convenience of the auditors.
4. Considered a resource to the staff; a useful tool and an integral part of project management.	4. Emphasizes the independent adversarial policing function, and is viewed by many staff as a painful and costly burden.
5. Emphasizes a select group of critical technical activities, de-emphasizing less applicable QA provisions.	5. "Force-fits" an equal emphasis on the full set of the 18 criteria of NQA-1, despite applicability or deficiency in guidance.
6. Emphasizes real-time reviews and surveillance activities during the conduct of the technical activities.	6. Emphasizes auditing activities, after the technical program is well underway or completed.

TABLE III

GCD Project QA Procedures

Doc. No.	Title
QP 2-1	Personnel Certification and Training Program for the GCD Project
QP 3-1	Plan and Procedure Preparation, Format and Content
QP 4-1	Guidelines for Establishing Data Quality for the GCD Project
QP 4-2	Tests, Experiments, and Scientific Investigations
QP 4-3	Reviews for the GCD Project
QP 6-1	GCD Document Control
QP 7-1	GCD Records Management
QP 10-1	Surveillance and Quality Review for the GCD Project
SQAP	WMSD Software Quality Assurance Procedures

Leaders to ensure that the system works for the GCD project.

IMPLEMENTATION

The resources required to develop the GCD QA program were significant, requiring the efforts of a number of SNL staff and contractors to prepare, review, and gain approval of the current set of plans and procedures. Implementation efforts are currently under way for Fiscal Year 1991 project activities. The overall QA Management Plan and activity-level QA Plans have been submitted to the DOE for review and approval. A series of training and familiarization modules have been developed and implemented. Table IV summarizes the initial set of training modules offered. In succeeding years it is expected that specialized training in specific areas of concern and emphasis will be provided. A comprehensive internal surveillance program has been developed to allow self-assessment of the adequacy of staff implementation of QA provisions, and the adequacy of the QA program itself. One of the primary objectives of the surveillance program is to provide continuing one-on-one training for all project staff. Table V lists in general the items and activities that will be subject to surveillances. It is too early to judge the success of this program and the acceptability of the approach until full implementation has occurred and the program of surveillances and quality reviews has been performed.

SUMMARY AND RECOMMENDATIONS

In summary, there is strong consensus among the technical staff and QA staff involved in the GCD project at SNL that the current QA program will be successful because (1) it was established based on a careful assessment of project-specific requirements, (2) the technical staff was involved in developing the plans and procedures, and (3) the plan was implemented at the beginning of the project. There is a feeling of ownership of the QA program by the project participants. If proven successful, this program can serve as an example of an acceptable alternative approach to the development and implementation of QA provisions appropriate to waste management R&D efforts. The following recommendations are offered by the authors of this paper for others who are attempting to establish similar QA programs:

1. The most important ingredient for success is to ensure solid management commitment.

Fig. 1. GCD QA program elements.

TABLE IV

GCD QA Training Program

No.	Session
1.	a. Overall GCD QA Program b. Project Planning
2.	a. Plan/Procedure and Report Preparation b. Technical/Peer Reviews
3.	a. Procurement b. Data Quality, Tests and Experiments
4.	a. Software and Data Base QA b. Analysis Documentation
5.	Document Control and Records Management
6.	Surveillance and Quality Reviews

TABLE V

Planned GCD Surveillances

- ✓ Primary surveillances against the stated requirements in the Task QA Plans.
- ✓ Task-specific surveillances against technical plan and procedure requirements.
- ✓ Documentation of personnel qualification certifications.
- ✓ Conduct and documentation of GCD project QA training program.
- ✓ Control of QA and technical plans and procedures.
- ✓ Implementation of document control and records management.
- ✓ Task-specific documentation of reviews.
- ✓ Task-specific documentation of analyses.
- ✓ Implementation of software and data base quality requirements.
- ✓ Documentation of data quality objectives and data quality rationale.
- ✓ Conduct and documentation of tests and experiments, including logbooks.

2. Start early and involve all project staff in developing the program.
3. The QA staff should be technically qualified to effectively communicate with the technical project staff. They should be engineers or scientists in addition to having QA experience.
4. Define the requirements for both the technical program and the QA provisions.
5. Emphasize what is important and avoid unnecessary QA "paperwork." Strive to be different, yet effective. Attempting to simply satisfy QA auditors and not the needs of the project is short-sighted and potentially meaningless from the standpoint of achieving quality.
6. The QA program should be flexible and modular in its structure to adapt easily to inevitable changes in project scope, direction, and funding. Tailor QA on a task-by-task basis for the technical program.
7. Emphasize planning, reviews, documentation, and verification activities.

Adherence to these principles will result in a QA program that is acceptable to both the project staff and, ultimately, the customer.

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