

NUCLEAR REGULATORY COMMISSION STAFF
SAFETY EVALUATION
OF
U. S. DEPARTMENT OF ENERGY
QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR THE
OFFICE OF CIVILIAN RADIOACTIVE
WASTE MANAGEMENT

MAY, 1989

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SAFETY EVALUATION

1. INTRODUCTION

The U. S. Department of Energy (DOE) established the Nevada Nuclear Waste Storage Investigations Project (changed to Yucca Mountain Project (YMP) in 1988) to investigate whether Yucca Mountain is a suitable site for the high-level radioactive waste repository. The YMP will perform investigations that will address items and activities which could affect the radiological health and safety of the public that the U. S. Nuclear Regulatory Commission (NRC) regulates.

To demonstrate compliance with legislative, regulatory, and DOE requirements for control and documentation of quality, DOE has established the Office of Civilian Radioactive Waste Management (OCRWM). (See Fig. 1a.) To establish a framework for consistency in the development of quality assurance (QA) programs, OCRWM has developed a Quality Assurance Requirements document (QAR), which defines the QA requirements governing activities affecting quality of all program participants. These participants include the OCRWM, Operations Offices, Project Offices, contractors, subcontractors, National laboratories, and other government agencies involved in performing quality-affecting activities. The requirements of the QAR document apply to the high-level radioactive waste repository, the monitored retrievable storage facility, transportation, and the Federal interim storage facility. QA plans and procedures of activities other than high-level radioactive waste activities will be prepared to implement QAR requirements. The QAR does not exclusively satisfy all QA requirements for a particular program. For the OCRWM program, the QAR is to be used in conjunction with the OCRWM Quality Assurance Program Description document (QAPD).

The QAPD implements and complies with the requirements of the QAR for the high-level radioactive waste repository, the monitored retrievable storage facility, transportation, and the Federal interim storage facility. The QAPD describes the QA program, for the DOE OCRWM, which includes the responsibilities for achieving and assuring quality at OCRWM, and the interfaces between OCRWM and project offices participating in the aforementioned DOE programs.

The NRC staff has prepared this Safety Evaluation (SE), which documents NRC's review of the information that DOE submitted in its QAPD, Revision 1. The QAPD addresses NRC's regulations, positions, and guidance documents on QA. This SE describes the regulatory criteria against which the QAPD was reviewed, summarizes the content of the QAPD, and provides a basis for NRC staff acceptance of it.

There is a limitation on the scope of this review. The QAR is the top-tier DOE requirements document; the QAPD implements its requirements. The NRC staff review has been limited to the QA requirements to be applied to the high-level radioactive waste repository program and has not included review of the monitored retrievable storage facility, transportation, and the Federal interim storage facility. These programs will be reviewed at a later date. Also, this review does not include the QA program plans and procedures of the organizations in the YMP responsible for preparing and implementing these QA program plans

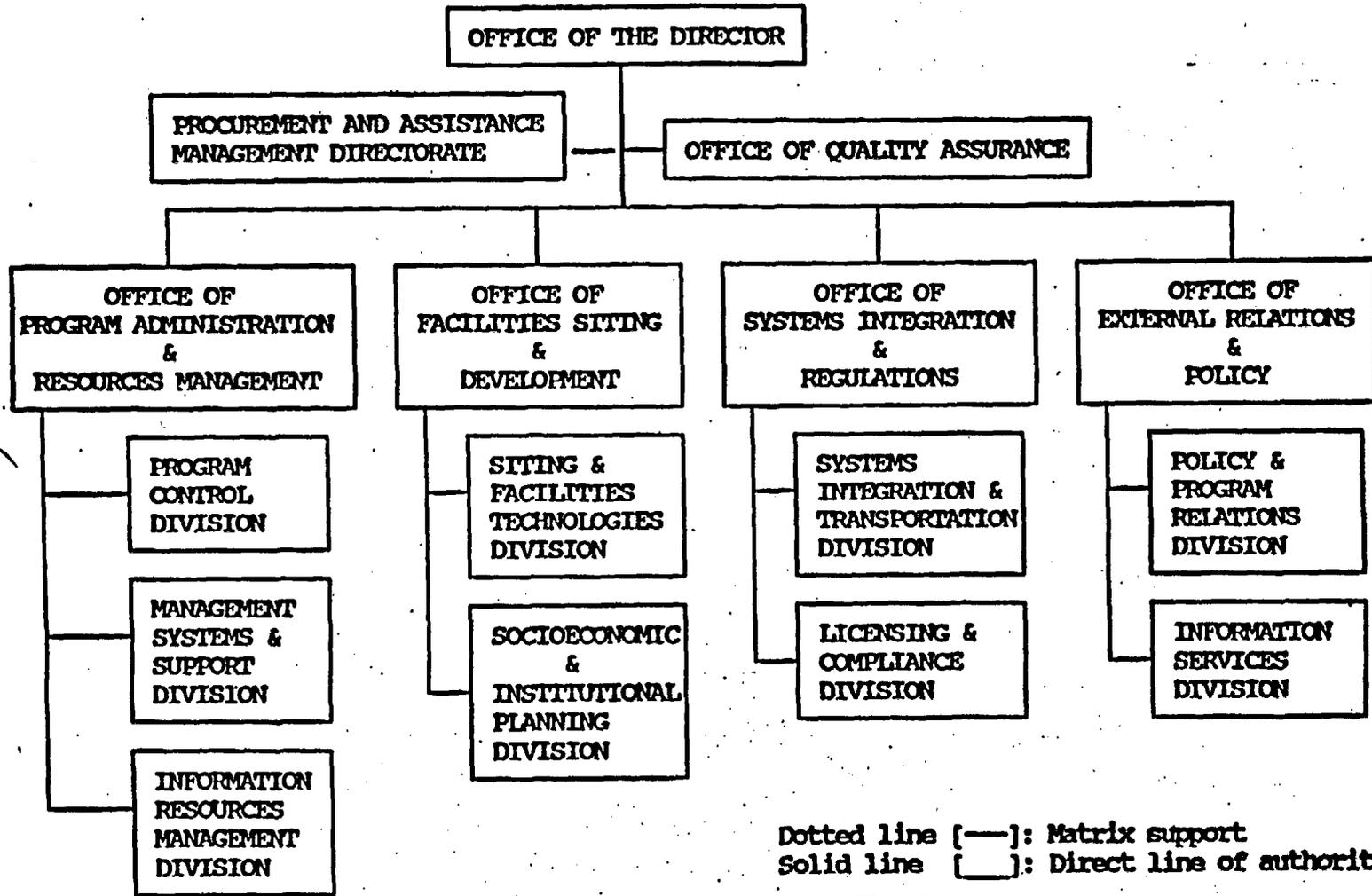


FIGURE 1
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
ORGANIZATION

in the site and laboratory investigations. These QA program plans and procedures will be designed to meet the requirements of the 88-9 QA Plan, Revision 2 (see Ref. 1), "Nevada Nuclear Waste Storage Investigation Quality Assurance Plan." This review also does not include the QA program plans and procedures of the OCRWM contractors that do not function under the OCRWM QA program, nor the waste glass producers.

2. BACKGROUND

On September 16, 1988, DOE submitted the QAPD, Rev. 0, to the NRC staff for review. As a result of the NRC staff review of the QAPD, a set of 15 comments was developed and discussed in a November 3, 1988 conference call between representatives of DOE, NRC, and State of Nevada. Resolutions of the NRC comments were subsequently discussed at a November 18, 1988 meeting between representatives of DOE and NRC, at NRC Headquarters in Rockville, Maryland. Other participants included representatives from the State of Nevada and the Utility Nuclear Waste Management Group.

At this meeting, DOE provided responses to NRC's comments. Some of the major items that were resolved pertained to the NRC Generic Technical Positions on "Peer Review," "Qualification of Existing Data," "Q-List," "Software QA" (NUREGS 1297, 1298, 1318, and 0856 respectively, see Refs. 2 to 5), the degree of involvement of the QA organization, and the amount of description in the QAPD necessary to address Appendix B to 10 CFR Part 50 Criteria 8 through 15. Based on the above, the NRC staff concluded it had sufficient information on which to base an SE for the QAPD.

The NRC staff used the following review criteria and NRC staff positions to determine whether the QAPD appropriately addressed Appendix B to 10 CFR Part 50:

- October 14, 1988 Safety Evaluation for the Quality Assurance Plan, Nevada Nuclear Waste Storage Investigations, NNWSI/88-9, Revision 1 (see Ref. 1);
- NRC staff Technical Position on Peer Review (see Ref. 2);
- NRC staff Technical Position on Qualification of Existing Data (see Ref. 3);
- NRC staff Technical Position on Q-List (see Ref. 4);
- NRC staff Technical Position on Documentation of Computer Codes for High-Level Waste Management (see Ref. 5);
- "Review Plan for High-Level Waste Repository Program Descriptions" (see Ref. 6);
- American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME), NQA-1-1986 (see Ref. 7);
- Regulatory Guide 1.28 (endorses ANSI/ASME NQA-1-1983)(see Ref. 8);
- American National Standards Institute/American Society of Mechanical Engineers, NQA-1-1983 (see Ref. 9);

- Criteria from ANSI/ASME NQA-3 (Revision 1, 2/88) on design data control (see Ref. 10); and
- U. S. Nuclear Regulatory Commission, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants" (see Ref. 11).

DOE, in lieu of repeating verbatim much of the material contained in the aforementioned reference documents, has elected to commit to all or the appropriate sections of these documents in the applicable sections of the QAR and QAPD. Since the QAR is to be used in conjunction with the QAPD, the NRC staff finds this methodology acceptable for the implementation of the QAPD.

3. STAFF EVALUATION

The following sections describe in detail the NRC staff's evaluation of the QAPD for each of the 18 criteria of Appendix B to 10 CFR Part 50. Each section identifies the areas of the QAPD that the NRC staff reviewed, summarizes the QA measures that apply (from the criteria listed above), and the content of the QAPD and, where necessary, provides the NRC staff analysis of DOE's justifications for various approaches taken to fulfill the requirements of Subpart G of 10 CFR Part 60.

3.1 "Organization" (Criterion I)

The NRC staff reviewed the description of "Organization" provided in Section 1 of the QAPD. The criteria identified in Section 2 of this SE were used to assess the description. These criteria, in summary, are:

- a. The responsibilities for establishing and implementing the QA program shall be established.
- b. Persons performing QA functions shall have sufficient independence, authority, and organizational freedom to identify, initiate, recommend, and provide solutions to quality problems.
- c. The responsibilities for achieving and assuring quality shall be clearly established.

Figure 1 shows the organization of the OCRWM for QA. This includes the Office of the Director and the Offices of: Quality Assurance; Program Administration and Resources Management; Facilities Siting and Development; Systems Integration and Regulations; and External Relations and Policy. The Director, OCRWM reports directly to the Office of the Secretary, U. S. Department of Energy and has overall responsibility for the high-level waste repository program. The QA responsibilities of the Director, OCRWM include: (1) establishing and executing a QA program to assure compliance with applicable regulatory and licensing requirements; (2) establishing QA policy

direction and controls; (3) approving the QAR and QAPD documents; (4) maintaining cognizance of QA issues, problems and resolution; (5) providing for the annual assessment of the status, scope, adequacy, and compliance of the QA program; and (6) retaining responsibility for the quality of work delegated to contractors, consultants, and agents.

The Director, Office of Quality Assurance (OQA) reports directly to the Director, OCRWM and has been delegated the management responsibility and authority to direct and control QA functions to ensure that QA objectives are consistently met. The Director, OQA has direct access to, and maintains liaison with, the Director, OCRWM; the Associate Directors of other OCRWM offices; and management personnel of other program participants. This reporting relationship provides the organizational freedom and authority to identify quality problems; initiate, recommend, or provide solutions; and prevent or control further processing, delivery, or use of nonconforming items or activities, until disposition is obtained. The Director, OQA is responsible for the coordination, interpretation, and overview of program QA activities and for ensuring that appropriate quality management, policy, training, and verification controls are in place. The Director, OQA is required to have appropriate management and QA knowledge and experience; to have no responsibilities that prevent full attention to quality activities; and to be independent from undue pressures due to cost and schedule considerations. The responsibilities of the Director, OQA are to:

- (1) establish QA program policies and requirements in baseline or other controlled documents; (2) coordinate the development of OCRWM QA program documents; (3) provide QA guidance and direction to all program participants; (4) overview the QA program activities by conducting internal and external audits, assessments, and readiness reviews; (5) review QA program documents of DOE-managed project offices and OCRWM-managed program participants, for QA program compliance, and develop approval or disapproval recommendations to the Director, OCRWM; (6) review OCRWM procurement documents for QA requirements; (7) assure the development and implementation of a QA indoctrination program for all personnel; and (8) review and approve the indoctrination and training requirements for OQA personnel.

The Associate Director, Office of Program Administration and Resources Management (OPARM) reports directly to the Director, OCRWM and has primary responsibility for the development, implementation, and maintenance of a program management system, program management information system, project decision schedule, and program schedule. OPARM is also responsible for: managing and administering the Nuclear Waste Fund and the Interim Storage Fund; establishing OCRWM's annual procurement plan; and coordinating the preparation, review, approval, and control of procurement documents with DOE's Procurement and Assistance Management Directorate. The Associate Director, OPARM is also responsible for assuring that technical and QA requirements specified by other offices are incorporated into procurement documents, and that data systems meet the QA records requirements specified in the QAR.

The Associate Director, Office of Facilities Siting and Development reports directly to the Director, OCRWM and has primary responsibility for: (1) screening and characterization of the geologic repository site; (2)

repository facility development, design, and engineering; (3) exploratory shaft design and engineering; (4) providing management oversight and technical direction of the high-level waste repository program's geoscience activities; and (5) socioeconomic and institutional planning.

The Associate Director, Office of Systems Integration and Regulations (OSIR) reports directly to the Director, OCRWM and has primary responsibility for: (1) planning, managing, and overseeing the integration of the high-level radioactive waste management system; (2) managing programs for the development of technologies for use at the geologic repository; (3) preparing and coordinating environmental impact statements; and (4) serving as the official contact for the high-level radioactive waste program with NRC and other regulatory agencies. OSIR also develops licensing plans, license applications, and safety analysis reports for the first geologic repository.

The Associate Director, Office of External Relations and Policy (OERAP) reports directly to the Director, OCRWM and he/she has primary responsibility within OCRWM for developing overall program policy and strategy, and is generally responsible for all external OCRWM interactions.

The organizational interfaces between OCRWM, OCRWM-managed program participants, DOE Nevada Project Office and DOE Project Office-managed participants are as follows.

For the DOE Nevada Project Office, the DOE/Nevada Manager has ultimate accountability and responsibility for the high-level radioactive waste repository project. Within the DOE/Nevada Project Office organization is the YMP Office, which has been established to manage the high-level radioactive waste repository project under the programmatic direction of OCRWM. The YMP Office is responsible for authorizing work and the management and technical direction of the activities that the respective participating organizations and Nevada Test Site Support Contractors conduct. This is accomplished through: the issuance of technical and programmatic guidance; technical integration; planning; and QA programmatic guidance.

The YMP manager, reporting to the DOE Manager, is responsible for YMP project actions, which include: (1) planning and directing; (2) establishing goals and objectives and assessing progress toward achieving these goals; (3) administering procurement of materials and services; (4) issuing technical and programmatic guidance; (5) organizing and conducting peer reviews; (6) complying with applicable regulations, laws, and DOE policies; and (7) implementing the YMP QA program. In addition, the YMP Manager is the point of contact for the flow of information to and from the Director, OCRWM and the YMP-managed program participants, and is responsible for implementing the Project QA program.

Responsibility for the overall high-level radioactive waste project is retained by OCRWM. The tasks of establishing and implementing selected portions of the overall OCRWM QA program for work associated with the YMP have been delegated to the YMP Office and project participants. The further delegation of work by YMP and other project participants is described in the respective QA program documents.

Differences of opinion involving technical or QA programmatic concerns at a given organizational level are brought to the attention of management at that level and, if not resolved, are elevated progressively to the Director, OQA and, if necessary, to the Director, OCRWM, for ultimate resolution.

Although not a regulatory requirement, DOE is establishing a system that provides individuals a means of registering an allegation of inadequate quality directly to the Director, OCRWM, without fear of reprisal. Each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity. The individual who registered the concern is notified of the investigation results. This system is also available to employees of program participants and persons outside the program. An employee of a program participant should use this system only when adequate resolution of a concern that involves potential inadequate quality cannot be obtained through normal reporting channels.

Stop-work authority at OCRWM, YMP, and the offices of other program participants is vested in line management, whenever imminent danger to personnel is involved, or continued work will produce results that are not in accordance with QA program requirements or would be considered unacceptable. In addition, the Director, OQA and QA management at the YMP and program-participants' offices have authority to identify quality problems; initiate, recommend, or provide solutions to problems; and prevent or control further processing, delivery, or use of nonconforming or unsatisfactory work, until proper disposition is obtained. OCRWM personnel who identify quality problems while performing quality verification activities at YMP inform YMP management, who initiate actions to prevent further work, through the YMP Manager.

The QAR and QAPD give the line organization responsibility for the achievement of quality and the performance of quality control verifications such as inspections and tests, to assure the achievement of quality. The QA organization's involvement is to provide assurance, to senior line management, of the line organization's achievement and verification of quality, through conduct of overview activities such as audits, surveillances and assessments.

Paragraph 2 of ANSI/ASME NQA-1-1986 Nonmandatory Appendix 1A-1 (see Ref. 7) contains the following nonmandatory guidance on the functions of the QA organization, which the staff believes clarifies the rules of the QA organization and line management:

"In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. The quality assurance group, however, should be designated to describe, integrate, and monitor the agreed-upon quality assurance activities of the various disciplines.

Quality assurance encompasses many functions and extends to various levels in all participating organizations, from the top executive to workers, such as designers, welders, inspectors, facility operators, craftsmen, and auditors, who perform activities affecting quality.

Different organizational structures may be effective, depending on the portion of the project or job in which the implementing organization is involved."

The NRC staff recommends that DOE incorporate the above guidance into the QAPD to better define the responsibilities of the QA and and line organizations. This is identified as an open item in Section 5 of this evaluation. With the inclusion of the above into the QAPD, the QAPD meets the ANSI/ASME NQA-1-1986 (see Ref. 7) criteria for QA organization responsibilities and is acceptable to the NRC staff. However, for the implementation of the QAR and the QAPD, the NRC staff believes that DOE should continue to have the additional QA involvement currently prescribed in the YMP 88-9 QA Plan (see Ref. 1) and the QAPD, since the program has not yet been shown to be effective. When DOE wishes to have less QA involvement, it should meet with the NRC staff and discuss which QA functions will be transferred to the line organization and how the independence will be maintained to assure that the line organization is effectively performing its respective QA/quality control functions and is in compliance with the requirements for organizational responsibilities, including paragraph 2 of NQA-1 (see above).

The NRC staff has assessed the above and the information on the organization described in the QAPD and finds it meets the regulatory review criteria described in Section 2 (Background) of this SE, pertaining to Criterion I of Appendix B to 10 CFR Part 50, with the exception of the modification identified in Section 5 of this evaluation.

3.2 "Quality Assurance Program" (Criterion II)

The NRC staff reviewed the description of the QA program provided in the QAPD in Section 2, "Quality Assurance Program," against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

- a. Activities that affect quality shall be planned and documented.
- b. The QA program shall be documented in policies, procedures and instructions.
- c. Management shall regularly assess the QA program for adequacy and implementation.
- d. Personnel performing work affecting quality shall be indoctrinated and trained
- e. Items and activities important to safety or waste isolation shall be identified and controlled under Appendix B to 10 CFR Part 50, as applicable.
- f. The QA program shall provide control over items and activities to an extent consistent with their importance to safety.

The QAPD requires each QA program to include provisions for QA planning to define the activities it applies to and the responsibilities for QA program control and verification activities. The QAPD also requires each program

participant to develop QA programs and procedures appropriate to their respective scope of work. These documents must be reviewed and approved by the next higher program organizational level.

For the high-level radioactive waste program, items and activities important to safety or waste isolation shall be classified in accordance with the guidance provided in NUREG-1318, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements" (see Ref. 4). This guidance document defines methods by which items and activities important to safety or waste isolation, a subset of the overall items and activities within the repository program, are to be identified.

The QAR and QAPD require a graded application of quality to be applied to items and activities, commensurate with the importance of their roles or functions in the YMP. A three-level system has been developed for grading QA measures.

Quality Level 1 (QL1) classifies items and activities requiring the application of the most stringent QA requirements and procedural controls because of their importance to public radiological health and safety and waste isolation. The assignment of QL1 imposes the applicable QA requirements of 10 CFR 60, Subpart G, and ANSI/ASME NQA-1-1986 (see Ref. 7). OCRWM and each Project Office shall establish a Q-List and a Quality Activities List. QL2 classifies items and activities requiring application of quality requirements and procedural controls because of their importance to the high-level radioactive waste repository program. QL2 contains items and activities defined by reliability, maintainability, public and repository worker non-radiological health and safety, repository worker radiological health and safety, and other operational factors that could have an impact on DOE and YMP concerns and the environment. NRC regulates some of the activities within QL2. QL3 items and activities are those which have no major function in the characterization of the site and design of the repository. The controls applied are those managerial, administrative, scientific, engineering, commercial and laboratory practices that are commonly used by the participating organizations in the project. NRC will not regulate any of the activities within QL3, if DOE classifies them properly.

Associate Directors, Division Directors, and other line managers will periodically assess the effectiveness of those portions of the QA program for which they are responsible. These management assessments will provide a basis for improving QA controls and procedures, clarifying responsibilities and authorities, and indicating that adverse quality trends and significant conditions adverse to quality are prevented or have been corrected. Independent management assessments of the QA program will be conducted at least annually by the Associate Directors or their designees who are independent of OQA. The independent management assessment will be conducted by, or at the direction of, the Director, OCRWM. The purpose of the independent management assessment is to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of the QA program. The results of the independent management assessment will be documented, and corrective

actions for those assessment results that indicate conditions adverse to quality will be identified and tracked. Independent management assessments will be conducted in accordance with written procedures.

In accordance with the requirements of the QAR, the QAPD requires that personnel who perform inspection and testing activities will be indoctrinated, trained, and qualified in accordance with Supplement 2S-1 and Appendix 2A-1 of ANSI/ASME NQA-1-1986 (see Ref. 7). All personnel shall use Supplement 2S-4; in addition, OCRWM management will analyze each job position to determine the quality-affecting task responsibilities of the position. The results will be documented in position descriptions that include education and experience prerequisites for each position involved in the performance verification of activities affecting quality. Personnel assigned to perform activities affecting quality will be required to have education, experience, and training commensurate with the functions associated with the work. Documented evaluations will be made of candidates' qualifications against the requirements, and education and experience will be verified. Associate Directors, the Director, OQA, Division Directors, and Branch Chiefs will review job functions or tasks involved in performing activities affecting quality for personnel under their supervision and determine, jointly with the appropriate training officer, any additional indoctrination and training required. Personnel assigned responsibility for performing activities affecting quality will be provided indoctrination and training as to the purpose, scope, and implementation of the QA program. Classroom training will be performed in accordance with documented and approved lesson plans. Records of training will be maintained. Persons verifying activities affecting quality such as lead auditors, auditors, and peer reviewers will be qualified in the principles, techniques, and requirements of the activity being performed. Specific qualification requirements will be contained in procedures for those functions, and qualification records will be maintained. Supervisors will evaluate, at least annually, the proficiency of personnel in the performance of their assigned duties. These evaluations will be documented. Additional training will be provided if it is necessary to improve or maintain proficiency.

The NRC staff finds that the QAPD meets the regulatory review criteria described in Section 2 ("Background") of this SE, pertaining to Criterion II of Appendix B to 10 CFR Part 50.

3.3 "Design Control" (Criterion III)

The NRC staff reviewed the descriptions of design, design control, computer software control, scientific investigations, data collection and data qualification provided in Section 3 of the QAPD. The NRC staff review criteria which pertain to Design Control are:

- a. Measures shall be established to assure that the regulatory requirements and design bases are correctly translated into specifications, drawings, procedures, and instructions for items important to safety or waste isolation.

- b. The design control program includes general plans and detailed procedures for site characterization data collection and analysis.
- c. Appropriate quality standards shall be specified.
- d. Interfaces between design organizations shall be controlled.
- e. Designs shall be verified for adequacy by individuals or groups other than those who performed the original design.
- f. Design changes shall be subject to control measures commensurate with those applied to the original design.
- g. For design or design activities which involve use of untried or beyond the state-of-the-art techniques, or where detailed technical criteria and requirements do not exist, a peer review should be conducted.
- h. Verification and validation should be performed on computer software.

For certain portions of the QAPD description on design control, especially in the area of scientific investigations, the QAPD must be used in conjunction with the requirements specified in the QAR for design control.

The description for design control in the QAR document, through its commitment to ANSI/ASME NQA-1-1986 Basic Requirement 3 and Supplement 3S-1 (see Ref. 7) and NUREG-1318 (see Ref. 4), includes the use of specifications, drawings, design criteria and component performance requirements for the natural and engineered components of the repository system. Data resulting from scientific investigations can be used to produce design input. The use of data shall be documented as part of the planning process for scientific investigation, and provisions will ensure that the data generated are valid, complete, and accurate. Design controls include measures for peer review; design analysis; design input, output, and verification; design analysis; change control; internal and external interface control; and control of computer software used to perform design analysis. In the QAR, DOE has committed to the NRC staff Technical Position NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," (see Ref. 5) for controlling computer software. The QAR, as an upper-tier requirements document, appropriately addresses, in a general manner, the QA controls to be applied to conceptual through final designs, including basic assumptions about the site, contained in the study plans.

Since OCRWM is not directly involved in performing design activities that require the use of computer software, design activities necessitating use of computer software will be conducted by OCRWM-managed and Project Office-managed participants. Provisions in the QAR for controlling computer software will be reflected in participants' technical and QA requirements documents and evaluated on a case-by-case basis by the NRC staff.

The QAR has included both scientific investigations (i.e., collection and analysis of data providing design input) and conventional design activities, within Section 3, which address Criterion III of Appendix B to 10 CFR Part 50, "Design Control." This approach is consistent with the NRC staff's definition of design control in the QA Review Plan. In addition, the QAR has also included a description on the rationale and applicability of the NRC requirements to scientific investigations pertaining to Appendix B to 10 CFR Part 50, Criteria IX ("Control of Special Processes"), X ("Inspections"), XI ("Test Control"), and XIV ("Inspection, Test, and Operating Status"). DOE has provided justification for this approach in Appendix B of the QAR and has demonstrated that these controls were equivalent to those in the above four criteria, or in some cases not appropriate, due to the nature of the work. The adequacy of the geologic repository design is heavily dependent on the results of the scientific investigations conducted for the characterization of the geologic repository site. Therefore, the performance of these scientific investigations will be controlled. Scientific investigations will be conducted by OCRWM or Project Office-managed participants. Provisions of the QAR for controlling scientific investigations will be imposed on the applicable participants involved in the high-level radioactive waste repository program.

The adequacy of technical documents will be verified before approval and issuance for use. Individuals assigned to review technical documents may supplement reviews with alternate calculations, to verify the correctness of original calculations, or qualification tests, to demonstrate the adequacy of the design under the most adverse design conditions, or both. Technical document reviews will be performed by one or more qualified individuals not involved in the performance of the original design. Reviews will be conducted in accordance with written procedures.

For the geologic repository, it may be necessary to conduct the design verification through the use of a peer review. Peer review will be used when the methods that were used were beyond the state-of-the-art and the adequacy of information, or the suitability of procedures and methods cannot be otherwise established through tests, alternate calculations, or reference to established standards. Peer reviews will be performed in accordance with the guidance provided in NUREG-1297 (see Ref. 2).

Changes to OCRWM-originated design documents will be justified and processed using the same methods applied to the preparation of the original document. Changes will be reviewed and approved by the organizations who reviewed and approved the original design document. The impact of design changes on procedures and training will be evaluated. The changes will be communicated to all affected groups or individuals.

The NRC staff has assessed the information and the additional information provided for "Design Control" and "Scientific Investigation Control" in the QAR and QAPD, and finds that the information satisfactorily addresses the regulatory review criteria described in Section 2 (Background), of this SE, with respect to Criteria III, and IX, X, XI and XIV of Appendix B to 10 CFR Part 50, as they pertain to scientific investigations and design control.

3.4 "Procurement Document Control" (Criterion IV)

The NRC staff reviewed Section 4 of the QAPD against the criteria identified in Section 2 of this SE. The criteria that pertain to Procurement Document Control, in summary, are:

- a. Procurement documents shall include all applicable requirements.
- b. Procurement documents shall require contractors or subcontractors to develop a QA program implementing portions or all of the requirements of Appendix B to 10 CFR Part 50.

In conjunction with the QAR, the QAPD incorporates the requirements in ANSI/ASME NQA-1-1986 Basic Requirement 4 and Supplement 4S-1 (see Ref. 7) and the NRC QA Review Plan (see Ref. 6). It includes a requirement to assure that applicable regulatory and technical requirements, design bases, and other necessary requirements are included in procurement documents. OCRWM suppliers are required to have a program implementing portions or all of ANSI/ASME NQA-1-1986 and the QAR requirements. When the scope of work or schedule requirements do not justify the cost of development or maintenance of a QA program by contractors, the contractors will work under OCRWM's QA program. The technical and QA requirements applied to contractors specify applicable OCRWM QA administrative procedures that will be used by the contractors. The NRC staff finds the requirements adopted in the QAPD acceptable.

3.5 "Instructions, Drawings, and Procedures" (Criterion V)

The NRC staff reviewed Section 5 of the QAPD, "Instructions, Drawings, Plans, and Procedures," against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

- a. Activities affecting quality shall be accomplished in accordance with instructions, procedures, and drawings.
- b. Instructions, procedures, and drawings shall include or reference acceptance criteria.

In conjunction with the QAR, the QAPD incorporates the basic requirements of Appendix B to 10 CFR Part 50, the NRC QA Review Plan (see Ref.6), and the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 5 (see Ref.7). The NRC staff finds the requirements adopted in the QAPD for control of instructions, procedures, plans and drawings to be acceptable.

3.6 "Document Control" (Criterion VI)

The NRC staff reviewed Section 6 of the QAPD against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

- a. Measures shall be established for the preparation, review, approval and issuance of documents that prescribe activities affecting quality.

- b. Document changes shall be properly controlled.

The QAPD requires that the preparation, review, approval, and issuance of documents be controlled to assure that only correct documents are used. Documents and changes to them are to state appropriate quality requirements and provide for the identification of responsibility for preparing, reviewing, approving and controlling changes to them. Obsolete documents are required to be controlled, and a controlled document list must be established, to identify the current list of documents.

In conjunction with the QAR, the QAPD incorporates the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 6 and Supplement 6S-1 (see Ref. 7) and the NRC QA Review Plan (see Ref. 6). The NRC staff finds the requirements adopted for Section 6, "Document Control," acceptable.

3.7 "Control of Purchased Items and Services" (Criterion VII)

The NRC staff reviewed Section 7 of the QAPD, "Control of Purchased Items and Services," against the criteria listed in Section 2 of this SE. These criteria, in summary, are:

- a. Measures shall be established to assure that purchased material, equipment, and services conform to procurement documents.
- b. Measures shall be established for source evaluation and selection.
- c. Objective evidence of quality shall be furnished by the contractor or subcontractor.
- d. The effectiveness of the control of quality by contractors and subcontractors shall be periodically assessed.

In conjunction with the QAR, the QAPD incorporates the guidance from the NRC QA Review Plan (see Ref. 6) and the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 7 and Supplement 7S-1 (see Ref. 7), addressing each of the requirements listed above. The commitment to ANSI/ASME NQA-1-1986 (see Ref. 7) addresses procurement planning, source evaluation and selection, bid evaluation, supplier performance evaluation, control of supplier-generated documents, control of changes in items or service, acceptance of items or services, control of non-conformances, and requirements for commercial grade items. The NRC staff finds the requirements listed in Section 7 of the QAPD acceptable.

The following lists Appendix B criteria that will be delegated by OCRWM.

3.8 "Identification and Control of Materials, Parts, Components, and Samples" (Criterion VIII)

3.9 "Control of Special Processes" (Criterion IX)

3.10 "Inspection" (Criterion X)

3.11 "Test Control" (Criterion XI)

3.12 "Control of Measuring and Test Equipment" (Criterion XII)

3.13 "Handling, Shipping, and Storage" (Criterion XIII)

3.14 "Inspection, Test, and Operating Status" (Criterion XIV)

3.15 "Control of Nonconforming Items" (Criterion XV)

The QAPD states that work associated with the aforementioned Appendix B, 10 CFR Part 50 Criteria VIII through XV, will be delegated by OCRWM to project offices and other program participants. OCRWM will overview this work through audits, surveillances and reviews to verify the implementation and effectiveness, and to assure compliance with the QAR.

In conjunction with the QAR, the QAPD incorporates the guidance from the NRC Review Plan (see Ref. 6) and the applicable requirements of ANSI/ASME NQA-1-1986 (see Ref. 7) to address each of the above criteria. The NRC staff finds the requirements adopted in the QAPD for Criteria VIII through XV of Appendix B to 10 CFR Part 50 acceptable.

3.16 "Corrective Action" (Criterion XVI)

The NRC staff reviewed the QAPD against the criteria in Section 2 of this SE. The criteria, in summary, are:

- a. Measures shall be established to assure that conditions adverse to quality are promptly identified and corrected.
- b. For significant conditions adverse to quality. (i.e., which, if uncorrected, would have a serious effect on safety or operability), the cause of the condition and the corrective action taken shall be documented and reported to management.

The QAPD requires conditions adverse to quality to be identified and promptly corrected at each organizational level, in accordance with written procedures. The procedures delineate the process to evaluate the condition and to determine the root cause, determine generic implications, corrective action to be taken, and action to be taken to preclude recurrence.

Conditions adverse to quality will be reported to the appropriate Associate Directors and Director, OQA. The Director, OQA will evaluate these conditions and take appropriate action to assess whether the condition, if uncorrected, could affect safety or waste isolation adversely.

In conjunction with the QAR, the QAPD incorporates the requirements in ANSI/ASME NQA-1-1986 (see Ref. 7) and the NRC QA Review Plan (see Ref. 6) guidance for meeting the above criteria. The NRC staff finds this approach acceptable.

3.17 "Quality Assurance Records" (Criterion XVII)

The NRC staff reviewed Section 17 of the QAPD, "Quality Assurance Records," and DOE/RW-0194 "Records Management Policies and Procedures" (see Ref. 12) against the criteria in Section 2 of this SE. The criteria, in summary, are:

- a. Records furnishing evidence of quality shall be maintained.
- b. Records include results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, qualifications of personnel, procedures, and equipment.
- c. Records shall be identifiable and retrievable.
- d. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented.

The QAPD requires the records management program to be accomplished in accordance with the provisions of DOE/RW-0194, "Records Management Policies and Requirements" (see Ref. 12). In addition, in conjunction with the QAR, the QAPD incorporates the provisions of the NRC QA Review Plan (see Ref. 6) and the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 17 and Supplement 17S-1 (see Ref. 7)

DOE/RW-0194 (see Ref. 12) provides policies that DOE OPARM developed for the implementation and control of QA Records. The Information Resources Management Division within OPARM manages QA records for the high-level radioactive waste repository program. Control and maintenance of QA records is delegated to the records management contractor for those QA records generated or received by OCRWM or OCRWM-managed program participants.

DOE/RW-0194 (see Ref. 12) covers the control, indexing, microfilming, storage, retention, preservation, and protection of records generated by OCRWM Headquarters and OCRWM Project Offices. DOE/RW-0194 (see Ref. 12) classifies documents as those of "limited value" and those listed as "typical post closure and lifetime records." Those records of "limited value" will not be captured in the records information system and may be disposed of. It is recognized that the lifetime records list is not inclusive or exclusive and can be modified to include other types of records, as the program develops. It appears that this list addresses those records to be retained for the lifetime of the project. The DOE/RW-0194 (see Ref. 12) document does not address, at this time, the post-closure records required to be retained to fulfill the requirements of 10 CFR Part 60, Section 60.51. However, since all records appear to be retained for the life of the project, this item does not need to be resolved during the site characterization phase of the repository. The NRC staff will review and evaluate DOE's scope of post-closure records, before issuing an amendment to the license application for permanent closure.

The NRC staff finds the QAPD approaches for meeting the requirements of Appendix B to 10 CFR Part 50 Criterion XVII acceptable. However, the NRC staff expects DOE to reevaluate DOE/RW-0194 to ensure that it is consistent with the recently promulgated LSS Rule (54 Federal Register 14925, April 14, 1989).

3.18 "Audits" (Criterion XVIII)

The NRC staff reviewed the QAPD against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

- a. QA audits shall be planned and documented to verify compliance with all aspects of the program and to determine the effectiveness of the program.
- b. The preparation, performance, reporting, response, and follow-up of audit activities shall be controlled.
- c. Follow-up action shall be taken, where indicated.

The QAPD contains requirements to establish and implement an independent verification of the status, adequacy, and compliance and effectiveness of the OCRWM QA program. Internal and external audits, both technical and programmatic, will be conducted to determine the degree of conformance with QA program requirements and the effectiveness in achieving QA program objectives. Audit planning, scheduling, preparation, performance, reporting, follow-up, and close-out methods, as well as methods for selection, training, and qualification of audit personnel, will be accomplished in accordance with QA procedural controls. The Director, OQA is responsible for the development, implementation, and maintenance of the OCRWM QA audit program.

In conjunction with the QAR, the QAPD incorporates the provisions of Basic Requirement 18 and Supplement 18S-1 of ANSI/ASME NQA-1-1986 (see Ref. 7) and the NRC QA Review Plan (see Ref. 6) guidance for audits. The NRC staff will audit and monitor the effectiveness of subcontractors', consultants', and vendors' programs during its own audits and observations of audits within the DOE program.

Although not an explicit staff position in the NRC QA Review Plan (see Ref. 6), nor a requirement in ANSI/ASME NQA-1-1986 (see Ref. 7), DOE has committed to using technical specialists on some audits. In practice, DOE has been using technical specialists in most cases. The NRC staff believes this is an essential practice highlighted in the Ford Study (NUREG-1055, see Ref. 11). The NRC staff will continue to monitor DOE's use of technical specialists to help assure that the audit teams use technical guidance to help assess the effectiveness of the program.

The NRC staff finds the approaches outlined in the QAPD acceptable.

4. CONCLUSION

The NRC staff review of the QAPD verifies that it meets the criteria of 10 CFR Part 60, Subpart G and Appendix B to 10 CFR Part 50, as applicable. NRC guidance to address Subpart G is contained in the "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions," (see Ref. 6) and the NRC staff Technical Positions on "Peer Review," "Existing Data," "Q-List," and "Documentation of Computer Codes" (NUREGs 1297, 1298, 1318, and 0856, respectively (see Refs. 2 to 5)). In addition, ANSI/ASME NQA-1-1986 (see

Ref. 7), and Regulatory Guide 1.28 (see Ref. 8) (endorses ANSI/ASME NQA-1-1983, see Ref. 9) were used as review criteria. The NRC staff review of the QAPD, which is to be implemented in conjunction with the QAR, concludes that it meets the guidance listed above, or DOE has provided acceptable alternatives. The QAR describes alternatives in the areas of special processes, inspection, testing, and inspections, test, and operating status, whereby the controls do not fully apply to scientific investigations. The NRC staff has evaluated these exceptions and finds they are acceptable alternatives as applied to the QAPD.

On the basis of its detailed review and evaluation of the QAPD, the NRC staff concludes that the QAPD contains adequate requirements and planned and systematic controls that address each of the appropriate criteria of Appendix B to 10 CFR Part 50, in an acceptable manner, with the exception of the open item listed below. With the resolution of this open item, the QAPD, if used in conjunction with the QAR, can serve as an adequate framework for DOE and its project participants to develop specific policies, plans, and procedures to implement the QA Program for the high-level radioactive waste repository.

5. OPEN ITEM

In Section 3.1 of this SE, a discussion is provided pertaining to guidance on the role of the QA organization. DOE should incorporate the guidance from paragraph 2 of ANSI/ASME NQA-1-1986 Nonmandatory Appendix 1A-1 into the next revision of the QAPD.

6. REFERENCES

1. Letter from J. Linehan, U. S. Nuclear Regulatory Commission, to R. Stein, U. S. Department of Energy, dated October 14, 1988, containing "Safety Evaluation of the Quality Assurance Plan, Nevada Nuclear Waste Storage Investigations," NNWSI/88-9, Revision 1.
2. U.S. Nuclear Regulatory Commission, "Generic Technical Position on Peer Review for High-Level Nuclear Waste Repositories," NUREG-1297, 1987.
3. U.S. Nuclear Regulatory Commission, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298, 1987.
4. U.S. Nuclear Regulatory Commission, "Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to 10 CFR Part 60 Quality Assurance Requirements," NUREG-1318, 1988.
5. U.S. Nuclear Regulatory Commission, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," NUREG-0856, 1983.
6. U.S. Nuclear Regulatory Commission, "Review Plan for High-Level Waste Repository Quality Assurance Program Descriptions," Rev. 2, 1989.

7. American National Standards Institute/ American Society of Mechanical Engineers, NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," 1986.
8. U.S. Nuclear Regulatory Commission, "Quality Assurance Program Requirements (Design and Construction)," Regulatory Guide 1.28, Rev. 3, 1985.
9. American National Standards Institute/American Society of Mechanical Engineers, NQA-1, "Quality Assurance Program for Nuclear Facilities," 1983.
10. American National Standards Institute/American Society of Mechanical Engineers, NQA-3 (Draft), "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories," Revision 1, 1988.
11. U. S. Nuclear Regulatory Commission, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants," NUREG-1055, 1984.
12. U. S. Department of Energy, "Records Management Policies and Requirements," DOE/RW-0194, July 1988