SAFETY EVALUATION

OF

QUALITY ASSURANCE REQUIREMENTS DOCUMENT

FOR THE

CIVILIAN RADIOACTIVE WASTE MANAGEMENT REPOSITORY PROGRAM

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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 (i.e., those items and activities important to safety or waste isolation) 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). To establish a framework for consistency in the development of quality assurance (QA) programs, the 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 will be prepared to implement the QAR requirements. Consequently, the QAR should not be misconstrued to exclusively satisfy all of the 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).

There is a limitation on the scope of this review. The QAR is the top-tier DOE requirements document. 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 regarding 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 into the site and laboratory investigations.

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

2. BACKGROUND

On August 26, 1988, DOE submitted the QAR to the NRC staff for review. As a result of the NRC staff review of the QAR, a set of 40 comments was developed and discussed at a September 28, 1988 meeting between representatives of DOE and NRC, at the 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, 1319, and 0856 respectively, see Refs. 2-5), and the use of scientific notebooks and detailed technical procedures. Based on the above, the NRC staff concluded it had sufficient information on which to conduct a review and base an SE for the QAR.

The NRC staff used the following review criteria and NRC staff positions to determine whether the QAR, Rev. 1, submitted by DOE in a letter dated November 29, 1988 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 (ANSI)/American Society of Mechanical Engineers (ASME) 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. The NRC staff finds this acceptable.

3. STAFF EVALUATION

The following sections describe in detail, the NRC staff's evaluation of the QAR for each of the 18 criteria of Appendix B to 10 CFR Part 50. Each section identifies the areas of the QAR reviewed by the NRC staff, summarizes the QA measures that apply (from the criteria listed above) and the content of the QAR 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. Since the QAR is a general requirements document applicable to all levels of the DOE high-level radioactive waste management program, it does not contain the detailed information found in a QA program description. The QAR must be used in conjunction with documents such as the OCRWM Quality Assurance Program Description.

3.1 "Organization" (Criterion I)

The NRC staff reviewed the description of "Organization" provided in the Introduction and Section 1 of the QAR. 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.

The QAR requires each program participant to identify a QA management position, within his or her organization, that is responsible for establishing and implementing his or her respective QA program. This position is required to be at the same or higher organizational level as the highest equivalent manager responsible for performing activities affecting quality and to have no other duties or responsibilities that could preclude full attention to QA matters. This position is also required to be sufficiently free from cost and schedule considerations and to have access to senior management to resolve unresolved quality concerns. It is required that this position shall have review and approval recommendation authority for QA programs, revisions to , and interpretations thereof.

By virtue of the QAR commitment to ANSI/ASME NQA-1-1986, Basic Requirement 1 (see Ref. 7), persons or organizations responsible for assuring that an appropriate QA program has been established and verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organization freedom to: identify quality problems; initiate, recommend or provide solutions to quality problems through designated channels; verify implementation of solutions; and assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. The QAR gives 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. Quality achievement is required to be a continuing responsibility of management at all levels of the program. It is required to be achieved through well-defined QA programs, with a set of management controls to be implemented by all program participants. 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 and the line organization:

> "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 QAR to help clarify the roles of the QA and line organizations. This is identified as an open item in Section 5 of this evaluation. With the inclusion of the above in the QAR, the QAR meets the ANSI/ASME NQA-1-1986 (See Ref. 7) criteria for QA organization responsibilities and is acceptable to the NRC staff. However, as agreed to by the NRC and DOE staff, and as committed to in the 88-9 QA Plan, DOE will continue to have the additional QA involvement in the implementation of the 88-9 QA Plan for the YMP. Additionally, based on the results of audits conducted to date, the QA programs of the program participants have not been totally effective. Therefore, if DOE wishes to have less QA involvement, it should meet with the NRC staff and discuss how 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.

Provisions will be established for disputes involving quality between QA personnel and others. If the dispute cannot be resolved at a given organizational level, it will be referred to the OCRWM Program Director for ultimate resolution.

The NRC staff has assessed the above and the information on the organization described in the QAR 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 QAR 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 QAR 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 QAR 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 waste repository 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.

A graded application of quality is to be applied to items and activities, commensurate with the importance of their roles or functions. 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 YMP. 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.

Independent management assessments are required to be conducted at least annually by persons above or outside the QA organization, to determine the adequacy and effectiveness of the QA program implementation. This assessment will include the evaluation of the adequacy of planning and procedural controls, effectiveness of the corrective action system, adequacy of the organizational structure and staffing systems, adequacy of the indoctrination and training program, and adequacy of the QA management information tracking, evaluation, and reporting system.

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, management of each organization shall be required to analyze each job position, to determine the quality-affecting task responsibilities of the position. Results of each analysis shall be documented in position descriptions, to include the education and experience prerequisites for each position involved in the performance or verification of activities affecting quality. Personnel selected to perform or verify activities affecting quality shall have education, experience, and training commensurate with the minimum requirements specified. Relevant education and experience shall be verified. To determine whether a person is qualified for a position, his or her education and experience will be evaluated and compared to the qualification requirements established for the position. Management shall monitor the performance of personnel doing work affecting quality and, at least annually, determine the need for retraining or reassignment.

The NRC staff finds the QAR description 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. This includes a commitment in the QAR to

apply the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 2; Supplements 2S-1, 2S-2, 2S-3, and 2S-4; Appendix 2A-1; and NUREG-1318 (see Ref. 4).

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 QAR. 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.

The description for design control in the QAR, 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 investigations, and provisions will assure 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. DOE has committed to the NRC staff Technical Position NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management," for controlling computer software (see Ref. 5).

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. The NRC staff has identified concerns with the implementation of these general requirements into the Title I design for the exploratory shaft and into the preparation of the study plans and will be tracking these items formally and separately to assure that they are satisfactorily resolved.

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 addresses 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.

Criterion IX of Appendix B to 10 CFR Part 50, "Control of Special Processes," requires that measures be established to assure that special processes be controlled and accomplished by qualified personnel using qualified procedures in accordance with codes, standards, specifications, etc. A special process is a process whose results depend upon the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product. Site characterization data collection activities, in most cases, cannot be inspected or tested after completion to measure their quality.

DOE has incorporated general controls into Section 3 of the QAR, which addresses those required by Criterion IX of Appendix B to 10 CFR Part 50. The QAR includes requirements for qualification of all personnel performing activities affecting quality, including those performing scientific investigations. The QAR also includes provisions for qualification or verification of procedures. It allows technical reviews or peer reviews of procedures and processes to assure that they are suitable for their intended use. This general approach is acceptable to the NRC staff and will be verified for appropriate implementation in NRC staff technical audits and reviews of procedures.

The QAR incorporates controls from Criterion X of Appendix B to 10 CFR Part 50, "Inspections," into the QAR section on scientific investigations. Surveillances will assure that such investigations are being performed in accordance with procedures. Surveillances are required to be performed by knowledgeable and independent personnel. Corrective action is required to be taken and documented in connection with any deviations noted. The NRC staff finds this approach acceptable for scientific work.

ANSI/ASME NQA-1-1986 Supplement 10S-1 (see Ref. 7) contains provisions for final inspections of items to assure that they conform to requirements. For scientific investigations, equipment and methods used to obtain and analyze data shall be

verified to ensure technical adequacy and proper selection. Data collection and analysis will be technically reviewed by qualified individuals other than those who performed the scientific investigation. The NRC staff finds this approach for verification in lieu of a final inspection to be acceptable and appropriate for the work to be performed.

The QAR incorporates controls from Section XI of Appendix B to 10 CFR Part 50, "Test Control," for scientific investigations. This section of Appendix B to 10 CFR Part 50 was written for confirmatory tests of items such as safety-related components in a nuclear power plant, to determine if they meet specified requirements. Many site characterization activities will produce data whose values are not known before testing and which will not fall within predetermined numerical acceptance criteria. Nevertheless, many of the controls of Section XI of Appendix B to 10 CFR Part 50 apply to data collection. The QAR includes controls for the use of technical procedures and/or lab notebooks for the documentation and control of the work, calibration of equipment, development of an overall test program, identification of test requirements, and others. The NRC staff finds the QAR measures applied to scientific investigations for Criterion XI of Appendix B to 10 CFR Part 50 to be acceptable.

The NRC staff has assessed the aforementioned information and the additional information provided for "Design Control" and "Scientific Investigation Control" in the QAR, 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, and XI 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 QAR against the criteria identified in Section 2 of this SE. The criteria which 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.

The QAR has incorporated 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. Suppliers are required to have a program implementing portions or all of ANSI/ASME NQA-1-1986. The NRC staff finds the requirements adopted in the QAR acceptable.

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

The NRC staff reviewed Section 5 of the QAR, "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.

The QAR has incorporated 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 QAR 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 QAR, 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 QAR 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 master list must be established, to identify the current list of documents.

The QAR has incorporated 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 QAR, "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.

The QAR has incorporated 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 non-conformances, and requirements for commercial grade items.

The NRC staff finds the requirements listed in Section 7 of the QAR acceptable.

3.8 "Identification and Control of Items" (Criterion VIII)

The NRC staff reviewed Section 8 of the QAR, "Identification and Control of Items, Samples, and Data" against the criteria in Section 2 of this SE. The QAR has expanded the scope of this section from the requirements in Appendix B of 10 CFR Part 50, which only addresses the identification and control of items. The NRC QA Review Plan added samples within this criterion. DOE has also included, under this section, certain measures for control of data, in addition to those it has prescribed in Section 3 of the QAR, "Scientific Investigation Control."

The requirements from the criteria listed in Section 2 of this SE, in summary, are:

a. Items and samples shall be identified and controlled according to procedures.

b. Correct identification of samples is verified and documented before release for use or analysis.

c. Items shall be identified throughout fabrication, erection, installation and use of the item.

d. Identification should be on the sample or its container when possible, or on records traceable to them.

Section 8 of the QAR provides a commitment to ANSI/ASME NQA-1-1986 Basic Requirement 8 and Supplement 8S-1 for controlling items, which is an acceptable method to the NRC staff for meeting the requirements of Appendix B to 10 CFR Part 50. The QAR also contains provisions, for control of samples, which meet the guidance in the NRC QA Review Plan, Section 8 (see Ref. 6).

Section 3 (paragraph 3.5.5) of the QAR also contains several additional requirements for control of data, under this section. All data are to be identified to help determine their correct use. This identification is to be verified as correct before releasing the data for use.

The NRC staff finds the requirements listed in the QAR for identification and control of items and samples acceptable.

3.9 "Control of Special Processes" (Criterion IX)

The NRC staff evaluated Section 9 of the QAR against the criteria identified in Section 2 of this SE. These criteria, in summary, are:

a. Processes affecting the quality of items or services shall be controlled.

b. Special processes that control or verify quality, such as welding, heat treating, and non-destructive examination, shall be performed using qualified personnel, using qualified procedures, in accordance with specified requirements.

The QAR has committed to ANSI/ASME NQA-1-1986 Basic Requirement 9 and Supplement 9S-1 (see Ref. 7) for fulfilling the requirements for process control in Appendix B to 10 CFR Part 50 and the NRC QA Review Plan (see Ref. 6) as they relate to engineered items. In this review, the NRC staff evaluated the controls for scientific investigations, using the requirements in Criterion IX of Appendix B to 10 CFR Part 50. The DOE identifies these controls within Section 3 of the QAR, and the NRC staff evaluation of the adequacy of those controls is discussed in Section 3.3 of this SE.

Based on the commitment to ANSI/ASME NQA-1-1986 Basic Requirement 9 and Supplement 9S-1 (see Ref. 7) requirements for control of processes related to engineered items, and the inclusion of appropriate controls for scientific investigations (see Section 3.3), the NRC staff finds the approach in the QAR for process control acceptable.

3.10 "Inspection" (Criterion X)

The NRC staff evaluated Section 10 of the QAR against the criteria identified in Section 2 of this SE. The criteria, in summary, are:

a. Inspections to verify conformance of an item or activity to specified requirements shall be planned and executed.

b. Inspections shall be performed by individuals other than those who performed or directly supervised the activity being inspected.

c. Hold points should be used, as appropriate.

d. Examinations, measurements, or tests shall be performed for each work operation, where necessary.

e. Process monitoring shall be used where necessary to assure quality.

The QAR has included provisions addressing the guidance in the NRC QA Review Plan (see Ref. 6) and a commitment to ANSI/ASME NQA-1-1986 Basic Requirement 10 and Supplement 10S-1 (see Ref. 7), with the exceptions that inspections are to be applied only to engineered items, and that inspectors need not be part of the QA organization (unless special expertise is needed). With respect to the first exception, Section 3.3. of this SE describes the DOE controls to be applied to scientific investigations and evaluates their acceptability. With respect to the NRC staff position in the NRC QA Review Plan that all inspectors be within the QA organization, see Section 3.1 of this SE.

The NRC staff finds the approach described in the QAR acceptable.

3.11 "Test Control" (Criterion XI)

The NRC staff reviewed QAR Section 11 against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. A test program shall be established to assure that all structures, systems, and components will perform satisfactory in service.

b. The program shall be performed in accordance with written test procedures which incorporates test requirements and acceptance limits.

c. Test procedures shall include provisions for assuring that all prerequisites for a test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

d. Test results shall be documented and evaluated.

"Testing" is defined in ANSI/ASME NQA-1-1986 (see Ref. 7) as "an element of verification for determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions."

Consistent with the above, the QAR applies these controls to engineered items only. Although most scientific investigations do not fall under this definition of testing, the NRC staff requested DOE to either incorporate the controls from Section XI of Appendix B to 10 CFR Part 50 and the NRC QA Review Plan (see Ref. 6) into the QAR, or provide justifications for why they did not apply. DOE's responses and the NRC staff evaluation of these responses are discussed in Section 3.3 of this SE. The QAR includes most of the above provisions within that section, rather than Section 11 of the QAR.

For engineered items, the QAR incorporates the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 11 and Supplement 11S-1 (see Ref. 7) and the guidance in the NRC QA Review Plan (see Ref. 6). The NRC staff finds the DOE approach for test control acceptable.

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

The NRC staff reviewed the description in Section 12 of the QAR against the criteria in Section 2 of this SE. These criteria, in summary, are:

a. Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted to maintain accuracy within the necessary limits.

The QAR has incorporated the requirements from ANSI/ASME NQA-1-1986 Basic Requirement 12 and Supplement 12S-1 (see Ref. 7) and the guidance in the NRC QA Review Plan (see Ref. 6). The scope of the program includes all measuring and test equipment or systems used to calibrate, measure, gauge, test, or inspect either to control or to acquire data to verify conformance to a specified requirement or to establish characteristics or values not previously known. The NRC staff finds the requirements described in the QAR acceptable.

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

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

a. Measures shall be established to control the handling, storage, shipping, cleaning, and preservation of material and equipment.

b. When necessary, special protective environments, such as an inert gas atmosphere, shall be specified and provided.

The QAR has incorporated the requirements of ANSI/ASME NQA-1-1986 Basic Requirement 13 and Supplement 13S-1 (see Ref. 7) for material and equipment. However, the NRC QA Review Plan (see Ref. 6) expanded the scope of this criterion to cover samples collected during site characterization. The QAR has incorporated the controls for sample identification, sample traceability, and archival samples from the NRC QA Review Plan into QAR Section 8, "Identification and Control of Samples." Controls for sample-handling, storage, and shipping have been incorporated into QAR Section 13. The NRC staff reviewed these controls in Sections 8 and 13 of the QAR and finds them acceptable for meeting the requirements of Appendix B to 10 CFR Part 50.

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

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

a. The status of inspections and tests performed on items shall be established by markings, such as stamps, tags, labels, routing cards or other suitable means.

b. These status markings shall provide for identification of items which have passed required inspections and tests.

c. Measures shall be established for indicating the operating status of structures, systems, and components, such as by tagging of values and switches, to prevent inadvertent operation.

Consistent with the language above (taken from Appendix B to 10 CFR Part 50, the NRC QA Review Plan (see Ref. 6), and ANSI/ASME NQA-1-1986 (see Ref. 7)), the QAR applies a requirement of the Appendix B to 10 CFR Part 50 Criterion XIV to engineered items only. DOE provided a detailed rationale for this approach in the meeting of July 8, 1988, which is documented in the minutes dated July 15, 1988.

The objective of Criterion XIV is to preclude inadvertent omission of required acceptance inspections and tests of nuclear plant components. This criterion also requires, for reasons of safety, the tagging of individual valves, switches, etc., to prevent their inadvertent operation. Since scientific investigations are not as directly related to safety as are nuclear plant components, the controls of Criterion XIV do not apply. Alternatively, DOE has established the following controls to assure that data collected from scientific investigations are valid:

a. All data shall be recorded so as to be clearly identifiable and traceable to the source from which they were generated. Identification and traceability shall be maintained throughout the needed lifetime of the data.

b. Data found to be erroneous, rejected, superseded, or otherwise unsuitable for the intended use shall be controlled and dispositioned. Controls shall include the identification and segregation of unsuitable data, to avoid inadvertent use. The disposition of unsuitable data shall be justified and documented.

The objective of all these controls is to assure that data are adequate when used in analyses of the repository.

In addition, to reduce the risk of losing data in the lab or the field due to inadvertent interruption, the QAR requires in Section 3 that all data be recorded so as to be clearly identifiable and traceable to the source from which they were generated.

For engineered items, the QAR has committed to the requirements in ANSI/ASME NQA-1-1986 Basic Requirement 14 (see Ref. 7) and the NRC QA Review Plan (see Ref. 6).

The NRC staff finds the approach described in the QAR for Criterion XIV of Appendix B to 10 CFR Part 50 acceptable.

3.15 "Control of Nonconforming Items" (Criterion XV)

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

a. Measures shall be established to control items and activities which do not conform to requirements.

b. Nonconforming items and activities shall be reviewed and accepted, rejected, repaired, or reworked in accordance with procedures.

The QAR has committed to the requirements in ANSI/ASME NQA-1-1986 Basic Requirement 15 and Supplement 15S-1 (see Ref.7) and the NRC QA Review Plan (see Ref. 6) guidance for control of nonconforming items. This approach is acceptable to the NRC staff for meeting the requirements of Appendix B to 10 CFR Part 50.

3.16 "Corrective Action" (Criterion XVI)

The NRC staff reviewed the QAR against the criteria in Section 2 of this SE. These 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., those 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 QAR has committed to 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 QAR, "Quality Assurance Records," and DOE/RW-0194 "Records Management Policies and Procedures" (see Ref. 11) 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 QAR 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). QA records programs are to be consistent with the requirements in DOE/RW-0194 (see Ref. 12) establishes policies, requirements, and responsibilities for the identification, collection, organization, processing and storage of records of the high-Level radioactive waste repository. The DOE/RW-0194 document 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 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 the DOE's scope of post-closure records, before issuing an amendment to the license application for permanent closure.

The NRC staff finds the QAR approaches for meeting the requirements of Appendix B to 10 CFR Part 50 Criterion XVII acceptable.

3.18 "Audits" (Criterion XVIII)

The NRC staff reviewed the QAR 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 QAR has incorporated 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. NRC staff position 18.1 of the NRC QA Review Plan states that DOE should audit prime contractors and representative subcontractors, consultants and vendors to assess the effectiveness of the prime contractor's program (i.e., the program participants). The NRC staff believes that the guidance in ANSI/ASME NQA-1-1986 (see Ref. 7) and Regulatory Guide 1.28, Revision 3 (see Ref. 8), is an appropriate interpretation of this position. These require that all DOE program participants audit contractors, subcontractors and consultants, as applicable. 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 QAR acceptable.

4. CONCLUSION

The NRC staff review of the QAR verifies that it meets the criteria of 10 CFR Part 60, Subpart G and Appendix B 50 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, 1319 and 0856 respectively (see Refs. 2-5)). 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 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 inspection, 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.

On the basis of its detailed review and evaluation of the QAR, the NRC staff concludes that the QAR 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 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.

The DOE and NRC staff have discussed the open item, and it will be added to Section 1.2 of Revision 1 to the QAR. With the implementation of this open item, the NRC staff will find the QAR fully acceptable.

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 QAR.

6. REFERENCES

1. October 14, 1988 letter from J. Linehan, NRC, to R. Stein, DOE, 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 (ANSI)/American Society of Mechanical Engineers (ASME), 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 (ANSI)/American Society of Mechanical Engineers (ASME), NQA-1, "Quality Assurance Program for Nuclear Facilities," 1983.

10. American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME), NQA-3 (Draft), "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories," Rev. 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.