

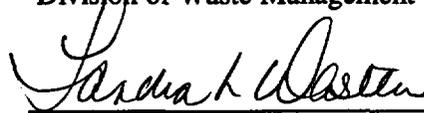
U.S. NUCLEAR REGULATORY COMMISSION  
ACCEPTANCE EVALUATION  
FOR  
NYE COUNTY QUALITY ASSURANCE PROGRAM PLAN

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Enclosure

## ACCEPTANCE EVALUATION

### INTRODUCTION

The U.S. Department of Energy (DOE) established the Yucca Mountain Site Characterization Office to investigate whether Yucca Mountain is a suitable site for the high-level radioactive waste repository. Nye County has established the Nuclear Waste Repository Project Office (NWRPO) to investigate the potential impact a repository at Yucca Mountain may have on the health, safety, and environment of Nye County residents.

For this investigation, NWRPO has initiated a program of monitoring, oversight, independent scientific investigations, impact assessment, and impact mitigation. Specifically, NWRPO and its contractors:

- 1) monitor DOE activities;
- 2) review and analyze plans, reports, data, and analyses from DOE and other sources; and
- 3) conduct independent investigations, as necessary, to:
  - a) evaluate and validate DOE data and designs; and
  - b) establish a NWRPO database for potential licensing and impact mitigation hearings.

The Nye County Quality Assurance Program Plan (QAPP) was established to ensure that NWRPO's program of monitoring, oversight, independent scientific investigations, impact assessment, and impact mitigation is properly implemented using appropriate quality assurance (QA) controls that are in conformance with the relevant criteria of Appendix B to Title 10 of the Code of Federal Regulations (10 CFR), which is referenced by 10 CFR Part 60 Subpart G.

### 1. BACKGROUND

The Nye County QAPP was formally transmitted to the U.S. Nuclear Regulatory Commission (NRC) in a letter from L. Bradshaw to J. Greeves, dated September 8, 1998. The Nye County QAPP consists of three sections; namely, a Policy Statement, Introduction, and QA Program Plan. NRC staff reviewed the QAPP to determine whether it contained adequate requirements and planned and systematic controls to address the relevant criteria of Appendix B to 10 CFR Part 50 as they pertain to the Nye County activities affecting quality. Staff also reviewed selected implementing procedures that had been prepared to execute the requirements of the QAPP. These procedures were reviewed on a sample basis for the NRC staff to gain confidence that the QAPP requirements were being adequately translated into the implementing procedures.

On September 30, 1998, the OR and an NRC technical member from the Division of Waste Management's Geosciences/Hydrology Section visited the Yucca Mountain Project with particular attention focused on the Nye County drilling and monitoring activities. This visit was predicated on the Nye County proposed drilling program

providing valuable data for the alluvial aquifer south of the proposed repository where compliance with the Environmental Protection standard may ultimately need to be demonstrated. The details of this visit are documented in Section 3.0 of the 1998, September-October OR Report. Two technical clarifications regarding packer verification and approved laboratories surfaced and were satisfactorily responded to.

As a result of the review of the QAPP, NRC staff generated a Request for Information that consisted of 25 comments which were forwarded to NWRPO in a letter from M. Bell to L. Bradshaw, dated October 15, 1998. The NWRPO revised the QAPP in response to the 25 comments and submitted a draft of the proposed revisions to the NRC OR QA representative on October 20, 1998. The proposed revisions were discussed at a November 4, 1998, meeting/telecon in the NRC OR office between the NRC OR and Nye County representatives. Five minor clarifications were needed in regard to commitments to ASME/NQA-1-1986 and NRC NUREGs 0856, 1298, and 4640. NWRPO resubmitted the audit of Revision 2 to the QAPP for NRC staff review and acceptance in the November 12, 1998, letter from D. Davidson to W. Belke.

## **2. STAFF EVALUATION**

The NRC staff evaluation of the QAPP for each of the 18 criteria of Appendix B to 10 CFR Part 50 is provided below. Each section identifies the areas of the QAPP reviewed by NRC staff, summarizes the QA measures that may pertain (from the criteria listed above) and the content of the QAPP, and where necessary, provides the NRC staff justifications in conformance with Appendix B to 10 CFR Part 50. NRC staff emphasizes that due to the nature of the quality-affecting activities associated with the Nye County Early Warning Drilling Program, not all of the guidance and commitments delineated in the NRC Review Plan For High-Level Waste Repository Quality Assurance Program Descriptions, Revision 2, dated March 1989 (RP), need to be considered, since this would be excessive and unnecessary. NRC staff fully recognizes that Nye County is collecting scientific data and not constructing a potential waste repository and, therefore, has considered this in its review approach for the QAPP.

### **3.1 CRITERION 1 - ORGANIZATION**

The enclosed Figure 1 provides the organization of the Nye County NWRPO. The County Board of Commissioners has ultimate authority for the QAPP and has authorized the County Manager to implement the Nye County Nuclear Waste Project by staffing the Project Manager position to manage the NWRPO and implement the QAPP. The On-Site Representative Geotechnical Representative is responsible for technical performance and staffing. The QA Officer reports to the On-Site Representative administratively and directly to the Project Manager for quality-affecting functions to assure independence for this position. The various Principal Investigators and contractors report to the On-Site Technical Representative and are responsible for planning, coordinating, performing, and documenting NWRPO work requirements in accordance with the QAPP. The QA Officer verifies through audits and surveillances that all aspects of the QAPP are being effectively implemented.

### **3.2 CRITERION 2 - QUALITY ASSURANCE PROGRAM**

The QAPP requirements are implemented through a series of Quality Administrative Procedures reviewed and approved by the Project Manger and QA Officer. All NWRPO and contractor personnel performing or managing quality-affecting functions are required to work to the QAPP requirements and implementing procedures.

The QAPP is based on the relevant portions of the following as they pertain to the NWRPO scope of work:

- 1) Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G which references 10 CFR Part 50, Appendix B;
- 2) ANSI/ASME NQA-1-1986;
- 3) NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Isolation;"
- 4) NUREG/CR-4640, "Handbook of Software Quality Assurance Techniques Applicable to the Nuclear Industry;" and
- 5) NUREG-1297, "Peer Review for High-Level Waste Repositories."

The QAPP does not address the controls of NUREG-1298, "Generic Technical Position of Qualification of Existing Data for High-Level Nuclear Waste Repositories," since all data collected under the QAPP is considered qualified. NWRPO does not intend to qualify data obtained from sources outside of the NWRPO QAPP, and such data will be considered not to be qualified. The controls of NUREG-1318, "Technical Position of Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements," are also not addressed. NUREG-1318 controls apply to the determination of activities subject to QA based upon their importance to safety as they apply to the actual construction of a geologic repository. NWRPO does not have responsibility for any aspects of geologic repository construction.

All NWRPO and contractor personnel will have experience and training commensurate with the scope, complexity, or special nature of the activities they perform. The effectiveness of the QA program implementation for personnel qualifications is monitored and verified by the QA Officer. The QA Officer also assures that an appropriate QA program is established, and independently verifies that activities have been correctly performed.

### **3.3 CRITERION 3 - DESIGN CONTROL**

In concert with the scope of the NWRPO program, the design aspect is within the scope of activities performed by NWRPO, as opposed to designing the repository, which is within DOE's scope. Consequently, NWRPO design work is limited to data acquisition and analysis of existing data, monitoring DOE activities, and executing a program of independent scientific investigation. Therefore, design for NWRPO is limited to independent review and analysis of the products of its monitoring/scientific investigations and of its QA Program.

The QA Officer performs an independent review of completed work plans, scientific notebooks, technical reports, and progress reports, to verify appropriate quality

standards have been incorporated and specified. The QA Officer's review also ensures that plans for data collection and analysis are completed before the actual collection and analysis activities. Peer reviews are conducted in those situations where uncertainties that exist in geotechnical/geological data, methodologies, interpretations, or conclusions cannot be resolved.

#### **3.4 CRITERION 4 - PROCUREMENT DOCUMENT CONTROL**

Since NWRPO or its contractors do not design repository facilities, there are no procurement activities directed towards aspects of design bases. The NWRPO QA Program does contain provisions to control procurement of services, equipment, and materials for NWRPO and its contractors. Prior to issuance, the QA Officer reviews all quality-affecting procurement documents to assure conformance to procurement requirements. Procurement documents contain acceptance and rejection criteria and the right of NWRPO access to the contractor or vendor facilities.

#### **3.5 CRITERION 5 - INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

All NWRPO and contractor quality-related activities are conducted in accordance with applicable NWRPO Quality Administrative Procedures, Technical Procedures, and Work Plans. The review, approval, and issuance of these documents are controlled to ensure technical and quality requirements are included prior to issuance. As relevant, these documents include the appropriate qualitative or quantitative acceptance criteria to determine activities have been satisfactorily accomplished.

#### **3.6 CRITERION 6 - DOCUMENT CONTROL**

The issuance and distribution of controlled documents for quality-related activities is the responsibility of the QA Officer. Superseded or canceled documents are required to be removed and replaced by applicable documents at the appropriate work areas. A master list of controlled documents is maintained identifying the current list of documents and to whom it is assigned.

#### **3.7 CRITERION 7 - CONTROL OF PURCHASED ITEMS AND SERVICES**

Source evaluation of objective evidence furnished by the supplier, source inspection, audits, or receipt inspection is performed on purchased material by the QA staff and technical specialists, if necessary, to assure conformance to procurement document requirements. Suppliers are required to furnish documentation that identifies the specific procurements that have not been met, along with any nonconformance resulting from not meeting the procurement requirements.

#### **3.8 CRITERION 8 - IDENTIFICATION AND CONTROL OF ITEMS**

NWRPO procedures require that geologic and hydrologic samples are adequately identified and controlled, and how their use is controlled. Correct identification of items or samples are verified and documented prior to release for use or analysis. The identification and control process is verified through audits and surveillances.

### **3.9 CRITERION 9 - CONTROL OF PROCESSES**

NWRPO performs no special processes for the design or construction of the repository or for site characterization. Therefore, there are no special process activities within the scope of this definition.

### **3.10 CRITERION 10 - INSPECTION**

When conformance of an item or activity is required, the QA Officer will ensure that this conformance will be accomplished by qualified personnel other than those that performed or directly supervised the work.

### **3.11 CRITERION 11 - TEST CONTROL**

Test procedures will contain or reference test objectives and provisions for assuring that prerequisites for a particular test have been achieved. Test procedures or instructions will provide requirements and acceptance limits; instructions for performing the test; calibrated instrumentation; adequate test equipment and instrumentation; suitable and controlled environmental conditions; mandatory hold points; acceptance and rejection criteria; methods for documenting and recording test results; and provisions for assuring test prerequisites have been met. Test items will be identified, controlled, and dispositioned. Samples will be archived as required by the test procedures.

### **3.12 CRITERION 12 - CONTROL OF MEASURING AND TEST EQUIPMENT**

Measures are established to assure that measuring and test equipment used in activities affecting quality are properly identified, controlled, calibrated at specified intervals, and adjusted to maintain accuracy within specified limits. If any equipment is found to be out of calibration, a documented evaluation shall be made of the previous data and acceptability of the items previously accepted. Out of calibration equipment shall be tagged or segregated.

### **3.13 CRITERION 13 - HANDLING, STORAGE, AND SHIPPING**

The NWRPO activities that apply to this criterion are geoscience cores, cuttings, fluids, and other physical samples collected for testing, and evaluation. The NWRPO Principal Investigator and QA Officer are responsible for specifying special handling, shipping, storage, preservation, and packaging requirements, and incorporation into the applicable procedures.

### **3.14 CRITERION 14 - INSPECTION, TEST, AND OPERATING STATUS**

Status indicators, such as tags and labels, are utilized to indicate the appropriate status for tests, inspections, segregation, and operating status of applicable NWRPO activities. The status of these activities will be indicated on the item or in documents traceable to the item to assure that an item that has not passed a required test or inspection is not inadvertently installed, used, or operated. Any alteration of the sequence of the required test or inspection will be documented and controlled. Modifications to tests or inspections will be subject to the same review and approval as the original.

### **3.15 CRITERION 15 - CONTROL OF NONCONFORMING ITEMS**

Nonconforming items, activities, and services are required to be documented on a nonconformance report and reported to the QA Officer and area supervisor within two days for further action. Nonconforming items are identified, tagged, and segregated when practical, to prevent inadvertent use.

### **3.16 CRITERION 16 - CORRECTIVE ACTION**

Nonconformance reports shall be reviewed and evaluated by the QA Officer for problem trends, resulting from failures, or deviations from requirements. Corrective action requests are issued to the area involved and describe the cause of the condition and the measures to prevent recurrence. Corrective action will consider the effect on past work, data, and experiments resulting from the deficiency. Audits or surveillances will be conducted to verify implementation of the corrective action.

### **3.17 CRITERION 17 - QUALITY ASSURANCE RECORDS**

Records are required to be prepared and retained to furnish documentary evidence of items and activities affecting quality. Records are stored in fire resistant metal fire cabinets protected from excessive heat, moisture or pressure. Records are required to be complete and legible. The QA Officer is responsible for reviewing, monitoring, and auditing NWRPO project records to assure that they meet QA requirements.

### **3.18 CRITERION 18 - AUDITS**

The QA Officer is responsible for scheduling audits and surveillance to verify compliance with all aspects of the NWRPO QA Program to determine its effectiveness. Audits are conducted in accordance with pre-established procedures and conducted by personnel having no direct responsibilities in the areas being audited. Audit results are documented and reported to management responsible for the areas audited for review and necessary corrective action. Audit results are documented and trended to determine whether repetitive conditions exist.

### **CONCLUSION**

Based on its evaluation and audit of the plan, NRC staff concluded Revision 2 of the QAPP is in conformance with the relevant provisions of 10 CFR Part 60, Subpart G and Appendix B to 10 CFR Part 50, as set forth in the NRC RP. Therefore, NRC staff concludes that the QAPP, as it applies to the activities for the Early Warning Drilling Program, contains sufficient requirements and planned and systematic controls to address each of the relevant criteria of Appendix B to 10 CFR Part 50 in an acceptable manner. NRC requests that Nye County provide a finalized copy of Revision 2 of the NWRPO QAPP.