U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT OAR–06–03, OBSERVATION AUDIT OF THE U.S. DEPARTMENT OF ENERGY, OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE, AUDIT OQA–USGS–06–03 OF U.S. GEOLOGICAL SURVEY

/RA/ T. Matula for 2/13/06
Jack D. Parrott,
Observation Team Leader
Project Management Section A
Licensing and Inspection Directorate
Division of High-Level Waste
Repository Safety

/RA/ T. Matula for 2/13/06
Rodney Weber, QA Specialist
Center for Nuclear Waste
Regulatory Analyses

/RA/ 2/13/06
Gene Peters, Observer
Repository Site Section
Technical Review Directorate
Division of High-Level Waste
Repository Safety

Reviewed and Approved by:

/RA/ 2/14/06
Elmo Collins, Deputy Director
Licensing and Inspection Directorate
Division of High-Level Waste
Repository Safety
Office of Nuclear Material
Safety and Safeguards

1.0 INTRODUCTION

On January 9–12, 2006, staff from the U.S. Nuclear Regulatory Commission (NRC), Division of High-Level Waste Repository Safety, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit OQA–USGS–06–03 of the U.S. Geological Survey (USGS). The OQA team audited the USGS quality assurance (QA) program at the USGS facilities in Denver, Colorado. The audit also included the USGS facility at Menlo Park, California, however, the NRC did not observe that portion of the audit. The objective of this audit was to evaluate the adequacy, implementation, and effectiveness of the QA program implementation by USGS in support of the Yucca Mountain Project. The NRC observers assessed the effectiveness of the audit team and the audit.

2.0 MANAGEMENT SUMMARY

DOE conducted an audit of the USGS QA program through evaluations of procedures for compliance with applicable requirements of Revision 16 of DOE/RM–0333P, Quality Assurance Requirements and Description (QARD), and of USGS implementation of those procedures. The audit team identified two conditions adverse to quality [Level B Condition Reports (CRs)] and one opportunity for improvement. The audit team concluded that the USGS QA program was adequate and USGS was effectively implementing it. The observers determined that the audit team performed effectively and met the audit objectives. The observers agreed with the audit team's conclusions and findings.

3.0 AUDIT PARTICIPANTS

DOE Audit Team Members

John Doyle, Navarro Quality Services (NQS), Audit Team Leader
Patrick Auer, NQS, Auditor
Robert Toro, NQS, Auditor

NRC Observers

Jack Parrott, NRC, Observation Team Leader
Gene Peters, NRC, Observer
Rodney Weber, CNWRA, QA Specialist

Other Observers

Jim Blaylock, DOE
Marilyn Kavchak, NQS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The auditors conducted the audit in accordance with Line Procedure (LP)–18.3Q–OCRWM, Quality Assurance Internal Audit Program. The auditors reported conditions adverse to quality in accordance with Administrative Procedure (AP)–16.1Q, Condition Reporting and Resolution.

The observers followed NRC Manual Chapter 2410, Conduct of Observation Audits, while observing the audit.

4.1 Scope of the Audit

The auditors evaluated the USGS QA program adequacy, implementation, and effectiveness. The auditors evaluated the activities in relation to the QARD and implementing procedures. The auditors covered the 18 elements of the QARD and its five supplements, except for Identification and Control of Items; Control of Special Processes; Inspection; Test Control; Handling Storage and Shipping; Inspection, Test, and Operating Status; Audits; and Field Surveying, which OQA deemed not applicable to the scope of the USGS activities supporting the Yucca Mountain Project. The audit team also examined corrective actions taken for CRs identified from previous audits of USGS.

4.2 Conduct and Timing of the Audit

The observers determined that the audit team performed the audit effectively and demonstrated sound knowledge of the applicable implementing procedures and QA program requirements. The audit team members conducted thorough interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The auditors caucused each afternoon with the observers to discuss the current audit status and potential issues. The auditors, USGS management, and observers met daily to discuss the audit status and any new and developing issues. The timing of the audit was appropriate in relation to the previous audit of USGS (OQA–05–23) in May 2005, ongoing corrective actions, and the activities being conducted at USGS.

The checklists prepared for audits prior to OQA–USGS–06–03 were based on the audited organizations' implementing procedures. The checklists used for this audit were based primarily on applicable QARD requirements, and secondarily on USGS implementing procedures. This was due to an OQA initiative to base audits primarily on evaluations against QARD requirements rather than on implementing documents. OQA is seeking feedback from the audit teams regarding the use of the checklists, and OQA will determine the effectiveness of the revised checklists for future use.

4.3 Audit Team Qualifications and Independence

The observers reviewed the qualifications for the Audit Team Leader and auditors. The observers determined that the Audit Team Leader and auditors were qualified and independent of the areas reviewed.

4.4 Examination of Quality Assurance Elements

4.4.1 Organization

The auditors reviewed documents describing the USGS interfaces, organizational structures, responsibilities, and authorities. All the appropriate documentation was found to be in place. The audit team did not identify any discrepancies in this area.

4.4.2 Quality Assurance Program

The auditors reviewed documentation, quality records, and procedures related to current work activities. The auditors also reviewed personnel qualifications and training records to verify appropriate assignment of staff to quality affecting work activities. The auditors interviewed USGS management personnel to determine their role in assuring that USGS is achieving and maintaining quality and that the required quality oversight was planned and performed. The auditors also determined that the USGS management reviewed these activities and the QA program for continued appropriateness and effectiveness. The audit team did not identify any discrepancies in this area.

4.4.3 Procurement Document Control

The audit team reviewed one procurement document (a Task Agreement) issued by the Yucca Mountain Project Branch, USGS (Denver), to USGS, Western Earth Surface Processes laboratory in Menlo Park, California, for laboratory analytical services. USGS did not comply with provisions of the Task Agreement relating to sample quality control plan and the sample preparation, specifically:

- USGS-Denver did not provide a blind quality control sample to USGS-Menlo Park as required.

- USGS-Menlo Park, rather than USGS-Denver, prepared samples.

The audit team identified the noncompliance with the Task Agreement as a potential Level B CR.

4.4.4 Implementing Documents

The audit team evaluated the applicable QARD requirements against USGS implementing documents used to perform work. The audit team reviewed procedures to verify that the procedures

- Were appropriate to the nature and the circumstances of the work
- Contained appropriate information
- Were reviewed, approved, and controlled

The audit team also verified that individuals performing the work complied with the implementing documents. The audit team evaluated technical and quality management procedure reviews and comment resolution for proper completion, concurrence, and approval. The audit team did not identify any discrepancies in this area.

4.4.5 Document Control

The audit team evaluated the implementation of the requirements in the QARD sections applicable to the USGS work scope. Specifically, the auditors reviewed the implementation of proper document control and the assignment of responsibility for preparing and maintaining documents. The auditors also evaluated the review, revision, approval, and distribution of

documents to verify proper implementation of requirements. The audit team did not identify any discrepancies in this area.

4.4.6 Control of Purchased Items and Services

The audit team reviewed implementing procedures and records regarding controlling purchased items and services against applicable requirements of the QARD. The audit team did not identify any discrepancies in this area.

4.4.7 Control of Measuring and Test Equipment

The audit team reviewed a sample of records documenting the use of measuring and test equipment. In addition, auditors visited laboratories and identified equipment being used and the methods for equipment control. Auditors reviewed records to verify the existence of calibration schedules and calibration documentation, and to verify that the proper actions were taken for out-of-tolerance conditions. When out-of-tolerance conditions were noted, the auditors verified that proper actions were taken to determine the impact on measurements taken since the last valid calibration. The audit team reviewed calibration records and verified traceability to national standards. The audit team did not identify any discrepancies in this area.

4.4.8 Nonconformances

The audit team reviewed the process for identifying and processing nonconforming items. Auditors identified CRs by reviewing the previous audit and surveillance reports, the Corrective Action Program (CAP) database, and the USGS QA logs. The auditors verified that the identification, reviews, disposition, and close-out of corrective actions were conducted in accordance with QARD requirements. The audit team did not identify any discrepancies in this area.

4.4.9 Corrective Action

The audit team reviewed the CAP to verify that conditions adverse to quality were identified and reviewed and that actions were taken by USGS according to the significance of the conditions. The audit team reviewed CRs issued between June 2005 and January 2006. Auditors determined that responsible management evaluated reports, determined the extent of adverse conditions, and completed remedial actions. The auditors verified that corrective actions were accomplished prior to documentation close-out and that USGS had taken appropriate corrective actions based on audits and surveillance findings. The audit team determined that previously identified conditions had not recurred, indicating the effectiveness of corrective actions. The audit team did not identify any discrepancies in this area.

4.4.10 Quality Assurance Records

The audit team reviewed QA records and determined that, in general, records were available, retrievable, and supported the quality-related activities. The auditors identified a scientific notebook that USGS submitted to the Records Processing Center in Las Vegas that was filed in the Records Information System under an incorrect file number. The audit team determined that this was an isolated incident. USGS issued a Record Problem Report describing the problem and requested a correction.

4.4.11 Software, QARD Supplement I

The audit team evaluated the implementation of the requirements in QARD Supplement I, including

- Software planning
- Software development and development life cycle requirements
- Configuration management
- Software defect reporting and resolution
- Software procurement
- Software qualification and control
- Software retirement

The audit team did not identify any discrepancies in this area.

4.4.12 Sample Control, QARD Supplement II

The audit team reviewed implementing procedures against applicable requirements of the QARD for the retention and management of samples (aqueous and non-aqueous). The USGS staff were able to locate samples identified by the audit team. The audit team also evaluated sample conditions against maintenance criteria (e.g., pH). The audit team did not identify any discrepancies in this area.

4.4.13 Scientific Investigation, QARD Supplement III

The audit team reviewed active scientific investigations and noted that, due to the more rapid turnaround time for Krypton/Argon (Kr/Ar) analyses, USGS supplemented the $^{40}Ar/^{39}Ar$ geochronology data with Kr/Ar data generated to provide an interim age for basalt samples. The Kr/Ar dates were classified as non-quality affecting (non-Q). The auditors recommended (in a level D CR) that these data be entered into the Technical Document Management System with annotations as non-Q data.

4.4.14 Control of the Electronic Management of Data, QARD Supplement V

The audit team reviewed electronic data and scientific notebooks pertaining to the geochemical investigations and analysis of samples. During this review, the auditors determined that analytical data were transferred electronically from the analytical instrumentation to a Microsoft® Excel spreadsheet for data reduction, manipulation, and calculation. The implementing procedures require a manual verification that data were transcribed accurately in the data import process. The audit team could find no written record that this verification had been performed and identified this deficiency as a potential Level B CR.

4.5 Audit Findings

The auditors identified two conditions adverse to quality identified as Level B CRs:

- USGS did not comply with provisions of a Task Agreement relating to a sample quality control plan and a sample preparation plan. USGS did not provide a blind quality control sample as required.

- USGS did not include in a data package a Data Transcription Sheet (required by a Technical Work Plan) that documents data verification when data is moved from one medium to another.

The auditors identified an opportunity for improvement, recommending that basalt samples that had been dated by the K/Ar method should be submitted to the Technical Data Management System as non-Q data.

5.0 NRC STAFF FINDINGS

5.1 NRC OBSERVATION SUMMARY

The observers determined that the audit was performed effectively and that auditors demonstrated sound knowledge of the applicable implementing procedures and QARD requirements. The auditors conducted thorough interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The observers determined that the audit team met the audit objectives. The observers agreed with the auditors' conclusions, findings, and process improvement recommendations.

The observers identified a good practice regarding the audit team. The audit team thoroughly reviewed the contracted work conducted by USGS Western Earth Surface Processes laboratory which had not been included in the initial audit scope.

5.2 NRC AUDIT OBSERVER INQUIRY

The observers did not initiate any Audit Observer Inquiries during this audit.