U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT
NO. OAR 06-04,
OBSERVATION AUDIT OF THE U.S. DEPARTMENT OF ENERGY, OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE, AUDIT OF QUALITY ASSURANCE PROGRAM IMPLEMENTATION AT THE LAWRENCE LIVERMORE NATIONAL LABORATORY, AUDIT OQA-LLNL-06-19

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## 1.0 INTRODUCTION

On May 1-5, 2006, staff from the U.S. Nuclear Regulatory Commission (NRC) Division of High-Level Waste Repository Safety observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), Audit OQA-LLNL-06-19 of the quality assurance (QA) program implementation at the Lawrence Livermore National Laboratory (LLNL) in Livermore, California. The DOE OQA audit team conducted the annual QA program compliance audit, of LLNL's activities, that provide or support input to the planned Yucca Mountain Repository license application (LA). The DOE audit was to evaluate the adequacy, implementation, and effectiveness of the QA procedures, in compliance with the requirements of DOE/RW-0333P, Rev 16, Quality Assurance Requirements and Description (QARD), for the LLNL scope of work. The NRC observer assessed the effectiveness of the QA program implementation on LLNL activities, as well as the effectiveness of the DOE audit team and the DOE audit process in achieving the DOE audit objective.

## 2.0 MANAGEMENT SUMMARY

The DOE conducted its annual QA program compliance audit, of LLNL's activities, that provide or support input to the planned Yucca Mountain Repository LA. These activities include long-term waste package material corrosion and phase stability testing, modeling, drift-scale testing, total system performance analysis support, and electrochemical testing of titanium alloys. The objective of this audit was to evaluate the adequacy, implementation, and effectiveness of QA applicable requirements. The DOE audit team determined that LLNL was effectively implementing its QA program commitments. The DOE audit team identified one minor adverse condition and one noteworthy practice.

The NRC observer determined that the DOE audit was well-planned and appropriate for the LLNL activities audited, and was performed effectively, and agreed with the DOE audit team's conclusions and findings.

## 3.0 PARTICIPANTS

DOE Audit Team

Elver D. Robbins, Audit Team Leader
James E. Flaherty, Audit Team Member
Donald J. Harris, Audit Team Member
Kristi A. Hodges, Audit Team Member

DOE Licensing Representative

Prasad Air

NRC Observer

Wilkins R. Smith, Observation Team Leader

## 4.0 REVIEW OF THE DOE AUDIT AND AUDITED ORGANIZATION

The DOE audit team conducted the audit in accordance with the QARD, Line Procedure 18.3Q–OCRWM, "Internal Audit Program," and Administrative Procedure 16.1Q, "Condition Reporting and Resolution." The observer followed NRC Manual Chapter 2410, "Conduct of Observation Audits," while observing the DOE audit.

### 4.1 Scope of the DOE Audit

The DOE audit team evaluated the adequacy, implementation, and effectiveness of applicable QA program requirements including project planning, testing records, and documents, relating to the LLNL activities that support the planned Yucca Mountain Repository LA. The DOE audit team evaluated LLNL's implementation in relation to DOE/RW–0333P, *Quality Assurance Requirements and Description* (QARD) Revision 16, and current Yucca Mountain Project (YMP), Bechtel SAIC Corporation (BSC), and LLNL implementing procedures.

### 4.2 Conduct and Timing of the DOE Audit

Prior to the start of the audit, the DOE auditors prepared an audit plan and checklists based on applicable procedure requirements, which they applied in their assessments. When appropriate, the DOE auditors and technical specialist went beyond the scope of their checklists to probe and resolve potential issues.

The DOE audit was scheduled as the annual audit, to evaluate the LLNL QA program implementation, and was timely in relation to the planned project activities. Although there were limited actual tests or other YMP activities in progress, the QA controls applicable to these activities were properly assessed though observation of laboratory equipment, samples, and operations. The DOE audit team also held interviews with LLNL management and staff, including program and engineering assurance managers, principal investigators, and administrative support personnel.

### 4.3 Audit Team Qualifications and Independence

The NRC observer reviewed the qualifications of the DOE audit team leader, auditors, and technical specialists, and determined that they were qualified by education, experience, and training, and independent of the areas reviewed. The DOE audit team had members with appropriate education and experience, so they were able to add performance-based components to their evaluations.

### 4.4 Examination of QA Elements

The LLNL activities were audited by the DOE audit team for the following applicable QA elements.

#### 4.4.1 Organization

The DOE auditors reviewed the LLNL organization and the DOE and BSC interfaces that are applicable to the LLNL YMP activities. The applicable procedures were reviewed and their implementation discussed with cognizant staff and senior management.

The DOE audit team concluded that the organizational interfaces, requirements, and responsibilities were adequately implemented and functioning properly for the LLNL activities.

The NRC observer determined that the DOE audit was effective in this area and agreed with the conclusion of the auditors.

### 4.4.2 QA Program

The DOE audit team evaluated the adequacy and implementation of QA program requirements for the LLNL activities, including the flowdown of requirements to and from DOE, BSC, and LLNL and the implementing procedures. The BSC FY2006 Statement of Work (to LLNL), Revision was reviewed by the DOE audit team, as were the Work Packages (WP) for which LLNL was authorized to work. These included WPs for Seismic Waste Package Analysis, Modeling Near Field Environment and In-Drift, TSPA Documentation, Infiltration Special Project Management and Administration (database maintenance), Drift Scale Testing, Aging and Phase Stability, Passive Film Stability and General Corrosion Testing (of waste package materials), and Electrochemical Testing of Titanium Alloys. The DOE audit team utilized this information to select a sample of project activities, scientific notebooks, records, and LLNL personnel to review or interview.

The DOE audit team interviewed the administrative coordinator for training who was responsible for maintaining records of training and verification of education and experience. A database training matrix of LLNL personnel performing YMP activities is updated every month. Records were available showing appropriate training for all personnel sampled.

The DOE auditors noted that LLNL was providing information to BSC on changes to the LLNL QA implementation requirements matrix, as required by the QARD. However, because of the implementation of another requirements management program, BSC is not maintaining the overall matrix. The DOE audit team leader stated that this generic issue was being addressed by a condition report (CR). The audit team also noted that the Technical Work Plans (TWP) for LLNL's 2006 had not yet issued by BSC. The DOE audit team did not find evidence that this had an impact on the quality of the activities audited.

The DOE audit team concluded that the QA program requirements for LLNL were adequate and being effectively implemented.

The NRC observer determined that the DOE audit was effective in this area and agreed with the conclusion of the auditors.

### 4.4.3 Procurement Document Control and Purchased Items and Services

The DOE auditors reviewed the control of procurement documents and procured items and services. There was little activity in these areas since procurements had been delayed by the lack of TWPs and other YMP issues. Procurement of measuring and test equipment (MTE) had been centralized through BSC and competitively selected vendors. The DOE audit team concluded that the QA program in these areas was adequately implemented and functioning effectively.

The NRC observer determined that the DOE audit was effective in this area and agreed with the conclusion of the auditors.

### 4.4.4 Implementing Documents and Document Control

The DOE auditors identified controlled documents and checked for correct maintenance of the documents. The DOE auditors interviewed managers and staff responsible for document preparation, processing, and review. The DOE audit team found that, contrary to the requirements of Procedure 033-YMP-QP-2.1, Revision 10, Section 2.1.5.7, the LLNL Engineering Assurance Manager had not performed a documented review of newly issued and/or revised procedures issued by BSC for the YMP. The DOE audit team did not find evidence of an impact on quality from this issue, and expected that this would be documented on a level "C" CR.

The DOE audit team concluded that the QA program in these areas was adequately implemented and functioning effectively, with the one exception of the noted potential CR.

The NRC observer determined that the DOE audit was effective in these areas and agreed with the conclusion of the auditors.

### 4.4.5 MT&E Control

The NRC observer accompanied auditors through various laboratory and support areas to review the M&TE control LLNL used for the YMP activities. In each testing and the M&TE control area, the DOE auditors examined test equipment, gages, and other MT&E. The DOE audit process included review of M&TE calibration records, interviewing M&TE users (i.e., lab technicians) on the use of such equipment, and discussions with the cognizant program coordinator on how the procedures ensured that M&TE used on YMP activities was properly calibrated. Applicable documentation and labels were examined.

The DOE audit team observed control of chemical reagents and standards in the laboratory and testing areas. All reagents and chemicals were segregated and labeled appropriately, as a result of the recent stop-work order, to address issues with the procurement and use of these items. This is being addressed by YMP level "A" CR-7875.

The DOE audit team also noted that the recalibration verification of MTE, particularly thermocouples, has, on occasion, been delayed for extensive periods because of overload at the calibration service. The DOE audit team did not note evidence of a quality issue in the MTE sampled.

The DOE audit team did not identify any programmatic deficiencies in this area, and concluded that the QA program requirements were adequate and effectively implemented in this area.

The apparent non-compliances documented in NRC Observation Audit Report (OAR-05-05) were outside the scope of this DOE audit team.

The DOE auditors were thorough and methodical in following the lines of inquiries prepared before the audit, and the NRC observer agreed with the conclusion the DOE audit team made.

### 4.4.6 Identification and Control of Items and Services, and Handling, Storage and Shipping

The DOE auditors reviewed the implementing procedures for these areas. There were limited recent activities in these areas. The DOE auditors observed identification, control, handling and storage of samples and tests in progress, in storage, and in record and databases.

The DOE audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in this area.

The apparent non-compliances documented in NRC Observation Audit Report (OAR-05-05) were outside the scope of this DOE audit team.

The NRC observer agreed with the conclusion made by the DOE audit team.

### 4.4.7 Corrective Action

The DOE auditors determined that the requirements for LLNL corrective action were adequate and were being properly implemented for the YMP activities, based on review of a sample of CRs and other documentation, and interviews of cognizant personnel. The DOE audit team identified a Noteworthy Practice in this area. The LLNL evaluation and documentation of the extent of condition of CR deficiencies were found to be appropriate, technically adequate, and overall very good. The DOE audit team concluded that the QA program requirements were adequate in these areas.

The apparent non-compliances documented in NRC Observation Audit Report (OAR-05-05) were outside the scope of this DOE audit team.

For the corrective actions evaluated within the DOE audit, the NRC observer agreed with the conclusion made by the DOE audit team.

### 4.4.8 QA Records

The DOE auditors reviewed the implementing procedures for records; sampled a representative selection of records, including calibration, training, and scientific notebooks; and discussed records requirements and processes with cognizant management and administrative personnel.

The DOE audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

The NRC observer agreed with the conclusion the DOE audit team reached.

### 4.4.9 Software

The DOE auditors reviewed the implementing procedures and sampled records for software used on YMP activities. Discussions with staff and management were held on software control and implementation.

The DOE audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

The NRC observer agreed with the conclusion the DOE audit team reached.

#### 4.4.10 Sample Control and Scientific Investigation

The DOE auditors reviewed the implementing procedures and project planning documents for sample control and scientific investigations. Discussions were held with the project technical staff and managers, and laboratory logs, databases, and scientific notebooks were examined for sample control identification and traceability and proper documentation of the scientific investigations.

The DOE audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

The NRC observer agreed with the conclusion the DOE audit team reached.

#### 4.4.11 Control of the Electronic Management of Data

The DOE auditors reviewed the implementing procedures for electronic management of data from tests and evaluations, examined records and related documentation, and interviewed responsible staff and management.

The DOE audit did not identify any programmatic deficiencies in this area, and the audit team concluded that the QA program requirements were adequate in these areas.

The NRC observer agreed with the conclusion the DOE audit team reached.

### 4.5 Potential Audit Findings

The DOE audit team identified one potential level “C” CR: the LLNL Engineering Assurance Manager had not performed a documented review of newly issued and/or revised procedures, as required by procedure.

The DOE audit team identified one Noteworthy Practice: the LLNL evaluation and documentation of the extent of condition of CR deficiencies were found to be appropriate, technically adequate, and overall very good.

## 5.0 NRC STAFF FINDINGS

The NRC observer determined that the DOE audit team leader and members were effective in planning and conducting the audit, and in evaluating the QA program adequacy and the LLNL implementation of the applicable procedures. This annual QA audit of LLNL program implementation focused on program compliance, however the NRC observer noted that the DOE audit team used its technical and programmatic knowledge of the YMP requirements and issues to apply risk-informed principles and approaches in selecting audit samples, in interviews with LLNL personnel, and in examining procedure implementation, records, and testing results.

## 5.1 NRC Observation Summary

The NRC observer determined that the DOE audit team was effective in evaluating the QA program adequacy and the LLNL implementation of applicable implementing procedures. The NRC observer agreed with the audit team's conclusions, findings, and recommendations. The NRC observer determined that the DOE audit team members were qualified, independent of the areas being audited, and had adequate knowledge and understanding of the requirements.

## 5.2 NRC Audit Observer Inquiry

No audit observer inquiries were submitted.