



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 26, 2006

MEMORANDUM TO: C. William Reamer, Director
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

FROM: Jack D. Parrott, Senior On-Site Licensing Representative **R/A**
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SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ON-SITE LICENSING
REPRESENTATIVES' REPORT ON THE YUCCA MOUNTAIN
PROJECT, FOR APRIL 1, 2006, THROUGH JUNE 30, 2006

The purpose of this memorandum is to transmit the U.S. Nuclear Regulatory Commission (NRC) On-Site Representatives' (ORs') quarterly report for the period of April 1, 2006, through June 30, 2006.

This report highlights a number of Yucca Mountain Project activities of potential interest to NRC staff. The ORs continue to respond to requests from NRC Headquarters staff to provide various documentation and feedback related to Key Technical Issues (KTIs) and their resolution. During this reporting period, the ORs continued to observe matters associated with Yucca Mountain Site activities, KTIs, and audits. The ORs also attended various meetings and accompanied NRC staff on visits to Yucca Mountain.

In accordance with 10 CFR 2.390 of NRC's "Rules of General Applicability," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records' component of NRC's document system, "Agencywide Document Access and Management System" (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions about this report or its attachments, please call Jack D. Parrott, on (702) 794-5047, or Robert M. Latta, on (702) 794-5048.

Enclosure(s):

1. "U.S. Nuclear Regulatory Commission On-Site Licensing Representatives' Report Number OR-06-02, for the Reporting Period of April 1, 2006, through June 30, 2006"
2. Table 1: "U.S. NRC On-Site Licensing Representatives' Tracking Report for Open Items Followed in Quarterly OR Report"

cc: See attached list.

Memorandum to C.William Reamer, Director, from R. Latta and J. Parrott, dated: September 26, 2006
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FROM: Jack D. Parrott, Senior On-Site Licensing Representative **R/A**
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**U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-06-02,
FOR THE REPORTING PERIOD OF
APRIL 1, 2006, THROUGH JUNE 30, 2006**

Enclosure 1

TABLE OF CONTENTS

U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-06-02
FOR THE REPORTING PERIOD OF APRIL 1, 2006, THROUGH JUNE 30, 2006

	Page
TABLE OF CONTENTS	i
ACRONYMS AND ABBREVIATIONS	ii
EXECUTIVE SUMMARY	1
REPORT DETAILS	
Introduction	
Objectives	
1. Site Activities and Data Acquisition	3
2. Outreach Activities	4
3. QA and Engineering	4
4. General Activities	13

ACRONYMS AND ABBREVIATIONS

ACRO	MEANING
ADAMS	Agencywide Documents Access and Management System
AP	Administrative Procedure
BSC	Bechtel SAIC Company, LLC
CAP	Corrective Action Program
CNWRA	Center for Nuclear Waste Regulatory Analyses
CR	Condition Report
CST	Condition Screening Team
DOE	U.S. Department of Energy
DTN	Data Tracking Number
FY	Fiscal Year
HLWRS	High-Level Waste Repository Safety
INPO	Institute of Nuclear Power Stations
IRPT	Integrated Requirements Product Team
IV&V	Instillation Verification and Validation
KTI	Key Technical Issue
LA	License Application
LLNL	Lawrence Livermore National Laboratory
LSN	Licensing Support Network
MRC	Management Review Committee
NCNP	Nevada Commission on Nuclear Projects
NCRs	Non-Conformance Reports
NRC	U.S. Nuclear Regulatory Commission
OAR	Observation Audit Report
OQA	Office of Quality Assurance
OR	On-Site Representative
PA	Performance Assessment
QA	Quality Assurance

QARD	Quality Assurance Requirements Description
QRM	QARD Requirements Matrix
RIV	Region IV
TSPA	Total System Performance Assessment

EXECUTIVE SUMMARY

SITE ACTIVITIES AND DATA ACQUISITION

Conclusion of Underground Thermal Experiment at Yucca Mountain - On April 4 and 18, 2006, an On-Site Representative (OR) and staff members from both the U.S. Nuclear Regulatory Commission (NRC) and Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy's (DOE's) Project Staff removing samples following the completion of an underground thermal experiment at Yucca Mountain.

QUALITY ASSURANCE (QA) AND ENGINEERING

Corrective Action Program (CAP) Self-Assessment - The DOE completed a self-assessment of the CAP process in February 2006. DOE's conclusions from the self-assessment were that the line organizations' are not using the CAP process effectively and that there is a reluctance to identify condition reports (CRs.) The assessment also determined that although the Management Review Committee (MRC) had made progress, it was not effective in resolving CAP implementation issues, such as those identified during the self-assessment. To address the conditions associated with the CAP self-assessment, DOE developed an action plan that strengthens the MRC structure, focuses the newly constituted MRC on priority CRs, and establishes clear expectations for CAP problem-solving and performance improvement.

Observation of Design Engineering Readiness Review - From April 17 through 21, 2006, the ORs observed DOE's readiness review of the Bechtel SAIC Company LLC, (BSC) Design Engineering Process. The purpose of this readiness review was to determine if BSC was prepared to initiate preliminary design activities and to determine if the work processes related to design efforts complied with the requirements of the Quality Assurance Requirements Description (QARD). Based on the results of the readiness review, DOE determined that BSC's engineering design process was "conditionally ready."

Evaluation of Current Trend Information - During this reporting period, the ORs reviewed the results of the Yucca Mountain Project's (Project's) "Trend Evaluation Report," for the second quarter of fiscal year (FY) 2006. Based on the Project's analysis of this trend evaluation information, a number of adverse trends, emerging trends, and monitoring trends were identified. The trend report also indicates that the predominant causal factor, for Level A, B, and C conditions, continues to be Human Performance issues. Despite attempts to address this lingering issue, DOE continues to struggle with reducing the occurrence of Human Performance conditions. In response to the Human Performance issues documented in CR-6399, the project has initiated actions to address the continuing problems within this area.

Observation of CAP Audit - The BSC QA organization conducted an Audit, from May 29, 2006, through June 13, 2006, to evaluate BSC's CAP. The audit used a performance-based approach to review the adequacy and effectiveness of corrective actions implemented for selected CRs related to activities at the Project. Based on the results of the audit, the ORs determined that this oversight activity was effective in reviewing the CRs included in the audit scope and in identifying several issues that will improve the CAP process.

Observation of Software Control Audit - From May 15 through 23, 2006, the ORs observed the DOE's Office of Quality Assurance (OQA) audit, of the software process implemented by BSC. Based on the results of this audit, the ORs determined that this oversight activity was effectively performed. The ORs identified a weakness in the planning, related to unanticipated changes in the audit scope subsequent to the initiation of this audit. **OR Open Item 06-03** was issued requesting a description of DOE's remediation process for the approximately 35 remaining Legacy Codes, and **OR Open Item 06-04** was issued requesting a basis and justification for the continued use of output from software on the baseline, that was not subject to Installation Verification and Validation (IV&V) remediation.

Observation of BSC QA Design Control Audit - From June 20-29, 2006, the ORs and a staff member from the CNWRA observed the BSC QA audit of design control processes and design products. Because of the lack of completed quality-affecting design products the BSC audit team reviewed selected design criteria, drawings, specifications, and calculations, to verify effective implementation of design control process for non-safety category activities associated with the lower muck-yard. Based on the NRC reviews within this area, it was determined that the audit was adequately performed. The NRC observers identified a concern regarding the ability of the audit team to independently establish the significance level of the conditions identified during the audit.

Review of Condition Screening Team Activities - During this reporting period, the ORs reviewed the activities performed by the Project's Condition Screening Team (CST). As a result of these reviews, one deficiency was identified regarding the failure to establish appropriate procedural controls, for the quality-affecting activities performed by the CST. The ORs identified a second deficiency, related to OQA's failure to process a QARD clarification concerning the content and completeness of the CR record packages, in accordance with the requirements of procedure AP-16.1Q, "Condition Reporting and Resolution.

REPORT DETAILS

INTRODUCTION

The principal purpose of the On-Site Representatives' (ORs') report is to inform U.S. Nuclear Regulatory Commission (NRC) managers, staff, and contractors about information on the U.S. Department of Energy's (DOE's) activities related to, repository design, performance assessment (PA), performance confirmation, and environmental studies. The primary focus of this and future OR reports will be on DOE's programs for subsurface and surface-based testing, PA, data management systems, environmental studies, and quality assurance (QA). Relevant information includes new technical data, DOE's plans and schedules, and the status of activities to support preparation of the License Application (LA). The ORs also take part in activities associated with resolving NRC Key Technical Issues (KTIs).

This report covers the period of April 1, 2006, through June 30, 2006.

OBJECTIVES

The ORs' missions are to act as points of prompt information exchange, and to identify preliminary concerns with site investigations and potential licensing issues. The ORs carry out these roles by gathering and evaluating information, identifying concerns, and bringing more significant issues to NRC management's attention. With input from NRC Headquarter's management, the ORs interact with DOE scientists, engineers, and managers on the implementation of NRC policies, programs, and regulations. The ORs also focus on issues such as design controls, data management systems, PA, and KTI resolution. A primary OR role is to identify areas, whether in site studies, activities, or procedures, that may be of interest or concern to the NRC staff.

5. SITE ACTIVITIES AND DATA ACQUISITION

1.1 Conclusion of Underground Thermal Experiment at Yucca Mountain

On April 4 and 18, 2006, an OR accompanied by staff from both NRC and CNWRA , and a representative from Clark County, NV, observed DOE project staff remove samples from a completed underground thermal experiment at Yucca Mountain. This experiment was designed to evaluate the thermal-mechanical-chemical response of water and rock to heat supplied by analog high-level waste packages. The packages were placed in a tunnel that is 47 meters long and 5 meters in diameter. The test started with a 4-year heating phase, where tunnel wall-rock temperatures reached approximately 200 degrees C. This phase was followed by a 4-year cooling phase. Mapping activities were initiated by DOE project staff to evaluate observed conditions that included: (1) patchy and streaky red stains on the analog waste packages and the tunnel floor; (2) precipitated minerals on tunnel walls; and (3) rock fragments that had fallen from the tunnel ceiling. DOE project staff also collected dust samples and retrieved metal and metal/microbial coupons. Photographs and videos to document visual observations were taken by both DOE and NRC staff.

DOE currently plans to analyze the samples collected from the underground thermal experiment during the latter part of calendar year (CY) 2006. Information obtained from this and other characterization activities planned for CY 2007 will be analyzed to enhance the understanding of coupled processes (e.g., the effect of long-term heat generation on water-rock interactions.) Information obtained from these activities will also be used to evaluate conditions identified during visual observations of inaccessible areas made during the eight-year test, and to help design and conduct other large scale thermal tests such as those planned for performance confirmation.

6. OUTREACH ACTIVITIES

N/A - this reporting period.

7. QA AND ENGINEERING

3.1 Corrective Action Program (CAP) Self-Assessment

In February 2006, DOE completed a self-assessment of the CAP process. This self-assessment, which focused on organizational implementation behaviors, used industry guidance contained in the Institute of Nuclear Power Operations' (INPO's), "Guidelines for Performance Improvement of Nuclear Power Stations." The INPO guidelines identified specific elements associated with an organization's ability to improve performance. Based on the results of selective interviews with management representatives and project personnel, a number of conclusions and recommendations were identified in DOE's self-assessment report, issued in March of 2006.

The self-assessment's primary conclusion was that the line organizations are not effectively using the CAP process. In particular, the self-assessment established that the line organizations were focused on condition report (CR) closure versus using the CAP to effectively trend, analyze, and correct issues, captured in CRs, that would improve organizational performance. A second conclusion of the self-assessment was that there is a reluctance within the line organizations' to identify CRs, because of potential negative consequences, perceived software difficulties, and challenges experienced in working with affected line organizations'. The self-assessment concluded that although the Management Review Committee (MRC) had made progress, it had not been effective in resolving CAP implementation issues, such as those identified during the self-assessment.

To resolve the issues identified during the CAP self-assessment, DOE developed an action plan, focused on three recommendations, involving: (1) strengthening the MRC structure, membership, and organizational participation; (2) focusing the reconstituted MRC to address priority CRs, to ensure that the corrective actions achieve the desired results; and, (3) setting clear MRC expectations for CAP problem-solving and performance-improvement capability, including line organizations' participation and accountability.

The MRC Charter and membership changes were initiated in mid-April. The CAP Screen Team (CST) membership and Charter have been revised to enhance senior management engagement and support for the CAP system. Specifically, the Yucca Mountain Site Operations Manager has been identified as the MRC Chairman, and DOE senior managers are expected to be directly involved as members. Bechtel SAIC

Company, LLC (BSC) and laboratory managers have also been identified as members. Additionally it was noted that a CAP "Performance Improvement Plan of Action and Milestones," has been developed to provide direction and integration of the actions that resulted from the CAP Self-Assessment. The ORs will continue to monitor the CAP implementation and oversight process.

3.2 Observation of Design Engineering Readiness Review

From April 17 through 21, 2006, the ORs observed the performance of DOE's Readiness Review of BSC's Design Engineering Process. The purpose of this readiness review was to determine if BSC was prepared to initiate preliminary design activities, and that the work processes related to design efforts complied with the requirements of the Quality Assurance Requirements Description (QARD). The ORs observed that subsequent to the previous evaluation of BSC's design engineering process in 2002, numerous deficiencies regarding requirements management, design processes, and procedural adequacy were identified. As a result of an employee concern investigation in 2005, and a DOE root-cause analysis related to CR 6278, DOE determined that the Project had not maintained nor properly implemented its requirements management program, and this resulted in inadequacies in the design control process. As described by DOE during the December 7, 2005 NRC/DOE Quarterly Management Meeting, these deficiencies raised uncertainty regarding the adequacy of engineering and pre-closure safety analysis products developed under these processes. On December 19, 2005, DOE suspended BSC's authority to approve engineering-related products until DOE had confirmed the adequacy of the Project's technical requirements baseline and had validated that the necessary processes to maintain and incorporate requirements into implementing mechanisms were properly controlled. Because of the cross-cutting nature of these issues, DOE formed an Integrated Requirements Product Team (IRPT) to provide the necessary direction, coordination, and oversight of the related corrective action, and actions to preclude recurrence.

Based, in part, on the direction provided by the IRPT, the Readiness Review Team developed Readiness Review Plan BSC-RR-06-01, in accordance with the requirements of procedure LP-2.16Q-OCRWM, "Readiness Review." To facilitate the analysis of BSC's design engineering processes, the Readiness Review Team developed detailed checklists that evaluated critical process parameters. These activities included: (i) verification of appropriate roles and responsibilities for the accomplishment of design functions; (ii) compliance with QARD requirements; and (iii) confirmation of the adequacy of the integrated process controls for design development. The Readiness Review Team also reviewed the list of open Level A and B deficiencies, related to requirements management and design control issues, provided by BSC's Engineering Design staff. However, the ORs observed that, the one Level A CR and five Level B CRs that the Engineering Design staff identified for this review did not appropriately encompass the numerous configuration control deficiencies associated with requirements management, design processes, and procedural adequacy issues integral to the resolution of the conditions the IRPT was addressing. At the conclusion of the Readiness Review, the ORs observed that BSC's Engineering Design staff had not provided a response regarding the limited number of CRs that had been identified for evaluation, and it was not clear how the corrective and preventive actions from the related CRs had been incorporated into BSC's engineering process controls.

As documented in DOE's report "BSC Engineering Design Process Readiness Review", BSC-RR-06-01, the Readiness Review Team determined that BSC's engineering design process was "conditionally ready." The conditions identified in DOE's readiness review report that must be satisfied prior to the initiation of BSC's design activities included: (i) reestablishment of, and contractual conveyance of, a valid DOE Level 2 repository technical baseline; (ii) development of a BSC Level 3 technical baseline that is consistent with the DOE Level 2 technical baseline; and (iii) the effective resolution of the four Level C CRs the Readiness Review Team identified. In addition to these issues, the ORs identified to the Readiness Review Team lead, that despite the existence of numerous CRs related to requirements management, BSC had not effectively described the planned and completed corrective actions that would resolve the deficiencies currently being overseen by DOE's IRPT. These issues were provided to the Readiness Review Team and to DOE's Licensing organization as; **OR Open Item 06-05**, "Limited scope of CRs impacting Engineering Design Provided to Readiness Review Team," and **OR Open Item 06-06**, "Establish the relationship between the actions to address deficiencies in the requirements management process and changes in the Engineering Design organization."

Subsequent to the identification of these OR Open Items, DOE's Regulatory Interactions Group entered the issues into the CAP system as CR 8162 and CR 8163, respectively. During this reporting period, the ORs reviewed the initial and amended responses to these CRs, provided by Engineering Design. Based on the results of these reviews it was determined that adequate information had been provided including the results of a detailed analysis of over 120 CRs related to requirements management, to address these conditions. Therefore, **OR Open Item 06-05** and **OR Open Item 06-06** are considered closed.

3.3 Evaluation of Current-Trend Information

During this reporting period, the ORs reviewed the results of the Project's "Trend Evaluation Report," for the second quarter of fiscal year (FY) 2006. The purpose of this report is to serve as a management process to measure and improve performance by identifying and correcting problematic trends and preventing adverse conditions identified through the CAP. Specifically, the objective of the trend program is to identify emerging issues and conditions, and to initiate timely corrective actions to address these issues. This process evaluates trends, patterns, and causes of CRs, to identify repeat occurrences that are categorized into: (i) adverse trends; (ii) emerging trends; and (iii) monitoring trends. Information used for this report is derived from level A, B, and C conditions, and non-conformance reports identified during the preceding 12 months, with emphasis on changes that occurred during the period from January 1, 2006, through March 31, 2006.

Based on the Project's analysis of this trend-evaluation information, seven adverse trends, 10 emerging trends, and 15 monitoring trends were identified for the second quarter of FY 2006. Adverse trends involving nuclear-safety-basis development activities included: (i) "Requirements Flow-Down Discrepancies," CR-7040; (ii) "NRC Report Documents Ineffective Audit at Lawrence Livermore National Laboratory (LLNL)," CR 7395; (iii) "NRC Report Identifies Use of Instrumentation Outside the Range of Calibration," (CR 7418); (iv) "Ineffective Identification and Correction of Adverse Quality Trending Program," (CR7458); and (v) "Inadequate Control of Chemical Calibration

Standards,” (CR 7875). The remaining two adverse trends involved non-quality affecting activities. As noted in the trend report, the implementation of an expanded and more definitive set of trending parameters for CAP data analysis has resulted in the identification of an increased number of adverse and emerging trends. The report further indicates that the majority of recently identified trends do not represent new nor evolving issues, but rather the identification of many long-standing project issues that are now being properly identified and analyzed.

Based on the review of the trend report, the ORs observed that, of the population of 350 Level A, B, and C combined CRs issued during the 2nd Quarter of FY 2006, four were Level As, 34 were Level Bs, and 312 were Level Cs. These values represent relative increases in all three categories, the most significant being a 78 percent increase in the identification of Level A CRs. However, as stated in the trend report, the sharp increase in Level A condition reports may not indicate a decline in performance, but, rather, may reflect the project personnel being willing to identify and evaluate previously existing organizational weaknesses. The report also indicates that, although there is a consistently higher volume of self-identified Level C conditions identified during the current 12-month rolling-average period, independent oversight activities are still identifying the predominance of Level A and B conditions.

As documented in previous OR Reports, the predominant causal factor for Level A, B, and C conditions continued to be attributable to Human Performance issues. Despite attempts to address this lingering issue, DOE continues to struggle with reducing the occurrence of Human Performance conditions. However, in response to the Human Performance issues documented in CR-6399, the project has initiated actions to address the continuing problems within this area. The ORs will continue to monitor the issues related to Human Performance and the results will be documented in a future report.

3.4 Observation of CAP Audit

During this reporting period a Senior Inspector from Region IV's, Nuclear Materials Safety Division, provided direct support to the OR office. This support included the observation of BSC QA's Audit, BQA-BSC-06-08, of the implementation of BSC's CAP process, performed from May 29, 2006, to June 13, 2006. The audit used a performance-based approach to review the adequacy and effectiveness of corrective actions implemented for selected CRs related to activities at the Project. The sample size included approximately 12 Level A and Level B CRs and several non-conformance reports (NCRs) that had been completed within the last 2 years. The audit process involved interviewing, when possible, both the initiator and the responsible manager associated with each of the CRs and NCRs.

The BSC audit team's interview checklist questions represented a subset of a broad range of topics used during the CAP Self-Assessment, which evaluated the organization's implementation behaviors. As noted in Section 3.1 of this report, the March 2006 CAP Self-Assessment employed the same guidance typically used at nuclear power plants for assessing CAP program performance. During the interviews, the audit team directed its questions toward specific CRs included within the scope of the audit. This technique provided the audit team with an opportunity to ask focused questions concerning CAP implementation related to the selected CRs. Although the original audit questions taken from the nuclear utility guidance were generic, the audit

team effectively interacted with the interviewees to obtain information related to the processing and resolution of the specific conditions. This process resulted in a meaningful exchange of information and an opportunity for the interviewed personnel to provide their assessment of the current CAP system and its ability to identify, track, and resolve conditions adverse to quality. Based on the ORs' observations, the interviewed personnel generally provided favorable comments regarding their ability to identify conditions, although most stated that the CAP software was somewhat difficult to use and that an infrequent user could be challenged by the system. The ORs also observed that several of the CRs reviewed during this audit had been submitted by individuals other than the person who had identified the condition. For these instances, the individual identifying the condition had obtained help from more experienced CAP system users, to properly process the CR. As an alternative to using the computer-based CR system, hard-copy condition forms were also made available to personnel at the site, with provisions for authorized individuals to enter them into the CR system.

The audit team identified several examples where the CR cause analysis had specified corrective actions; however, there was insufficient documentation in the CR to demonstrate that these actions had been completed. These conditions were appropriately documented on issue forms during the audit and subsequently entered into the CR system. The ORs observed that the audit team members interfaced effectively with project personnel during the interviews and, in several instances went beyond the original checklist questions to evaluate issues that interviewed personnel had identified. Based on the results of the audit, the ORs determined that this oversight activity was effective in reviewing the CRs included in the audit scope and in identifying several issues that will improve the CAP process. No audit observation inquiries were identified and the ORs concurred with the audit team's findings, as presented at the exit.

3.5 Observation of Software Control Audit

From May 15 through 23, 2006, the ORs observed DOE's Office of Quality Assurance (OQA) limited-scope audit, OQA-BSC-06-10, of the software process implemented by BSC. Specifically, the audit team evaluated the implementation and effectiveness of BSC's software control processes and the adequacy of the incorporation of program requirements into implementing procedures. Additionally, the audit team evaluated the effectiveness of completed corrective actions for previously issued CRs, to determine if these conditions had been appropriately resolved, and that repetitive deficiencies had not been identified.

To evaluate the effectiveness of the software control process, the audit team examined a representative sample of software record packages, to ensure that the requisite phases of configuration management had been properly implemented. In particular, the audit team examined software planning, procurement, life-cycle requirements, error/defect reporting and resolution, control and use of software, and legacy code remediation (i.e., code developed before January 13, 2003). Subsequent to the initiation of the audit, questions related to the "deliberative process" classification of many of the software record packages were identified by DOE personnel, which potentially impacted the audit scope. Although the audit team's ability to review the requisite information was ultimately resolved, and the audit scope was not adversely impacted, the failure of OQA to adequately consider legal review criteria during the audit planning phase is identified as a program weakness. It is also noted that this condition

is repetitive to a weakness in the audit planing activities previously identified by the NRC Observers, during the BSC Audit at Lawrence Livermore National Laboratory (LLNL), documented in NRC Observation Audit Report (OAR)-05-05, dated January 9, 2006.

The audit team also reviewed BSC's software control procedures, to determine if the requirements specified in the QARD, Supplement I, had been adequately addressed in implementing procedures. Within this area, the team examined the relevant information contained in the Project's QARD Requirements Matrix (QRM), to identify the set of procedures that implemented the corresponding requirements. As a result of this review the audit team identified a deficiency (CR-8437) in the error/defect process, concerning inadequate procedural controls for problems associated with retired software. The audit team also identified that once a license for a software product has expired, the supplier has no obligation to notify the user of defects. Therefore, latent errors in these retired codes which produced output data used in other technical products may produce incorrect results that would remain undetected. Based on the ORs observations, this issue is similar to the deficiency (CR-7267) identified in NRC's Observation Audit Report, OAR-05-05, dated January 9, 2006, concerning the referencing of canceled documents in technical products used to support the potential LA.

As a result of the audit team's reviews related to software life-cycle requirements, configuration management, error/defect reporting and resolution, and the control and use of software, several deficiencies were identified and documented on CRs. However, these conditions were determined to be minor in nature and the audit team's overall assessment, was that the process controls were satisfactory for these activities. Relative to the incorporation of requirements into implementing procedures, the team concluded that this activity was generally satisfactory. The audit team did identify a condition (CR-8439), related to the QRM that incorrectly assigned several implementing procedures to each individual requirement, that were not applicable.

The audit team also examined BSC's processes associated with retesting of legacy codes, used to support the Project's LA. Approximately 330 Legacy Codes that represent software used in technical products supporting the potential LA, were developed prior to the implementation date of January 13, 2003, for the Instillation Verification and Validation (IV&V) process. Based on the review of documentation related to the testing of Legacy Codes, the audit team concluded that the procedural controls and retesting processes within this area were satisfactory. Despite the overall determination that the IV&V process for the remediation of Legacy Codes was acceptable, the audit team identified two issues that potentially affect the software quality program. These issues involve the incomplete remediation of a subset of approximately 35 Legacy Codes from the retesting program and the use of software codes within the Data Tracking Number (DTN) system that have not been reverified, qualified, or baselined. Although the audit team did not identify a specific area of non-compliance related to these issues, a concern was identified by the ORs, related to potential impact of these issues that affect the Projects response to KTI TSPA issue, Agreement 4.07. At the conclusion of the audit, DOE had not completed the technical disposition of these two issues. Accordingly, the ORs initiated Open Item 06-03, requesting a description of DOE's remediation process related to the approximate 35 Legacy Codes, and Open Item 06-04, requesting a basis and justification for the continued use of the output from software on the baseline that has not undergone IV&V remediation.

In summary, the ORs determined that this oversight activity was effectively performed. The audit team's software selection methodology which focused on recently baselined codes, was appropriate, and the audit team's technical reviews of the software packages were comprehensive. However, the ORs identified a weakness, in the planning, related to unanticipated changes in the audit scope, subsequent to the initiation of this oversight activity. These changes, which potentially limited the audit team's ability to review designated software record packages, were similar to the change in scope identified as a weakness during the BSC audit at LLNL, documented in NRC Observation Audit Report OAR-05-05, dated January 9, 2006. Based on the ORs observations, the repetitive nature of these inadequate audit planning activities bring into question the effectiveness of the corrective and preventive actions associated with the Project's response to NRC's documented concerns related to the effectiveness of BSC's audit of LLNL scientific activities. Additionally, **OR Open Item 06-03** was issued requesting a description of DOE's remediation process for the approximately 35 remaining Legacy Codes associated with KTI TSPA issue, Agreement 4.07, and **OR Open Item 06-04** was issued requesting a basis and justification for the continued use of output from software on the baseline, that was not subject to IV&V remediation.

3.6 Observation of BSC QA Design Control Audit

From June 20 through 29, 2006, the ORs, and a staff member from CNWRA, observed BSC QA's audit (BQA-BSC-06-04) of design control processes and design products. The BSC audit team reviewed selected design criteria, drawings, specifications, and calculations to verify effective implementation of design control requirements. Since DOE currently has an administrative hold on approving and issuing quality-affecting design products, this audit focused on procedural compliance and the product quality regarding the design and engineering of the proposed non-safety category, non-quality-affecting lower-muck yard facilities. These facilities are part of the infrastructure improvements the Project is proposing.

The procedures evaluated by the audit team were issued earlier this year. However, the engineering procedures that are used to control both quality affecting and non-quality affecting work activities have not been fully implemented for quality-affecting work because of the previously noted administrative hold on the approval of engineering documents. Based on the limited number of quality-affecting engineering products currently available for review, BSC QA concluded that the scope of the audit which examined non-quality affecting documents, that were developed using quality-affecting procedures, was appropriate at this time.

As a result of the NRC's reviews, it was observed that this oversight activity was limited in scope, and was primarily focused on design process evaluation rather than engineering products. The NRC observers also ascertained that the evaluation of interfacing process areas, (e.g., design-input control) was not included within the scope of the audit, and only limited inquiries, outside of design process-specific checklist items, were conducted by the audit team. In response to the issues identified by the NRC observers, BSC QA's management acknowledged the limited scope of the audit and stated that the design-control areas that were not specifically assessed during this audit, would be evaluated during the performance of future audits.

As a result of their reviews, the audit team's overall conclusion was that, BSC's Design Engineering work activities were adequate. However, the audit team did identify instances of procedural noncompliance that appeared to be the result of either the lack of procedural clarity, or the audited organization's inconsistent interpretation of requirements. Areas where procedural inconsistencies were identified by the audit team included, design inputs, constraints, calculation documentation, records database accuracy, revision designators, document checklist use, and safety categorization. As a result of these reviews, the audit team determined that the attention to detail during the implementation of these procedures was less than adequate.

Based on the NRC's observation of BSC QA's audit of design control processes, it was determined that this oversight activity was adequately performed and the NRC observers concurred with the audit teams findings as presented at the audit exit. However, as a result of recent changes to procedure AP-16.1Q, "Condition Reporting and Resolution," the NRC observers identified a concern related to the ability of the audit team, to independently evaluate the effectiveness and implementation of the audited activities, and to establish the significance level of CRs identified during the audit. Specifically, procedure AP-16.1Q, was recently revised to eliminate the ability of project personnel, including the respective QA organizations' to identify or recommend a significance level for CRs. As a result of the revision to AP-16.1Q, it was not clear to the NRC observers how the audit team could effectively determine the adequacy, implementation, and effectiveness of the audited organization/activity, without the corresponding ability to establish the relative significance of the condition(s) adverse to quality, identified during the audit.

As currently defined in procedure AP-16.1Q, proposed conditions are submitted to the CST without a significance level. During the initial screening process the CST determines the significance level based on the limited information contained in the CR, without the context and relevance of the audit teams findings. The NRC observers concern with this approach is that although the audited organization is represented on the CST, the QA auditor who initiated the CR is not involved with the deliberative screening process. It was also noted by the NRC observers that without the ability to identify the relative significance level of a condition adverse to quality, the independence of the auditing organization may be in question. Specifically, the requirements of QARD, Section 18.2.5, "Audit Team Independence," which state, in part, that ... "Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective," may not be fully implemented if the audit teams do not have the ability independently make the determination as to the significance of the conditions adverse to quality that they identify. The ORs will continue to monitor this issue during the observation of future audit observations.

3.7 Review of CST Activities

During this reporting period, the ORs reviewed the activities performed by the Project's CST, including the evaluation of screened CRs, observation of selected Screening Team meetings, and discussions with CST members. As described in the CST Charter, the members assist the CAP manager in the implementation of the CR evaluation process, consistent with the requirements established in procedure AP-16.1Q. The Charter is a non-quality-affecting document, and it indicates that the CST represents a

multi-disciplined team with representatives from DOE, BSC and the lead Laboratory. The ORs also observed that the Charter provides information related to the composition of the CST, member responsibilities and functions, screening criteria, and certification requirements for the members and alternates.

Based on the ORs' observations of the CST, it was determined that the recent changes, instituted in response to the CAP Self-Assessment that emphasized increased DOE participation and line management involvement in the problem identification and resolution process, have resulted in overall improvements in the CST process. Specifically, the CST goals of processing CRs forward in a timely manner, conducting discussions in an open and candid environment, and the assignment of CR significance levels are generally achieved during the CST meetings. However, as determined by the ORs, several functions performed by the CST including: (i) establishment of CR extent of condition/extent of cause; (ii) identifying causal analysis; (iii) cause code determinations; (iv) trending evaluation; (v) combining of conditions; and (vi) cancellations of CRs, involve quality-affecting activities that are not adequately addressed in either the CST Charter or AP-16.1Q.

As defined in QARD, Section 5.2, quality-affecting "Work shall be performed in accordance with controlled implementing documents." Therefore, the failure to establish appropriate procedural controls in accordance with the requirements of QARD, Section 5.2, for the quality-affecting activities performed by the CST is identified as a deficiency, in accordance with the criteria defined in NRC Manual chapter 2410, "Conduct of Observation Audits."

The ORs also reviewed recent CST actions related to the proposed closure of outstanding CRs. Based on the results of these reviews, it was determined that the CST was appropriately evaluating the proposed closure documentation, and that CRs that did not contain the requisite information were returned to the responsible organizations for remediation. As a result of these reviews, the ORs identified a concern, related to the documented response to CR 6036, associated with "Incomplete Corrective Action Program CR Record Packages." Specifically, CR 6036 identified a deficiency, involving the development of CR record packages, which currently only include the final contents of the fields on the completed CR. As described in CR 6036, if the response to a condition has been rejected, or returned to the responsible organization, the change history that the Project currently maintains does not represent a complete record, because the original information contained in the rejection or return information is no longer contained in the final record copy of the CR.

In response to the deficiency identified in CR 6036, the OQA disposition states, in part,: "On November 14, 2006, a dispute resolution meeting was held with senior representatives from BSC ... and DOE ..., to resolve an issue on the content and completeness of the CR record packages. As the acting Director of OQA, I concur with the decision that the record package for a condition report is sufficiently complete with the final description of actions and steps taken that satisfactorily resolve the issues documented in the Condition Report. Please process CR 6036 forward as written."

Based on the review of OQA's documented response in CR 6036, the ORs determined that the directed actions regarding QARD requirements retained as CR records represent a "Clarification" of the existing record requirements specified in AP-16.1Q,

Section 6.1. "QA Records." Specifically, AP-16.1Q states that record packages shall be submitted for "Completed CRs that document a Condition Adverse to Quality in accordance with the QARD, including the CR **and its related actions** (emphasis added) and any unique attachments to the CR in its related actions that exist in the CAP system." Therefore, the direction, contained in CR 6036, that allows revising or overwriting the CR change history (i.e., related actions) constitutes a clarification to the established processing of CR record packages. However, as observed by the ORs, clarifications to the requirements specified in the QARD must be processed in accordance with the requirements of procedure LP-2.2Q, "Development and Maintenance of QA Requirements, Program and Specification Documents." As specified in LP-2.2Q, Section 5.9, clarifications of the requirements contained in the QARD shall be prepared that include a description of the aspect of the document requiring clarification and the resulting statement of clarification. Contrary to the above, the clarification provided in the response to CR 6036 does not comply with the requirements of LP-2.2Q, in that, a documented analysis was not performed and a disposition form was not appropriately prepared and processed. Therefore, the failure to process the clarification related to the content and completeness of CR record packages in accordance with the requirements of LP-2.2 Q, is identified as a deficiency, in accordance with the criteria defined in NRC Manual chapter 2410, "Conduct of Observation Audits." As part of the resolution of this concern, DOE should consider whether modification of the documentation requirements as discussed above, could have impacts on other documentation and reporting requirements outside of the established quality assurance area. Pending resolution of this concern, it is identified as **OR Open Item 06-07**.

4.0 GENERAL ACTIVITIES

4.1 Meetings

- 4.1.1 Technical Exchange on Yucca Mountain Preclosure Safety Analysis - On May 16-17, 2006, the ORs participated in an NRC and DOE Technical Exchange on "Preclosure Safety Analysis" and supporting information regarding the proposed Yucca Mountain High-Level Waste Repository. The exchange covered the reliability of structures, systems, and components in preclosure safety analysis, and 10 CFR Part 63 preclosure safety analysis regulatory requirements. The State of Nevada, other stake holders, and interested members of the public attended.
- 4.1.2 High-Level Waste NRC/DOE Quarterly Management Meeting - On June 6, 2006, the ORs participated in the NRC/DOE "Quarterly Management Meeting" in Las Vegas, NV. The purpose of this meeting was to discuss management issues and progress in the High-Level Waste Repository Program. DOE provided updates on Project design activities, QA, and the CAP program.
- 4.1.3 Yucca Mountain Technical Exchange on Seismic Design - On June 7, 2006, the ORs participated in an NRC and DOE Technical Exchange in Las Vegas, NV, on "Preclosure Seismic Design Methodology and Performance Demonstration." The draft Interim Staff Guidance (ISG), High-Level Waste Repository Safety (HLWRS)-(ISG)-01, "Review Methodology for Seismically Initiated Event Sequences," was among the items discussed at the Exchange. This guidance supplements Yucca Mountain Review Plan NUREG-1804, Revision 2, for review of seismically initiated event sequences in the preclosure safety analysis of the proposed Yucca Mountain geologic repository.

4.2 Other Activities During This Reporting Period

4.2.1 Nevada Commission on Nuclear Projects Meeting - On April 26, 2006, an OR attended the Nevada Commission on Nuclear Projects (NCNP) meeting in Las Vegas, Nevada. The NCNP received briefings on the State of Nevada Yucca Mountain oversight program and a summary of legal actions being pursued by the State. Dr. Victor Gilinsky, consultant and former NRC Commissioner, and Robert Halstead, transportation advisor to the NCNP, made additional presentation respectively on Global Nuclear Energy Partnership, and on Spent Nuclear Fuel Transportation issues. Irene Navis, Director of the Clark County, Nevada, Nuclear Waste Program activities gave an update of that program.

4.2.2 Yucca Mountain Field Orientation

From April 27-29, 2006, CNWRA staff, with OR participation, conducted a site visit and field orientation of Yucca Mountain and vicinity for CNWRA and NRC staff new to the NRC high-level waste program. The site visit introduced new staff to the scale of the underground operations, geology, hydrology, geophysics, volcanic history, erosion processes, deposition processes, local environment, land uses, and the cultural setting. The experience gained from this trip will help new staff to conduct pre-license application activities, and is one of the training requirements to qualify as an NRC reviewer of a potential Yucca Mountain LA.

4.2.3 Visit to Nevada Test Site Test Area - On June 8, 2006, an OR and a staff member from NRC's HLWRS, visited the test site for the proposed large-scale, open-air explosive detonation test, entitled "Divine Strake." The test, that is being conducted by the Defense Threat Reduction Agency, is sited approximately 20 miles from the proposed repository at Yucca Mountain. The test will provide a controlled seismic event that will monitor the regional and Yucca Mountain seismic networks. In addition, seismic monitoring in the near-field area of the tunnel under the explosion will provide data on the effect of a large-scale ground acceleration, produced by the test, on the tunnel and equipment in the tunnel.

**U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN
ITEMS FOLLOWED IN
OR REPORTS**

Table 1

<i>OPEN ITEMS NUMBER (For Tracking Only)</i>	<i>BRIEF DESCRIPTION OF OPEN ITEM</i>	<i>OPEN ITEM OR-REPORT NO.</i>	
AOI-OCRWM-OQA-05-20-02	Revise procedure AP-3.13Q to reflect 10CFR63.21 requirements related to completeness of information necessary for LA review.	OR-05-03	
AOI-OCRWM-OQA-05-20-01	Procedural controls for "preliminary" classification of Engineering calculations will be revised to clearly define the designation of completed calculations suitable to support the requisite safety analysis.	OR-05-03	
AOI-YMSCO-ARC-02-12-01	Identifies the need for DOE OQA to ensure that procedure development and review process include a documented evaluation to verify compliance with the requirements of the YMP's QARD.	OR-03-01	
OR Open Item 06-06	Establish a relationship between actions to address deficiencies in requirements management processes and changes to the Engineering Design organizations.	OR-06-02	
OR Open Item 06-05	Despite the existence of numerous CRs related to requirements management, BSC did not effectively describe the planned and completed CA that would resolve the deficiencies currently being overseen by DOE's IRPT.	OR-06-02	
OR Open Item 06-04	Based on Audit observation of Software Control (OQA-BSC-06-10) - requesting a basis and justification for the continued use of the output from software on the baseline that has not undergone IV&V remediation.	OR-06-02	
OR Open Item 06-03	Based on Audit observation of Software Control (OQA-BSC-06-10) - requesting a description of DOE's remediation processes related to the approximately 35 legacy codes.	OR-06-02	
OR Open Item 06-02	Requirements Flow-Down and Procedural Adequacy Audit Observation: Involved the inconsistent use of quality-affecting document designators that indicated inadequate corrective actions related to similar conditions documented in CR-3448.	OR-06-01	
OR Open Item 06-01	Requirements Flow-Down and Procedural Adequacy Audit Observation: Concerned discrepancy in the definition of the term "requirement" in a BSC desktop instruction, which was inconsistent with the requirements for design input control defined in QARD Section 3.2.1	OR-06-01	
OR Open Item 05-02	Pending Project response to the discovery of potential falsification of QA records - completion of second and third initiatives described in the work plan.	OR-05-03	
OR Open Item 05-01	Inconsistencies in the root-cause statements developed by the root-cause analysis team, specifically the root cause related to traceability and transparency issues. Pending resolution of the apparent discrepancies in the root-cause analysis for CR-3235 identified in this Open Item.	OR-05-02	
OR Open Item 04-01	A concern regarding the safety analysis of the ground support system in the ESF.	OR-04-01	
OR Open Item 03-06	Based on review of CR-756, 12 quality-affecting procedures were approved without meeting the applicable QARD requirements.	OR-03-05	
OR Open Item 03-05	The continued use of unqualified software in quality-affecting technical products appears to be in conflict with the governing requirements of the implementing procedures and the QARD.	OR-03-04	

**U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN
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Table 1

OR Open Item 03-04	With a tentative date of mid-June to evaluate CAR BSC(B)-03-©)-107, the RCD has not acted on this CAR in a timely manner and it has remained open for 4 months without resolution.	OR-03-03	
OR Open Item 03-03	An evaluation in DOE's progress in implementing corrective actions associated with CAR B.C.-01-C-001, concerning model validation, the OR reviewed TAPS (approx. 43 models). Based on the results, it could not be established if the evaluation criteria will result in the development of models with adequate confidence for the LA.	OR-03-02	
OR Open Item 03-02	During a review of the MII confirmation packages, it was identified that the action statement execution task descriptions and completion schedules for many of the reviewed pkgs had been modified without appropriate justification. Therefore, pending the resolution of this apparent deviation from a commitment to administer the MII in accordance with the requirements of AP-5.1Q, this issue is identified as this OR Open Item.	OR-03-02	
OR Open Item 03-01	This Open Item is based on issues on separate DRs: (1) the effective resolution of concerns related to inadequate personnel training; 2) the failure to establish an effective transition plan; and 3) the evaluation of the SCWE issues.	OR-03-01	
OR Open Item 02-13	The current status of corrective & preventive actions associated with CAR No. BSC-02-C-01 revealed that not all corrective actions stated had been completed.	OR-02-05	
OR Open Item 02-12	Contrary to requirements of the QARD Supplement III 2.4.C, AP-SIII.2Q inappropriately allows for the use of unqualified data. BSC QA procedure change control program failed to identify this issue.	OR-02-05	
OR Open Item 02-11	Based on surveillance not identifying specific problems with software functionality for codes tested, 7, including NUFT, did not pass ITP and/or VTP surveillance.	OR-02-05	
OR Open Item 02-10	Pending appropriate evaluation and documentation of the design control attributes associated with requirements of 10 CFR 63.44 and 10 CFR Part 21.	OR -02-04	
OR Open Item 02-09	Pending revision of engineering procedures to include appropriate design verification considerations.	OR-02-04	
OR Open Item 02-08	The required performance of annual audits justification for delaying a scheduled audit of YMSCO for 3 months, with an additional extension, does not appear to be adequately supported. Deviation from requirement of sub-section 18.2.1E of the QARD.	OR-02-04	
OR Open Item 02-07	Model Validation Impact Assessment addressed the effect of inappropriately validated models on TSPA-SR. Many cases of impact assessments used TSPA-SR results to evaluate the local impacts. It's unclear how this practice evaluated the cumulative impact of all the models in question.	OR-02-01	
OR Open Item 02-06	Unqualified Data Impact Assessment - NRC staff identified unqualified data that could be replaced with qualified data for the performance assessment. For the risk-significant components, an evaluation of unqualified data replaced with qualified data would help determine if efforts should be undertaken to qualify the removed data.	OR-02-01	

**U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN
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Table 1

OR Open Item 02-05	Provisions are in place that allow for model validation to continue past issuance of the documentation. The models used in the performance assessment should have adequate support for their representation at the time the performance assessment documentation is issued.	OR-02-01	
OR Open Item 02-04	A number of criteria have been developed related to various forms of review. If a review is relied on for model validation, it should be directed at validating the model and it should encompass the full body of information to the extent practical.	OR-02-01	
OR Open Item 02-03	More objective criteria (comparison to data not used in the development of the model), typically resulting in higher confidence in model validation are not distinguished from the more subjective, problematic criteria.	OR-02-01	
OR Open Item 02-02	Current process controls specify that one or more of nine criteria may be used to validate a model. All the criteria should increase confidence in the modeling process; some criteria do not appear to be appropriate for addressing whether the model is valid for its intended use.	OR-02-01	
OR Open Item 02-01	Failure to properly include the specific issues identified in the Concerns Program Final Report in the resolution process may result in not adequately addressing the original employee's concern.	OR-02-01	