



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

April 30, 2007

MEMORANDUM TO: Aby Mohseni, Deputy Director
Licensing and Inspection Directorate
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety and Safeguards

FROM: Jack D. Parrott, Senior On-Site Licensing Representative **/RA/**
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SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ON-SITE LICENSING
REPRESENTATIVES' REPORT ON THE YUCCA MOUNTAIN
PROJECT, FOR JANUARY 1, 2007, THROUGH MARCH 31, 2007

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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 enclosure(s), please call Jack D. Parrott, at (702) 794-5047, or Robert M. Latta, at (702) 794-5048.

Enclosure(s):

1. "U.S. Nuclear Regulatory Commission On-Site Licensing Representatives' Report Number OR-07-01, for the reporting period of January 1, 2007, through March 31, 2007"
2. Table 1: "U.S. NRC On-Site Licensing Representatives' Tracking Report for Open Items Followed in OR Report(s)"

Memorandum to A. S. Mohseni, Deputy Director, LID, from J. Parrott, and R. Latta, dated:
April 30, 2007

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U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES REPORT
NUMBER OR-07-01
FOR THE REPORTING PERIOD OF
JANUARY 1, 2007, THROUGH MARCH 31, 2007

Enclosure 1

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ACRONYMS AND ABBREVIATIONS

<u>Acronym</u>	<u>Meaning:</u>
ADAMS	Agency-wide Documents Access and Management System
AP	Administrative Procedure
BSC	Bechtel SAIC Company, LLC
CAP	Corrective Action Program
CAQ	Conditions Adverse to Quality
CNWRA	Center for Nuclear Waste Regulatory Analyses
CR	Condition Report
DOE	U.S. Department of Energy
HLWRS	High-Level Waste Repository Safety
KTI	Key Technical Issue
LA	License Application
MRC	Management Review Committee
NRC	U.S. Nuclear Regulatory Commission
NWTRB	Nuclear Waste Technical Review Board
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
OR	On-Site Representative
PA	Performance Assessment
PSHA	Probabilistic Seismic Hazard Analysis
QA	Quality Assurance
QARD	Quality Assurance Requirements Description
RCA	Root Cause Analysis
RCAT	Root Cause Analysis Team
SMF	Sample Management Facility
USGS	U.S. Geological Survey

EXECUTIVE SUMMARY

SITE ACTIVITIES AND DATA ACQUISITION

Implementation of Phase II Drilling Activities

At the end of this reporting period, the Yucca Mountain Project (Project) implemented Phase II of the ongoing site drilling activities that are being undertaken to characterize the geotechnical and seismic properties of the area beneath planned waste-handling facilities.

Curtailement of Underground Activities

As of the end of this reporting period, the Project curtailed both underground activities and all routine access to that part of the Exploratory Studies Facility beyond the Bow Ridge Fault (just past Alcove 2).

QA AND ENGINEERING

Ongoing Corrective Action Program Review

During this reporting period, an On-Site Representative (OR) reviewed the results of the U.S. Department of Energy's (DOE's) root-cause analysis (RCA) for Level A, Condition Report (CR) 9774, concerning the ineffectiveness of the Corrective Action Program (CAP) process. Based on the review of the RCA report for CR 9774, the RCA team determined that Project management did not identify the marginal performance of the CAP despite numerous indications identified during the 2005-2006 time frame. As a result of the ORs review within this area, it was determined that DOE performed a comprehensive RCA in a timely manner.

Review of Level A CR10141, concerning Quality Assurance (QA) Program Inadequacies

Based on the results of an independent assessment of the Project's QA program, which used standardized industry performance criteria, multiple conditions adverse to quality were identified in early December 2006. However, the CRs related to these conditions were not entered into the CAP system for approximately two months. Subsequent to the identification of these issues, DOE's Office of Quality Assurance initiated Level A, CR 10141 in February 2007 to address the cumulative significance and impact of these conditions. However, at the conclusion of this reporting period, the Project had not assigned a root-cause team, nor established a Charter for this activity. Therefore, the significant delay in entering the associated conditions into the CAP system, and the failure to promptly address the significant conditions adverse to quality documented in CR 10141, are identified as **OR Open Item 07-01**.

Site Audit Observation of Sample Management Facility (SMF) Activities

On February 14, 2007, an OR observed a portion of Bechtel SAIC Company, LLC (BSC) Quality Assurance (QA) (BSC QA) audit (BQA-BSC-07-04) on facility operations at the Yucca Mountain Site.

Site Surveillance Observation of Drilling and SMF Activities

On March 19, 2007, an OR observed the BSC QA surveillance (BQA-SI-07-020) of BSC Sample Management and Processing of Borehole Samples. The surveillance covered the implementation of BSC procedure PA-PRO-0806, "Sample Management Facility Field Logging, Handling, and Documentation of Borehole Samples."

Observation Audit of the Technical Data Management System

During March 12 – 22, 2007, NRC and Center for Nuclear Waste Regulatory Analyses staff, with ORs' participation, completed an observation of an Office of Civilian Radioactive Waste Management Office of Quality Assurance audit of the Technical Data Management System in Las Vegas, Nevada. The observers addressed the effectiveness of DOE's audit team and audit process in achieving the audit objectives. An NRC observation audit report will be issued to document the results of this activity.

Review of OR Open Items

As previously documented in OR Report 06-04, dated January 31, 2007, OR Open Item 06-10, was identified concerning inadequate corrective actions related to the requirements management program. In response to this issue, the Project initiated Level A CR 10381, to document the conditions concerning ineffective recurrence control for previous Level A, CRs. Based on the significance of the recurring deficiencies related to inadequate requirements management, it is recommended that this issue be discussed at the next NRC/DOE management meeting, currently scheduled for June 6, 2007, in Las Vegas, Nevada. Pending the resolution of this issue, **OR Open Item 06-10** will remain open.

OR Open Item 06-08 concerned the deletion of the requirement in Administrative Procedure (AP)-16.1Q "Condition Reporting and Resolution," to identify and document the appropriate event code when issuing a condition report. Based on the ORs review of the response to this issue, it was determined that appropriate corrective actions had been implemented. Therefore, **OR Open Item 06-08** is closed.

OR Open Item 06-02 concerned the inconsistent application of quality-affecting designators on Project documents. OR Report 06-01, dated June 12, 2006, described this condition and identified a concern related to inadequate corrective actions related to similar conditions documented in CR 3448, which had remained open for over two years. Based on the ORs reviews within this area, it was determined that DOE failed to perform an adequate extent of condition for the conditions adverse to quality identified in CRs 7963 and 8050. Pending the resolution of this deficiency, **OR Open Item 06-02** will remain open.

OR Report 05-03, dated August 10, 2005, described the contents of a publicly released Project work plan, containing three initiatives, to address concerns raised by the discovery of e-mails written by certain employees of the U. S. Geological Survey. Since the U.S. Nuclear Regulatory Commission (NRC) believed that the results of these initiatives could provide relevant new information, and were a potential licensing issue, the completion of the second and third initiatives, were identified as OR Open Item 05-02. All the initiatives identified in the work plan have been completed. Therefore, **OR Open Item 05-02** is closed.

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: (1) repository design; (2) performance assessment (PA); (3) performance confirmation; and (4) environmental studies. The primary focus of this and future OR reports will be on DOE's programs for: (1) subsurface and surface-based testing; (2) PA; (3) data management systems; (4) environmental studies; and (5) 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 January 1, 2007, through March 31, 2007.

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. 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.

1. SITE ACTIVITIES AND DATA ACQUISITION

1.1 Implementing of Phase II Drilling Activities

At the end of this reporting period, the Yucca Mountain (Project) implemented Phase II of the ongoing site drilling activities that are being undertaken to characterize the geotechnical and seismic properties of the area beneath planned waste-handling facilities. Information from these boreholes will feed both the Post-Closure Probabilistic Seismic Hazard Analysis, as well as engineering design for building foundation design and ground motion inputs (i.e., seismic hazard curve development) for building design calculations.

1.2 Curtailment of Underground Activities

As of the end of this reporting period, the Project curtailed both underground activities and all routine access to that part of the Exploratory Studies Facility beyond the Bow Ridge Fault (just past Alcove 2). This will mean that the collection of certain data from the tunnel will cease and other data (primarily from the Drift Scale Test in Alcove 5) will be collected remotely. There will be provisions for scheduled quarterly entries to observe the tunnel and collect data from data storage devices, as well as provisions for unplanned entries in response to an event. This curtailment was undertaken in response to budget restrictions and new safety requirements.

2. **OUTREACH ACTIVITIES**

- 2.1 On January 24, 2007, an OR attended a meeting of the U.S. Nuclear Waste Technical Review Board (NWTRB) in Las Vegas, Nevada. The meeting was primarily comprised of presentations by DOE on Office of Civilian Radioactive Waste Management (OCRWM) program overview, and the ongoing and planned activities of the OCRWM Offices of the Chief Scientist and Chief Engineer, Waste Management Planning and Integration, Yucca Mountain Transportation Strategic Plan, and Yucca Mountain Site Operations.
- 2.2 On March 23, 2007, an OR attended the OCRWM meeting with the Affected Units of Government. The meeting included a Project update from the OCRWM Director, a transportation update, and a question and answer period.

3. **QA AND ENGINEERING**

3.1 Ongoing Corrective Action Program (CAP)

During this reporting period, the ORs reviewed the results of DOE's root-cause analysis (RCA) for Level A, Condition Report (CR) 9774, concerning the ineffectiveness of the CAP process. Specifically, in response to CAP implementation deficiencies identified during the Office of Quality Assurance's (OQA's) audit OQA-OCRWM-06-15, DOE established an RCA team (RCAT) to evaluate the conditions described in CR 9774 and to determine the extent of these conditions. The charter for the RCAT specified a detailed analysis of the current CAP process, including an assessment of the behaviors of Project staff and management, and a review of the corrective actions associated with previous CAP evaluations (e.g., Evaluations performed by DOE's Office of Inspector General and U.S. General Accounting Office.) On March 20, 2007, DOE's OCRWM issued the RCA Report for CR 9774.

3.1.2 Failure of Management to Implement an Effective CAP

The RCAT determined that the primary root-cause was "OCRWM senior management failed to consistently exercise leadership by establishing expectations and standards for CAP performance and enforcing them as a core business activity for all Project personnel." As stated in the RCA report, "interviews conducted by the RCAT confirmed managements awareness of marginal CAP performance as well as the magnitude of improvement necessary for adequate performance as a licensee."

In addition to the primary root-cause, the RCAT identified the following behavioral based contributing causes, associated with the failure of management, to implement an effective CAP:

- Lack of effective barriers (e.g. management expectations, Management Review Committee (MRC) oversight, QA oversight, performance measures, and trending) contributed to the lack of recognition by management of the ineffective CAP performance.

- Significant unresolved CAP issues identified by internal and external assessments have been tolerated by management.
- The organizations' self-assessments for continuous improvement are ineffective (e.g., not self critical).
- Line management does not effectively utilize CAP to drive continuous improvement and does not demonstrate ownership and follow-through necessary to resolve issues and prevent recurrence.
- Authority and accountability for CAP effectiveness have not been either clearly defined or effectively enforced.

Relative to the extent of cause and conditions, the RCAT determined that similar management behaviors could be actively impeding the success of other line programs including the effectiveness of the QA program and the overall safety culture of the Project.

Based on the condition and performance of the CAP, the RCAT concluded that the corrective action system has not had the consistent management support (i.e., MRC and above) needed for effectiveness. Furthermore, as stated in the RCA report, "The RCAT concluded that given the way business has been conducted on the Project, the condition of other Project programs may be similar to the condition of the CAP." The RCA also concluded that the ineffectiveness of the CAP system resulted from: "a breakdown in several barriers (e.g., management expectations, MRC oversight, QA oversight, performance measures, and trending) contributed to CAP ineffectiveness."

3.1.3 Historical CAP Performance Problem

The RCA report further states that: "even though the RCAT focused on the more current issues, CAP ineffectiveness can be traced back many years (e.g., Management Improvement Initiatives as submitted to the NRC in 2002). Thus, the RCAT considered CAP performance to be a chronic, long-term problem." As a result of these findings, the RCAT identified the following Problem Statement: "Management failed to recognize the significance of repeated internal and external reviews that identified the CAP as ineffective and did not take aggressive actions to correct the identified problems and ensure effectiveness of the CAP." Based on a review of the RCA report for CR 9774, the RCA team determined that Project management did not identify the marginal performance of the CAP despite numerous indications identified during the 2005-2006 time frame.

3.1.4 Weakness in the CAP

The RCA report also states, in part, "...there was no evidence that OCRWM considered the CAP function (problem identification and resolution) as part of core business, but rather it is a little value added activity..." and "OCRWM has not identified performance expectations for an effective CAP." Additionally, the RCA report stated that: "The indications of a weakness in the CAP include the following: ineffective and inconsistent use of CRs by Project personnel, incorrect or inconsistent classification of CRs for Conditions Adverse to Quality (CAQs), ineffective and untimely corrective actions, inappropriately closed CRs, inconsistent trending methodology that did not identify issues, and ineffective self-assessment of the CAP process."

Based on the results of their reviews, "The RCAT concluded that the available data, in concert with the failure of the CAP to effectively assess and adjust its own performance justified a conclusion of "ineffectiveness" that warrants prompt correction. The ineffectiveness of the CAP is not the result of deficient procedures or software. The accumulation of issues, which resulted in the determination of CAP ineffectiveness at the end of 2006, was present because of management's failure to recognize and respond to indications that the CAP had important weaknesses."

3.1.5 Corrective Actions

Therefore, to determine which programs are impacted, the RCA specified that the Office of Chief Engineer and Chief Scientist are to conduct self-assessments in 2007, with assistance by outside expertise, to evaluate whether the impacts of previous weaknesses in the CAP system require changes in their implementing processes and procedures. The RCA also indicated that to address the extent of condition, a review of activities associated with Level A, B, and C, conditions that were closed between the end of July 2006, and the middle of January 2007, (effective date of Revision 9 of Administrative Procedure (AP)-16.1Q, "Condition Reporting and Resolution") be conducted to assess the adequacy of the corrective actions to resolve the identified problem(s) and preclude recurrence.

3.1.6 ORs Evaluation

Based on the ORs reviews within this area, and discussions with the RCAT members, the ORs determined that DOE performed a comprehensive RCA in a timely manner. The ORs noted a strength of the RCA, in that DOE performed a timely RCA using an independent team of personnel that included representatives from the commercial nuclear industry. The results of the RCA, which included reliance on industry expertise, were clearly articulated, (including the root-cause and contributing causes, the extent of condition and the associated effectiveness reviews). As a result of the ORs observations of the activity, a strength was identified.

However, based on further review, the ORs observed the following:

- 1) At the conclusion of the reporting period, DOE had not completed the action plan for addressing the issues identified in the RCA for CR 9774.

- 2) Relative to the breakdown of barriers, while the RCAT concluded that the ineffectiveness of the CAP process was a “chronic, long-term problem,” the CAP performance indicators continue to indicate acceptable performance. The RCA report did not adequately address the disparity between the Project’s CAP performance indicators which generally reflected acceptable levels of performance and the contrasting RCA report that concluded that the CAP system was ineffective. Specifically, the OCRWM CAP Performance report for March 2007, reflects adequate performance in all but two metrics related to timeliness of CR resolution (by department) and trending of CRs over 100 days old.

The ORs will continue to observe the implementation of the corrective actions identified for CR 9774 and the results will be documented in a future report.

3.2 Review of Level A CR 10141, Concerning QA Program Inadequacies

During the week of December 3-8, 2006, a group of Senior Industry Quality Representatives performed an independent assessment of the Project’s QA program, using the standardized industry performance criteria for excellence. Specifically, the industry criteria used for this assessment, were based on a clear set of objectives, and attributes necessary, for achieving and maintaining excellence in the implementation of the QA Program. The purpose of this assessment was to evaluate the OQA’s oversight of the Project using the industry standard criteria.

Although the team identified a number of positive attributes, the conclusion of the assessment was that eight of the ten areas reviewed, were not effectively implemented. The eight areas included: Quality Organization Effectiveness, Internal Audit Program, CAP System, Self-Assessments, Line Ownership of Quality Activities, Performance Indicators, Independent Review Program, and Safety Culture. Based on the results of the industry assessment, multiple conditions adverse to quality (CAQs) were identified, and entered into the CAP system. However, as noted by the ORs, there was a significant delay (approximately two months) between the identification of these issues, and the initiation of the respective CRs. This condition represents a deficiency, in that Section 16.1 of the Quality Assurance Requirements Description (QARD) requires that CAQs shall be promptly identified and corrected as soon as practical.

Based on the number, and significance of CRs that were documented in response to the industry assessment, OQA initiated Level A, CR 10141, on March 1, 2007, to address the cumulative impact of these conditions relative to the implementation of OCRWM’s QA program. However, at the conclusion of this reporting period, the Project had neither selected a root-cause team, nor established a charter for this quality-affecting activity. Therefore, the failure to take prompt corrective actions, related to the significant condition adverse to quality documented in CR 10141, is identified as a second example of the deficiency concerning the requirements specified in QARD Section 16.1. Pending the resolution of these conditions associated with ineffective corrective actions, this issue is identified as **OR Open Item 07-01**.

3.3 Site Audit Observation Sample Management Facility (SMF) Activities

On February 14, 2007, an OR observed a portion of BSC QA audit (BQA-BSC-07-04) on "Facility Operations at the Yucca Mountain Site." The portion of the audit observed was on BSC procedure PA-PRO-008, "Requesting, Transferring, and Returning Yucca Mountain Project Specimens from the Sample Management Facility." The OR determined that the portion of the audit observed was adequately performed.

3.4 Site Surveillance Observation of Drilling and SMF Activities

On March 19, 2007, an OR observed the BSC QA surveillance (BQA-SI-07-020) of BSC sample management and processing of borehole samples. The surveillance covered the implementation of BSC procedure PA-PRO-0806, "Sample Management Facility Field Logging, Handling, and Documentation of Borehole Samples." This surveillance was done in conjunction with the ongoing Phase I of the geotechnical drilling activities and the early implementation of Phase II (see Section 1 above). One issue was identified related to the capture of specific detail on the processing of core samples obtained from sonic drilling. The OR determined that the portion of the surveillance observed was adequately performed. The ORs plan to observe any future surveillances of Phase II of the site drilling activities.

3.5 Review of OR Open Items

OR-Open Item 06-10: As previously documented in OR Report 06-04, dated January 31, 2007, the ORs observed the performance of BSC's QA Audit of the Flow-Down of Program Requirements. Based on the results of this audit, OR Open Item 06-10, was identified concerning inadequate corrective actions related to the requirements management program. In order to address the conditions identified in this Open Item, BSC's Licensing and Nuclear Safety organization initiated CR 10285 on March 22, 2007. However, the characterization of the issues in CR 10285, (Level D, non-CAQ) which focused on inadequate trending, failed to adequately capture the significance of the ineffective corrective actions associated with the requirements management process. Subsequent to the identification of the failure of CR 10285, to adequately document the conditions concerning ineffective recurrence control for previous Level A CRs, DOE Licensing initiated Level A, CR 10381. As described in CR 10381, the conditions initially identified in Open Item 06-10, are indicative of ineffective recurrence control for previous Level A CRs involving root-cause analysis (i.e., CRs 6278 and 7038).

The ORs will monitor the resolution of Level A CR 10381, concerning inadequate corrective actions to prevent recurrence for conditions related to requirements management and the results will be reported in a future OR report. Additionally, based on the significance of the recurring deficiencies related to inadequate requirements management, it is recommended that this issue be discussed at the next NRC/DOE management meeting, currently scheduled for June 6, 2007, in Las Vegas, Nevada. Pending the resolution of this issue, OR Open Item 06-10 will remain open.

OR Open Item 06-08: This open item concerned the deletion of the requirement in Procedure AP-16.1Q "Condition Reporting and Resolution," Revision 09/ICN 1 to identify and document the appropriate event code when issuing a condition report. In response

to this open item, DOE issued CR 9658, "Inadequate Procedural Controls for the Assignment of Event Codes." Corrective action for this condition report included the reinstatement of the requirement to assign event codes in Procedure AP-16.1Q, Revision 10/ICN1, effective March 5, 2007. Step 5.2.7 has been added to procedure, restoring the requirement to identify and document the appropriate event code for the condition. OR Open Item 06-08 is closed.

OR Open Item 06-02: During the ORs observation of DOE's Audit OQA-BSC-06-07, of BSC requirements management process, performed from March 13, through 22, 2006, the audit team identified an issue concerning the inconsistent application of QA:QA; QA:NA; and Non-Q designators on quality affecting documents. These are nuclear industry designations used to indicate records retention requirements i.e., QA:QA indicates lifetime retention, QA:NA and Non-Q indicate non-permanent retention. The DOE audit issue stated in part: "There is a lack of conformity in applying Administrative Procedure (AP)-17.1Q [Record Problem Report] requirements in designated QA records. Some of the procedures, such as....BSC top-level policy document GM-POL-1, Revision 0, *Management Description*,.... are designated as 'QA:NA'. In August 2004, a similar issue was captured in CR 3448, "QA:QA; QA:NA; Q; Non-Q; and Qualified are not applied consistently." This CR identified inconsistencies in the use of QA:QA; QA:NA; and Non-Q designators on quality-affecting documents.

The issue identified in the OQA audit was documented in CR 7942. The ORs noted that the issue described in CR 7942, "Procedure, desktop instruction inadequate in meeting QA:QA designation requirement," was related to the issues previously identified in CR 3448, indicating that ineffective corrective actions had been implemented to address CR 3448. However, the characterization of the audit issue identified in CR 7942, was subsequently changed from the inadequate application of designators on four quality-affecting documents, which potentially involved a much larger population of technical products, to a narrower issue of procedural adequacy for the development of only recent documents. Therefore, the ORs issued OR Open Item 06-02 and requested that the Project provide a documented analysis of the issues identified in CR 3448, versus the conditions identified in CR 7942, and the basis for changing the characterization of this condition in CR 7942.

The ORs reviewed the response to OR Open Item 06-02. This response included DOE's analysis of the issues identified in CR 3448. It also included the extent of condition documented in a new CR 8050. CR 8050, questioned the effectiveness of the corrective actions for CR 3448, related to the inconsistent application of document categories to Project procedures and work products. The review of this response indicated that DOE had established that three of the four documents identified as inappropriately marked in CR 7942, were appropriately marked QA/QA on a traveler attached to the documents. However, the fourth document was determined to have the incorrect application of the quality designator. This issue was captured in a new CR (CR 7963). However, CR 7963 was designated such that it was able to be closed with no extent of condition performed.

As described in the extent of condition for CR 8050, "The investigative findings described ... for CR 3448 and CR 7942 conclude the condition on designating records QA:QA or QA:NA is adequately covered in BSC procedures and with one exception

have been correctly implemented on the cited documents. The one exception, GM-POL-1, is being corrected under CR 7963. No further extent of condition is needed.”

Based on the initial concern involving the inconsistent use of quality-affecting designators, the effectiveness of the corrective actions for CR 3448, and the lack of an extent of condition for CR 7963, the OR’s reviewed recent CRs, to determine if other similar conditions had been identified. The ORs identified approximately 150 CRs involving inconsistencies in document categories applied to Project procedures and work products. Despite the repetitive nature of these conditions, no CRs had been initiated to address this apparent adverse trend, and the extent of condition evaluations performed for CRs 7963 and 8050 failed to consider the cumulative impact of these other related conditions. As required by the QARD, Section 16.2.3, B. Conditions Adverse to Quality, “Responsible management shall determine the extent of the adverse condition and complete remedial action as soon as practical.” Additionally, Procedure AP-16.1Q, “Condition Reporting and Resolution,” Section 5.3.2 [7] a. requires that the cause analysis, “Collect AND organize data on the problem(s), including the identification of similar historic problems to prevent the implementation of corrective actions that have been tried before and failed.” Contrary to the above requirements, DOE failed to perform an adequate extent of condition for the conditions adverse to quality identified in CRs 7963 and 8050. Pending the resolution of this deficiency, OR Open Item 06-02 will remain open.

OR Open Item 05-02: OR Report 05-03, dated August 10, 2005, described the contents of a publicly released Project work plan containing three initiatives to address concerns raised by the discovery of e-mails written by certain employees of the U.S. Geological Survey (USGS). The e-mails seemed to indicate that these employees falsified documentation of QA records of their work involving the estimation of future climates and infiltration of water at a potential repository at Yucca Mountain. The work plan’s three initiatives were: 1) an investigation of deliberate misconduct; 2) an evaluation of the completeness and accuracy of information associated with the site recommendation and LA; and 3) evaluation of effectiveness of project management, QA, and culture. Since the NRC believed that the results of these initiatives could provide relevant new information and were a potential licensing issue, the pending completion of the second and third initiatives were identified as OR Open Item 05-02.

The investigation of the first initiative was referred to the Offices of the Inspectors General for both the DOE and the Department of Interior. Their reports were released in April and May, respectively, of 2006. The investigations found that there was no criminal misconduct or that the substance of the e-mails and conduct discussed did not occur or could not be substantiated.

In February 2006, OCRWM published a technical evaluation entitled “Evaluation of the Technical Impact on the Yucca Mountain Project Technical Basis Resulting from Issues Raised by Emails of Former Project Participants.” This evaluation concluded that the net infiltration rate estimates developed by the USGS employees were independently corroborated by the results of several studies conducted by other organizations regarding water infiltration and recharge rates in the southwestern United States. This evaluation completed the second initiative of the Project’s work plan.

On March 27, 2007, OCRWM released a report entitled "Root Cause Analysis Report in Response to Condition Report 5223 Regarding Emails Suggesting Noncompliance with Quality Assurance Requirements." This Root Cause Analysis found no evidence that information associated with USGS work was falsified or modified as suggested in the e-mails. However, certain infiltration modeling products, on which the employees worked, did not meet OCRWM traceability and transparency requirements, and that corrective action to address issues associated with the infiltration products, were not always effective. Overall, the following root cause was identified: "OCRWM senior management failed to establish and hold the OCRWM organization accountable for meeting quality expectations with regard to the infiltration products."

With the release of the root cause analysis report, all of the initiatives identified in the work plan have been completed. Therefore, OR Open Item 05-02 is closed.

4. **GENERAL ACTIVITIES**

- 4.1 On March 14, 2007, an OR attended the NWTRB meeting in Berkeley, California, that focused on DOE's infiltration estimates for the proposed repository at Yucca Mountain. The results of new infiltration studies, undertaken by DOE because of QA questions about the previous infiltration work done by the USGS, were presented.
- 4.2 On March 27, 2007, at NRC Headquarters, NRC and DOE staffs held a "Quarterly Management Meeting" on the DOE high-level waste program. Discussions included program updates and QA issues, such as the DOE root-cause analysis regarding U.S. Geological Survey e-mails. The meeting was open to the public and was attended by interested parties, stakeholders, and members of the press. The ORs attended by video-conference from the NRC Atomic Safety Licensing Board Panel hearing facility in Las Vegas.

U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN ITEMS FOLLOWED IN OR
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Table 1
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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
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 Report No: OR-03-03 August 15, 2006
OR Open Item 07-01	Failure to take prompt corrective actions related to documenting CAQs in the CAP system and initiating a RCA in response to QA Program inadequacies identified in Level A, CR 1041	OR-07-01	

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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
OR Open Item 06-10	BSC had not implemented effective requirements management system for the QMD sections that were reviewed during an audit, indicating inadequate corrective actions for previous conditions identified in CRs - signify emerging adverse trends.	OR-06-04	
OR Open Item 06-09	Based on OR review of the RCA for CR7395, it was determined that the RCA for CR7395 does not support the stated conclusions nor does it adequately address the extent of the condition and impact.	OR-06-03	
OR Open Item 06-08	The Project has failed to maintain adequate procedural controls related to the assignment of event codes to condition reports as required by the QARD, Section 16.2.6a	OR-06-03	OR Report No.: OR-07-01 April 30, 2007
OR Open Item 06-07	Failure to process clarification related to the content and completeness of a CR record package in accordance with requirements of LP2.2Q, is identified as a deficiency. Clarification in response does not comply with the requirement.	OR-06-02	

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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
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 Report No: OR-06-02 September 26, 2006
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 Report No: OR-06-02 September 26, 2006
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	

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OR Open Item 06-02	Requirements Flow-Down and Procedure Adequacy and Audit Observation: Involved the inconsistent use of quality-affecting document designators that indicated inadequate corrective actions related to similar conditions documented in CR3448.	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 Report No: OR-06-04 January 31, 2007
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 Report No: OR-07-01 April 30, 2007
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 CR3235 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 Report No: OR-04-04 October 27, 2004

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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
OR Open Item 03-06	Based on the review of CR756, twelve quality-affecting procedures were approved without meeting the applicable QARD	OR-03-05	OR Report No: OR-04-04 March 4, 2005
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	OR Report No: OR-06-04 January 31, 2007
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 opened for 4 months without evaluation.	OR-03-03	OR Report No: OR-03-05 January 12, 2004
OR Open Item 03-03	An evaluation in DOE's progress in implementing corrective actions associated with CAR BSC(B)©-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 Report No: OR-05-02 July 12, 2005

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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
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 Report No: OR-04-02 July 8, 2004
OR Open Item 03-01	This Open Item is based on issues on separate ORs: (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 Report No: OR-03-04 October 20, 2003
OR Open Item 02-13	The current status of corrective and preventive actions associated with CAR No.; BSC-02-C-01 revealed that not all corrective actions stated had been completed.	OR-02-05	OR Report No: OR-03-05 January 12, 2004
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 Report No: OR-04-06 March 4, 2005

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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
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 Report No: OR-03-06 February 16, 2004
OR Open Item 02-10	Pending appropriate evaluation and documentation of the design control attributes associated with requirements of 10CFR63.44 and 10CFR 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 Report No: OR-03-06 February 18, 2004
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 Report No: OR-02-06 January 23, 2003
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 cumulation impact of all the mdels in question.	OR-02-01	OR Report No: OR-03-06 February 18, 2004

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OPEN ITEMS NUMBER (For Tracking Only)	BRIEF DESCRIPTION OF OPEN ITEMS	OPEN ITEM OR REPORT NO.:	DATE OPEN ITEM CLOSED
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	OR Report No.: OR-03-06 July 8, 2004
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 Report No: OR-03-06 February 18, 2004
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 Report No: OR-03-01 April 14, 2003
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 Report No: OR-03-02 June 11, 2004

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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 Report No: OR-03-01 April 14, 2003
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	OR Report No: OR-02-06 January 23, 2003