



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

August 10, 2005

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

FROM: Robert M. Latta, Senior Site Representative **/RAI/**
Fuel Cycle & Decommissioning Branch
Division of Nuclear Material Safety
Region IV

Jack D. Parrott, Senior On-Site Licensing Representative **/RAI/**
Project Management Section A
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ON-SITE LICENSING
REPRESENTATIVES' REPORT ON THE YUCCA MOUNTAIN
PROJECT FOR MAY 1, 2005, THROUGH JUNE 30, 2005

The purpose of this memorandum is to transmit the U.S. Nuclear Regulatory Commission (NRC) On-Site Representatives' (ORs') report for the period of May 1, 2005, through June 30, 2005.

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 activities 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 Documents 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 Robert Latta on (702) 794-5048, or Jack Parrott on (702) 794-5047.

Attachments:

1. "U.S. Nuclear Regulatory Commission On-Site Licensing Representatives' Report Number OR-05-03 for the Reporting Period of May 1, 2005, through June 30, 2005"
2. Table 1: "U.S. NRC On-Site Licensing Representatives' Tracking Report for Open Items Followed in Bi-Monthly OR Report"

cc: See attached list.

Memorandum to C.William Reamer, Director, from R. Latta and J. Parrott, dated: August 10, 2005
cc:

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J. Brandt, Lander County, NV	B. J. Garrick, NWTRB
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M. Baughman, Lincoln County, NV	P. Golan, DOE/Washington, D.C.
A. Robinson, Lincoln County, NV	G. Runkle, DOE/Washington, D.C.
L. Mathias, Mineral County, NV	C. Einberg, DOE/Washington, D.C.
D. Swanson, Nye County, NV	S. Gombert, DOE/Washington, D.C.
C. Trummell, Nye County, NV	J. Arthur, DOE/ORD, Las Vegas, NV
G. Hollis, Nye County, NV	R. Dyer, DOE/ORD, Las Vegas, NV
D. Hammermeister, Nye County, NV	A. Benson, DOE/ORD, Las Vegas, NV
M. Simon, White Pine County, NV	J. Ziegler, DOE/ORD, Las Vegas, NV
J. Ray, NV Congressional Delegation	A. Gil, DOE/ORD, Las Vegas, NV
M. Henderson, NV Congressional Delegation	W. Boyle, DOE/ORD, Las Vegas, NV
BJ Vonderheide, NV Congressional Delegation	D. Brown, DOE/OCRWM, Las Vegas, NV
S. Wade, DOE/ORD, Las Vegas, NV	C. Marden, BNL, Inc.
C. Hanlon, DOE/ORD, Las Vegas, NV	J. Bacocho, Big Pine Paiute Tribe of the Owens Valley

T. Gunter, DOE/OCRWM, Las Vegas, NV
N. Hunemuller, DOE/ORD, Las Vegas, NV
M. Van Der Puy, DOE, Las Vegas, NV
J. Williams, DOE, Las Vegas, NV
R. Craun, DOE/ORD, Las Vegas, NV
A. Capoferri, DOE, Las Vegas, NV
J. Mitchell, BSC/SAIC, Las Vegas, NV
T. Feigenbaum, BSC/SAIC, Las Vegas, NV
M. Mason, BSC/SAIC, Las Vegas, NV
S. Cereghino, BSC/SAIC, Las Vegas, NV
E. Mueller, BSC/PR, Las Vegas, NV
D. Beckman, BSC/B&A, Las Vegas, NV
R. Hassan, NQS, Las Vegas, NV
E. Opelski, NQS, Las Vegas, NV
P. Rail, BSC, Las Vegas, NV
J. Bess, BSC/SAIC, Las Vegas, NV
J. Birchim, Yomba Shoshone Tribe
R. Holden, NCAI
R. Clark, EPA
R. Anderson, NEI
R. McCullum, NEI
S. Kraft, NEI

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J. Kennedy, Timbisha Shoshone Tribe
C. D. Sorensen, BSC/BSC, Las Vegas, NV

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D. Crawford, Inter-Tribal Council of NV
T. Hanford, GAO

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U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-05-03,
FOR THE REPORTING PERIOD OF
MAY 1, 2005, THROUGH JUNE 30, 2005

Attachment 1

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U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-05-03

FOR THE REPORTING PERIOD OF MAY 1, 2005, THROUGH JUNE 30, 2005

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ACRONYMS AND ABBREVIATIONS

ACRO	MEANING
ADAMS	Agencywide Documents Access and Management System
BSC	Bechtel SAIC Company, LLC
CAP	Corrective Action Program
CNWRA	Center for Nuclear Waste Regulatory Analyses
CR	Condition Report
DOE	U.S. Department of Energy
ESF	Exploratory Studies Facility
FY	Fiscal Year
KTI	Key Technical Issue
LA	License Application
MRC	Management Review Committee
NCR	Nonconformance Report
NRC	U.S. Nuclear Regulatory Commission
OQA	Office of Quality Assurance
OR	On-Site Representative
PA	Performance Assessment
QA	Quality Assurance
QARD	Quality Assurance Requirements Description
SCWE	Safety-Conscious Work Environment

EXECUTIVE SUMMARY

SITE ACTIVITIES AND DATA ACQUISITION

During this reporting period, the On-Site Representatives (ORs) continued to observe the Project's response to the seepage identified in the Exploratory Studies Facility. The seepage stopped during this reporting period. Also, the Project worked on two initiatives to address concerns raised by the discovery of e-mails that may indicate falsification of the documentation of quality assurance records. Pending issuance of the reports on these initiatives, this issue is identified as **OR Open Item 05-02**. See Section 1.

OUTREACH ACTIVITIES

The U.S. Nuclear Regulatory Commission (NRC) management and staff met informally with members of the public in Pahrump, Nevada. See Section 2.

EVALUATION OF CURRENT TREND INFORMATION

The Yucca Mountain Project's "Trend Evaluation Report," for the second-quarter fiscal year 2005, was released on May 20, 2005. Based on the analysis of information contained in this report, three major contributors to the cause of Condition Reports (CRs) were identified. These contributors involved: 1) human performance errors, 51 percent; 2) management problems, 18 percent; and 3) communication issues, 12 percent. The trend report also identified that the average number of conditions issued per month has dropped from 99 during the first quarter, to 76 during the second quarter.

The ORs will continue to monitor the Project's human performance improvement initiatives, as well as the Corrective Action Program (CAP) actions, to resolve the reported decline in self-identification of conditions, and the results will be documented in a future report. See Section 3.1.

OBSERVATION OF CAP AUDIT

The ORs observed selected portions of Bechtel SAIC Company, LLC (BSC's) performance-based audit of the implementation of the CAP. The audit team concluded that there was satisfactory performance in the areas of CR initiation, causal analysis and corrective action development, trending, and documentation of objective evidence. However, the team determined that the performance of effective extent-of-condition evaluations was unsatisfactory.

Based on the ORs' observations, it was determined that the audit team appropriately evaluated the implementation of the CAP process. However, concerns were identified, relative to the audit findings that indicated: 1) a continuing pattern of ineffective corrective actions related to extent-of-condition evaluations for CRs; and 2) the Project's approach to problem identification and resolution outside of the CAP process. See Section 3.2.

REVIEW OF CR 5559, EXTENSIVE REWORK OF TECHNICAL PRODUCTS SUPPORTING THE POTENTIAL LICENSE APPLICATION

The ORs reviewed the results of BSC's evaluation of Level-A CR 5559. This CR identified inadequacies in the checking and quality review of technical products (i.e., models, technical

reports, software, calculations, and scientific notebooks), that support the U.S. Department of Energy's (DOE's) potential license application. The condition description for CR 5559 includes the identification of inadequacies related to checking and quality review processes, performed on technical products, that resulted in significant rework.

Based on the ORs' review of the processing of CR 5559, it was determined that the evaluation team used a structured approach to analyze the specific conditions identified in this CR. However, several potential areas of concern were identified relative to the evaluation process, and the reclassification of CR 5559 from Level A to Level B. The ORs will continue to monitor DOE's response to these issues and the results will be documented in a future OR report. See Section 3.3.

OBSERVATION OF OFFICE OF QUALITY ASSURANCE PROCEDURE COMPLIANCE AUDIT

The ORs observed the conduct of DOE's Office of Quality Assurance compliance-based audit of procedure adequacy related to BSC's quality-affecting programs at the Yucca Mountain Project. The purpose of this audit was to evaluate the adequacy of procedures in addressing selected elements of the program requirements delineated in the Quality Assurance Requirement Description (QARD).

Based on the ORs' observations, it was determined that the audit team appropriately evaluated the effectiveness of procedures that implement the selected QARD requirements. However, a concern was identified by the ORs, related to the inadequate translation of the QARD requirements into implementing procedures, that had previously been identified in CRs 2363, 3899, and 5538. The ORs will continue to monitor this issue and the results will be documented in a future report. See Section 3.4.

REVIEW OF OPEN ITEMS

From January 24 through 28, 2005, DOE conducted a performance-based audit of activities related to "Pre-closure Safety Analysis." As a result of issues identified by the NRC observers during the audit, two Audit Observation Inquiries (AOIs) were initiated.

Based on the ORs' reviews of the completed documents referenced in DOE's response to these AOIs, it was determined that the relevant procedures had not been revised in accordance with the information contained in DOE's response letter. Therefore, pending the resolution of the disparity between the commitments described in DOE's docketed correspondence and the revised text of the implementing procedures, the subject AOIs will remain open. See Section 3.5.

GENERAL ACTIVITIES

During this reporting period, NRC staff, including the ORs and DOE staff, held two Technical Exchanges in Las Vegas, Nevada. The first Technical Exchange was on DOE's revised performance indicators and the results of its most recent "Safety-Conscious Work Environment (SCWE)" survey. The second Technical Exchange was on "Pre-Closure Interaction Plans and Aircraft Crash Hazards." Also during this reporting period, management and staff from NRC -- including the ORs -- and DOE staff and management, held a public quarterly management meeting in Pahrump, Nevada. See Section 4.

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) programs in repository design; performance assessment (PA); performance confirmation; and environmental studies that may be useful in fulfilling NRC's role during prelicensing consultation. 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 May 1, 2005, through June 30, 2005.

OBJECTIVES

An OR's mission is to serve principally as a point of prompt information exchange and to identify preliminary concerns with site investigations and potential licensing issues. The ORs carry out this role by gathering and evaluating information, identifying concerns, and bringing more significant issues to NRC management's attention. Communication with DOE is accomplished by exchanging information on data, plans, schedules, documents, activities and pending actions, and resolution of issues. The ORs interact with DOE scientists, engineers, and managers, with input from NRC Headquarter's management, regarding the implementation of NRC policies, programs, and regulations. The ORs also focus on such issues as design controls, data management systems, PA, and KTI resolution. A primary OR role is to identify areas, 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 Continued Seepage Observation in the Exploratory Studies Facility

During the last reporting period, DOE informed the ORs, that seepage was observed in the south ramp of the Yucca Mountain Exploratory Studies Facility (ESF). During this reporting period, the ORs continued to observed the Project's response to the seepage. The seepage continued into this reporting period, but eventually stopped in June. The Project is in the process of comparing its observations of the event to the conceptual and numerical models of unsaturated zone flow, to confirm that what occurred is within the range of what would be expected from the performance assessment modeling.

1.2 Project Response to Discovery of Potential Falsification of QA Records

As documented in CR 5223 dated March 11, 2005, DOE discovered that certain employees of the U.S. Geological Survey may have falsified documentation of QA records of their work, involving water infiltration and climate, pertaining to a potential repository at Yucca Mountain. The Project, in a publicly released work plan, described three initiatives to address concerns raised by the discovery of the e-mails. These three initiatives are: 1) investigation of deliberate misconduct; 2) evaluation of completeness and accuracy of information associated with the site recommendation and LA; and 3) evaluation of effectiveness of project management, QA and culture.

The investigation of the first initiative was referred to the offices of the Inspectors General both to DOE and the Department of Interior. During this reporting period, DOE and Bechtel SAIC Company, LLC (BSC) began conducting the second initiative, with an expected completion date of May 31, 2005. The third initiative is to be conducted by a Project sponsored independent panel to begin its work in April 2005 and complete it by September 2, 2005. As of the end of the reporting period, the results of the second initiative had not yet been finalized nor reported, and the third initiative had not yet begun. NRC believes that the results of these initiatives may be relevant new information, and a potential licensing issue. Therefore, pending completion of the second and third initiatives described in the work plan, and the forwarding of the results to NRC, an **OR Open Item (05-02)** has been identified.

2. OUTREACH ACTIVITIES

2.1 NRC Open House

After the June 6, 2005, NRC and DOE Management Meeting (see Section 4.1), NRC management and staff met informally with members of the public in Pahrump, Nevada, to discuss matters of interest related to the Yucca Mountain Project and NRC's role in licensing a geologic repository.

3. QA AND ENGINEERING

3.1 Evaluation of Current Trend Information

The Yucca Mountain Project's "Trend Evaluation Report," for the second-quarter fiscal year (FY) 2005, was released on May 20, 2005. This report is an integral part of the Corrective Action Program (CAP), and is used to identify patterns and the causes of Condition Reports (CRs), so management can identify effective resolutions. The report used the source data from adverse conditions associated with the Office of Repository Development activities from the previous 12 months -- April 1, 2004 to March 31, 2005. (The adverse conditions included those CRs classified as Level A, B, or C.)

Based on the analysis of information contained in this report, three major contributors to the cause of CRs were identified. These contributors involved: 1) human performance errors, 51 percent; 2) management problems, 18 percent; and 3) communication issues, 12 percent (i.e., procedure content). These values represent approximately the same relative distribution as reported in the previous trend report. To address the lingering issues related to human performance, the Project formed the Human Performance Steering Committee in FY 2004, to oversee the implementation of management initiatives and improvements in human performance. However, the Project's efforts, which have been focused on reducing error-likely situations and reinforcing the actions and behaviors necessary to support a nuclear safety and quality culture, have not resulted in discernable improvements in this area.

The trend report also identified that the average number of conditions issued per month has dropped from 99 during the first-quarter, to 76 during the second quarter. The higher volume of CRs in the first quarter was attributed to the extent-of-condition review associated with Level A CR 3235, concerning traceability, transparency, and technical adequacy of products supporting the LA. Irrespective of the first quarter results, the 12-month average for adverse conditions has remained at approximately 70 CRs per month. The ORs also noted that the results of a recent CAP management assessment identified an adverse trend related to a decline in the number of self-identified Level A and B conditions, from 41 percent to 19 percent. (NOTE: Both the CAP goal and management expectation, in this area, are for 80-percent line identification.)

The ORs will continue to monitor the Project's human performance improvement initiatives, as well as the CAP actions, to resolve the reported decline in self-identification of conditions, and the results will be documented in a future report.

3.2 Observation of CAP Audit

The ORs observed selected portions of BSC's performance-based audit of the implementation of the CAP. The purpose of this audit was to determine if the performance of critical process steps were adequate and whether these activities resulted in the effective resolution of identified conditions. Specifically, the audit team evaluated BSC's current actions related to: (a) CR initiation; (b) causal analysis and corrective action development; (c) extent-of-condition evaluations; (d) nonconformance reports (NCRs); (e) documentation of objective evidence; and (f) condition trending. The audit scope also included evaluation of BSC's compliance with the applicable elements of the Quality Assurance Requirements Description (QARD) and the review of previous CRs, to determine if the corrective actions were adequate and if there were any recurrences of those conditions.

Methods the audit team used to evaluate performance objectives involved: (a) direct observation of field conditions for open NCRs; (b) interviews of staff and management; (c) examination of the effectiveness of root cause determinations and apparent-cause evaluations; (d) analysis of the CAP implementation processes; and (e) review of completed CRs for adequacy and effectiveness. The ORs also noted that the products the audit team selected, included the focused evaluation of recently completed CRs, Work Orders, Document Action Requests, and current-trend report information.

As a result of this oversight activity, the audit team concluded that overall, BSC was satisfactorily implementing the QARD requirements related to Section 15.0, "Nonconformances" and Section 16.0, "Corrective Action." The audit team also confirmed satisfactory performance in the areas of: (a) CR initiation; (b) causal-analysis and corrective action development; (c) trending; and (d) documentation of objective evidence. However, the team determined that the performance of effective extent-of-condition evaluations was unsatisfactory. As noted by the audit team, this deficiency, was previously identified and documented on a CR, during DOE's Office of Quality Assurance (OQA) audit of the CAP in January 2005. Consequently, a new Level B CR was initiated, to identify the repeat occurrence of inadequate extent-of-condition evaluations and to document that immediate actions taken in response to the CR initiated during OQA's CAP audit were not effective. The audit team also identified a deficiency related to the Project's approach, which allows the resolution of adverse conditions and conditions adverse to quality outside of the CAP process.

Based on the ORs' observations, it was determined that the audit team appropriately evaluated the implementation of the CAP process. The team was well-prepared for the audit, and the areas for review were appropriately examined, using detailed checklists, which focused on performance objectives. No audit observations were identified and the ORs determined that this oversight activity was effectively performed. However, concerns were identified relative to the audit findings, which indicated: 1) a continuing pattern of ineffective corrective actions related to extent-of-condition evaluations for CRs', and 2) the Project's approach to problem identification and resolution outside of the CAP process. Because of the significance of these issues, the results of this audit and the overall effectiveness of the CAP process will be a topic for discussion at the next NRC/DOE Management Meeting, scheduled for September 15, 2005.

3.3 Review of CR 5559, Extensive Rework of Technical Products Supporting the LA

During this reporting period, the ORs reviewed the results of BSC's evaluation of Level-A CR 5559. This CR identified inadequacies in the checking and quality review of technical products (i.e., models, technical reports, software, calculations, and scientific notebooks), that support DOE's potential LA. The condition description for CR 5559 includes the identification of inadequacies related to checking and quality review processes, performed on technical products that resulted in significant rework. The CR also indicates that analysis of recent CAP data, document-review record packages, and the results of QA audits and surveillances (i.e., FY 2004/05) indicate that there is a long-standing, significant condition, adverse to quality, regarding: 1) less than adequate work by technical-product originators/authors; and 2) inadequate/ineffective quality reviews and checking of technical-work products for completeness, accuracy, transparency, traceability, and defensibility. Furthermore, CR 5559, which references over 120 previous CRs as examples of the conditions, identified that the ineffectiveness of these processes has contributed to poor quality and significant delays in developing technical products adequate for submittal in support of the safety basis, as presented in the Safety Analysis Report. It was noted that this CR was entered into the CAP process as a Level A condition and was subsequently reviewed by the CAP screening team, which confirmed that the issues identified in CR 5559 constituted a significant condition adverse to quality. However, as a result of the recommendation of the Management Review Committee (MRC), an evaluation of the issues identified in CR 5559 was directed before initiating the root-cause analysis process specified in the governing procedure.

As a result of the direction provided by the MRC, the Project initiated a multi-disciplined team to evaluate the conditions identified in CR 5559. The stated purpose of this evaluation was "To determine if the data cited in CR 5559 substantiates the conclusions with respect to conditions adverse to quality, and if the existing processes in place are adequate to identify trends adverse to quality." The evaluation team's scope of review for the issues identified in CR 5559 included: 1) determination of whether the referenced Level-D CRs were appropriately characterized; 2) trend analysis of the cited CRs for review/checking errors; and 3) evaluation of any emergent trend information, to determine the relationship to the identified issues.

The evaluation team's analysis of the approximately 120 referenced conditions established that 41 CRs were relevant to the issues identified in CR 5559, in that the specified corrective actions required changes to technical products. Of these 41 CRs, approximately one-half involved post-closure conditions and approximately one-fourth

were related to either pre-closure or facility-design conditions. The evaluation team's analysis also concluded that the changes resulting from the identified CR issues were not pervasive and had no impact on the technical adequacy/integrity of the final product, or the material specifications. Additionally, the team concluded that there were no systemic procedural issues and that the associated document changes were largely attributable to an inconsistent interpretation of procedural controls related to product transparency. Therefore, based on the evaluation team's findings and recommendations, the MRC changed the significance classification of CR 5559 from Level A to Level B.

Based on the ORs' review of the processing of CR 5559, it was determined that the evaluation team used a structured approach to analyze the specific conditions identified in the CR. However, several potential areas of concern were identified relative to the evaluation process, and the reclassification of CR 5559 to Level B. These areas of concern include the preemptive evaluation of the information cited in the CR, which appears to be outside the established CAP process, and the evaluation team's apparent failure to consider the collective significance of all the information appended to the CR. This appended information, which supported the identified condition, included: (a) document-review record packages; (b) results of previous audits and surveillances; and (c) the relevance of additional CAP data-base search information. Another concern was identified regarding the evaluation team's conclusion that the identified conditions were not pervasive, in that this conclusion was based solely on a review of the listed CRs and did not consider any other database information. Furthermore, the ORs determined that similar errors related to the checking and quality review activities were recently identified in CR 6011, concerning the data checking process, which could indicate a broader area of concern with incomplete checking reviews.

At the conclusion of this reporting period, the remedial and corrective actions associated with CR 6011 were under development and DOE was evaluating the relationship of this condition to the issues identified in CR 5559. However, the continued identification of errors in the checking and quality review of technical products represents an area of concern which, if not corrected, could adversely impact the quality of the information supporting the potential LA. Therefore, the ORs will continue to monitor DOE's response to these issues and the results will be documented in a future OR report.

3.4 Observation of OQA Procedure Compliance Audit

The ORs observed the conduct of DOE's OQA compliance-based audit of procedure adequacy related to BSC's quality-affecting programs at the Yucca Mountain Project. The purpose of this audit was to evaluate the adequacy of procedures in addressing selected elements of the program requirements delineated in the QARD. Specifically, the audit team examined the effectiveness of a representative sample of quality-affecting procedures that addressed the requirements described in QARD Section 3.0, "Design Control;" Supplement I, "Software;" and Supplement III, "Scientific Investigation." The team also evaluated the effectiveness of corrective actions associated with previously identified CRs, within the scope of this audit.

The audit team used detailed checklists, based on the requirements for Section 3, and Supplements I and III of the QARD, to evaluate the respective procedures identified in BSC's Quality Requirements Matrix. As a result of this evaluation, the audit team examined seven procedures related to requirements for design control, five procedures

concerning implementation of software requirements, and 10 procedures involving requirements for scientific investigation. Based on these oversight activities, the audit team identified three conditions adverse to quality. One of these conditions involved procedural inadequacies related to the control of information in scientific notebooks. The remaining two conditions pertain to deficiencies in the requirements management process, which resulted in the inadequate implementation of the QARD requirements.

Based on the ORs' observations, it was determined that the audit team appropriately evaluated the effectiveness of procedures that implement the selected QARD requirements. No audit observations were identified and the ORs determined that this oversight activity was effectively performed. However, a concern was identified, related to the inadequate translation of the QARD requirements into implementing procedures, that had previously been identified in CRs 2363, 3899, and 5538. The ORs will continue to monitor this issue and the results will be documented in a future report.

3.5 Review of Open Items and Audit Observation Inquiries

During the week of January 24 through 28, 2005, DOE conducted a performance-based audit of activities related to "Pre-closure Safety Analysis." As a result of issues identified by the NRC observers during the audit, two Audit Observation Inquiries (AOIs) were initiated. Both AOIs involved the clarification of design-control information contained in Project procedures. The ORs reviewed the Project's response to these AOIs, contained in a DOE letter from J. D. Ziegler to C. W. Reamer, dated May 20, 2005.

Based on the results of the preliminary review of the response to the AOIs and consultation with cognizant NRC Headquarters personnel, the determination was made that the proposed resolution adequately addressed the identified procedural discrepancies. However, as a result of the ORs' reviews of the completed documents, it was determined that the relevant procedures had not been revised in accordance with the information contained in the DOE response letter. Therefore, pending the resolution of the disparity between the commitments described in the DOE docketed correspondence and the revised text of the implementing procedures, the subject AOIs will remain open.

4. **GENERAL ACTIVITIES**

4.1 Meetings

"Technical Exchange on Yucca Mountain Project Performance Indicators and Safety-Conscious Work Environment" - On May 19, 2005, staff from NRC, including the ORs and DOE, held a Technical Exchange in Las Vegas, Nevada. NRC Headquarters staff and the Center for Nuclear Waste Regulatory Analyses (CNWRA) staff attended via video conference. The Technical Exchange was open to the public and allowed DOE to present its revised performance indicators for the Yucca Mountain project and the results of its most recent Safety-Conscious Work Environment (SCWE) survey. DOE staff discussed the basis for the Project's new set of performance indicators and went into further detail on performance indicators for human performance. DOE also presented a summary and analysis of the results from its latest SCWE survey, taken in the fall of 2004. Finally, DOE staff presented the Project's plans for acting on the survey results. A meeting summary, agenda, list of attendees, and the presentations are published on NRC's High-Level Waste Disposal Meeting Archive web page.

"Technical Exchange on Pre-Closure Interaction Plans and Aircraft Crash Hazards" - On June 1, 2005, both staff from NRC -- including the ORs -- and DOE staff, held a

Technical Exchange in Las Vegas, Nevada. NRC Headquarters staff and CNWRA staff participated by video conference. The meeting was open to the public. A meeting summary, agenda, list of attendees, and the presentations are published on NRC's High-Level Waste Disposal Meeting Archive web page.

"Quarterly NRC/DOE Management Meeting on Proposed High-Level Waste Repository"
- On June 6, 2005, both management and staff from NRC -- including the ORs -- and DOE management and staff, held a public quarterly management meeting in Pahrump, Nevada. At the meeting, the progress of the proposed geologic repository at Yucca Mountain, Nevada, was discussed. A meeting summary, agenda, list of attendees, and the presentations are published on NRC's High-Level Waste Disposal Meeting Archive web page.

4.2 Other Observations

On May 9 - 13, 2005, NRC staff, including an OR, observed a CNWRA Internal QA Audit conducted in San Antonio, Texas. The NRC observers evaluated this performance-based audit to determine whether the CNWRA is effectively implementing the requirements of its QA program. The NRC observers agreed with the CNWRA audit team findings that the CNWRA QA program is being effectively implemented and appears to provide adequate controls for technical product development.

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

Table 1

OPEN ITEMS NUMBER <i>(For Tracking Only)</i>	BRIEF DESCRIPTION OF OPEN ITEM	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, 2003
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 RCA team specifically the root cause related to traceability and transparency issues. Pending resolution of the apparent discrepancies in the RCA for CR-3235 are 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
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 Report No. OR-04-06 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 Open Item 03-04	With a tentative date of mid-June to evaluate CAR BSC(B)-03-(C)-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 Report No: OR-03-05 January 12, 2004

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

Table 1

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 Report No: OR-05-02 July 12, 2005
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 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 Report No: OR-03-04 October 20, 2003
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 complete.	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 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 18, 2004
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 Report No: OR-03-06 February 18, 2004

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

Table 1

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 cumulative impact of all the models in question.	OR-02-01	OR Report No: OR-03-06 February 18, 2004
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-04-02 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
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