

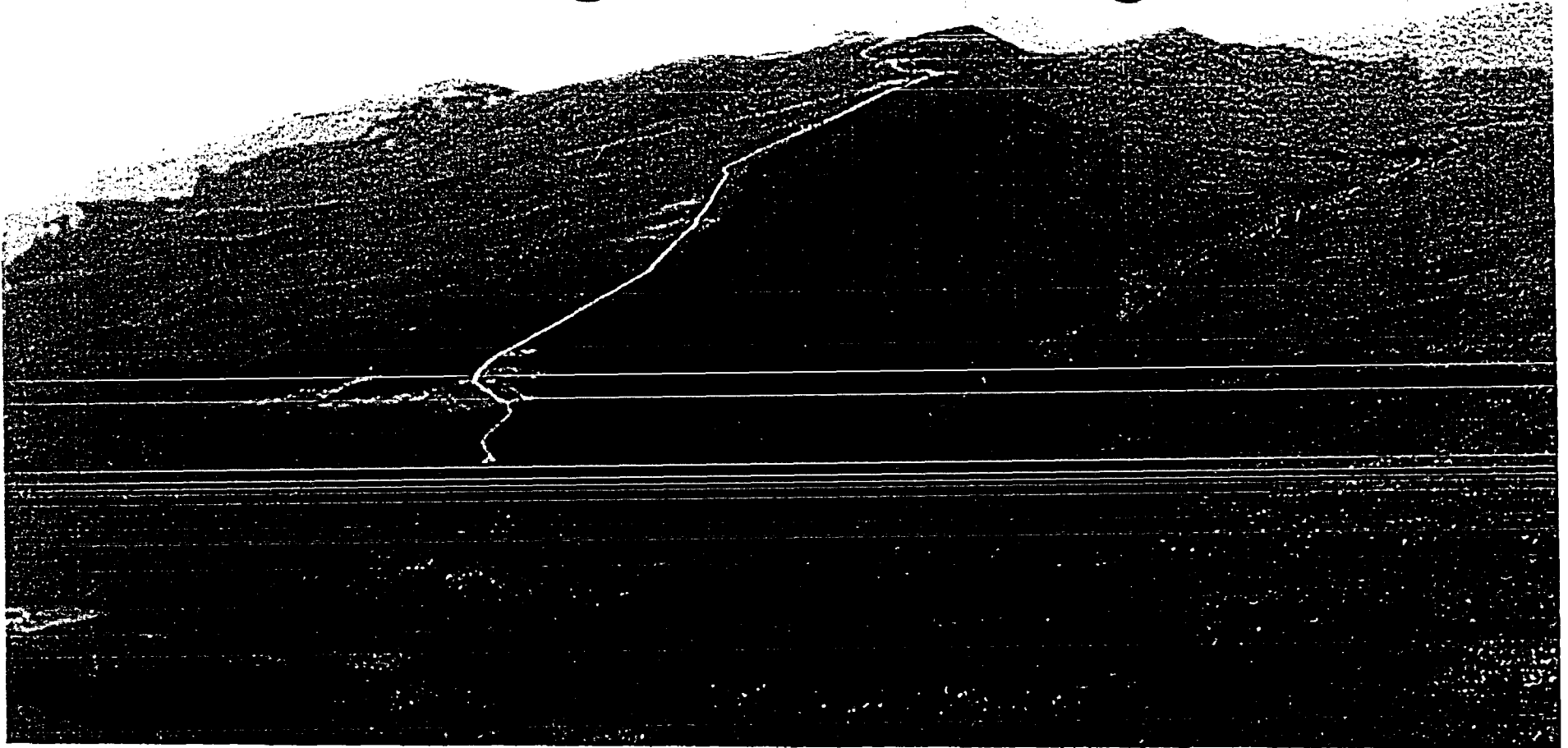


U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



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# DOE/NRC Quarterly Management Meeting



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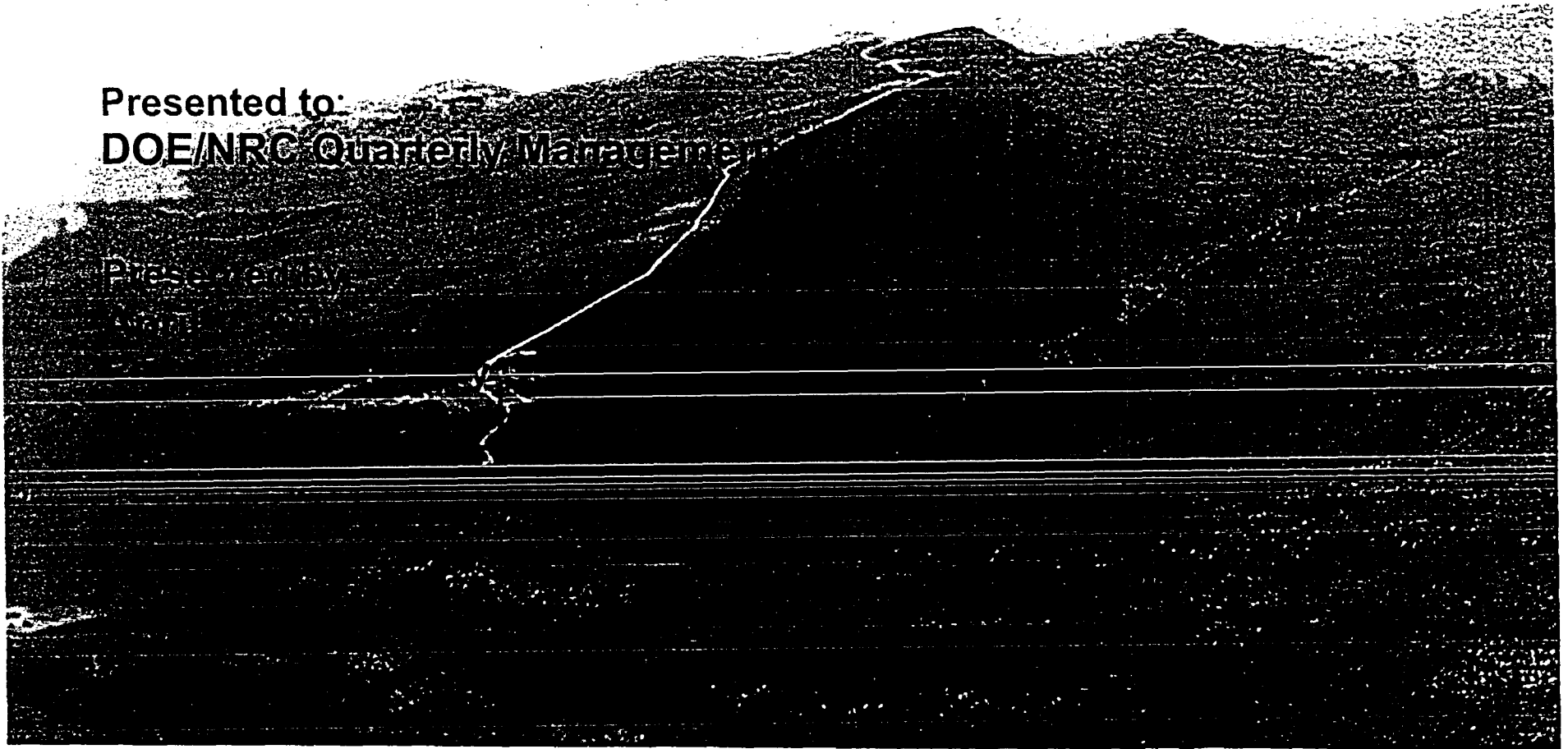
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# Licensing Status

Presented to:  
DOE/NRC Quarterly Management

Prepared by:



# Summary of Interactions

- **Recent Interactions:**
  - **June 26, 2007: Technical Exchange on Quality Assurance**
  - **June 28, 2007: Technical Exchange on Physical Protection, Material Control and Accountability, and Emergency Planning**
  - **July 11 to 12, 2007: Appendix 7 Meeting on Colloids, In-Package Chemistry, Multiscale Thermohydrologic Models, and Near-Field Environment**
  - **August 16, 2007: Technical Exchange on Preclosure and Postclosure Criticality**
  - **August 22 to 23, 2007: Appendix 7 Meeting on Unsaturated Zone Testing**
  - **September 13, 2007: Technical Exchange and Management Meeting on Licensing Process Topics**



# Summary of Interactions (Continued)

## Summary of Licensing Process Topics:

1. NRC/DOE interactions protocol during LA review
2. License Application content
3. NRC Office of Nuclear Material Safety and Safeguards (NMSS) organizational structure to support LA review
4. Status of future Interim Staff Guidance (ISGs)
5. Handling of sensitive information in the LA
6. Key Technical Issues (KTIs)
7. License Specifications
8. Timing of 10 CFR 63.44: *Changes, tests, and, experiments, applicability*
9. Electronic Information Exchange (EIE)



# Summary of Interactions (Continued)

- **Scheduled Interactions:**
  - **October 10 to 12, 2007: Appendix 7 Meeting on Drift Degradation and Seismic Consequences**
  - **October 23 to 24, 2007: Appendix 7 Meeting on Security and Safeguards (Las Vegas, NV - Closed to Public)**
  - **November 1, 2007: Appendix 7 Meeting: Igneous Activity – Redistribution Model**
  - **December 19, 2007: Quarterly Management Meeting**





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# Corrective Action Program Status

Presented to:  
DOE/NRC Quarterly Management

Presented by:  
[Illegible]



# AP-16.1Q Procedure Rewrite

- **AP-16.1Q has been rewritten to simplify and clarify the CR process**
- **The rewrite was based on feedback from users**
- **Draft procedure has been through formal review and concurrence and is projected for completion in October 2007**
  - **Rewrite provides increased consistency of CR level assignments**
  - **Requirements for MRC and CST functions are defined**
  - **Complexity of procedure has been significantly reduced**
- **Change Management Plan and Implementing Team have been established**



# Current Focus Areas

- **OCRWM is currently focusing on the following areas to maintain the improvements completed to date and to drive continuous improvements in the effective implementation of CAP**
  - **Condition Screening Team (CST)**
  - **Management Review Committee (MRC)**
  - **Monthly Program Review (MPR)**
  - **Use of Metrics**
  - **Trending Program**
  - **Management Accountability**





# Condition Screening Team

- **Purpose:** The purpose of the CST is 1) to categorize and assign new Condition Reports (CRs), 2) review CR closure packages for adequacy
- CST is comprised of 10 primary members from DOE, BSC, and Lead Laboratory
- Recent CST size reduction and consistency of member attendance has improved screening and closure review
- Quality of CR resolution is improving through CST review of closure package:
  - Every CR is reviewed by CST prior to closure
  - Feedback provided to line organizations on adequacy of CR
  - Noted deficiencies must be corrected prior to CR closure
- The quality assurance organizations have been performing a secondary review of CR closure packages to ensure effective resolution by line organizations



# **Condition Screening Team** (Continued)

- **CST screening CRs for potential impacts to the License Application (LA)**
  - BSC LA Assurance Review (LAAR) group reviews CRs screened by CST with potential LA impacts
  - LAAR group assesses each CR to determine whether the corrective actions have mitigated the LA impact
  - These LAAR reviews are documented in the CR
  - BSC Licensing and Nuclear Safety updates MRC and MPR monthly on status of CRs impacting the LA
- **Well executed CRs are noted by CST and posted on CAP web page as examples for use by project personnel**
- **MRC members are invited and encouraged to attend CST meetings**
- **Flash reports are provided to Senior Managers daily which detail level and organization assignment for newly screened CRs**
  - CR content is included in Flash Report for Level A and B CRs



# Management Review Committee

- During scheduled weekly meetings, MRC provides the senior management oversight of the CAP
- MRC participation has improved significantly over the last 6 months
- Use of performance metrics by the MRC has improved the timeliness of CR planning and resolution
  - Daily metrics are available to MRC
  - Monthly summary reports are regularly scheduled for review by MRC and Senior Management
- MRC has initiated focus on CRs identified as impacting the LA
  - Schedule of planned CR closure relative to LA submittal
  - Effectiveness of CR resolution in mitigating LA impact



# Monthly Program Review

- **Senior Managers from OCRWM, BSC, Lead Laboratory, USGS, and Naval Reactors meet monthly and review CAP Metrics**
  - **During the MPR, CAP metrics reviewed include**
    - ♦ **Timeliness and effectiveness of CR closure**
    - ♦ **Rework required to improve initial CR inputs**
    - ♦ **Individual organization performance**
    - ♦ **CRs that impact the LA**



# Use of Metrics

- **New department level metrics developed and available on CAP Web Page**
  - Metrics include total number of CRs by level, late plans, late actions, planned completion dates, and LA impacting CRs
  - Access to these metrics is real time, the metrics are updated hourly, and are available 24/7
  - Metrics used to drive performance in CAP on a daily basis in a proactive rather than reactive manner
  - This has resulted in a reduction in the number of late plans and late actions
- **Broader program metrics have also been created to address CR quality through plan approval, quality assurance closure review, and effectiveness reviews**



# Trending Program

- **A new combined DOE/BSC/Lead Lab Trending Program has been developed and implemented**
  - CRs are reviewed daily by Trend Working Group for event code assignment and identification of potential monitoring, emerging, or adverse trends
- **First and Second Quarter's FY07 Trend Report has been issued**
  - New report format is focused and concise
  - OCRWM Director provided specific continuous improvement comments to this report
- **Level A CR 7458 on trending has been submitted for closure**
  - Effectiveness review planned for 120 days subsequent to CR closure to ensure corrective actions have been effective and fully implemented



# Management Accountability

- **OCRWM Director and Deputy Director continue to review CAP performance with DOE, BSC, and Lead Laboratory Managers**
- **Review has focused management attention on:**
  - **All Level A CRs**
  - **CRs greater than 365 days old**
  - **CRs that have late corrective actions or plans**
  - **Actions that have been in a step greater than 100 days**
  - **Actions or plans with unassigned status**
  - **CRs validated with impacts to the LA**



# Conclusion

- **Positive feedback on CAP from outside organizations**
- **CAP performance is continuing to improve**
- **OCRWM Director has emphasized the importance of CAP and his expectations for the OCRWM management team and staff to fully embrace CAP**
- **CAP recognized as key to program success**







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# Status of NRC On-Site Representative (OR) Open Items

Presented to:  
DOE/NRC Quarterly Management

Presented by:

April 2001

# Status of NRC Open Items

#	Open Item	Description From NRC OR's Report	Responsible DOE Manager	Status and Schedule for Resolution
1	AOI-OCRWM-OQA-05-20-02	<p>"Revise procedure AP-3.13Q to reflect 10CFR63.21 requirements related to completeness of information necessary for LA review."</p> <p>[Note: issue with BSC citation of "draft" design documents.]</p>	Paul Harrington	<p>The NRC completed the review of the closure package during the week of July 30, 2007.</p> <p>The NRC informed DOE/BSC that this item would be closed in the next ORs quarterly report.</p>
2	AOI-OCRWM-OQA-05-20-01	<p>"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."</p> <p>[Note: issue with BSC citation of "preliminary" design documents]</p>	Paul Harrington	<p>The NRC completed the review of the closure package during the week of July 30, 2007.</p> <p>The NRC informed DOE/BSC that this item would be closed in the next ORs quarterly report.</p>
3	OR-OI-07-01	<p>"Failure to take prompt corrective actions related to documenting Conditions Adverse to Quality in the CAP system and initiating a Root Cause Analysis in response to QA Program inadequacies identified in Level A CR 10141."</p> <p>[Note: issue is related to delay in entering CR's based on NEI assessment of QA program.]</p>	Larry Newman	<p>This Closure Package was delivered to the ORs on 8/5/07</p> <p>Closure Package is under review for Closure by NRC</p>
4	OR-OI-06-10	<p>"BSC had not implemented effective requirements management system for the Quality Management Directive sections that were reviewed during an audit, indicating inadequate corrective actions for previous conditions identified in CRs – signifying emerging adverse trends."</p> <p>[Note: Issue pertains to Requirements Management Audit]</p>	Paul Harrington	<p>This issue is being addressed by CR 10285, "NRC Open Item OR-OI-06-10 regarding Requirements Management," and CR 10381, "Inadequate corrective actions to prevent recurrence for conditions related to requirements management."</p> <p>CR 10285 is currently implementing appropriate corrective action and scheduled for completion in December 2007.</p> <p>CR 10381 is being dispositioned in the CR system as a non-issue and will be closed.</p> <p>Closure Package will be delivered to the ORs by 12/31/2007.</p>



# Status of NRC Open Items (Continued)

#	Open Item	Description from NRC OR's Report	Responsible DOE Manager	Status and Schedule for Resolution
5	OR-OI-06-09	<p>"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."</p> <p>[Note: Issue pertains Lead Lab Audit]</p>	Larry Newman	<p>This issue is being addressed by CR 9664, "Inadequate Root-Cause Analysis (RCA) for Condition Report (CR) 7395."</p> <p>Closure Package will be delivered to the ORs by 10/15/2007</p>
6	OR-OI-06-07	<p>"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."</p> <p>[Note: issue deals with retention of records from Correction Action Program.]</p>	James Hollrith	<p>This Open Item was closed in ORs Quarterly Report O7-02. Reporting Period Ending 6/30/07.</p> <p><b>CLOSED</b></p>
7	OR-OI-06-03	<p>"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."</p> <p>[Note: Issue pertains to remediation of legacy codes]</p>	Russ Dyer	<p>This issue is being addressed in CR 8460, "NRC OR Open Item 06-03 regarding legacy software remediation."</p> <p>Closure Package will be delivered to the ORs by 10/31/2007</p>
8	OR-OI-06-04	<p>"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&amp;V remediation."</p> <p>[Notes: Issue pertains to Software IV &amp; V remediation]</p>	Russ Dyer	<p>This issue is being addressed in CR 8461, "NRC OR Open Item 06-04 regarding retesting of legacy software codes embedded in DTNs.</p> <p>CR 8461: resolution for this CR has been planned, approved and is being implemented. Implementation is now being overseen.</p> <p>Closure Package will be delivered to the ORs by 5/21/2008</p>



# Status of NRC Open Items (Continued)

#	Open Item	Description from NRC OR's Report	Responsible DOE Manager	Status and Schedule for Resolution
9	OR-OI-06-02	<p>"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."</p> <p>[Note: Inconsistencies in the application of QA/QA;QA/NA and non-Q designators on Quality affecting documents]</p>	James Hollrith	<p>A closure package was delivered to the NRC ORs on 7/26/2006 and the latest OR Report, dated 4/30/2007, provides results of the NRC review of this item. The NRC OR Report states 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." DOE will prepare a revised response to this item addressing the ORs concerns noted in the latest ORs Quarterly Report issued on 4/30/2007.</p> <p>CR 10740 "Inconsistent Use of Quality-Affecting Document Designators" was initiated to address this issue and is presently in the planning stage.</p> <p>Closure Package was delivered to the ORs on 9/18/2007.</p>
10	OR-OI-05-01	<p>"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."</p> <p>[Note: Transparency and Traceability]</p>	Paul Harrington	<p>The closure package was delivered to the NRC on 10/31/05. OR's are reviewing the package and will document the results in a future report.</p> <p>The Closure Package is under review for closure by the NRC</p>
11	OR-OI-02-10	<p>"Pending appropriate evaluation and documentation of the design control attributes associated with requirements of 10CFR63.44 and 10CFR Part 21."</p> <p>[Note: 63.44 and 10 CFR Part 21 were not addressed in the readiness report]</p>	Mark Williams	<p>A closure package was delivered to the ORs' on 11/30/05 and has been reviewed by NRC. DOE is developing additional documentation with respect to its position on timing of applicability of regulatory requirements in 63.44 and 10 CFR Part 21 and will provide that documentation to the OR's as a supplement to the original closure package.</p> <p>Closure Package will be delivered to the ORs by 10/31/2007</p>

AOI: Audit Observation Inquiry  
 OR-OI: NRC On-Site Representative's Open Item



**Consolidated Action Items  
From NRC/DOE Quarterly Management Meetings  
(September 25, 2007)**

Item No.	Action Item	Description	Status
1	MM 0402-C1	DOE will identify any to-be-verified (TBV) data in the LA that needs to be qualified (if any) at the time of LA submittal (Commitment).	Open. This item will remain open until LA submittal.
2	MM 0506-01	DOE and NRC to determine the dates for the list of proposed technical interactions discussed during previous Management Meetings.	Open. This item will remain open as a continuing action and progress will be reported at future management meetings.
3	MM 0509-01	DOE/NRC to hold technical exchange after the DOE report addressing the USGS alleged falsification of documents has been released by the Secretary.	Open. The referenced report including the root cause, extent of condition, and action plan was issued and was handed out during the March 27, 2007 MM.
4	MM0606-01	DOE and NRC to hold an interaction (management meeting or technical exchange - technical exchange preferred) on DOE's response to NRC's audit observation report (January 9, 2006) regarding the BSC's LLNL report.	Open. Pending completion of DOE's response to NRC's review comments on initial DOE response.
5	MM0706-01	DOE and NRC to hold an interaction within a month after submittal of the LA to walk through the LA.	Open.
6	MM0706-02	DOE will prepare a letter for submittal to the NRC by the end of June 2007 outlining DOE's issues of interest.	Complete. DOE to NRC letter dated July 10, 2007

Note: The Quarterly Management Meeting action items are designated as "MM yymm-nn" where yy is the two digit year, mm is a two digit month and nn is a two digit action item number from that meeting.