



Department of Energy

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QA: N/A
Project No. WM-00011

AUG 12 2003

OVERNIGHT MAIL


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RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVATION AUDIT REPORT (OAR) NO. OAR-03-02 OF AUDIT OQAP-BSC-03-05

During NRC's observation of Office of Civilian Radioactive Waste Management audit, OQAP-BSC-03-05, relative to data integrity associated with License Application, one Audit Observer Inquiry (AOI) was identified. This AOI is documented in OAR-03-02. The response to the AOI is detailed in Enclosure 1.

In addition, the OAR identified several comments related to the scheduling of the audit and performance of the audit team. The U.S. Department of Energy's response to those comments is detailed in Enclosure 2.

If you have any questions, please contact April V. Gil of my staff at (702) 794-5578.


Joseph D. Ziegler, Acting Director
Office of License Application and Strategy

OQA:KMG-1599

Enclosures:
As stated

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Response to NRC AOI

AOI – The Audit Observation Team determined that BSC performed a review of approximately 46 data-related Deficiency Reports issued from 1998 to present. BSC has indicated their intent to document the results of this review in a Corrective Action Report (CAR), BSC (B)-03-107. The initial entries are being developed by BSC. The NRC requests that DOE provide the outcome of the CAR evaluation, the results of the root cause analysis, and the associated corrective action plan. If BSC does not issue the CAR, NRC requests the justification for this decision.

Because of the importance of this matter, the NRC requests a response to their audit inquiry within 45 days of the date of this Audit Observer Inquiry. If these actions are not completed by this date, please respond verbally or in writing.

Response - CAR BSC (B)-03-C-107 was issued by Bechtel/SAIC (BSC) on April 14, 2003 to document this issue. The NRC Onsite Representative (OR) was provided a copy of the CAR and briefed on the status of the root cause analysis on June 3, 2003. The root cause analysis is still being performed. In addition, the CAR was discussed at the DOE/NRC Quarterly Quality Assurance Meeting on April 29, 2003. The status of the root cause analysis was discussed at the DOE/NRC Quarterly QA Meeting on July 15, 2003.

DOE will keep the NRC OR informed of the progress in resolving the issue documented in the CAR.

Enclosure 1

Response to OAR Comments

Comment #1 – The observers noted that certain audit team members were not familiar with the automated Tracking Data Management System (TDMS), which was a critical tool in accomplishing the objectives of this audit. This resulted in some delays and inefficiency in performing data verification activities.

Response – OCRWM agrees that one audit team member was not familiar with the TDMS. The level of experience of each audit team member was carefully reviewed and found acceptable before the team was finalized. Use of the TDMS was not required for the technical specialist. The only auditor inexperienced in the TDMS was paired with an auditor knowledgeable in using TDMS to prevent any delays. The audit was conducted efficiently and completed as scheduled.

Comment #2 – The NRC observers concluded that the actual conduct of this audit may have been more appropriately performed at a time when a larger sample of completed technical products critical to LA were available.

Response – Performance-based audits may be conducted on in-process activities without having completed products. A conscious decision was made to verify data supporting License Application (LA) in two phases before products were completed. Samples were selected from draft technical products, which is appropriate for a performance-based audit. If a large number of technical products had been through the review process the sample selection would have been broader, but not larger. The two-phased audit approach, i.e., two separate audits, of data verification was planned to review other areas critical to LA before phase one was initiated.

Comment #3 – However, during the conduct of the audit, observers initiated an Audit Observer Inquiry (AOI) OQAP-BSC-03-05-01 regarding the identification of trends associated with the data-related deficiency reports written in the last four years that the audit team did not identify during this audit.

Response – The AOI referenced in the statement requested follow-up information related to BSC's initiation of a Corrective Action Report (CAR) regarding the identification of trends associated with the data-related deficiency reports. Audit teams do not perform trend analysis before or during audits. The audit team does follow-up on corrective actions associated with selected deficiency reports. Follow-up was completed during the subject audit and prior corrective actions were found to be effective.