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Project No. WM-00011

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OVERNIGHT MAIL

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TRANSMITTAL OF RESPONSE TO U.S. NUCLEAR REGULATORY COMMISSION (NRC) STAFF EVALUATION OF U.S. DEPARTMENT OF ENERGY (DOE) ANALYSIS AND MODEL REPORTS (AMRs), PROCESS CONTROLS, AND CORRECTIVE ACTIONS

Reference: Ltr, Virgilio to Chu, dtd 4/10/04 (NRC Staff Evaluation of DOE AMRs, Process Controls, and Corrective Actions)

As the person responsible for the effective implementation of the Yucca Mountain Project (Project) quality assurance (QA) program, Dr. Margaret S.Y. Chu has asked me to provide the written response to the referenced letter. The conclusions from the subject evaluation were issued in a report transmitted to the DOE by the referenced letter. The letter also requested a written response within 30 days from the Technical Exchange the NRC conducted in Las Vegas, Nevada, on May 5, 2004, on the results of its evaluation. At the Technical Exchange, DOE provided a summary of the actions taken or planned regarding the concerns identified by the NRC. The DOE reviewed the actions during the May 11, 2004, Quarterly NRC/DOE Management Meeting.

In the fall and winter of 2003/2004, the NRC conducted three technical evaluations to evaluate the technical information in selected Project AMRs. The NRC team also evaluated the processes for developing and controlling AMRs, and the effectiveness of recent corrective actions in the areas of models, software, and data. These technical evaluations were conducted in Las Vegas, Nevada, and focused on three AMRs the NRC considered to be of high or medium significance to repository performance: *General Corrosion and Localized Corrosion of Waste Package Outer Barrier*; *Commercial Spent Nuclear Fuel Waste Form Degradation Model*; and *Drift Degradation Analysis*.

The DOE appreciates the professionalism shown by the NRC team during the evaluation and the depth and nature of the detailed review. The DOE considers the major summary conclusions of the NRC evaluation to be:

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- Technical information in AMRs was improved over what had been available for the Total System Performance Assessment (TSPA) for Site Recommendation;
- Support from, interaction with, and openness of the Project staff during the assessments was found to be exceptional;
- The NRC team identified concerns with both the clarity of explanation of the technical bases presented in the AMRs evaluated and with the presentation of adequate technical information to support that explanation;
- The concerns identified could reasonably have been found by Project staff during document reviews;
- The team confirmed DOE's and Bechtel SAIC Company, LLC's (BSC), findings that the Project has not been fully successful in carrying out effective actions to eliminate recurring concerns;
- The Project's current efforts to implement a formal integrated program to improve human performance may increase the effectiveness of corrective actions in preventing recurrence; and
- Continued application of the same level of rigor in policy, method and procedure implementation could result in a large volume of requests for additional information and prevent the NRC from making a timely construction authorization decision.

The DOE is addressing the results of the NRC staff evaluation and previous DOE and BSC review results which identified the overarching issues of transparency and traceability associated with the key products supporting the TSPA for the License Application (LA). In April 2004, upon receipt of the NRC report, the Project reviewed the results of the NRC evaluation to determine the extent of the issues, and to identify the actions necessary to improve the transparency and traceability of the AMRs directly supporting the LA. The Project concluded that a narrow interpretation of regulatory requirements and lack of focused attention to transparency, traceability, completeness and regulatory perspective were significant factors leading to the issues identified by the NRC staff.

The Project found that of the specific, detailed concerns and observations identified in the NRC report:

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- Approximately 45 percent were transparency or traceability issues for which actions were underway to improve the transparency and traceability;
- Approximately 30 percent were technical issues of which the Project was aware and had work underway to address;
- Approximately 25 percent were positive observations, such as that software documentation was found to be extensive, the trending program was improving, and technical information in AMRs was improved over what was presented at the time of Site Recommendation; and
- The Project had a differing view on two of the issues identified by the NRC concerning emplacement drift degradation analysis methods and codes. The Project believes these are both low risk issues. Nevertheless, modifications and clarifications are underway to better substantiate the Project bases and conclusions.

With the one exception noted above, the Project accepts the conclusions described in the referenced letter. The Project agrees that the key documents that support the LA must be reviewed and clarified.

In March 2004, the Project initiated a comprehensive evaluation of the technical documents that will be used to support the LA. The newly created Regulatory Integration Team (RIT) is conducting these evaluations. The *Technical Work Plan For: Regulatory Integration Evaluation of Analysis and Model Reports Supporting the TSPA-LA*, TWP-MGR-PA-000014, effective April 8, 2004, is enclosed for additional detail (enclosure 1). The RIT is made up of approximately 150 technical and regulatory experts. Additionally, full time QA staff is assigned to the RIT. The RIT evaluations are expected to be completed by the end of May 2004. As of May 21, 2004, 96 percent of all RIT evaluations and action plans were complete. The Project is now in the process of prioritizing the revisions of these technical documents, giving highest priority to those documents related to model validation and TSPA inputs.

The RIT is taking the following actions to further strengthen the AMRs supporting the LA:

- Integrating the AMRs to assure consistency and ease of technical and regulatory reviews;
- Reviewing and revising the AMRs to assure that they are suitable for intended technical and regulatory audiences;

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- Reviewing and revising the AMRs to assure adequate transparency and traceability so that technical experts, regulatory decision-makers and interested parties have a well-defined roadmap of the relevant issues; and
- Identifying and resolving technical issues to support regulatory decision-making.

The RIT is performing a comprehensive evaluation of the set of AMRs that are identified as those that provide either direct or indirect input to the TSPA-LA. The AMRs are being integrated to ensure they provide a coherent, consistent, and traceable description of the technical basis for the postclosure safety case. The RIT is conducting a review of the AMRs from a regulatory perspective, identifying issues, then updating and revising the reports to address the identified issues.

The RIT is reviewing the data and parameters used as input to the AMRs, with regard to (1) transparency and traceability, (2) compliance with applicable data management requirements, and (3) suitability for use. The RIT is reviewing the AMRs for technical accuracy and validity of models and analyses; traceability of inputs and outputs; consistency of assumptions between associated AMRs; identification of applicable *Yucca Mountain Review Plan* (YMRP) criteria; how YMRP criteria are addressed in the AMRs; whether model documentation adequately describes conceptualization and development of numerical or mathematical models; and model abstraction for use in other related AMRs or in the TSPA-LA. The RIT is also implementing the corrective actions for those conditions reports (CRs) initiated in conjunction with the NRC staff evaluation. A listing of the "Status of CRs Related to the NRC Technical Evaluation" is enclosed for additional detail (enclosure 2).

As stated in the NRC report, the observations concerning the Corrective Action Program (CAP) were not new to the Project. As discussed in the May 2004 Quarterly QA and Management Meetings, the Project has implemented actions that improved the technical baseline, the processes for development of technical products and the license application, the human performance of the Project employees, and the identification and implementation of timely corrective actions. These improvements were exemplified by the closure of the data CR (CR16, formerly Corrective Action Report [CAR] BSC(B)-03-C-107) on March 2, 2004, closure of the software CR (CR102, formerly CAR BSC-01-C-002) on March 30, 2004, and the expected closure of the model validation CR (CR99, formerly CAR BSC-01-C-001) by late summer 2004. Additionally, performance indicators showing improvements in the CAP were discussed at the May 2004 Quarterly QA and Management Meetings.

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The Project has completed the following CAP enhancements: expansion of reporting capability to meet user requirements; training of line personnel in trend program software and trending techniques; increase in formality of the condition screening team activities; and refinement of CAP system metrics. These enhancements were discussed with members of the NRC staff during the Quarterly NRC/DOE QA Meeting held in Las Vegas, Nevada, on May 4, 2004.

The Project is continuing to make CAP improvements to increase line management involvement, so as to: enhance the ability of the line organizations to manage their corrective action scope; expand the ability to trend corrective action data; refine the metrics for measuring CAP performance; and improve the usability of the CAP system software. CAP enhancements planned over the next three months include: issuing a CAP user's guide to assist personnel with CAP system software manipulations; implementing trending software and establishing expectations for line organization use; providing additional training to managers and supervisors on senior management expectations for increased line management involvement in CAP with subsequent rollout to the work force; further enhancing the condition report screening team process, so as to establish clear expectations and knowledge requirements; revising the CAP CR significance levels; and implementing a process for "find and fix" and "corrected on the spot" CRs for Conditions Adverse to Quality.

Also as discussed in the May 2004 Quarterly QA and Management Meetings, improved CAP trend analysis led to the self-initiation of CRs to address human performance issues that were identified as a contributing factor in recurring conditions. Improvements in human performance have occurred since the NRC evaluation. The latest trend report (2nd Quarter fiscal year 2004) showed a marked decrease in skill-based human errors. Actions addressing the human performance issues are planned to be completed over the next six months. One of these actions was implementing a set of human performance indicators based on nuclear power industry best practices to monitor error prevention behaviors, human performance awareness, backlog management, and a learning culture. These indicators became effective April 21, 2004, and were discussed with members of the NRC staff at a public technical exchange on the Project's performance indicators on May 3, 2004, in Las Vegas, Nevada. As further continuing improvement action, the Project plans to issue a human performance management directive visibly supported by the Project's Leadership Council.

In summary, the Project takes the NRC review results seriously and has initiated actions to address the concerns identified by the NRC team. The RIT actions, planned for completion in September 2004, address the concerns with the clarity of the technical bases presented in AMRs and the sufficiency of technical information used to support DOE's explanation of the technical bases. The DOE reviews the AMR products as they are completed by BSC. The concerns with the effectiveness of DOE's corrective actions were addressed by CAP enhancements that have been completed and discussed with the NRC at the May 2004 Quarterly QA and Management

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Meetings. Furthermore, the Project has supplementary CAP and human performance improvements planned to be completed over the next three and six months, respectively.

The actions described in this letter provide information on the Project's progress regarding improvements to our technical products and implementation of an effective corrective action program. Although we plan to continue these improvements, monitor progress, and make adjustments to our plans as appropriate, there are no new regulatory commitments in the body or enclosures of this letter. Please direct any questions regarding this letter and its enclosures to Joseph D. Ziegler at (702) 794-5567 or by e-mail at joseph_ziegler@ymp.gov.



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Deputy Director

OLA&S:NKH-1301

Enclosures:

1. *Technical Work Plan For: Regulatory Integration Evaluation of Analysis and Model Reports Supporting the TSPA-LA, TWP-MGR-PA-000014*
2. Status of CRs Related to the NRC Technical Evaluation

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