June 2, 2004

Mr. Joseph Ziegler, Director Office of License Application and Strategy U.S. Department of Energy Office of Repository Development 1551 Hillshire Drive North Las Vegas, NV 89134-6321

# SUBJECT: PRE-LICENSING EVALUATION OF TOTAL SYSTEM PERFORMANCE ASSESSMENT AND INTEGRATION KEY TECHNICAL ISSUE AGREEMENT 4.07

Dear Mr. Ziegler:

In a letter dated March 25, 2004, the U.S. Department of Energy (DOE) submitted information to address Total System Performance Assessment and Integration (TSPAI) Key Technical Issue (KTI) Agreement 4.07. The agreement between DOE and the U.S. Nuclear Regulatory Commission (NRC) was reached during the TSPAI Technical Exchange and Management Meeting held from August 6-10, 2001. DOE's transmittal letter requested NRC to consider TSPAI KTI Agreement 4.07 complete based upon review of the methodology and subsequent review of DOE procedures and quality assurance documents at its Las Vegas offices.

The agreement states:

"DOE's software qualification requirements are currently documented in procedure AP SI.1Q which is under review for process improvement as part of software CAR-BSC-01-C-002. During its review of AP SI.1Q, DOE will consider: 1) the procedure it would follow to conduct a systematic and uniform verification — all areas of a code analyzed at a consistent level, 2) the process it would follow to ensure correct implementation of algorithms, and 3) the process it would follow for the full disclosure of calculations and results. DOE will document compliance with the improved process in the verification documentation required by AP SI.1Q. Software qualification record packages for the affected programs will be available for NRC review in FY 2003."

In a letter dated December 23, 2002, DOE submitted information pertaining to TSPAI KTI Agreement 4.07. This letter stated that DOE had revised AP-SI.1Q and had developed two new procedures (AP-SI.2Q and AP-SI.3Q) to provide more specific guidance on qualification, verification, and validation of software. DOE also made a regulatory commitment to retest legacy software by developing a new procedure applicable to legacy software that would apply the key steps of AP-SI.3Q. However, the NRC staff in its response dated April 22, 2003, stated that important information requested in the agreement had not been provided by DOE. Consequently, DOE needed to supplement its original response to fully address TSPAI KTI Agreement 4.07.

#### J. Ziegler

In the March 25, 2004, response, DOE reported that: 1) the procedure for retesting of legacy software had been prepared, and 2) that software qualification record packages for 65 codes had been developed in accordance with the new procedures. In addition, DOE stated that "verification of compliance by a review of selected quality assurance records is an activity more appropriately conducted onsite."

NRC staff has reviewed the latest version of all relevant procedures and found that they provide a reasonably complete framework for ensuring adequate verification of software used in support of a potential license application. Prior to submission of any potential license application, NRC may choose to assess the implementation of these procedures through NRC observation of DOE's corrective action program. However, should DOE submit a license application, NRC would assess implementation by inspection/independent review of selected software qualification record packages.

NRC staff concludes that DOE has adequately addressed TSPAI KTI Agreement 4.07 by identifying specific procedural requirements for software verification that generally satisfy the considerations of the agreement. Resolution of TSPAI KTI Agreement 4.07 by the NRC staff does not prevent anyone from raising any issue for NRC consideration during the licensing proceeding. Also, resolution of TSPAI KTI Agreement 4.07 by NRC during prelicensing does not prejudge the NRC staff evaluation of this or any other issue during the licensing review. Based upon the above review, the NRC staff has no further questions or comments about how DOE has addressed the agreement item. Therefore, NRC staff considers TSPAI KTI Agreement 4.07 "complete." If you have any questions regarding this matter, please contact Gregory Hatchett, at 301-415-3315 or by e-mail to <u>GXH@nrc.gov.</u>

Sincerely,

/RA/

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

cc: See attached list

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Sincerely,

/RA/

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

cc: See attached list

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