



Department of Energy
Office of Civilian Radioactive Waste Management
Office of Repository Development
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QA: N/A
Project No. WM-00011

MAR 25 2004

OVERNIGHT MAIL

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TRANSMITTAL OF INFORMATION ADDRESSING KEY TECHNICAL ISSUE (KTI)
AGREEMENT TOTAL SYSTEM PERFORMANCE ASSESSMENT AND INTEGRATION
(TSPA) 4.07

References: (1) Ltr, Schlueter to Ziegler, dtd 4/22/03
(2) Ltr, Ziegler to Schlueter, dtd 12/23/02

In Reference 1, the U.S. Nuclear Regulatory Commission (NRC) informed the U.S. Department of Energy (DOE) that after review of the DOE response to KTI Agreement TSPA 4.07 (Reference 2), the NRC staff considers the response incomplete because only a portion of the information requested by the agreement has been provided for the NRC review.

KTI Agreement TSPA 4.07 states that:

"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."

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The DOE response (Reference 2) reported that the update to AP-SI.1Q had been completed and that it had been augmented by two new procedures that were developed to provide more detailed requirements for the qualification (AP-SI.2Q) and verification and validation (AP-SI.3Q) of software. The procedural and programmatic changes that have been implemented to address each of the items specified for consideration in the agreement were discussed in Reference 2.

The DOE response further reported that it has determined that independent verification and validation should also be performed on legacy codes that otherwise would not be subject to the requirements of the new AP-SI.3Q prior to submittal of a license application. An additional procedure, AP-SI.4Q, has been developed to specify the requirements for verification and validation of these legacy codes. Finally, the DOE response reported that the initial qualification records packages for software, verified and validated under the new AP-SI.3Q, would be completed by March 2003. Qualification records packages for 65 codes have now been completed. These record packages are Yucca Mountain Project quality assurance records subject to the requirements of 10 CFR 63.142 (r).

In Reference 1, the NRC correctly points out that, while the DOE response discussed the revised and new procedures, documentation of compliance had not been completed and that neither the procedures nor qualification records packages had been provided for NRC review. The response in Reference 2 contained a complete description of the procedural and programmatic controls resulting from actions specified by KTI Agreement TSPA1 4.07 and a statement of DOE's intentions regarding documentation of compliance. Verification of compliance by review of selected quality assurance records is an activity more appropriately conducted onsite and would be consistent with traditional NRC practice for such high volume documentation issues. In addition, project staff familiar with the genesis and content of the work and supporting documentation would be available for NRC onsite consultation.

The methodology in the software procedures, assuming adequate implementation, will result in appropriately qualified, validated, and verified software. The NRC can formally inspect DOE performance and use traditional inspection techniques for citing and tracking any DOE failure to appropriately implement the submitted methodology. In addition, any discrepancies that are found with the implementation of these procedures will be addressed and resolved through the DOE corrective action program.

The procedures were verified to be adequate as part of the verification of CAR-BSC-01-C-002. There will be follow-up Quality Assurance oversight activities to evaluate implementation of the procedures. The NRC staff will be invited to participate in these oversight activities as observers and will be notified of the exact date and location of the oversight activities.

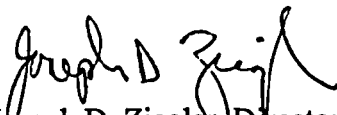
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It should be noted that the procedures discussed above have recently been revised to address findings from a performance-based Quality Assurance audit in June 2003. As part of this revision, the procedures were changed from administrative procedures (AP) to line procedures (LP) (a category of procedures implemented by DOE's contractors and not by DOE), with AP designation changed to LP designation as follows:

- LP-SI.11Q-BSC, Rev. 0, ICN 0, *Software Management* (effective date 3/23/04)
- LP-SI.12Q-BSC, Rev. 0, ICN 0, *Qualification of Software* (effective date 3/23/04)
- LP-SI.13Q-BSC, Rev. 0, ICN 0, *Software Independent Verification and Validation* (effective date 3/23/04)
- LP-SI.14Q-BSC, REV 0, ICN 0, *Software Independent Verification and Validation Legacy Code* (under development)

Based on the above information, the DOE requests that the NRC: 1) consider Agreement TSPA 4.07 as completed based upon review of methodology, and 2) conduct its reviews of the DOE procedures and quality assurance documents to verify compliance at our offices in Las Vegas, Nevada. The DOE believes that this approach would be a more efficient use of resources for both the NRC and the DOE. For example, CAR-BSC-01-C-002 documents software issues that are being addressed through the corrective action program. The DOE believes that it is more appropriate for NRC to follow the software qualification, validation, and verification issues through their review of the corrective action process until these issues are resolved.

There are no new regulatory commitments in the body of this letter. If you have any questions, please contact Carol L. Hanlon at (702) 794-1324 or Mark C. Tynan at (702) 794-5457.



Joseph D. Ziegler, Director

Office of License Application and Strategy

OLA&S:CLH-0438

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