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QA: N/A

**DEC 23 2002**

**OVERNIGHT MAIL**

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**TRANSMITTAL OF INFORMATION TO ADDRESS KEY TECHNICAL ISSUE (KTI) AGREEMENT  
TOTAL SYSTEM PERFORMANCE ASSESSMENT AND INTEGRATION (TSPAI) 4.07**

This letter provides information addressing the subject KTI agreement associated with software qualification. Specifically, KTI Agreement TSPAI 4.07 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.”

The following programmatic and procedural actions have been initiated. A major revision of AP-SI.1Q, *Software Management* has been developed. Two additional software procedures, AP-SI.2Q, *Qualification of Level A Developed or Modified Software*, and AP-SI.3Q, *Software Independent Verification and Validation*, have also been developed. AP-SI.1Q is the quality assurance (QA) plan for software management that establishes the processes, identifies the roles, and defines the responsibilities for management of software to be used in support of quality-affecting activities. AP-SI.1Q also specifies requirements and controls for the complete software life cycle, including the requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement phases. Software used for quality-affecting activities must be qualified and documented according to this procedure.

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AP-SI.1Q is augmented by AP-SI.2Q, which contains more detailed requirements for qualification of Level A<sup>1</sup> software developed or modified by Office of Civilian Radioactive Waste Management contractors or subcontractors, and AP-SI.3Q, which specifies the requirements for independent verification and validation applicable to software used in support of quality-affecting activities.

The items that the U.S. Department of Energy (DOE) agreed to consider during review of AP-SI.1Q, and procedural or programmatic changes that have been implemented to address each item of the KTI agreement are discussed below:

- 1) "...the procedure it would follow to conduct a systematic and uniform verification – all areas of a code analyzed at a consistent level...."

AP-SI.1Q, Section 5.0, Process, has been substantially revised to clearly define the roles and responsibilities of the personnel involved in the software life cycle. The life cycle process has been better defined, and a new procedure expanding on the requirements for qualification of Level A software AP-SI.2Q has been developed and approved for use to provide additional control in the processing of developed or modified software. The new software procedure AP-SI.3Q provides for an independent, systematic verification process applicable to all quality-affecting software. The new procedures AP-SI.2Q and AP-SI.3Q, together with the revised AP-SI.1Q, ensure systematic and uniform verification and validation of analytical computer codes.

- 2) "...the process it would follow to ensure correct implementation of algorithms...."

AP-SI.2Q, Subsection 5.1.2, Software Definition – Requirements Phase, which includes the functional and performance requirements, ensures that the user needs, including algorithms, are clearly defined. The design document addressed in AP-SI.2Q, Subsection 5.1.3.1, requires the development and documentation of the software structure, system inputs and outputs and data and logical model. This further ensures that the user algorithms are being correctly implemented. The installation test process, the validation test process, and the independent verification and validation activities provide final confirmation that the algorithms are correctly implemented.

- 3) "...the process it would follow for the full disclosure of calculations and results...."

The structured and well-defined approach specified in AP-SI.1Q for the entire life cycle of software, beginning with software categorization and continuing through requirements, design, implementation (including coding), validation (including independent verification and validation), operations and maintenance (including checkout and installation), and retirement, ensures full disclosure of computations. The requirement phase ensures a clear and consistent translation of the user needs into software functional capabilities. The validation test process and

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<sup>1</sup> AP-SI.1Q categorizes software as one of the following:

**Level A** - Software that requires a high level of confidence through validation and verification based on its nature, function, and complexity (e.g., software that is the numerical implementation of a model; mathematical algorithms that may use complex numerical methods, approximations, or simulations).

**Level B** - All other non-Level A software subject to the qualification requirements of AP-SI.1Q that requires validation and verification based upon its nature, function, and complexity (e.g., software that is used to acquire, manipulate, or transform data, or perform calculations using mathematical algorithms that give exact results). Except for data acquisition software, Level B software gives identical results when re-run.

DEC 23 2002

the independent verification and validation activities ensure that the test cases are run and the technical adequacy evaluated using alternate methods. The processes above ensure that the computations are fully disclosed and the verification and validation processes further ensure that the software performs the intended functions.

- 4) The last part of the agreement item stated that, "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."

The new procedure, AP-SI.3Q, provides for a comprehensive documentation of the verification and validation process. The document reviews to be conducted during the different stages of the software life cycle and documented per software and other project procedures are QA records and are required to have the appropriate levels of review and signature. Initial qualification record packages for software qualified under the new software procedures discussed above are expected to be completed by March 2003, and will be available for the U.S. Nuclear Regulatory Commission (NRC) review. The Bechtel SAIC Company, LLC (BSC) self-assessments, and audits or surveillances conducted by BSC and/or DOE QA will provide additional confirmation of compliance with the improved processes.

The revision to AP-SI.1Q and the new procedures, AP-SI.2Q and AP-SI.3Q, have been approved for use. These procedures are to become effective on January 13, 2003, following training of affected personnel.

In addition, the DOE has determined that independent verification and validation should be performed on "legacy" codes used in technical products supporting the License Application (LA). Such legacy codes are those that otherwise would not be subject to an independent verification and validation performed in accordance with the new AP-SI.3Q, effective January 13, 2003.

Because AP-SI.3Q contains many new administrative and documentation requirements, the direct application of AP-SI.3Q to legacy codes would result in unnecessary work. For this reason, an additional software procedure is being prepared to control the retesting of the legacy codes used in technical products supporting the LA. The legacy code retesting procedure will apply the key steps of AP-SI.3Q, including independent execution of installation test plans and validation test plans to legacy software. Retesting of legacy software, used in technical products supporting the LA, will be completed prior to submittal of the LA.

This letter makes one new regulatory commitment: Retesting of legacy software used in technical products supporting the LA will be completed prior to submittal of the LA.

The DOE considers KTI Agreement TSPA 4.07 to be fully addressed by this letter. With the above commitment, and pending review and acceptance by the NRC, the agreement should be closed. Please direct any questions concerning this letter to Timothy C. Gunter at (702) 794-1343 or Mark C. Tynan at (702) 794-5457.

  
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