

AUG 20 1993

Dr. Budhi Sagar, Technical Director
 Center for Nuclear Waste Regulatory Analyses
 Southwest Research Institute
 6220 Culebra Rd.
 San Antonio, TX 78228-0510

Dear Dr. Sagar:

**SUBJECT: QUALITY ASSURANCE CONTROLS FOR ITERATIVE PERFORMANCE
 ASSESSMENT**

Recently there has been considerable discussion within the Division of High-Level Waste Management (HLWM) regarding the software quality assurance (SQA) requirements for iterative performance assessment (IPA) activities undertaken jointly between NRC and Center for Nuclear Waste Regulatory Analyses (CNWRA) staff members. From these discussions it has become apparent that there are different opinions regarding what level of SQA control is required or appropriate for the development and usage of software for IPA activities.

In an effort to more clearly define the issues affecting the IPA SQA requirements a meeting was held on June 17, 1993. The meeting participants included J. Linehan, M. Federline, N. Eisenberg, K. Hooks and J. Buckley from HLWM and B. Sagar from CNWRA. Discussion at the meeting focused mainly on; 1) the level of software control required of the CNWRA by the contract, and 2) what level of control is appropriate for various phases of IPA activities.

The NRC/CNWRA contract, Section E.2, page 12, states that "All work (ie. data collection, analyses, computations, methods, etc.) conducted under the contract shall be performed in accordance with an accepted QA program addressing the criteria of 10 CFR Part 50, Appendix B, as appropriate..." Software developed and used for IPA Phase 2 activities are controlled by Technical Operating Procedure (TOP) - 018. CNWRA management has determined that controlling IPA Phase 2 software in accordance with TOP-018 satisfies the above stated contractual requirement. It was stated during the meeting that the rationale for this position is documented in the Center Quality Assurance Manual (CQAM), Section 3.6.1. The CNWRA was requested to submit any additional documentation of the rationale supporting this position. The HLWM staff will review CQAM Section 3.6.1 and any additional documentation submitted to evaluate the rationale for use of TOP-018 in a graded approach to fulfillment of the Appendix B requirement.

On July 29, 1993, NRC management determined that IPA Phase 2 activities will continue with the current SQA practices because

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Dr. Budhi Sagar

On July 29, 1993, NRC management determined that IPA Phase 2 activities will continue with the current SQA practices because; (1) software development and use is virtually complete for Phase 2 and the report is in preparation, and (2) NRC management considers the major objective of Phase 2 activities to be staff development exercises intended to develop staff IPA capability.

In an effort to determine what level of control is appropriate for IPA activities, the HLWM QA staff has identified the need to reevaluate the requirement for implementing an Appendix B QA program, as appropriate, for all CNWRA activities. When the NRC/CNWRA contract was written it was intended that the CNWRA would apply the Part 50, Appendix B requirements to the same level as required of the Department of Energy (DOE) and program participants. HLWM will reevaluate this position for the various types of activities conducted by the CNWRA. Joint computer software development activities among the CNWRA, Office of Nuclear Material Safety and Safeguards, and Office of Nuclear Regulatory Research may not have been originally envisioned when the CNWRA contract was initiated and should be addressed in this reevaluation. The CNWRA rationale supporting the implementation of TOP-018 for IPA Phase 2 activities may also be useful in determining what level of SQA control is appropriate for future IPA activities. The results of this reevaluation effort, should be factored in planning activities for IPA Phase 3.

If you have any questions or comments regarding this letter please contact me at (301) 504-3406.

Sincerely,

ORIGINAL SIGNED BY:

John J. Linehan, Deputy Director
Division of High-Level Waste
Management
Office of Nuclear Material Safety
and Safeguards

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