

OCT 14 1988

Mr. Ralph Stein, Acting Associate Director
Office of Systems Integration and Regulations
Office of Civilian Radioactive Waste
Management
U. S. Department of Energy, RW-24
Washington, D. C. 20545

Dear Mr. Stein:

On August 15, 1988, the U. S. Department of Energy (DOE) forwarded Revision 1 of the Nevada Nuclear Waste Storage Investigation (NNWSI) "Quality Assurance Plan" (hereafter the 88-9 QA Plan) for the Yucca Mountain project, for U. S. Nuclear Regulatory Commission (NRC) staff review and acceptance. Our review conclusions are in the enclosed Safety Evaluation (SE). In it, we have concluded that, with the exception of six needed modifications identified in Section V of this evaluation, the 88-9 QA Plan meets the requirements of Subpart G of 10 CFR Part 60 and Appendix B to 10 CFR Part 50, as applicable. Our staffs have recently discussed and agreed on these modifications and incorporating them into the plan should be straightforward.

It was our mutual goal to resolve all open items on the 88-9 QA Plan in our meeting on July 8, 1988 and to issue the SE within 30 days. However, at the conclusion of that meeting, several open items remained. Since that time, our staffs have been discussing approaches for resolving open items. These approaches will be incorporated into the next revision of the 88-9 QA Plan. An alternative approach to resolving these items was for the NRC staff to issue the SE with the open items simply identified, without any expectation that resolution could be achieved quickly. While it has taken more time than originally expected, the approach we selected has led to our agreement on the resolution of all open items and we are optimistic about being able to formally close them out when they are documented.

We request that you provide a revised plan, within thirty days, which incorporates the modifications that the SE describes. The staff will then issue a supplement to the SE that acknowledges that the necessary changes have been made.

DOE may make changes to the 88-9 QA Plan if the changes do not reduce the commitments that DOE previously made to and which were accepted by NRC. Changes that reduce DOE's commitments should be submitted to and accepted by NRC before implementation. A copy of this letter and SE should be included with each controlled copy of the 88-9 QA Plan. One copy should be resubmitted to NRC.

The 88-9 QA Plan addresses, in a general manner, design control and the assignment of quality levels to design phases. At the July 18 and 19, 1988 exploratory shaft facility (ESF) meeting, however, it was established that DOE's approach to implementing ESF design control was unacceptable to the NRC staff. The staff believes that lack of an adequate design control process is a root cause of many of the outstanding ESF design issues. These NRC concerns

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have been expressed in the August 5 and August 22, 1988 letters to you. Since design control is an important element in the repository program, NRC will monitor the implementation of the quality assurance (QA) aspects for design control closely. NRC will consider successful implementation of these aspects a significant factor in determining the acceptability of the overall DOE QA program.

During our review, DOE provided additional clarification on how 10 CFR Part 50, Appendix B, Criteria IX ("Control of Special Processes"), X ("Inspections"), and XI ("Test Control") would be applied to site characterization activities. The additional clarification described how Appendix B controls from these criteria were incorporated into Section III of the 88-9 QA Plan, which addresses scientific investigations. This information was included in the July 15, 1988 meeting minutes for the July 8, 1988 meeting and in the August 15, 1988 DOE submittal of the 88-9 QA Plan to NRC. The NRC staff urges DOE to include this clarification as part of the 88-9 QA Plan. It is a useful explanation for persons using the plan and eliminates possible misinterpretation.

In summary, with the incorporation of the agreed upon modifications to resolve the open items, the staff finds the plan fully acceptable. Should you have any questions on our review, please contact Bill Belke of my staff on (301) 492-0445.

Sincerely,

ORIGINAL SIGNED BY

John J. Linehan, Chief
Project Management and Quality
Assurance Branch
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: L. Barrett, OCRWM
R. Loux, State of Nevada
C. Gertz, DOE/NV

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* See previous concurrence

OFC :HLP	:*HLP	:*HLP	:HLP	:	
NAME:BBelke	:JHolonich	:JKennedy	:JLinehan	:	BJ Youngblood
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Should you have any questions on our review, please contact Bill Belke of my staff on (301) 492-0445.

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John J. Linehan, Chief
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J. Gilray

OGC has no legal objection per Treby on 10/7/88.
JK 10/11/88

OFC : HLOB	: HLOB	: HLOB	: HLOB	:	:	:
NAME: BBelke	: JHolonich	: JKennedy	: JLinehan	:	:	:
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