

MAY 08 1989

Mr. Ralph Stein, 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:

Your letter of April 21, 1989 identified two concerns of the U.S. Department of Energy (DOE) regarding the U.S. Nuclear Regulatory Commission (NRC) staff's understanding of audits of the DOE quality assurance (QA) program. The purpose of this letter is to address those concerns.

The first is related to the staff's intention to audit the Design Acceptability Analysis (DAA), as we indicated in our letter from R. Bernero to S. Rousso of March 1, 1989. You noted that our prior agreement in December 1988 was to conduct a visit to evaluate the DAA, rather than an audit. As I indicated in the January 25, 1989 meeting with DOE on quality assurance, the staff believes it may need to perform an audit of the DAA to gain the necessary confidence to determine whether the DAA was performed satisfactorily. Regardless of the name of this activity, the staff would expect to be able to look at whatever records and talk with whatever DOE or contractor staff are needed for us to make our determination. We are currently evaluating the need for conducting this audit.

Audits give the staff an opportunity to directly evaluate selected areas of the DOE program that we believe are important. Although the staff does some evaluation during its observations of DOE audits, the depth of the evaluation is limited. Therefore, it is important that the staff conduct its own audits in certain areas of the DOE program so that the staff can gain the confidence it needs to assure that DOE is proceeding in an acceptable manner. We would expect DOE to facilitate the performance of such audits.

The second DOE concern is related to the staff's position that DOE qualification audits should include an evaluation of "selected technical products" in order to conclude that a QA program is effective in its implementation. The staff believes it is essential to assess the implementation of the program before considering it to be qualified and before the staff can accept it for new site characterization work or exploratory shaft construction. This should not be a problem for DOE since before new site characterization work (i.e. field and laboratory investigations) is performed, there should be available for audit numerous aspects of program implementation. These include study plans, technical procedures, design drawings, design reports, and design bases documents.

Your letter noted that if little or no technical work were being performed at the time of the original qualification audit, a follow-up implementation audit or surveillance would be necessary prior to program qualification. The staff agrees with this position, provided that any surveillances would be on-site reviews of contractor programs, rather than the surveillances that DOE

has recently performed involving only document reviews. The staff would also observe any surveillances needed to qualify a QA program.

I hope that this information clarifies our positions.

Sincerely,

ORIGINAL SIGNED BY

John J. Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
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- cc: C. Gertz, DOE/NV
- R. Loux, State of Nevada
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