



Department of Energy

Washington, DC 20585

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John Linehan, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level
Waste Management
Office of Nuclear Materials
Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Linehan:

Reference:

- 1) Letter from R.M. Bernero to S. Rousso; dated March 1, 1989; re: SCP Acceptance Review.
- 2) Letter from J.J. Linehan to R. Stein; dated March 23, 1989; re: Qualification Audits.

The purpose of this letter is to address concerns that the Department has related to the Nuclear Regulatory Commission (NRC) staff's apparent understanding of our agreements on the topic of program audits, as indicated in parts of the referenced correspondence.

As part of a discussion of items which could impact NRC's Site Characterization Analysis (SCA) schedule (Reference 1), you indicate that NRC is expecting to conduct an "on-site audit of the DAA" (Design Acceptability Analysis) in mid-April. DOE did not commit to a formal NRC audit for this activity during the discussions related to the DAA. Specifically, step 7 of the DAA process, which was agreed to by the Department and NRC, indicates that "NRC staff will assess the need for it to conduct a visit (emphasis added) to evaluate the QA and technical aspects of the ESF Title I Design and the Design Acceptability Analysis." This was not an agreement for NRC to perform an audit of the DAA.

Your most recent correspondence (Reference 2) indicates that the NRC "will be unable to issue a letter accepting the QA Program" for the upcoming planned series of "qualification audits" anticipating that the audits will not address inclusion of "selected technical products." The designation of a QA program as "qualified" presumes a determination of the adequacy of the program for its intended purpose on the part of both the Department and the NRC (i.e. "NRC acceptance"). Our proceeding with new site characterization activities is predicated on first establishing that we have a "qualified QA program" in place for such activities.

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Your term "selected technical products" promotes considerable uncertainty regarding exactly what "products" the NRC expects to see resulting from the implementation of a QA program before it is qualified. For example, new site characterization technical activities could not be performed because of our commitment to have "NRC acceptance" of a participant's QA program before beginning new site characterization activities. Conversely, we expect that audits would assess approved technical work that is ongoing at the time of the audit. If little or no technical work is being performed at the time of the audit, we agree that a follow up implementation audit or surveillance would be necessary prior to program qualification.

We fully agree that a determination of achievement of a qualified QA program should include evidence of successful implementation. For audits of project participants that are currently planned, DOE is examining all aspects of that program that are being implemented and which have been approved by YMP. These audits will fully address the QA program and its implementation for any technical activities that are being performed under the QA program. In the case of the recent Fenix & Scisson and upcoming Holmes & Narver audits, conducted in the month of April, the amount of technical products audited is very limited. However, we expect that future audits will not be restricted in this manner.

In order to understand your position more completely, it would be beneficial to discuss this matter with the NRC staff. We agree with your suggestion that this would be an appropriate agenda topic for an upcoming QA status meeting. Please contact G. Appel of my staff at 586-1462 or D. Shelor in the Office of Quality Assurance at 586-5851 if you wish to explore this matter further.

Sincerely,



Ralph Stein
Associate Director for Systems
Integration and Regulations
Office of Civilian Radioactive
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cc:

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