



Department of Energy

Washington, DC 20585

OCT 20 1988

Mr. B. J. Youngblood
Deputy
Division of High Level Waste Management
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Youngblood:

The Department of Energy (DOE) has reviewed the Nuclear Regulatory Commission (NRC) document titled "Draft Review Plan for NRC Staff Review of DOE Study Plans and Procedures" and would like to provide comments.

The draft review plan provides a logical explanation of the process that the NRC will utilize for the review of DOE study plans and procedures. The review plan follows the same basic framework as the review process for the Site Characterization Plan (SCP). This rationale is appropriate since study plans and procedures are extensions of the SCP and are intended to provide a greater level of detail than the SCP.

Although stated within the review plan, it is important to reiterate that both study plans and procedures must be reviewed within the context of the entire site characterization program. Reviewers must keep in mind the study plan/procedure's relationship to other study plans/procedures and to the appropriate sections of the SCP and SCP progress reports with which the study is associated.

The DOE is concerned that the draft NRC review plan contains an acceptance review. In the DOE's view this part of the plan is unnecessary and inappropriate during the pre-license application phase as the study plans are provided for information and as a vehicle for the NRC to state regulatory concerns. The positive features of the acceptance review could be blended with the start-work review without loss of time, while still achieving the desired information exchange.

Specific comments, developed during the review of this document, have been provided in the enclosure. I appreciate the

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opportunity to review this document. If you have any questions, please feel free to call Mr. Gordon Appel of my staff at 586-1462.

Sincerely,



Ralph Stein
Associate Director for Systems
Integration and Regulations
Office of Civilian Radioactive
Waste Management

Enclosure: As stated

Comments on Draft Review Plan for NRC Staff Review of DOE
Study Plans and Procedures

1. Page 1, Section 1.0

The introduction accurately summarizes the hierarchy of scientific programs described in the May 7-8 agreement. However, the SCP contains one additional level that is not described. Studies in the SCP are composed of one or more activities which consist of a combination of tests and analyses. The activity level in the hierarchy has not previously been noted in DOE/NRC communications.

2. Page 2, Section 2.2, 4th Item

This section of the draft review plan states that an objective of the NRC review is to: "Evaluate whether an adequate quality assurance (QA) program is in place for the study." This objective will be difficult to achieve through the review of the study plan. The evaluation of whether an adequate QA program is in place should be performed at the program level, not at the study level. The study plan should be reviewed to determine if appropriate QA program requirements have been adequately implemented for the study.

The 4th item should be revised to read: "Evaluate whether adequate quality assurance requirements have been imposed for the study".

3. Page 3, Section 3, 2nd Paragraph

The draft review plan does not accurately reflect the commitments of the May 7-8, 1986 Level-of-Detail meeting. The review plan states that "the NRC staff expects to receive a study plan six months before work is initiated under the study plan as agreed to during the Level-of-Detail meeting." Although this statement is correct, the actual agreement of the Level-of-Detail meeting as interpreted from the meeting minutes was as follows:

- o The study plans for Exploratory Shaft studies and those studies to be initiated within one year of the SCP issuance will be issued with the SCP or as soon as possible after SCP issuance.
- o The study plans for those studies that are presently ongoing and will continue past the date of SCP issuance will be issued with the SCP.

- o The study plans for those studies to be conducted beyond one year of the SCP issuance will be issued at least six months prior to the start of the study.
- o The study plans for new studies that will be initiated prior to the SCP issuance should be developed in consultation with the NRC and provided to them for review before initiating the study.

The draft review plan should be revised to reflect the correct Level-of-Detail meeting agreements.

4. Page 3, Section 3.0, 2nd Paragraph; Page 5, Section 5.1, 1st Paragraph; Page 6, Section 5.3, 6th Item

The draft review plan states that the NRC will provide objections regarding a study plan within three months of receipt of the plan. We anticipate that comments and questions also will be provided at this time. Objections are commonly derived from comments and questions that arise during a review. Therefore, if significant comments and questions exist, the NRC should provide them, along with the objections.

5. Page 3, Section 4.0

During the pre-license application period of site characterization, exchanges between DOE and NRC are viewed as 'informal' as opposed to the later, 'formal' exchanges following license application. In this light the rationale for an acceptance review is unclear for the pre-licensing phase of the program contained in the study plans. If a study plan should be received by NRC and require additional information, it is believed that the missing information could be provided while the review proceeds. Thus, the DOE believes the Acceptance Review process should be blended into the Start-Work Review process.

6. Page 3, Section 4.2.1, 2nd Item

The draft review plan states that the DOE will supply a copy of all references cited in the study plan at the time it is issued. This expectation is not part of the Level-of Detail meeting agreement. The DOE agreed to supply all the references cited in the SCP at the time that document is issued, but did not commit to providing study plan references. The majority of study plan references will most likely have been provided with the SCP. However, if during their review, the NRC should find it necessary to review a reference that is not available the specific reference from the DOE will be provided. But, again, we believe the review should proceed.

7. Page 5, Section 5.2.1, 3rd Item

This section states that the "study plan should present a quality assurance program adequate to ensure that the studies . . . will produce data of demonstrably high quality usable for licensing". As noted in Comment 2, the QA program should be reviewed at the program level rather than the study plan level. In addition, Attachment 4 to the May 7-8, 1986 NRC/DOE Level-of-Detail meeting minutes indicates that the applicable QA requirements need only to be referenced in the study plans.

It is suggested that the 3rd item should be revised to state: "The study plan should reference the applicable specific QA requirements to be imposed to ensure that the studies . . . will produce data of demonstrably high quality usable for licensing".

8. Page 6, Section 6.1

The decision to perform a detailed technical review of only selected study plans is appropriate. However, the criteria for selecting which plans will receive the detailed review should be provided. The draft review plan states that study plans will be selected for further review if they are related to "one or more key site-specific issues" or "relative to NRC licensing concerns." The NRC should define the key issues and licensing concerns.

It is suggested that in order to expedite DOE preparation and NRC review of the study plans, the licensing concerns and key issues should be clearly defined upon completion of the NRC review of the Consultation Draft SCP and subsequent technical meetings with the DOE. An early indication by the NRC of which study plans they are particularly concerned with will enable the DOE to address such concerns in a timely manner.

9. Page 8, Section 6.3, 6th Item

This item states that the NRC will provide DOE with a letter "containing the results of the Detailed Technical Review and requesting the procedures identified as a result of the review." What procedures will be requested? Per the Level-of-Detail Meeting agreements, the DOE will issue a study plan six months prior to the study's scheduled start date and any non-standard procedures 60 days prior to the start date. Therefore, the NRC should be in possession of the necessary procedures for review 60 days before the scheduled completion of the study plan review. The DOE recognizes that the NRC may request additional procedures and we will promptly respond. However, the initiation of the study should not be delayed to provide additional time for review of the requested procedures.

10. Page 9, Section 7.3

In discussing the requirements for procedure reviews, there is no step for informing the DOE of objections to a procedure within the 30 day timeframe agreed to during the May 7-8, 1986 Level-of Detail meeting.

11. Page 10, Section 8.0

This section indicates that the NRC will solicit the concerns of States and Indian Tribes during their review of study plans. The NRC should seek to develop comments, and questions, with appropriate consideration of States and/or Indian Tribes concerns in a period of time consistent with the May 7, 8 agreement.

12. Page 10, Section 9

The draft review plan does not recognize that some studies are presently ongoing, while others are yet to be initiated. Ongoing studies will not be suspended until their study plans have been reviewed. The review plan should emphasize the existence of ongoing studies.

For example, the draft review plan states that "the NRC review of the study plan is to be completed before the work described in the study plan is scheduled to begin." This statement is NRC's commitment to a timely review. However, it may be appropriate to clearly state that DOE does not need to delay its planned activities beyond the agreed schedule while NRC completes its review.