



Department of Energy
Washington, DC 20585

MAY 8 1991

Mr. John J. Linehan
Deputy Director
Division of High-Level
Waste Management
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Linehan:

In October 1990, the Yucca Mountain Site Characterization Project Office (YMPO) sent to your office a set of three controlled copies of a study plan prepared by the U.S. Department of Energy (DOE) for the Yucca Mountain Site.

Since the study plan was not sent through this office, it was not considered an official transmission. This office has now received confirmation that YMPO wishes the study plan indicated below to be officially transmitted. This office requests that NRC consider the copies of the study plan, received in October 1990, to be officially transmitted by the DOE as of the date of this letter. The study plan numbers correspond to the same numbers used in the Site Characterization Plan (SCP) for the Yucca Mountain Site. The study plan is identified as follows:

<u>Number</u>	<u>Title</u>
8.3.1.2.2.7, Revision 0	Study Plan for Hydrochemical Characterization of the Unsaturated Zone

DOE has reviewed the study plan for consistency with the content requirements for study plans, as given in Attachment B to the Summary of the DOE/Nuclear Regulatory Commission (NRC) meeting on the Level-of-Detail for the SCP (May 7-8, 1986). DOE is submitting these plans to NRC as agreed to in the meeting.

As discussed during the DOE/NRC meeting (December 15, 1988) on study plans, DOE has decided to control preparation and review of study plans as a quality activity. Because this study plan was in preparation prior to that decision, it was not prepared under current Project Office and DOE Headquarters quality assurance (QA) procedures. During the December 15, 1988, meeting on study

plans, DOE agreed to prepare an assessment of the five construction phase Exploratory Shaft Facility study plans relative to current QA requirements. This assessment was transmitted to you on June 23, 1989. An abbreviated quality assessment, similar in intent and complementary to the earlier assessment, has been performed for Study Plan 8.3.1.2.2.7 and is enclosed with this letter. This evaluation has been performed under current Office of Civilian Radioactive Waste Management (OCRWM) QA procedures. Results of this quality assessment indicated that the plan listed above meets all major quality assurance requirements for planning documents and is of sufficient technical quality for NRC review.

Please note that the Quality Assurance Level Assignments (QALAs) for the activities to be performed under this study plan are included as part of a QA appendix to the study plans. These QALAs were included in the study plans to satisfy the May 7-8, 1986, Level-of-Detail Agreement for content of study plans. As you are aware, DOE is currently in the process of implementing QA procedures that are consistent with approved OCRWM QA requirements and NUREG 1318. Following the implementation of these procedures, DOE will reevaluate existing QALAs as appropriate. All study plans will be distributed as controlled documents, and, as such, any revision to the study plans and appended QALA lists will be distributed as controlled documents.

It should also be noted that there are some inconsistencies in the milestone report titles and schedules given in this study plan and those in the SCP. Study plans, in general, represent a further evolution of the study in the areas related to schedules and milestones relative to the SCP, and, as such, represent DOE's current plans. A status on the schedule for preparation, review and approval of study plans is provided in site characterization progress reports.

Should you have any questions, please contact Sharon Skuchko of my office at (202) 586-4590.

Sincerely,



Linda J. Desell, Acting Chief
Regulatory Integration Branch
Office of Systems and Compliance
Office of Civilian Radioactive
Waste Management

Enclosure:

Study Plan Assessment for Study Plan 8.3.1.2.2.7, Revision 0,
"Hydrochemical Characterization of the Unsaturated Zone"

cc w/copy of Enclosure:

Arturo Ramose, CNWRA, San Antonio, TX

R. Loux, State of Nevada

M. Baughman, Lincoln County, NV

D. Bechtel, Clark County, NV

S. Bradhurst, Nye County, NV

P. Niedzielski-Eichner, Nye County, NV

Study Plan Assessment for
8.3.1.2.2.7: Hydrochemical Characterization
of the Unsaturated Zone

1. Introduction

The Nuclear Regulatory Commission (NRC) has expressed a concern that the quality assurance (QA) Level II controls used to prepare and review the five construction phase Exploratory Shaft Facility (ESF) Study Plans may not have been adequate and therefore the technical quality of the documents should be assessed and verified (DOE, 1989). Study Plans prepared under QA Level II controls were partially prepared and reviewed prior to the effective dates of Revision 1 of the OCRWM QA Requirements Document (QARD), Revision 2 of the Project Quality Assurance Plan (QAP), NNWSI/88-9, the Yucca Mountain Project Administrative Procedure (AP)-1.10Q (Preparation, Review and Approval of SCP Study Plans), and the HQ Implementing Line Procedure (ILP) 22.3.1 (DOE/HQ Review of Study Plans). NNWSI/88-9 became effective December 9, 1988, and AP-1.10Q was approved December 14, 1988.

This document provides the Yucca Mountain Site Characterization Project Office assessment of Study Plan 8.3.1.2.2.7 and associated documentation of the DOE process for preparation and review against current QA requirements. The purpose of this assessment is to evaluate the controls that were in place during the development of this Study Plan and to determine whether the document is of the technical quality expected under QA level I controls.

2. Evaluation of Study Plan 8.3.1.2.2.7

2.1 Basis for the Assessment

Since the responsibility for preparation and review of Study Plans has been delegated by OCRWM to the Project Office, the evaluation is based on the requirements established in the Project Office QA Plan, NNWSI/88-9, Revision 2, which was accepted by the NRC on December 30, 1988. A fundamental premise of this assessment is that Study Plans developed in accordance with NNWSI/88-9 are adequate to meet NRC requirements. To support this premise, OCRWM maintains documentation that relevant requirements established in NNWSI/88-9, Revision 2, were not reduced in subsequent revisions, nor in the consolidated OCRWM and Project Office QA Requirements contained in the QA Requirements Document (QARD), Revision 4. NNWSI/88-9 imposed several requirements on the preparation, review and approval of Study Plans:

- 1) Study Plans must be prepared and reviewed by qualified personnel.
- 2) The format and content of Study Plans must meet all applicable requirements (including specific provisions for technical, regulatory and quality-related content).
- 3) The process of development, review, approval, issuance and revision must be controlled.

- 4) Records documenting that all the requirements have been met must be maintained.

The following section summarizes the controls that were in place during the preparation and review of this Study Plan and provides an evaluation of these controls against the relevant requirements of the OCRWM QARD.

2.2 Description of the Review Process

At the time that this Study Plan was prepared by the United States Geological Survey (USGS), procedures for qualification of personnel, and for technical review of plans and procedures governed by the USGS QAP were in effect at the USGS (DOE, 1989). The review procedure required independent and documented technical review by qualified reviewers. At this time, however, Study Plan reviews were governed by DOE procedures rather than the USGS QAP. The USGS desk procedure for study plan preparation and review was issued on November 16, 1987. This procedure required that study plans be prepared in accordance with the DOE/NRC Agreement guidance and that study plans be reviewed in accordance with the USGS technical review procedure (DOE, 1989).

The USGS submitted an initial draft of the study plan to the Project Office on October 24, 1988. The Project Office completed an acceptance review of the study plan on November 4, 1988 and initiated a technical review on November 18, 1988. The Project Office technical review was conducted by three technical specialists following draft procedures defined in Revision 2 of the SCP Management Plan (effective date: April 21, 1988). These reviewers generated 85 comments which were documented, including final dispositions, on comment resolution forms. This technical review was completed and the results were forwarded to the USGS on February 21, 1989.

The study plan was forwarded to DOE/HQ for its review on November 21, 1988. The DOE/HQ review was governed by its revised final procedure for DOE/HQ approval of study plans, which became effective on April 14, 1987, and by the July 26, 1987, clarification of the final procedure (DOE, 1989). DOE/HQ provided nine technical specialists who generated 101 comments that were documented on comment resolution forms.

The Project Office initiated an AP-1.10Q management, regulatory, and QA review of the Study Plan on February 23, 1989. Because of the previous Project technical review, the AP-1.10Q screening and technical reviews were judged not necessary. The plan was reviewed by three reviewers who made 49 comments (22 management, 24 regulatory, and 3 QA).

A comment resolution meeting was held with DOE/HQ on March 29-31, 1989, to develop proposed resolutions to each comment. The USGS then revised the Study Plan to address the DOE/HQ comments. The revised study plan was submitted to the Project Office on July 31, 1989. The final disposition of each comment was documented on comment resolution forms and the DOE verified the resolution of each comment prior to approving the Study Plan.

2.3 Evaluation of the Technical Quality of the Study Plan

The requirements of the participant, Project Office, and DOE/HQ implementing procedures for Study Plan development are summarized in the Study

Plan Assessment for the Five Construction Phase Study Plans for the Exploratory Shaft Facility (DOE, 1989). For this assessment, these requirements were compared against the requirements of NNWSI/88-9. The USGS, the Yucca Mountain Project, and the DOE/HQ procedures for Study Plan preparation, review and approval adequately implement the applicable requirements of NNWSI/88-9 (DOE, 1989).

Although some minor revisions will be made to the DOE and participant procedures to improve the implementation of the relevant QA requirements, these changes would not affect the technical content of Study Plan 8.3.1.2.2.7. Documented, traceable technical reviews were completed by qualified reviewers; the Study Plan was also reviewed by QA and regulatory specialists, and management. The Project Office and DOE/HQ technical comments were reviewed and were found to constitute an adequate detailed technical review of the plan. The review process described above supports the conclusion that the technical quality of this Study Plan was not adversely impacted by the quality controls that were in place when the document was written and reviewed.

3. Summary and Conclusions

The DOE believes that the preparation and review of Study Plan 8.3.1.2.2.7 were substantially in accordance with AP-1.10Q and ILP 22.3.1, which implement the NRC-reviewed and accepted controls described in the OCRWM QARD. This assessment demonstrates that the development of the Study Plan was conducted under quality controls that were equivalent to those which would be found in a QA Level I program. Moreover, this assessment of the Study Plan and associated quality assurance records indicate that the technical content of the Study Plan would not change in any substantive way if the development of the Study Plan had been completed at QA Level I. The DOE considers this Study Plan to be technically acceptable for NRC review. The four requirements that provide the bases for this assessment have been fulfilled.

4. References

U.S. Department of Energy, Yucca Mountain Project Office,
Administrative Procedure (AP)-1.10Q, Preparation, Review and Approval of SCP
Study Plans, Revision 0.

U.S. Department of Energy, OCRWM Implementing Line Procedure, DOE/HQ Review of
Study Plans, (ILP)-22.3.1, DOE/RW-0246.


U.S. Department of Energy, Yucca Mountain Project Office,
Quality Assurance Plan, NNWSI/88-9, Revision 2.

U.S. Department of Energy, Yucca Mountain Project Office (DOE), 1989, DOE Assessment of the Process Used to Review and Approve the Five Construction Phase Exploratory Shaft Study Plans.

U.S. Department of Energy, OCRWM Quality Assurance Requirements Document, DOE/RW-0214.

Approval:

 **ACTING**
Chief, Regulatory Interactions Branch 3/4/91


Director, Regulatory and Site Evaluation Division 3/4/91


Director, Quality Assurance 3/6/91