REVIEW PLAN FOR

NRC STAFF REVIEW OF DOE

STUDY PLANS

Revision 1

December 6, 1990

DIVISION OF HIGH-LEVEL WASTE MANAGEMENT
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

ENCLOSURE

TABLE OF CONTENTS

1.0 INTRODUCTION

The Department of Energy (DOE) is responsible under the Nuclear Waste Policy Act of 1982 (NWPA) for carrying out a comprehensive national program that has as its goal the eventual construction of geologic repositories for the permanent disposal of high-level nuclear waste. The program has advanced to the site characterization stage, during which DOE is to conduct activities intended to collect the information necessary to determine if the site is suitable and to support a license application for a geologic repository.

The DOE has developed a Site Characterization Plan (SCP) for the Yucca Mountain, Nevada proposed geological repository site which describes in broad detail how DOE intends to obtain the needed information. Programs, such as the geology program, and investigations, which consist of one study or a set of related studies, are presented in the SCP, in accord with agreements reached in the May 7-8, 1986 NRC-DOE Level of Detail for Site Characterization Plans and Study Plans Meeting (hereafter Level of Detail Meeting); however, the finer level of detail about DOE's plans, and in particular, how the investigations are to be carried out, is to be presented in study plans that are being issued subsequent to issuance of the SCP.

A study has specific objectives that, if achieved, contribute to meeting the broad objectives of the investigation with respect to obtaining an adequate understanding of the site. Studies are comprised of one or more activities, each of which is intended to provide certain data or knowledge necessary to satisfy the objectives of the study. Each activity is a combination of tests and analyses which deal with a single or several related objectives within a given area. A test consists of a combination of procedures (detailed stepwise processes specifying how a test will be conducted) that produces information about some parameter through one or more experiments. An analysis consists of an assessment of test results through calculations, modeling, or technical judgment. Details for studies, activities, tests, and analyses will be presented in the aforementioned study plans; individual test procedures will be identified in both the SCP and study plans.

During the Level of Detail Meeting, agreement (hereafter the Agreement) was reached and documented in the meeting summary (Enclosure 4, Attachment B to that summary) on the content of study plans. Appendix A to this Review Plan consists of a table comparing the level of detail required in study plans with that required in the SCP descriptions of investigations.

As indicated above, the study plans (in this review plan, the term study plan includes its supporting references and procedures) document how DOE plans to implement the site characterization program DOE has designed to resolve the issues related to regulatory requirements that DOE identified in the SCP. The NRC staff's independent evaluation of DOE's program to resolve these issues will give guidance to DOE that is intended to result in DOE submitting a

complete and high quality License Application. This in turn will help assure that the NRC staff will be able to make a decision regarding construction authorization within the three-year statutory licensing time period.

NRC concerns, i.e., objections, comments, or questions (as these terms are defined in Appendix B to this Review Plan) that the staff presents in its written review of any study plan or procedure will be entered in the Open Item Tracking System (OITS) that is being used to track the progress toward resolution of NRC open items. These include the objections, comments, and questions presented by the staff in the Site Characterization Analysis (SCA) of the SCP, as well as other NRC open items from NRC-DOE interactions and NRC reviews of DOE documents. The new open items identified during the review of a given study plan have the same significance and are to be tracked just as the SCA open items and other NRC open items. Furthermore, the staff review of a particular study plan may result in closure of some SCA or other NRC open items if DOE has proposed certain items be closed based upon the material in the study plan.

This Review Plan for NRC Staff Review of DOE Study Plans provides guidance for the NRC staff designed to assure the quality and consistency of reviews of any study plan submitted by DOE and thereby fulfills the internal quality assurance function for review of major DOE HLW documents mandated in the Division of High-Level Waste Management Internal Quality Assurance (IQA) Plan. This plan also serves as documentation for later reference during the licensing process of the way in which the NRC staff reviewed study plans.

This review plan replaces the Draft Review Plan for NRC Staff Review of DOE Study Plans and Procedures issued in December 1987. Numerous significant changes have been incorporated into the new review plan. The most significant change involves streamlining of the review process in two respects. Whereas the 1987 review plan contained a three-phase review process (Acceptance Review; Start-Work Review; Detailed Technical Review) of study plans, the new review plan contains a two-phase review process (Phase I Review; Detailed Technical Review), wherein the Phase I Review represents a combination and modification of elements of the original Acceptance and Start-Work Reviews. In addition, whereas the 1987 review plan delineated a separate Procedure Review, the new review plan has absorbed the review of procedures into the Detailed Technical Review.

Concomitant with the streamlining of the review process, the format of the review plan has been simplified. The Review Guides which appeared in the old review plan have been eliminated in favor of an approach that more directly conveys the substance of the reviews.

Other important changes reflected in the new study plan include an increased emphasis during the reviews on evaluation of the study plans for potential progress toward resolution of SCA or other NRC open items. Also, the IQA

responsibilities of NRC staff and management involved in the reviews have been more clearly defined. In addition, a section has been added to the review plan to cover staff interactions with the Advisory Committee on Nuclear Waste (ACNW) regarding staff reviews of study plans.

2.0 PURPOSE, OBJECTIVES, AND SCOPE

2.1 Purpose

The general purpose of the NRC review of the study plans is to continue the NRC staff's efforts since passage of the NWPA toward early identification and resolution of potential licensing issues during the pre-licensing part of DOE's HLW program. During these reviews, the NRC staff intends to identify any significant concerns with DOE's plans to gather the information that DOE indicated in the SCP is needed to resolve licensing issues or to gain an adequate understanding of the site.

2.2. Objectives

To accomplish the purpose of the NRC staff review of the study plans, the following specific objectives must be achieved:

1. Determine whether the content of the study plan is substantively consistent, as appropriate for the activities, tests, and analyses described, with the Agreement.

2. Evaluate whether the objectives of the study plan are consistent with those proposed in the investigation plan presented in the SCP and whether the objectives of the study plan are technically defensible in the context of the overall site characterization program.

3. Assess whether the activities, tests, and analyses presented in the study plan could have significant unmitigable adverse effects on the waste isolation capabilities of the site.

4. Evaluate, to the extent possible based upon the SCP and available study plans, whether the activities, tests, and analyses presented in the study plan could significantly interfere with or be interfered with by other site characterization testing and/or construction of the exploratory shaft facility (ESF) such that the ability to obtain information needed for licensing is precluded.

5. Determine whether the study plan was developed under an acceptable QA program and whether it references a QA program that is in place and accepted by NRC to provide assurance that the activities, tests, and analyses comprising the study plan can produce data of demonstrably high quality usable for licensing.

6. Evaluate whether the proposed use (if any) of radioactive materials in testing is necessary to obtain the information that the study is designed to obtain.

7. For any study plan selected for detailed technical review (see sections 3.0 and 4.2 for selection criteria), evaluate the extent to which the activities, tests, and analyses presented in the study plan will enable DOE to obtain the information for licensing that the study is designed to obtain and that it should obtain.

8. If DOE has proposed that one or more NRC open items be closed on the basis of the material in the study plan, determine whether those items can be closed.

9. For any study plan selected for detailed technical review, evaluate whether progress toward resolution of any SCA or other NRC open items can be identified on the basis of the contents of the study plan.

10. Document review results in a review package for transmittal to DOE. For any study plan selected for detailed technical review, document results of that review in a separate review package.

11. Enter new concerns and progress toward resolution of existing concerns into the OITS.

2.3 Scope

In accord with this Review Plan, the review of a study plan should consider whether it meets the requirements for content of study plans in the Agreement and whether it can result in obtaining the information to fulfill its objectives. It should be considered as well in terms of its relationship to appropriate parts of the SCP and SCP progress reports (e.g., the investigation that the study is implementing; relevant portions of the performance allocation process). In addition, a study plan is to be examined relative to other available study plans which are designed to acquire complementary information or which propose testing that could interfere with or be interfered with by the testing in the particular study plan under review. A study plan is also to be examined for potential progress toward resolution of NRC open items, especially if DOE has proposed closure of one or more NRC open items on the basis of the material in the study plan.

3.0 GENERAL APPROACH

The NRC staff will perform a Phase I Review of all study plans issued by DOE. The Phase I Review is to confirm that a particular study plan contains the material specified in the Agreement on the content of study plans. The NRC staff will also review relevant QA documents, such as QA audit and surveillance reports, to assure that there are no QA open items that could significantly

affect the quality of the study plan or the work to be conducted under the study plan. In addition, the Phase I Review is to identify objections (as defined in Section 4.1.2 and Appendix B) with respect to the study, and to evaluate whether any open items that DOE has proposed for closure on the basis of the study plan may be closed. Results of the Phase I Review are to be transmitted to DOE ordinarily within two months of NRC receipt of the study plan.

A second review phase, which will be undergone by only selected study plans, is a Detailed Technical Review to evaluate in detail the adequacy of a given study to provide the information for licensing that it should provide and that it is designed to provide. Study plans that are related to key site-specific issues or NRC open items or that feature unique, state-of-the-art test or analysis methods are typical candidates for this second phase of review. Results of the Detailed Technical Review are to be transmitted to DOE ordinarily within four months of NRC receipt of the study plan and any procedures requested by NRC.

4.0 PHASE I REVIEW

4.1 Specific Approach

4.1.1 Evaluation of Study Plans Relative to the Agreement and to the Responsible DOE Contractor's QA Program (Reference Section 2.2, Objectives 1 and 5)

In the Level of Detail Meeting, agreement was reached on the content requirements for descriptions in study plans (Enclosure 4, Attachment B of the Meeting Summary; Appendix A of this Review Plan). One aspect of the Phase I Review (and the first part of the review to be done) is to determine if the content of the study plan under review is reasonably consistent, as appropriate for the activities, tests, and analyses described, with the Agreement. This will be more than a simple check of the table of contents to note whether items have been addressed; it will also be to determine if the material provided is substantive enough for NRC staff resources to be productively used in continuing the Phase I Review of the document. This implies that all key supporting study plan references not already provided by DOE or not readily available in the open literature need to be provided to NRC at the time the study plan is issued.

This first part of the Phase I Review also involves a check to confirm that there are no open items relative to the QA program of the DOE contractor responsible for the study plan that could call into question the quality of the study plan. If such open items are found to exist, there will be no basis for NRC staff resources to be committed to continuing the Phase I Review of the study plan until those QA-related open items have been resolved.

4.1.2 Identification of Objections (Reference Section 2.2, Objectives 2-6)

Assuming that the Phase I Review continues, a second aspect of the review is the identification of any objections to the study plan. An objection is a concern with the DOE program as presented in the study plan related to either: (1) potential adverse effects on repository performance; (2) potential significant and irreversible/unmitigable effects on characterization that would physically preclude obtaining information necessary for licensing; (3) potential significant disruption to characterization schedules or sequencing of studies that would substantially reduce the ability of DOE to obtain information necessary for licensing; or (4) inadequacies in the QA program which must be resolved before work begins. Objections are reserved primarily for concerns with activities, tests, and analyses which, if started, could cause significant and irreparable adverse effects on the site, the site characterization program, or the eventual usability of the data for licensing (programmatic fatal flaws). Due to the irreparable nature of objections, NRC would recommend that DOE not start work until the objections are satisfactorily resolved. If objections are identified by the staff, they are to be transmitted in writing to DOE in the letter containing the results of the Phase I Review.

4.1.3 Closure of NRC Open Items (Reference Section 2.2, Objectives 8 and 11)

If DOE has proposed in its letter transmitting the study plan that one or more NRC open items be closed based upon material in the study plan and its supporting references, a third aspect of the Phase I Review is the NRC staff's determination whether it agrees with DOE that those open items are closed. The NRC staff is to review the material presented to support resolution and needs to indicate (a) agreement on complete or partial closure (certified by signature of the appropriate Section Leader and Branch Chief) and, if necessary, an explanation of why the material provided for closure is inadequate; or (b) disagreement on closure and an explanation of why the material provided for closure is inadequate. The results of the NRC staff evaluations will be recorded in OITS and included in the letter to DOE containing the results of the Phase I Review.

4.2 Activities/Products

The Phase I Review is to consist of the following steps:

1. The Project Manager (PM) transmits the study plan to the QA Section Leader and to the Section Leader whose Section is to be responsible for providing the technical lead for the review.

2. The QA Section Leader and the appropriate technical Section Leader appoint the QA reviewer and the technical lead (henceforth "lead") respectively. The activities of the lead throughout the review are to be coordinated with the lead's Section Leader. The PM confirms

that the lead, the QA reviewer, their Section Leaders, and any other staff members involved in the review have read and understand this Review Plan.

3. The PM, lead, and the lead's Section Leader briefly scan the study plan to determine whether there are obvious major concerns that need to be called to the attention of DHLWM management. In addition, they ascertain, based upon the amount, substance, and complexity of the material provided, whether it will be necessary to seek assistance from other Sections in DHLWM, other parts of the NRC (e.g., Office of Research), or from the Center for Nuclear Waste Regulatory Analyses (CNWRA), and recommend to DHLWM management a schedule for completion of the review. The PM arranges through appropriate channels for whatever outside assistance is deemed necessary. Further assistance may be sought by the PM at any time during the review if a need for it is identified.

4. The lead and the QA reviewer review the study plan relative to the Agreement and to the responsible DOE contractor's QA program under which the study plan was developed (see Section 4.1.1 of this Review Plan). If significant deficiencies are not found, the review continues (Proceed to Step 5). If significant deficiencies are found, such that in the judgment of the reviewers, their Section Leaders, and the PM further review of the study plan cannot productively be done, the PM documents the deficiencies and this conclusion in a letter he prepares for the Project Director to transmit to DOE.

5. The lead, the QA reviewer, and any other technical reviewers review the study plan to determine whether there are any objections with respect to it. The QA reviewer particularly checks relevant QA audit and surveillance reports to ascertain whether there are any open items related to the QA program of the responsible DOE contractor that could call into question the quality of the activities, tests, and analyses to be conducted under the study plan. The reviewers may at this stage also identify procedures that need to be be reviewed. The PM requests these procedures from DOE.

6. The lead and any other technical reviewers review the study plan as a candidate for detailed technical review. If the study plan (1) may be related to one or more key site-related issues, (2) pertains to some NRC open items, (3) describes unique, state-of-the-art test or analysis methods that therefore do not have a supportive scientific history of providing data usable in licensing, (4) describes a study critical to evaluation of site performance that cannot be repeated for a number of years due to its disruption of the natural baseline,

or (5) has some other critical relationship to potential licensing concerns, the study plan is a viable candidate for detailed technical review.

7. The lead briefs the PM and appropriate Section Leaders on the results of the Phase I Review and makes a recommendation about whether a Detailed Technical Review of the study plan should be conducted. The PM and appropriate Section Leaders consider the recommendation of the lead and, with appropriate recognition of the budgetary and resource limitations on the number of Detailed Technical Reviews that can be supported, recommend to DHLWM management whether a Detailed Technical Review is warranted.

8. If DOE has proposed that one or more NRC open items should be considered closed based upon the material in the study plan and its supporting references, the lead and other technical reviewers as appropriate review the material related to those open items and determine whether the NRC staff agrees that they are closed.

9. The lead prepares a package containing the results of the Phase I Review, including (1) objections, as defined in Section 4.1.2 and Appendix B, and written in the format of the SCA open items, (2) a recommendation concerning the need to conduct a Detailed Technical Review of the study plan and the rationale for that recommendation, and (3) if applicable, whether the NRC staff agrees with DOE's proposed closure of NRC open items based on the study plan and its references. The lead incorporates the comments of all reviewers and resolves any significant comments raised during the Section Leader/PM briefing. He transmits this package to his Section Leader for review.

10. The Section Leader reviews the package, coordinates any changes needed with the technical lead, and transmits the package to his Branch Chief for review.

11. The Branch Chief reviews the package and transmits it to the Project Director, with a copy sent to the PM.

12. The PM determines whether the DHLWM Director and Deputy Director want to be briefed on the results of the Phase I Review. The lead briefs them if they so desire.

13. The PM prepares a letter from the Project Director to DOE containing the results of the Phase I Review and informing DOE whether a Detailed Technical Review of the study plan will be conducted. The letter may also request any procedures needed for review if those have not already been requested by the PM.

14. The Project Director issues the cover letter and review package to DOE with copies to the State and affected units of local government and Indian Tribes.

15. PM arranges to have objections placed in the OITS and to have the closure of any open items based on the Phase I Review recorded there. Agreement that an open item is partially or totally closed is certified by signatures of the appropriate Section Leader and Branch Chief.

5.0 DETAILED TECHNICAL REVIEW

5.1 Specific Approach

5.1.1 Evaluation of Study Plan Relative to Obtaining Data Needed for Licensing (Reference Section 2.2, Objective 7)

A primary objective of the Detailed Technical Review is to evaluate in detail whether the activities, tests, and analyses comprising that study plan are adequate to provide the data for licensing that the study plan should provide and that it was designed to provide. If the staff perceives that execution of the activities, tests, or analyses as presented would not achieve their intended purpose, or that that intended purpose is not consonant with the information needed for licensing, comments or questions (as defined in Appendix B) documenting such concerns will be transmitted in the letter to DOE containing the results of the Detailed Technical Review.

5.1.2 Evaluation of Progress toward Resolution of NRC Open Items (Reference Section 2.2, Objective 9)

The study plans provide a greater level of detail about implementation of DOE's site characterization plan than was contained in the SCP, and as such, may contain information relevant to certain open items being tracked in OITS. If, in its transmittal letter, DOE has proposed closure of any open items based upon material in the study plan, the staff evaluated the status of those open items in the Phase I Review (Section 4.1.3). However, even if DOE did not make such proposals, a second objective of the Detailed Technical Review is for the NRC staff to examine the study plan in the context of progress toward resolution of open items. Such progress may form the basis for interactions with DOE leading to ultimate resolution of the open items and therefore needs to be recorded in OITS and documented in the letter to DOE containing the results of the Detailed Technical Review.

5.2 Activities/Products

The Detailed Technical Review is to consist of the following steps:

1. PM, lead, and the lead's Section Leader scope the review and determine whether assistance is needed from other disciplines in DHLWM, other parts of the NRC (e.g., Office of Research) or the Center for Nuclear Waste Regulatory Analyses (CNWRA), and recommend to DHLWM management a schedule for completion of the review. The PM arranges through appropriate channels for whatever outside assistance is deemed necessary.

2. Reviewers conduct review of activities, tests, and analyses for adequacy to obtain the licensing information sought and that should be sought. As part of this activity, they may identify procedures (in addition to those obtained from DOE during the Phase I Review) they wish to have furnished by DOE. The PM requests the needed procedures from DOE.

3. Reviewers examine the study plan for progress (other than that already identified in the Phase I Review) toward resolution of NRC open items.

4. Procedures selected for detailed review are evaluated for their technical acceptability to obtain data usable in licensing.

5. Lead, in coordination with his Section Leader, prepares draft comments and questions (both terms as defined in Appendix B), incorporating those of all reviewers.

6. Lead briefs PM and appropriate Section Leaders on comments and questions resulting from the Detailed Technical Review.

7. Lead prepares revised draft of comments and questions, resolving any significant comments raised during the Section Leader/PM briefing. He transmits the package to his Section Leader for review.

8. The Section Leader reviews the package, coordinates any needed changes with the lead, and transmits the package to his Branch Chief for review.

9. The Branch Chief reviews the package and transmits it to the Project Director, with a copy sent to the PM.

10. The PM determines whether the DHLWM Director and Deputy Director want to be briefed on the results of the Detailed Technical Review. If they so desire, the lead briefs them.

11. PM prepares a letter from the Project Director to DOE containing the results of the Detailed Technical Review.

12. Project Director issues the cover letter and review package to DOE with copies sent to the State and affected units of local government and Indian Tribes.

13. PM updates the OITS by arranging for entry of the new open items resulting from the Detailed Technical Review and for recording of progress toward resolution of the existing open items based on the Detailed Technical Review.

6.0 INTERNAL QUALITY ASSURANCE (IQA) REQUIREMENTS/RESPONSIBILITIES/RECORDS FOR STUDY PLAN REVIEWS (PHASE I AND DETAILED TECHNICAL REVIEWS)

6.1 IQA Requirements

In accord with the IQA plan for DHLWM, IQA requirements for Phase I and Detailed Technical Reviews of study plans are as follows:

1. Before the technical reviewers begin their review, ensure through a required reading of this Review Plan and subsequent group question-and-answer sessions that they have familiarized themselves with this Review Plan.

2. Conduct the reviews and develop the review packages consistent with this Review Plan.

3. Conduct IQA reviews of the review packages using the following review criteria:

   a. Technically defensible;

   b. Accurately represents information in the study plan, supporting references, and procedures;

   c. Consistent with appropriate sections of this Review Plan;

   d. Consistent with the description of open items (objections, comments, questions) given in Appendix B;

   e. Technically consistent within a discipline and across disciplines;

   f. Consistent with 10 CFR Part 60;

g. Written in a clear, concise, complete, and specific manner with clear and adequate support given for concerns, responses addressing DOE's proposed resolution of concerns, and observations regarding progress toward resolution of other open items;

h. Written in an objective and factual tone;

i. Written in a grammatically correct manner and with editorial consistency throughout;

j. Products transmitted by the Branch Chiefs to the Project Director reflect internal resolution of significant comments;

k. Entries into OITS accurately reflect the results of the study plan reviews with respect to new NRC concerns and to closure or progress toward resolution of existing NRC concerns.

4. Document that the requirements above have been satisfactorily completed. The signature of the Section Leader on the review package submitted to the Branch Chief, the signature of the Branch Chief on the review package submitted to the Project Director, and the signatures of appropriate Section Leaders and Branch Chiefs certifying the total or partial closure of NRC open items constitute the documentation that the requirements above have been met.

6.2 Responsibilities

Within the DHLWM, the lead and the other technical reviewers, Section Leaders, Branch Chiefs, and the PM are jointly responsible for assuring that the IQA criteria in section 6.1 are met. In particular, the technical reviewers are responsible for following this Review Plan, conducting the Phase I and Detailed Technical Reviews in their technical areas, and providing input to the lead, who has the responsibility for incorporating the products of the technical reviewers and preparing internal comments for briefings and a review package for transmittal to his Section Leader. The lead is also responsible for keeping his Section Leader informed of and involved in the conduct of the review.

The Section Leaders are responsible for assuring that: (1) their staff follow this Review Plan; and (2) their staff's products are of technically high quality. The lead's Section Leader is specifically responsible for the IQA review of the lead's review package. Appropriate Section Leaders are also responsible for certifying the total or partial closure of open items.

The Branch Chiefs are responsible for assuring that all significant internal comments are resolved in the final products transmitted to the Project Director. The lead's Branch Chief is specifically responsible for the IQA

review of the review package which is transmitted to him by the lead's Section Leader. Appropriate Branch Chiefs are also responsible for certifying the total or partial closure of open items.

The PM is responsible for overall project management of the review, and especially for: (1) assuring that the technical reviewers have familiarized themselves with this Review Plan prior to starting their study plan reviews; (2) coordinating (as necessary) the efforts of the technical reviewers in the different disciplines; (3) verifying that necessary concurrences and certifications have been obtained for review packages and totally or partially closed open items; (4) preparing letters from the Project Director to DOE that preserve the technical quality of the packages transmitted by the Branch Chiefs and that are written in an objective and factual tone; (5) arranging for entry into the OITS of information relative to new and existing NRC concerns that accurately reflects the results of the study plan reviews; and (6) compiling the IQA record of the study plan reviews.

6.3 Records

The IQA record contains those documents judged necessary to document the study plan reviews. All other documents not identified as part of the IQA record are unnecessary to retain for IQA purposes. The following documents comprise the IQA record:

1. This Review Plan;

2. Signed review package(s) transmitted by the Branch Chief to the Project Director;

3. Review package(s) transmitted by the Project Director to DOE.

4. Certifications by signatures of the appropriate Section Leader(s) and Branch Chief(s) of total or partial closures of NRC open items as a result of the review of the study plan.

Examples of documents that are not part of the IQA record and therefore need not be retained for IQA purposes include:

1. Early technical reviewer drafts leading to the review package(s) submitted by the technical lead to his Section Leader;

2. Various drafts between the documents designated above for retention;

3. Mark-ups of drafts;

4. Personal notes.

The DHLWM IQA coordinator is available during study plan reviews to provide assistance in determining whether there is an IQA rationale for retaining particular documents.

7.0 OPEN ITEM IDENTIFICATION, TRACKING, AND RESOLUTION

7.1 Identification of NRC Open Items

The SCA contains objections, comments, and questions as defined on p. 186 of the SCP Review Plan (modified here as Appendix B). These are staff concerns for which the staff has made recommendations for resolution to DOE and are considered to be open items which need to be resolved by DOE and tracked in terms of progress toward resolution by NRC staff via OITS. In this Review Plan it has been indicated that open items may be generated as the result of the Phase I Review or of the Detailed Technical Review. These are to be entered as new open items in OITS and treated in the same way as SCA and other NRC open items.

SCA open items are clearly related to the DOE program organization in Chapter 8 of the SCP and are tied to those portions of DOE's Issues Hierarchy which correlate with Part 60. The open items resulting from study plan reviews should be similarly related.

7.2 Tracking Progress Toward Resolution of NRC Open Items

Earlier sections of this Review Plan have emphasized the need for the staff (in the Phase I Review) to evaluate whether the information provided in the study plan is sufficient to close out any open items proposed for closure by DOE on the basis of the study plan, and (in the Detailed Technical Review) to investigate whether the contents of the study plan mark progress toward resolution of any other NRC open items. All progress toward resolution is to be documented in OITS.

8.0 ADVISORY COMMITTEE ON NUCLEAR WASTE (ACNW) INTERACTIONS

Interactions with the ACNW regarding NRC staff reviews of study plans are to be conducted in accordance with the October 1990 Memorandum of Understanding (MOU) between the ACNW and the NRC Executive Director for Operations (EDO). Upon NRC's receipt of a study plan, the PM is to transmit a copy to the Office of Nuclear Material Safety and Safeguards (NMSS) staff contact for ACNW, who will in turn transmit it to his ACNW counterpart. If the ACNW wishes to interact with the NRC staff regarding the staff's review of the study plan, the ACNW contact will so inform the NMSS staff contact. A briefing will then be scheduled for an appropriate time.

9.0 STATE, TRIBAL, AND LOCAL GOVERNMENT INTERACTIONS

Study plans are provided by DOE to the State of Nevada and affected units of local government and Indian Tribes at the same time that they are provided to NRC. Those parties have the opportunity to communicate their concerns with respect to a particular study plan to the PM at any time during the NRC review process. They may also inquire at any time about the status of the NRC review process. When NRC's review results are sent to DOE, they are also sent to all affected parties.

APPENDIX A

COMPARISON OF LEVEL OF DETAIL REQUIRED IN DOE STUDY PLANS VERSUS THAT REQUIRED IN SCP DESCRIPTIONS OF INVESTIGATIONS

Appendix A consists of a table comparing the level of detail required in DOE study plans with that required in the SCP descriptions of investigations. This table is considered by NRC and DOE to accurately summarize the agreements relative to content of study plans made at the May 7-8, 1986 NRC-DOE Level of Detail for Site Characterization Plans and Study Plans Meeting.

Comparison of DOE [illegible]tent Requirements for Descriptions of [illegible] Plans and Investigations

	Study Plans	Investigations
I. Purpose and Objectives	• Describe the information to be obtained in the study	• Describe the information to be obtained in the investigation
	• Provide the rationale for information to be be obtained	• Provide the rationale for the information to be obtained
II. Rationale for Study/Investigation	• Provide the rationale for tests and analyses, indicating alternatives considered and options, advantages and limitations	• Provide the rationale for investigations, identifying relevant issues
	• Provide the rationale for number, location, duration, and timing of tests, considering uncertainties, and identify obvious alternatives	
	• Describe the constraints for the study, considering:	• Describe the constraints for the investigation affecting selection of studies, including interferences among studies and between studies and the exploratory shaft
	- potential site impacts	
	- need to simulate repository conditions	
	- required accuracy and precision	
	- limits of analytical methods	
	- capability of analytical methods	
	- time required vs. time available	
	- scale of phenomena and parameters	• Discuss the strategy for resolving issues
	- interference among tests	
	- interference between tests and exploratory shaft	
III. Description of Tests and Analyses/Studies		For each study:
		• State objectives of study
		• Indicate if the study is to provide information for development of conceptual models
		• Indicate if study is being performed to guide characterization activities
	For each type of test:	
	• Describe general approach that will be used in test	• List tests, test methods, data/parameters, locations, numbers, technical procedures and duration of tests
	• Describe key parameters that will be measured in test and experimental conditions under which test will be conducted	• Reference study plans

Comparison of DOE [illegible]ent Requirements for Descriptions of S[illegible] Plans and Investigations (Continued)

	Studies	Investigations
III. Description of Tests and Analyses/Studies (continued)	• Indicate number of tests and locations • Summarize test methods; if non-standard procedure, summarize steps of test, how it will be modified, and reference technical procedure • Indicate level of QA and provide rationale for any tests not QA Level 1 • Reference the applicable specific QA requirements applied to test. • Specify tolerance, accuracy, and precision required in test • Indicate range of expected results and basis for these results • List equipment requirements, describing briefly special equipment • Describe techniques to be used for data reduction and analysis • Discuss representativeness of test, indicating limitations and uncertainties that apply to use of results • Provide illustrations of test locations • Discuss relationship of test to set performance goals and confidence levels For each type of analysis: • State purpose of analysis, indicate conditions to be evaluated and describe any uncertainty analysis	For each analysis: • List method of analysis and information that will result from analysis

Comparison of DOE C[illegible]nt Requirements for Descriptions of St[illegible]Plans and Investigations (Continued)

	Studies	Investigations
III. Description of Tests and Analyses/Studies (continued)	• Describe methods of analysis, including analytical expressions and numerical models to be used • Reference the technical procedures document that will be followed during analysis • Indicate levels of QA applied • Identify data input requirements • Describe expected output and accuracy • Describe representativeness of analytical approach, indicating limitations and uncertainties that apply to results	
IV. Application of Results	• Briefly discuss where results from study will be used for support of other studies • Refer to specific performance assessment analyses • Describe where information from study will be used in construction equipment and engineering system, design and development • Describe where information from study will be used in planning other characterization activities	• Briefly discuss where results from investigation will be used for support of other investigations • Refer to specific performance assessment studies • Indicate where information from studies will be used in construction equipment and engineering system, design and development • Describe where information from studies will be used in planning other characterization activities
V. Schedule and Milestones	• Provide durations of and interrelationships among principal activities associated with conducting the study • List key milestones including decision points associated with study activities • Describe timing of study relative to other studies and other program activities • Provide dates for activities for the study plans; reference Sec. 8.3 in SCP	• Show interrelationships and sequencing of (groups of) tests and analyses; use PERT chart to illustrate • List major milestones which will result from studies • Present schedule for studies supporting the investigation, providing beginning and end dates

APPENDIX B

DEFINITION OF OPEN ITEMS IDENTIFIED IN NRC STAFF REVIEW OF DOE STUDY PLANS

Objection: a concern with the DOE program as presented in the study plan related to either: (1) potential adverse effects on repository performance; (2) potential significant and irreversible/unmitigable effects on characterization that would physically preclude obtaining information necessary for licensing; (3) potential significant disruption to characterization schedules or sequencing of studies that would substantially reduce the ability of DOE to obtain information necessary for licensing; or (4) inadequacies in the QA program which must be resolved before work begins. Objections are reserved primarily for concerns with activities, tests, and analyses which, if started, could cause significant and irreparable adverse effects on the site, the site characterization program, or the eventual usability of the data for licensing (programmatic fatal flaws). Due to the irreparable nature of objections, NRC would recommend that DOE not start work until the objections are satisfactorily resolved.

Comment: a concern with the DOE program as presented in the study plan that would result in a significant adverse effect on licensing if not resolved, but would not cause irreparable damage if site characterization started before resolution. The DOE program could be modified in the future, with some risk to not having the necessary information for licensing; the adverse effects would be primarily related to the program schedule. Therefore, for these concerns, DOE could start work at its own risk before resolving such concerns with NRC. NRC would recommend timely resolution of comments. If resolution is not achieved in a timely manner, comments might evolve into the third category of objections described above (i.e., potential significant disruption of schedules).

Question: a major concern with the presentation of the DOE program in the study plan, such as missing information that should be in the study plan, level of detail, contradictions, and ambiguities that preclude understanding a part of DOE's program, thereby preventing the staff from being able to comment. NRC would recommend timely DOE response to such questions. If a question is related to a potential objection, satisfactory resolution should be accomplished before work begins. If the question is not related to an objection, then DOE could choose to proceed with work at its own risk, and resolve the question in future reports. Questions should be reserved for major items; minor inconsistencies, etc., should not be included.