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3/12/93*

**REVIEW PLAN FOR  
NRC STAFF REVIEW OF DOE  
STUDY PLANS  
Revision 2  
March 10, 1993**

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

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## 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 (HLW). 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 geologic repository.

The DOE has developed a Site Characterization Plan (SCP) for the Yucca Mountain, Nevada proposed geologic 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) and formally revised February 23, 1993 as the "1993 DOE/NRC Level of Detail and Review Process Agreement for Study Plans" (Hereafter Agreement or LOD; see copy, Appendix A); 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; an up-to-date list of individual test procedures will be identified in the SCP and will accompany all DOE study plans transmitted to the NRC.

As indicated above, the study plans (in this review plan, the term study plan includes its supporting references) 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 resolution of some SCA or other NRC open items if DOE has proposed certain items be resolved 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 Review Plan for NRC Staff Review of DOE Study Plans and Procedures issued in December 6, 1990. It incorporates a major change from the previous review plan as it no longer requires two separate phases of 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.

Reflected in this study plan is 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 clearly defined.

## 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 clearly stated and 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 studies 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 requiring detailed technical comments, 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 resolved on the basis of the material in the study plan, determine whether those items can be closed and prepare an evaluation of the information provided by DOE to resolve the open item(s) in the format of the examples provided in Appendix C.

9. Document review results in a review package for transmittal to DOE. For any study plan requiring detailed technical comments, document comments. Detailed technical comments may be submitted as a separate package.
10. 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 resolution 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 review of all study plans issued by DOE. Study plan reviews are intended to accomplish the following; (1) confirm that the study plans contain the material specified in the Agreement on content of study plans, (2) identify objections (as defined in Section 4.1.2 and Appendix B) with respect to the studies, (3) evaluate whether any open items that DOE has proposed for closure on the basis of the study plans may be determined to be resolved, and (4) evaluate in detail the adequacy of the study plans to provide the information for licensing that should be provided and that they are designed to provide.

Results of the reviews are to be transmitted to DOE ordinarily within three months after NRC receipt of the study plans. If the NRC elects to transmit detailed technical comments, these comments are to be transmitted to DOE ordinarily within six months of NRC receipt of the study plans and any procedures requested by NRC. In addition, the 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 resolution on the basis of the study plan may be resolved.

## 4.0 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)

The revised Agreement provides the content requirements for study plans (Appendix A of this Review Plan). One aspect of the 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 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 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 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 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 significance 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 within three months of the receipt of the study plan.



#### 4.1.3 Resolution of NRC Open Items (Reference Section 2.2, Objectives 8 and 10)

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

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

The staff should evaluate whether the activities, tests, and analyses comprising the 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 intended purpose may not provide the information needed for licensing, comments or questions (as defined in Appendix B) documenting such concerns will be transmitted in to DOE.

#### 4.1.5 Evaluation of Progress Toward Resolution of NRC Open Items (Reference Section 2.2, Objective 8)

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. The NRC staff should 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 detailed technical comments.

### 4.2 Activities/Products

The 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 HLWM 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 HLWM, other parts of the NRC (e.g., Office of Research), or from the Center for Nuclear Waste Regulatory Analyses (CNWRA). The PM arranges through appropriate channels for whatever assistance is deemed necessary from other parts of the NRC. The appropriate CNWRA Program Element Manager will make arrangements for any necessary assistance from the CNWRA. 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.
6. Reviewers examine the study plan for progress toward resolution of NRC open items. If DOE has proposed that one or more NRC open items should be considered resolved based upon specific 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 document, using the format provided in Appendix C, whether or not the NRC staff agrees that they are resolved. If DOE, in its letter of transmittal of the study plan, has stated that the study plan addresses particular SCA concerns, the reviewer should document, as part of the review, what SCA concerns were addressed by the study plan.
7. Reviewers conduct a 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 technical procedures and not-readily-obtainable references needed for their review that they wish to have furnished by DOE. The PM requests the needed procedures and references from DOE.

8. The lead briefs the lead's Section Leader and Branch Chief on the scope of the review and whether or not detailed comments may be warranted. The lead advises the PM of the results of the briefing.
9. Procedures selected for review are evaluated for their technical acceptability to obtain data usable in licensing.
10. The lead prepares a draft package containing the results of the review. For any study plan requiring detailed technical comments, the reviewer may elect to include those comments in this review package or to submit detailed comments as a separate package. The review package should include (1) objections, as defined in Section 4.1.2 and Appendix B, and written in the format of the SCA open items, (2) comments and questions, if the reviewer elects to transmit detailed comments at this time, or a statement concerning the need to prepare detailed technical comments on the study plan, and (3) if applicable, whether the NRC staff agrees with DOE's proposed resolution 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. He transmits this package to his Section Leader for review.
11. The Section Leader reviews the package, coordinates any changes needed with the technical lead, and transmits the package to his Branch Chief for review.
12. The Branch Chief reviews the package and transmits it to the Project Director, with a copy sent to the PM.
13. If the review results in an objection, the HLWM Director and Deputy Director will be briefed on the results of the review by the lead.
14. The PM prepares a letter from the Project Director to DOE containing the results of the review including detailed comments or informing DOE whether or not detailed technical comments on the study plan will be prepared. The letter may also request any procedures or references needed for review if those have not already been requested by the PM.
15. The Project Director issues the letter and any preliminary review comments to DOE with copies to the State and affected units of local government and Indian Tribes.
16. PM arranges to have objections, comments, and questions placed in the OITS and to have the resolution of any open items based on the 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.
17. If it is determined that detailed technical comments will be prepared, the lead, in coordination with his Section Leader and Branch Chief, prepares comments and questions (both terms as defined in Appendix B), incorporating those of all reviewers.

18. If the detailed comments are to be transmitted by separate package, the lead transmits the package to his Section Leader. The Section Leader reviews the package, coordinates any needed changes with the lead, and transmits the package to his Branch Chief for review.
19. The Branch Chief reviews the package and transmits it to the Project Director, with a copy sent to the PM.
20. The PM determines whether the HLWM Director and Deputy Director need to be briefed on the detailed technical comments. If so, the lead briefs them.
21. The PM prepares a letter from the Project Director to DOE transmitting the detailed technical comments and questions.
22. The 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.
23. The PM updates the OITS by arranging for entry of the new open items resulting from the review and for recording of progress toward resolution of the existing open items based on the Review.

## **5.0 INTERNAL QUALITY ASSURANCE (IQA) REQUIREMENTS/RESPONSIBILITIES/RECORDS FOR STUDY PLAN REVIEWS**

### **5.1 IQA Requirements**

In accord with the IQA plan for HLWM, IQA requirements for the review of study plans are as follows:

1. Before the reviewers begin their review, ensure through a required reading of this Review Plan and subsequent group question-and-answer sessions that reviewers 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 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 an 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 review with respect to new NRC concerns and to resolution 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.

## 5.2 Responsibilities

Within HLWM, 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 5.1 are met. In particular, the technical reviewers are responsible for following this Review Plan, conducting the 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 resolution of open items.

The Branch Chiefs are responsible for assuring that all significant internal comments are resolved in the final product 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 resolution 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 difference disciplines; (3) verifying that necessary concurrences and certifications have been obtained for review packages and totally or partially resolved 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.

### 5.3 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 resolution 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 submitted by the technical lead to his Section Leader;
2. Various drafts between the documents designed above for retention;
3. Mark-ups of drafts;
4. Personal notes.

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

## **6.0 OPEN ITEM IDENTIFICATION, TRACKING, AND RESOLUTION**

### **6.1 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 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 Issues Hierarchy which correlate with Part 60. The open items resulting from study plan reviews should be similarly related.

### **6.2 Tracking Progress Toward Resolution of NRC Open Items**

Earlier sections of this Review Plan have emphasized the need for the staff to evaluate whether the information provided in the study plan is sufficient to resolve any open items proposed for resolution by DOE, and 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.

## **7.0 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 check the Regulatory Information Distribution System to verify that the ACNW has been placed on distribution for each study plan. If the ACNW wishes to interact with the NRC staff regarding the staff's review of a study plan, the ACNW contact will so inform the NMSS staff contact. A briefing will then be scheduled for an appropriate time.

## **8.0 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**

**1993 DOE/NRC LEVEL OF DETAIL AGREEMENT  
AND REVIEW PROCESS FOR STUDY PLANS**



**1993 DOE/NRC LEVEL OF DETAIL AGREEMENT  
AND REVIEW PROCESS FOR STUDY PLANS**

1. Study plans are documents that present details of the studies and activities from Chapter 8 of the Yucca Mountain Project (YMP) Site Characterization Plan (SCP). Study plans are developed by the YMP participant organizations and are approved by the Yucca Mountain Project Office (YMPO). The content requirements for study plans are presented in Attachment 1. These requirements are not retroactive to study plans that have already been submitted to the YMPO. The DOE will determine if any study plans now approved or in review would benefit from conversion to the revised format. NRC will be provided a list of study plans to be converted or developed under the revised format.
2. Only those study plans transmitted from DOE headquarters, Office of the Associate Director for Systems and Compliance to the Director of NRC's Repository Licensing and Quality Assurance Project Directorate will be considered official transmittals for NRC review. The time allowed for NRC review will only start after the official controlled copy of the study plan is received by the NRC.
3. For study plans that could affect the waste isolation capability of the site, DOE will ordinarily provide NRC with these study plans 90 days prior to the start of any work. The NRC will notify DOE within the 90 days as to whether or not NRC identified any objections to DOE starting work. At the same time DOE will be notified whether or not NRC plans to provide detailed technical comments on the study plan to DOE. If the NRC review for objection-level concerns is not completed within the 90 day time frame, DOE may begin work at its own risk. For studies that involve no surface disturbance or subsurface penetrations or that involve work outside the controlled area, DOE has the option to begin work (again, at its own risk) as soon as the study plan is submitted to the NRC. For studies that are on a critical path, the DOE will notify the NRC of the need for an expedited review. In these cases, if resources permit, the NRC will agree to notify DOE within 30 days whether or not there are any objections to DOE initiating activities described in the study. Following the notification to DOE of any objection-level concerns, if warranted, NRC will provide detailed comments or questions on selected study plans.
4. Technical procedures for the site characterization activities described in study plans are developed by the YMP participant organizations. A current list of approved technical procedures for each approved study plan will be maintained by the participants and will be submitted to NRC as an attachment to the study plan transmittal letter. The listed procedures will be provided to the NRC staff or on-site representative upon request. Technical procedures are not required to be listed in a study plan if an up-to-date list is provided as stated above. The DOE agrees to notify the NRC staff when any technical changes to procedures result in changes to activities in the study plan.

5. Not-readily-obtainable references (Attachment 2) that have not previously been submitted to the NRC will be made available, upon request, within approximately 10 days of the request, if those references are needed to complete the review of the study plan. Delays of greater than 10 days may impact schedules for completion of the NRC review.
6. If a study plan is revised after the NRC has conducted its review, the DOE letter transmitting the revised study plan will summarize the technical changes and specifically highlight changes to discussions of potential impacts or interferences. Changes to the revised study plan will be marked in the margins.
7. Copies of all transmittals and communications, including enclosures, between DOE and NRC regarding study plans and their review as described in this agreement and its attachments will be provided to the affected state and local governments by the originating organization at the time of original issuance.

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## **ATTACHMENT 1**

### **DOE CONTENT REQUIREMENTS FOR DESCRIPTIONS OF STUDIES IN SCP STUDY PLANS**

The test program presented in Chapter 8 of the SCP will be subdivided into a hierarchy of increasing detail. The SCP test program hierarchy will include (in increasing detail); generic program, investigation, study, activity, and test procedures. Details for the studies listed in Chapter 8 of the SCP will be presented in the study plans. Study plans will be separate from the SCP proper and will be issued as required for site characterization. Individual test methods will be discussed in study plans.

The following outline describes the information on studies that will be presented in SCP study plans. A study plan may involve a single activity or a set of activities and corresponding analyses, as appropriate. An activity includes preparation of procedures, test set-up, data acquisition, and data reduction. Analyses include those calculations or other evaluations needed to assess site characteristics and support design activities. All site characterization studies will be completed under a quality assurance program that has been accepted by the NRC.

The items listed in the outline will be addressed for studies and activities, to the extent that each item applies. Not all items will be applicable to all studies.

In some cases, activities may be planned for later stages in the study when detailed plans depend on the results of earlier activities. Under these circumstances, it will not be possible to provide the same level of detail for all activities at the time the study is first issued. In such cases, revision 0 of the study plan will present complete descriptions of activities that occur early in the study and less detailed information for activities that occur later.

#### **I. PURPOSE AND OBJECTIVES**

Describe the objectives of the study: what technical issues of importance to the project will be addressed by the study and what aspect of site characterization will be accomplished through the study. Note any changes from activities as described in the SCP (all changes should also be documented in DOE site characterization progress reports).

#### **II. SCOPE OF WORK**

Describe the general approach for completing the study, including (as appropriate) an evaluation of existing literature; a description of the key parameters that will be measured or observed and analyzed in the study, and a description of the methods that will be used to complete the study including a discussion of the technical methodology to be used. Provide illustrations such as maps, cross sections, and schematic layouts of tests or other planned activities.

If the study proposes the observation and description of features in the field, provide discussion on:

- The area (and its approximate boundaries) to be studied.
- Aspects of the area that are known or are poorly known.
- Type of data to be collected.
- Approximate location and number of tests.
- Methodology or classification system to be used.
- Product, maps, cross sections, etc., to be produced.

If the study proposes laboratory or field testing, provide discussion on:

- The test methods to be used.
- Approximate location and number of tests.
- The representativeness of the test in terms of spatial and temporal variability of the parameters that will be measured.
- Specific constraints on testing described in the study. Factors to be considered include:
  1. Potential impacts on the site from testing.
  2. Whether the tests need to simulate repository conditions.
  3. Applicability of tests conducted in the laboratory to the scale of phenomena in the field.
  4. Generic and site specific test to test interference.
  5. Significant interference between tests and design and construction of the Exploratory Studies Facility.
  6. Alternative tests methods and a rationale for selecting a specific method, if appropriate.

If the study proposes analyses, provide discussion on:

- The purpose of the analysis. Indicate any sensitivity or uncertainty analyses that will be performed.
- The methods of analysis, including any analytical expressions or statistical methods that will be employed.
- The data input requirements of the analysis.

- The representativeness of the analytical approach (e.g., with respect to spatial and temporal variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

If the study or analyses propose synthesis and modeling, provide discussion on:

- Scope of the data to be included in the study.
- The methods to be used, including computer software, if applicable.
- The objectives or problems that will be addressed by the study.
- The relationship of this study to preexisting models or syntheses.
- The sensitivities of the model to input and calculation methods.
- How the model or synthesis will be tested against data and other models.
- How the model will be updated to incorporate new data.

### III. APPLICATION OF RESULTS

Discuss how the results of this study will support performance assessment and design activities and other site characterization studies. Provide specific information about the way data from this study will be used in other studies and/or activities, including performance assessment design and site characterization. Discuss the technical issues that will be addressed by the data collected under this study.

### IV. SCHEDULE

Summarize the schedule for the study, including the estimated length of the investigation and any milestones and decision points for the study. Show the interrelationship with other studies, indicating dependencies on data derived from other studies and activities that will affect or be affected by the scheduled completion of this study.

## ATTACHMENT 2

### REFERENCES THAT DOE WILL SUPPLY UPON REQUEST

1. Contractor and participant reports such as Open-File Reports, Sandia reports, Los Alamos reports, etc.
2. Reports published in foreign national journals and books.
3. State publications.
4. Symposium, meeting, and workshop abstracts and papers.
5. Commercial and trade contract reports (e.g., EPRI).
6. Academic M.S. theses and dissertations.
7. Participant management plans, QA plans, etc.
8. Computer code manuals.
9. Draft, unpublished, or "letter" reports and documents (personal and oral communications are not acceptable references unless documented in letter reports).
10. Manuscripts of "in press" works (manuscripts "in review" or "in preparation" are not acceptable references in study plans).
12. Monograph reports and handbooks from Federal agencies (e.g., local USDA soil reports).

## 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 analysis 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 would 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 that would reduce the ability to obtain information necessary for licensing).

**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.

**APPENDIX C**

**FORMAT FOR THE EVALUATION OF DOE RESPONSES  
TO OPEN ITEMS**



Section 8.3.1.8      Overview of the postclosure tectonics program:  
Description of future tectonic processes and events  
required by the performance design issues (p. 8.3.1.8-40)

SCA COMMENT 46

The current representation of the physical domain for postclosure tectonics issues (i.e., brittle crust, southern Great Basin) appears to be inadequate to evaluate the full range of processes and events likely to occur at the site and should not act as a limit on conceptual tectonic models or site investigations.

EVALUATION OF DOE RESPONSE

- o    The response to this comment indicates that there is philosophical agreement between NRC and DOE that the definition of the "physical domain" should not be a limiting factor in consideration of alternative conceptual models and that areas for consideration of alternative conceptual tectonic models should be extended to areas outside of the southern Great Basin.
- o    The response indicates that the terms "physical domain" and geologic setting" are not synonymous.
- o    The response to SCA Comment 75 indicates the "geologic setting" will be defined specifically for different investigative elements of the SCP and that the specific meaning of the term should be readily apparent within the context of the individual investigation.
- o    The NRC staff considers this comment closed.

Section 8.3.1.15.1 Investigation: Studies to provide the required information for spatial distribution of thermal and mechanical properties, p. 8.3.1.15-31

Section 8.3.5.20 Analytical techniques requiring significant development

SCA COMMENT 56

The validation of models should be a part of the overall test program. It is not clear that these aspects have been addressed by the test program.

EVALUATION OF DOE RESPONSE

- o DOE refers to discussion of model validation presented in several places in the SCP, and specifically to SCP Section 8.3.1.15.1 for "testing related to the validation of rock-mechanics models." However, it recognizes that the details of the validation process are not presented in the brief descriptions of in situ tests in Section 8.3.1.15.1. DOE states in its response to this comment that additional detail will be provided in the study plans relating to the in situ tests, as was done for the study plans for excavation investigations.
- o DOE further indicates that it "is currently developing a general validation strategy,... which will be implemented through the Test and Evaluation Plan (see response to Comment 1) using the present structure of study plans, augmented by procedures regarding data and model evaluation."
- o DOE's response does not address any of the specific concerns that form the basis of Comment 56.
- o Progress toward closure of Comment 56 will require DOE to submit (1) the study plans relating to the in situ tests cited in the DOE's response, when they become available, and (2) the general validation strategy, to be implemented by DOE in the Test and Evaluation Plan.
- o The NRC staff considers this comment open.