

DRAFT  
REVIEW PLAN FOR  
NRC STAFF REVIEW OF DOE  
STUDY PLANS AND PROCEDURES

DECEMBER 22, 1987

DIVISION OF HIGH-LEVEL WASTE MANAGEMENT  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
U.S. NUCLEAR REGULATORY COMMISSION  
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## 1.0 INTRODUCTION

The Department of Energy (DOE) is responsible under the Nuclear Waste Policy Act of 1982 (NWP) 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 support a license application for a geologic repository. The DOE has been developing site characterization plans (SCPs) which describe in broad detail how they intend 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 is to be presented in study plans that are to be published at the same time as or later than the consultation draft SCPs (CDSCPs). A study is a combination of tests and analyses (assessments of test results) which deal with a single or several related objectives within a given area. A test or analysis 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. Details for studies, tests, and analyses will be presented in the afore-mentioned study plans; individual test procedures will be identified in both the SCP and study plans. During the Level of Detail Meeting agreement was reached and documented in the meeting summary (Enclosure 4, Attachment B) on the content of study plans.

This Review Plan for Study Plans and Procedures provides the technical guidance for the NRC staff 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 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.

## 2.0 PURPOSE, OBJECTIVES, AND SCOPE

### 2.1 Purpose

The general purpose of the NRC review of the study plans is to continue the effort of the past five years since passage of the NWP toward early identification and resolution of potential licensing issues during the pre-licensing part of DOE's HLW program. With specific reference to the study plans, the NRC staff intends to identify any concerns with DOE's plans to go about gathering the information that DOE indicated in the SCPs is needed to resolve licensing issues or to understand the site.

Objections, comments, or questions that the staff presents in its written review of any study plan or procedure will be entered in the same Open Item Tracking System (OITS) that is being used to track the progress toward resolution of the objections, comments, and questions presented by the staff in the CDSCP Point Papers and the Site Characterization Analysis (SCA) of the

final SCP. The new items identified during the review of a given study plan have the same significance and are to be tracked just as the SCP open items. Furthermore, it is possible that the staff review of a particular study plan may result in closure of some SCP open items.

## 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 study plan contains the information agreed to (henceforth herein the Agreement) in the May 7-8, 1986 NRC-DOE Meeting on the Level of Detail for Site Characterization Plans and Study Plans (henceforth Level of Detail Meeting);
2. Assess whether the tests presented in the study plan will have significant adverse effects on the waste isolation capabilities of the site;
3. Evaluate whether the tests presented in the study plan will significantly interfere with the ability of other site characterization activities to obtain needed information;
4. Evaluate whether an adequate quality assurance program is in place for the study;
5. 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.
6. Determine whether progress toward resolution of any SCP open items can be identified on the basis of the contents of the study plan.
7. For any study plan selected for detailed technical review (see sections 3.0 and 7.1 for selection criteria), evaluate the extent to which the tests and analyses presented in the study plan will enable DOE to obtain the information that the study is designed to obtain. Also, evaluate if the objective of the study plan is consistent with that proposed in the investigation plan presented in the SCP.

## 2.3 Scope

A study plan and its references are to be reviewed as individual entities in accord with this Review Plan as discussed in the following sections. 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 relative to the open items in the OITS in case it represents progress toward resolution of any open items.

### 3.0 GENERAL APPROACH

The NRC staff will perform a multi-stage review of all study plans issued by DOE. The first stage is an Acceptance Review to confirm that a particular study plan contains the material specified in the NRC-DOE Agreement on the content of study plans. The second stage is a Start-Work Review to identify any major concerns in the study (e.g., significant adverse effects on the waste isolation capabilities of the site) that would cause NRC to object to initiation of the tests and analyses comprising the study by DOE. The third stage, which will be undergone by only selected study plans, is a Detailed Technical Review (DTR) to ascertain the adequacy of a given study to provide the information for licensing that it is designed to provide. Study plans that are related to key site-specific issues or CDSCP concerns or that feature unique, state-of-the-art test or analysis methods are likely candidates for this third stage of review.

With regard to the timing of the study plan reviews, the NRC staff expects to receive a study plan six months before work is initiated under that study plan as agreed during the Level of Detail Meeting. Major comments are to be furnished to the DOE within three months of NRC's receipt of a study plan, and other comments within six months of receipt, consistent with agreements on this subject at the Level of Detail Meeting.

### 4.0 ACCEPTANCE REVIEW

#### 4.1 Approach

In the Level of Detail Meeting agreement was reached on the content requirements for descriptions in study plans (Enclosure 4, Attachment B). The approach to the Acceptance Review is to determine if the study plan under review is reasonably consistent with that agreement. This will be more than a simple check to note whether items in the table of contents have been addressed; it will also be to determine if the material provided is substantive enough for it to be a productive use of staff resources to move on to the Start-Work Review. A letter will be sent to DOE giving the results of the Acceptance Review.

#### 4.2 Review Guide for Acceptance Reviews

##### 4.2.1 Criteria

1. The study plan content is substantively consistent, as appropriate for the studies, tests, and analyses described, with the Agreement on content resulting from the Level of Detail Meeting.
2. All study plan references have been provided at the time of the study plan issuance. (This does not include procedures, which are to be selectively requested during the Detailed Technical Review.)

#### 4.2.2 Applicable Section of 10 CFR Part 60

None.

#### 4.2.3 Documents to Consider

Summary of the NRC-DOE meeting on the Level of Detail for Site Characterization Plans and Study Plans, May 7-8, 1986.

#### 4.3 Activities/Products/Responsibilities

The Acceptance Review will consist of the following activities:

1. The PM transmits the study plan by memorandum to the SL of the site team technical lead (henceforth "lead"), along with a TAC number for the Review (TAC number is to be used for all stages of the study plan review and for review of any procedures associated with the study plan).
2. The lead becomes familiar with and reviews the study plan using section 4.2 above. Other team members are to be involved in this and later Review stages as determined by the lead, his SL, other SLs, and the PM.
3. The lead briefs the PM and appropriate SLs on the review results and the recommendation for acceptance/rejection of the study plan for further review.
4. The PM makes the determination whether to accept the study plan for further review.
5. If the study plan is not accepted for further review, the PM prepares a letter from the HLOB Projects Section SL to DOE providing the results of the Acceptance Review, including a statement of why the study plan is not acceptable for further review. If the study plan is accepted for further review, the PM readies a form letter from the HLOB Projects Section SL communicating this information to DOE.
6. HLOB dispatches the letter to DOE with copies to States and affected Indian Tribes.

### 5.0 START-WORK REVIEW

#### 5.1 Approach

The Start-Work Review is to be conducted for each DOE study plan issued that is deemed adequate for further staff review after completion of the Acceptance Review. The Start-Work Review is intended to identify concerns with studies, tests, and analyses that 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 (fatal flaws). If such concerns, or objections (as defined in section 6.3.2 of the CDSCP-APP), are identified by

the staff, they are to be communicated in writing to DOE within three months of receipt of the study plan.

## 5.2 Review Guide for the Start-Work Review

### 5.2.1 Criteria

1. Appropriate consideration should be given to the potential effects of the studies, tests, and analyses on the capability of the site to isolate high-level waste. If potential effects exist, the study plan should include an acceptable discussion of preventive/mitigative measures.
2. The description of the planned studies, tests, and analyses should include appropriate consideration of interferences with other studies, tests, and analyses and/or construction of the exploratory shaft facility. Other constraints on the studies, tests, and analyses should be adequately considered.
3. The study plan should present a quality assurance (QA) program adequate to ensure that the studies, tests, and analyses comprising the study plan will produce data of demonstrably high quality usable for licensing.
4. If any planned studies, tests, or analyses require the use of radioactive material, this requirement should be identified, and the quantities to be used and any plans for retrieval should be adequately discussed.

### 5.2.2 Applicable Sections of 10 CFR Part 60

60.15(d)(1)  
60.17(a)(2)(11)  
60.151  
60.152

### 5.2.3 Documents to Consider

1. DOE Site Characterization Plan for the site to which the study plan pertains.
2. Other DOE study plans of possible relevance to the study plan under review.
3. NRC Site Characterization Plan Technical Review Plan.
4. NRC-DOE Meeting on Level of Detail in the SCP and Study Plans, Enclosure 4, Attachment B.
5. NRC Review Plan: QA Programs for Site Characterization of High Level Nuclear Waste Repositories.

### 5.3 Activities/Products/Responsibilities

The Start-Work Review is to consist of the following activities:

1. Appropriate site team members (as determined during scoping of the Acceptance Review) review the studies, tests, and analyses in the study plan for major flaws that could cause NRC to object to DOE's starting the work delineated in the study plan.
2. Site team members also review the study plan in terms of its possible relationship to key site-specific issues, SCP open items, non-standard tests or analyses, or any other relationship to potential licensing concerns that could make the study plan a likely candidate for detailed technical review.
3. Lead technical reviewer briefs the PM and appropriate SL's on the results of the Review and makes a recommendation about whether to do a Detailed Technical Review of the study.
4. PM makes the determination whether to do a Detailed Technical Review of the study.
5. Lead prepares written objections (if any) to the study plan, incorporating those of other reviewers, and resolving any significant comments raised during the briefing. His SL transmits objections by memorandum to the PM.
6. If DHLW has objections to the study plan, the PM prepares a letter from the HLOB Projects Section SL to DOE containing the NRC objections and informing DOE whether a Detailed Technical Review of the study plan will be conducted. (Reasons why a Detailed Technical Review is to be done need not be provided.) If NRC has no objections to the study plan, the PM readies a form letter to that effect from the HLOB Projects Section SL to DOE, with the additional information that NRC does or does not intend to do a Detailed Technical Review of the study plan.
7. HLOB dispatches the letter to DOE with copies to States and affected Indian Tribes.
8. PM arranges to have objections placed in the Open Item Tracking System (OITS).

## 6.0 DETAILED TECHNICAL REVIEW

### 6.1 Approach

Selected study plans will undergo the third review stage, the Detailed Technical Review (DTR). The criterion for selection is the potential importance of the study plan relative to NRC licensing concerns. The study plan may be related to one or more key site-specific issues, or it may pertain to some of the CDSCP open items. It also might describe unique,

state-of-the-art test or analysis methods that therefore do not have a supportive scientific history of providing data usable in licensing. Alternatively, it might describe 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 (thus essentially a "one shot" test). For those study plans selected for detailed technical review, the basic objective is to ascertain whether the tests, analyses, and studies comprising that study plan are adequate to provide the data for licensing that the study plan was designed to provide. If the staff perceives that execution of the studies, tests, or analyses as presented would not achieve their intended purpose, comments documenting such concerns will be transmitted to the DOE as expeditiously as possible, but no more than six months from NRC receipt of the study plan.

## 6.2 Review Guide for Detailed Technical Reviews

### 6.2.1 Criteria

Criteria to determine whether the study plan is adequate to provide the information for licensing it was designed to provide must necessarily be specific to each study plan and will be identified as the first step in a Detailed Technical Review. It may be possible for the staff to adapt one or more of the Detailed Review Guides in the NRC SCP Technical Review Plan for this Detailed Technical Review of the study plan.

### 6.2.2 Applicable Sections of 10 CFR Part 60

Variable, depending on the licensing concern that the study plan is designed to address.

### 6.2.3 Documents to Consider

1. DOE Site Characterization Plan for the site to which the study plan pertains.
2. Other study plans of relevance to the study plan under review.
3. NRC SCP Technical Review Plan.
4. NRC-DOE Meeting on Level of Detail in the SCP and Study Plans, Enclosure 4, Attachment B.

## 6.3 Activities/Products/Responsibilities

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

1. PM and lead scope the review. Appropriate site team members (as determined during scoping of the Acceptance Review) and their SLS identify the criteria to be used in conducting the review.
2. Site team members review studies, tests, and analyses for adequacy to obtain the licensing information sought and against the other



criteria identified. As part of this activity, they identify procedures that they would like DOE to furnish to NRC.

3. Site team members review the study plan for resolution/progress toward resolution of open items in OITS.
4. The lead briefs PM and appropriate SL's on comments and questions (both terms as defined in CDSCP-APP, section 6.3.2) concerning the study plan and on open items addressed by the study plan.
5. The lead prepares written comments and questions concerning the study plan, incorporating those of other reviewers, and resolving any significant comments raised during the briefing. His SL transmits comments and questions by memorandum to the PM.
6. The PM prepares a letter from the HLOB Projects Section SL to DOE containing the results of the Detailed Technical Review and requesting the procedures identified as a result of the Review.
7. HLOB dispatches the letter to DOE with copies to States and affected Indian Tribes.
8. PM updates the OITS by arranging for entry of the new open items and recording of any progress toward resolution of the existing open items.

## 7.0 PROCEDURE REVIEW

### 7.1 Approach

Procedures are the detailed stepwise processes specifying how a test will be done or an analysis will be carried out. In accord with the Level of Detail Meeting Agreement, individual test procedures are to be referenced in the study plans. The NRC does not expect to receive all the DOE procedures supporting the tests, analyses, and studies presented in the study plans. Rather, by the Agreement DOE will release non-standard test procedures 60 days in advance of work. Furthermore, the staff will identify any additional procedures that it wishes to review and will request those of DOE. The bases for selection of the procedures for review are the importance of the data for licensing to be obtained by the associated test and the potential for concerns with the procedure itself. The procedure may be technically difficult and subject to error; it may for that reason or others be controversial. It may be a non-standard, state-of-the-art, or unique procedure that has not been used in the past to obtain data for licensing purposes. If the staff review results in concerns with a given procedure, those concerns will be transmitted to the DOE within 30 days.

## 7.2 Review Guide for Procedure Reviews

### 7.2.1 Criteria

Criteria must necessarily be specific to the procedure being reviewed and will be identified as the first step of the Review.

### 7.2.2 Applicable Sections of 10 CFR Part 60

Variable depending upon the licensing issues that are to be addressed by the data being obtained through the procedure under review.

### 7.2.3 Documents to Consider

Industry or other standard procedures, if such exist, for conducting the specific test that is supported by the procedure under review.

## 7.3 Activities/Products/Responsibilities

The Procedure Review is to consist of the following activities:

1. PM transmits the procedure by memorandum to the SL of lead.
2. PM and lead technical reviewer scope the Review. Other team members are to be involved in the review as determined by the PM, the lead, his SL, and other SLs.
3. The involved team members and their SLs identify the criteria to be used in conducting the Review.
4. Site team members review the procedure using the criteria identified.
5. Site team members review the procedure for progress toward resolution of open items in OITS.
6. Lead briefs the PM and appropriate SL's on results of the Review.
7. Lead prepares written comments and questions (as defined in the CDSCP-APP, section 6.3.2) on the procedure, incorporating those of other reviewers, and resolving any significant comments raised during the briefing. His SL transmits comments and question by memorandum to the PM.
8. PM prepares a letter from the HLOB Projects Section SL to DOE containing the results of the Review.
9. NRC dispatches the letter to DOE with copies to States and affected Indian Tribes.
10. PM updates the OITS by arranging for entry of new open items from the Procedure Review and for recording of any progress toward resolution of existing open items.

## 8.0 STATE AND TRIBAL INTERACTIONS

During any Start-Work Review, Detailed Technical Review, or Procedure Review, the PM is to contact the States and affected Indian Tribes to solicit their concerns regarding the document under review. The PM and lead jointly determine whether there is need for further interaction during the Review. The States and affected Indian Tribes have the opportunity to communicate their concerns to the PM at any time during the Review.

## 9.0 SCHEDULE FOR REVIEW MILESTONES AND ACTIVITIES

The NRC review of the study plan is to be completed before the work described in the study plan is scheduled to begin. The review period for the Acceptance Review is one week. For the Start-Work and Detailed Technical Reviews, the review period is to be determined during the scoping of the Review but should not exceed three and six months respectively, consistent with agreements reached in the Level of Detail Meeting. If non-standard and/or selected procedures are received two months in advance of the beginning of a particular test or analysis, the NRC review is to be completed before the work is scheduled to begin.

## 10.0 RESOURCE COMMITMENT

It is anticipated that most of the Reviews will be done by the site teams. Additional staff support and contractor support are to be determined by the lead technical reviewer and his SL on a case-by-case basis. Contractor involvement could range from technical review of the document to internal quality reviews of the Review results.

## 11.0 INTERNAL QUALITY ASSURANCE (IQA) REQUIREMENTS/REQUIREMENTS FOR STUDY PLAN REVIEWS AND PROCEDURE REVIEWS

### 11.1 IQA Requirements

In accord with the IQA plan for the Division of High-Level Waste Management, IQA requirements for reviewing study plans and procedures are as follows:

1. Conduct the Review and develop the products consistent with the Study Plan and Procedure Review Plan.
2. Conduct internal quality review of the results using the following review criteria:
  - A. Technically defensible.
  - B. Accurately represents information in the study plan or procedure.
  - C. Consistent with appropriate sections of Study Plan and Procedure Review Plan, including those describing Review products.

- D. Consistent with the description of open items (objections, comments, questions) given in section 6.3.2 of the CDSCP-APP.
  - E. Technically consistent within a discipline and across projects in cases where study plans or procedures covering the same studies, tests, analyses, or procedures are received from different projects.
  - F. Technically consistent across different disciplines within one project.
  - G. Consistent with 10 CFR Part 60.
  - H. Written in a clear, concise, complete, and specific manner with clear and adequate support given for concerns.
  - I. Written in an objective and factual tone.
  - J. Written in a grammatically correct manner and with editorial consistency throughout.
  - K. Product transmitted by the SL to the PM reflects internal resolution of significant comments.
- 3. Assure that the quality review of the results was satisfactorily conducted.
  - 4. Document that the requirements in 1-3 above have been satisfactorily completed.

## 11.2 Responsibilities

The site team members and other technical reviewers, the SLs, and the PM are jointly responsible for assuring that the IQA criteria in section 11.1 are met. In particular, the technical reviewers are responsible for following the Study Plan and Procedure Review Plan, conducting the technical review of the study plan or procedure in their technical areas, and providing input to the lead reviewer, who has the responsibility for incorporating the products of the technical reviewers and preparing internal comments for briefings and written input to the PM, as described in this Review Plan. The SLs are responsible for assuring that: (1) their staff follow this Review Plan; (2) their staff's products are of technically high quality; and (3) all significant internal comments are resolved in the final products transmitted to the PM. The PM is responsible for overall project management of the review, and especially for: (1) providing guidance to the lead technical reviewer during all phases of the review; (2) coordinating the efforts of the team members in the different disciplines; and (3) preparing letters from the HLOB Projects Section SL to DOE that preserve the technical quality of the products transmitted by the SL and that are written in an objective and factual tone.

## 12.0 OPEN ITEM IDENTIFICATION, TRACKING, AND RESOLUTION

### 12.1 Identification of Open Items

According to the CDSCP-APP, the CDSCP Point Papers and the SCA for each SCP are to contain objections, comments, and questions (terms that are defined in sections 6.3.2 of the CDSCP-APP). 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 Start-Work Review (primarily objections), the Detailed Technical Review (primarily comments and questions), and the Procedure Review (primarily comments and questions). These are to be entered as new open items in OITS.

According to section 9.1 of the CDSCP-APP, SCP open items are to be clearly relatable to the DOE programmatic breakdown in Chapter 8 of the SCP and are to be tied to those portions of DOE's Issues Hierarchy which correlate with Part 60. The open items resulting from Study Plan and Procedure Reviews should be similarly relatable.

### 12.2 Tracking Progress Toward Resolution of Open Items

Earlier sections of this Review Plan have emphasized the need for the staff to investigate during the Detailed Technical Review and the Procedure Review whether the contents of the study plan and/or procedure mark progress toward resolution of any existing open items (e.g., SCP open items) or even provide information needed to close them out. If so, such progress toward resolution should be documented in the OITS.