Received w/Ltr Dated 6/23/89

DOE Assessment of the Process Used to Develop, Review and Approve the Five Construction Phase Exploratory Shaft Study Plans

U.S. Department of Energy
Yucca Mountain Project Office
February, 1989

prepared by

David C. Dobson
Yucca Mountain Project Office

Martha W. Pendleton
Science Applications International Corporation

Maxwell B Blanchard
Director, Regulatory and Site Evaluation Division

6/2/89
Acting Director, Quality Assurance

102

EXECUTIVE SUMMARY

This assessment documents the actions involved with the review and approval process for the five exploratory-shaft facility (ESF) construction-phase Study Plans. Documented steps in the preparation and review of these documents are evaluated against the major program Quality Assurance requirements. Current requirements and controls were compared to the review process to come to final conclusions regarding the adequacy of the review process.

Each Study Plan received reviews for technical, regulatory, management, and Quality Assurance adequacy. The final project review included a real-time evaluation for adequacy and compatibility with the Statutory Site Characterization Plan (SCP).

The assessment concludes the five ESF Study Plans fulfill the requirements of the DOE/NRC agreement on content and level of detail. The assessment also concludes that the Study Plans meet all major quality assurance requirements for planning documents and are of sufficient technical quality. Potential improvements in requirement documents are also proposed.

TABLE OF CONTENTS

		Page
1	Introduction	1
1.1	Background	1
1.2	Purpose and Scope	2
2	Summary of Quality Assurance Controls Applied to Study Plans	4
2.1	Derivation of Required Quality Controls	4
2.1.1	Applicable NQA-1 Criteria	4
2.1.2	Summary	8
2.2	Implementation of Controls in the Current Program	9
2.2.1	Project Office Procedures	9
2.2.2	DOE Headquarters Procedures	12
2.2.3	Project Participant Procedures	12
2.2.4	Summary of the Adequacy of Current Controls	14
2.3	History/Evolution of Quality Controls for Study Plans	15
2.3.1	Yucca Mountain Project Quality Controls	15
2.3.2	DOE Headquarters Quality Controls	19
2.3.3	Project Participant Quality Controls	19
3	Evaluation of the Five Exploratory Shaft Facility Study Plans	21
3.1	Description of the Reviews	21
3.1.1	Excavation Investigations	21
3.1.2	Water Movement Test	25
3.1.3	Characterization of Percolation in the Unsaturated Zone — Exploratory Shaft Facility Studies	28
3.1.4	Characterization of Structural Features in the Site Area	33
3.1.5	Characterization of Site Ambient Stress Conditions	37
3.2	Evaluation of the Adequacy of the Quality Controls in Place During the Review and Approval of the Study Plans	40
3.2.1	Evaluation of the Requirements for Control of the Study Plan Process	40
3.2.2	Inconsistencies Identified in the Study Plan Process	42
3.2.2.1	Yucca Mountain Project Controls	43
3.2.2.2	DOE/HQ Quality Controls	44
3.2.2.3	Project Participant Controls	46
4	General Summary	48
4.1	Conclusions	48
4.2	Recommendations	48
5	References	50

LIST OF FIGURES

Figure	Title	Page
2-1	Matrix Showing Preparation and the Review and Approval Process for the ESF Construction Phase Study Plans	16

LIST OF TABLES

Table	Title	Page
2-1	NQA-1 Criteria	5
2-2	Project Participant Procedures	13
3-1	DOE/HQ and Project Reviewers for Study Plan 8.3.1.15.1.5	22
3-2	DOE/HQ and Project Reviewers for Study Plan 8.3.1.2.2.2	26
3-3	DOE/HQ and Project Reviewers for Study Plan 8.3.1.2.2.4	30
3-4	DOE/HQ and Project Reviewers for Study Plan 8.3.1.4.2.2	34
3-5	DOE/HQ and Project Reviewers for Study Plan 8.3.1.15.2.1	38
Appendix A	Enclosures	A1

1.0 INTRODUCTION

This report describes a U.S. Department of Energy (DOE) assessment of the process that the DOE used to prepare, review, and approve five Exploratory Shaft Facility (ESF) construction phase Study Plans. The assessment was conducted to address a U.S. Nuclear Regulatory Commission (NRC) concern that the Study Plans had been prepared and reviewed under Quality Assurance (QA) Level II controls. Because of this concern, the NRC requested documentation that the QA program used to control Study Plan development was adequate. Section 1.0 of this report summarizes the background and basis for the NRC concern and the purpose and scope of the Study Plan assessment. This assessment compares the process used to prepare and review the five ESF Study Plans against the requirements of the current Yucca Mountain Project (Project) procedure for Study Plan preparation, review, and approval (Administrative Procedure 1.10Q). Section 2.0 describes the QA controls applied to the Study Plans and is divided into three parts: (1) a summary of applicable requirements, (2) a summary of the measures the DOE is currently using to control Study Plan development, and (3) a brief history of the process and procedures used by the DOE for Study Plan control since May 1986, when Study Plans were created. Section 3.0 presents a summary and evaluation of the controls used during the development of the five ESF Study Plans, and Section 4.0 contains the conclusions that have resulted as recommendations for future improvements. Although the assessment has resulted in the identification of several improvements in the Study Plan Process, the general conclusion is that the controls applied to Study Plans were adequate, and that the five ESF Study Plans are of substantially the same quality as if they had been prepared under a QA Level I program.

1.1 BACKGROUND

On May 27, 1988, the DOE submitted two Site Characterization Plan (SCP) Study Plans to the NRC for review. The NRC completed an acceptance review of these documents and informed the DOE in a letter of August 5, 1988, that the NRC staff found the Study Plans to be incomplete. In the letter, the NRC expressed concern that the DOE had prepared and reviewed the Study Plans under QA Level II controls. The NRC stated that the development of a Study Plan includes activities such as technical evaluations and decisions on the kinds and amounts of testing to be completed during site characterization. Because the NRC considers that these evaluations will be needed to support the use of data in licensing, the NRC believes the preparation and review of SCP Study Plans should be a QA Level I activity.

The DOE has carefully considered the NRC concern on QA level assignments for the preparation and review of SCP Study Plans. In an NRC/DOE meeting on Study Plans on December 15, 1988, the DOE indicated that the preparation and review of SCP Study Plans would, in the future, be conducted at QA Level I, because SCP Study Plans serve as a direct link between the SCP and the technical procedures used to implement site characterization activities.

Following the DOE presentation at the December meeting, the NRC noted that the five Study Plans related to ESF construction phase testing, which were to be submitted to the NRC with the SCP, were not prepared under QA Level I controls. For this reason, the NRC stated that it would accept the Study Plans for information, but would not initiate a formal review until the DOE provided an evaluation supporting its contention that the five Study Plans are of the same technical quality as if they had been prepared under a QA Level I program.

In order to address the NRC concerns, the DOE agreed to assess the Study Plans and associated documentation and to present the results of that assessment. This report describes the methodology used to review the Study Plans and provides the results of the assessment.

1.2 PURPOSE AND SCOPE

The Yucca Mountain Project Office (Project Office) has reviewed the five ESF construction phase Study Plans and associated documentation against current and past QA requirements. The purpose of this assessment was to evaluate the process used to prepare, review, and approve the Study Plans, and to determine if the Study Plans meet the QA requirements delineated in the Project Quality Assurance Plan (QAP), Revision 2 (NNWSI/88-9). This revision of the QAP was reviewed and approved by the Project Office, accepted by the NRC, and formally issued on December 9, 1988. In this report, it is assumed that a QA program for Study Plan development and approval, which meets all requirements of NNWSI/88-9, is adequate to meet NRC requirements.

In parallel with the development of NNWSI/88-9, the Project Office developed and approved Administrative Procedure (AP)-1.10Q, entitled "Preparation, Review, and Approval of SCP Study Plans." The administrative procedure superseded the project procedure for Study Plan preparation and review contained in Section 6 of the SCP Management Plan (SCPMP). AP-1.10Q was issued to the Project on December 14, 1988, and was intended to provide sufficient QA controls to govern preparation and review of SCP Study Plans consistent with the QA requirements in NNWSI/88-9. As part of this review, a comparison of the requirements of AP-1.10Q to NNWSI/88/9 was completed to verify that AP-1.10Q adequately implements the QA requirements of NNWSI/88-9. This report documents inconsistencies between the requirements of AP-1.10Q and NNWSI/88-9, and provides recommendations for their resolution. These inconsistencies are minor and do not impact the technical quality of the Study Plans.

Following the definition of the applicable current QA controls, the Study Plans and associated DOE records were evaluated against the requirements of AP-1.10Q. This assessment did not include verification of records at Project participants because the DOE considers that the DOE Study Plan reviews provided adequate verification of the quality of the process used to prepare Study Plans by examining the controls in place as the existing plans were developed and by quality of the final documents. This review assessed the extent to which the Study Plans meet the requirements described in NNWSI/88-9 and AP-1.10Q. Because the preparation and review of Study Plans were assigned

QA Level II when AP 1.10Q was developed, it was necessary to determine whether the controls were equivalent to those that would have been required in a QA Level I program. As noted in Section 2 of NNWSI/88-9:

> "In most cases, activities controlled in accordance with a Quality Assurance Level II program cannot be used subsequently to directly support Quality Assurance Level I activities unless it can be substantiated that quality assurance requirements equivalent to those which would have been applied to a Quality Assurance Level I activity were implemented or that a technical justification process is applied in accordance with NNWSI AP 5.9Q 'Acceptance of Data and Data Interpretations Not Developed Under the NNWSI Project QA Program.'"

In summary, the intent of this report is to evaluate whether it can be demonstrated that the QA requirements applied to the preparation and review of these plans were equivalent to those that would have been required if the activity had been assigned QA Level I. The purpose of the SPA is also to determine if there are any technical deficiencies in the plans as a consequence of their being prepared as QA level II documents. The results of this assessment are provided in Section 3.0 of this report.

2.0 SUMMARY OF QUALITY CONTROLS APPLIED TO STUDY PLANS

2.1 DERIVATION OF REQUIRED QUALITY CONTROLS

The requirement for the DOE to write Study Plans was formally created during a DOE/NRC meeting on the level of detail in the SCP and Study Plans, on May 7 and 8, 1986 (the DOE/NRC Meeting). As discussed below, technical planning documents in the high-level waste program, including Study Plans, have always been regarded as subject to the requirements of a QA program.

10 CFR 60, Subpart G, requires the implementation of a QA program that is consistent with 10 CFR 50, Appendix B, as appropriate, for (1) all systems, structures and components important to safety; and (2) design and characterization of barriers important to waste isolation. Activities related to design and characterization, as well as to systems, structures, and components, are also subject to quality controls. 10 CFR 50, Appendix B, specifies that measures shall be established to ensure that applicable regulatory requirements, and the design basis (as specified in the license application), for structures, systems, and components important to safety are correctly translated into specifications, drawings, procedures, and instructions.

Although the preparation and review of Study Plans was assigned Quality Level II, the DOE has consistently interpreted the requirements of 10 CFR 60, Subpart G, and 10 CFR Part 50, as summarized above, to apply to the site characterization activities described in Study Plans, because they are designed to collect information to be used in a license application. Furthermore, the set of NQA-1 criteria we have judged to be applicable to Study Plan activities is identical for either QA Level I or QA Level II.

2.1.1 APPLICABLE NQA-1 CRITERIA

In order to implement an adequate program for the control of the development and review of Study Plans as a QA Level II activity, the DOE examined the 18 NQA-1 criteria, and determined that nine criteria apply to the development of Project Study Plans (note that additional criteria normally apply to the activities described in the Study Plans). Table 2-1 summarizes the 18 criteria and the rationale for applying specific criteria to the Study Plan process.

Of the applicable criteria, Criteria 2, 3, 5 and 6 impose specific requirements for actions related to the control of the preparation, review, and approval of Study Plans. The requirements derived from the criteria are described in NNWSI/88-9, which has been accepted by the NRC as an adequate plan for the control of site characterization. The requirements are summarized briefly below. Enclosure 1 to this report contains copies of pertinent sections of the NNWSI/88-9.

Table 2-1. NQA-1 Criteria

QA Criterion	Applicable/Not Applicable (Y/N)	Justification
1. Organization	Y	Criterion 1 requires that the authority and duties of persons and organizations performing activities affecting safety-related functions be clearly established and delineated in writing. See QMP-01-01.
2. QA Program	Y	Criterion 2 requires that a QA program which complies with 10 CFR 50, Appendix B, be established. See NNWSI/88-9 and subordinate QA Program Plans (QAPPs).
3. Scientific Investigation and Design Control	Y	Criterion 3 requires that measures be established to control primary design and scientific investigations.
4. Procurement Document	N	There are no procurement activities associated with Study Plan preparation, review, and approval.
5. Instructions, Procedures, and Drawings	Y	Procedures are required for Study Plan preparation, review, and approval.
6. Document Control	Y	Study Plans are controlled documents.
7. Control of Purchased Materials, Equipment, and Services	N	There are no procurement activities associated with Study Plan preparation, review, and approval.
8. Identification and Control of Material, Parts and Components	N	There are no materials, parts, or components to be identified or controlled.
9. Control of Processes	N	There are no special processes associated with Study Plan preparation, review, and approval.

Table 2-1. NQA-1 Criteria (continued)

QA Criterion	Applicable/Not Applicable (Y/N)	Justification
10. Inspection	N	The Study Plan process is monitored by audit and/or surveillance.
11. Test and Experiment/ Research Control	N	Tests and experiments are not conducted to support the Study Plan process.
12. Control of Measuring and Test Equipment	N	No measuring or test equipment is used to support the Study Plan process.
13. Handling, Shipping, and Storage	N	No material or equipment require special measures for handling, shipping, and storage.
14. Inspection, Test, and Operating	N	Inspections and tests are not conducted to support the Study Plan process.
15. Control of Nonconformances	Y	Deficiencies noted in audits and surveillances are controlled by Criterion 15.
16. Corrective Action	Y	Measures adverse to quality are controlled by Criterion 16.
17. QA Records	Y	QA records are maintained.
18. Audits	Y	Audits and surveillances are conducted to monitor the Study Plan process.

Criterion 2: QA Program (NNWSI/88-9, Section II)

Criterion 2 requires the implementation of a QA program sufficient to control activities that will contribute to the development of the license application for the Project. Section II of NNWSI/88-9 describes, in general terms, the scope, application, and requirements of the QA program. Section II is, of course, generally applicable to all aspects of the Project, including Study Plan development. However, the portion of Section II that most directly affects the Study Plan process is Subsection 5, which describes personnel selection, indoctrination, and training (see Enclosure 1).

Subsection 5 requires that the Project establish requirements for personnel (normally in position descriptions), that personnel qualifications be evaluated and documented, and that indoctrination and training be performed where necessary. Training requirements shall be appropriate to the activities to be conducted. Records of the qualification, evaluation, indoctrination, and training of personnel shall be maintained.

Criterion 3: Scientific investigation control and design control (NNWSI/88-9, Section III)

The DOE and NRC have agreed that Criterion 3, which was originally specific to design control, also applies (for the high-level waste program) to the control of scientific investigations. As such, and since Revision 0 of the Project QAP (effective date: August, 1980), all QAPs for the project have included language that sets specific requirements for scientific planning documents. Enclosure 1 includes a copy of NNWSI/88-9, Section III, which contains provisions that apply to the preparation and review of Study Plans. The section describes specific responsibilities of the principal investigator (PI) and Project Office.

Scientific plans, including Study Plans, are required to contain a description of the work to be performed. Specific content requirements are noted in Subsection 1.1.1.1 of Section III, and in Appendix K, which reproduces the content requirements for Study Plans agreed to by the DOE and NRC (the DOE/NRC Agreement) at the DOE/NRC Meeting. Further, scientific planning documents are required to contain a level of detail sufficient to enable an independent reviewer to determine the appropriate QA level to be applied to the planned work.

Requirements for the review and approval of Study Plans are summarized in Subsection 1.3 of Section III. Project participants originating Study Plans are required to perform documented technical reviews of the plans. The Project is also required to perform technical, QA and management reviews, and to approve the plans. Study Plans are also reviewed and approved by the DOE/Headquarters (DOE/HQ) Office of Civilian Radioactive Waste Management (OCRWM) prior to release to the NRC.

Changes to planning documents are discussed in Subsection 1.7 of Section III. They are subject to the same review and approval process as the initial drafts of the plans.

Criterion 5: Instructions, procedures, plans, and drawings (NNWSI/88-9, Section V)

Criterion 5, as specified in Section V of NNWSI/88-9, requires that activities affecting quality be prescribed by and performed in accordance with documented instructions, procedures or drawings. If plans are used in lieu of procedures, the plans must include or reference acceptance criteria, and identify QA records that will be generated. The planning documents must be controlled as required by Section VI of NNWSI/88-9.

Independent reviews of all instructions, procedures, plans and drawings must be performed by the originating Project participant. The Project Quality Manager shall be provided with controlled copies of all procedures, plans, and drawings used for QA Level I activities.

Criterion 6: Document control (NNWSI/88-9, Section VI)

Criterion 6, as reflected in Section VI of NNWSI/88-9, requires that documents containing or specifying quality requirements, or prescribing activities affecting quality, be controlled. In addition, the control system shall be documented, and the QA organization shall provide appropriate review, comment resolution, and concurrence with respect to quality-related aspects of controlled documents.

Specific requirements relating to the implementation of document control are described in Subsection 1.2 of Section VI. They include the following:

1. Identification of the documents.

2. Identification of the assignment of responsibility for preparing, reviewing, approving, and issuing documents.

3. Review for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements.

4. A method for removal or marking of obsolete or superseded documents.

5. A method for ensuring that correct, applicable documents are available at the location where they are to be used.

6. A master list to identify the correct, updated revisions of documents.

7. Coordination of interface documents.

Subsection 2.0 of Section VI contains requirements for revision of approved, controlled documents. It specifically requires that organizations responsible for approving proposed changes consider whether activities being changed have the potential of affecting the waste isolation capability of the site, or could interfere with other site characterization activities.

Subsection 3 of Section VI provides requirements for the distribution of controlled documents.

2.1.2 SUMMARY

The Project QAP (NNWSI/88-9) imposes several important requirements on the preparation, review, and approval of Study Plans that describe site characterization activities. These requirements are:

1. Study Plans must be prepared and reviewed by qualified personnel.

2. The format and content of Study Plans must meet all applicable requirements (including specific provisions for technical, regulatory, and quality-related content).

3. The process of development, review, approval,issuance, and revision must be controlled.

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

In response to NRC concerns with respect to the QA level assignment for Study Plans, the Project has committed to assigning the entire process QA Level I. It should be noted, however, that all of controls and requirements described above would apply, regardless of whether a specific level had been assigned to the Study Plan process. These controls are consistent with prudent practice in producing technically adequate planning documents with the proper documentation.

The Project has implemented the requirements described in this section by developing procedures to control Study Plans. The implementation of this process has been subjected to a QA surveillance at the Project Office. The results of these surveillances are summarized in Section 3.1 of this report. The procedures currently in effect, as well as earlier revisions, are described below.

2.2 IMPLEMENTATION OF CONTROLS IN THE CURRENT PROGRAM

2.2.1 PROJECT OFFICE PROCEDURES

For activities that involve multiple participants (e.g., Study Plan development, which involves (1) scientific organizations that prepare the plans; (2) the Project Office and Technical and Management Support Services Contractor, which participate in review and approval; and (3) other Federal agencies, which provide independent review), the requirements of the Project QAP are implemented by developing and utilizing administrative procedures. AP-1.10Q (Enclosure 2) defines the requirements and responsibilities that apply to Project Study Plans. Several other project procedures such as AP-1.5Q "Issuance and Maintenance of Controlled Documents," also contain requirements that apply. While the discussion below focuses primarily on AP-1.10Q, it does address briefly important aspects of other procedures that apply.

AP-1.10Q was developed in parallel with Revision 2 of the Project QAP (NNWSI/88-9), and was approved on November 23, 1988. The procedure became effective on December 14, 1988, superseding Section 6 of the SCPMP, Revision 2. It applies to all Study Plans developed by the Project.

AP-1.10Q contains specific responsibilities and requirements for each stage of the preparation, review, and approval of Study Plans. Sub-section 5.1, Study Plan Preparation, requires that a Project participant's Technical Project Officer (TPO) designate qualified PIs to prepare Study Plans. It further specifies that plan: (1) must conform to the level of detail, format, and content specified in the DOE/NRC Agreement; (2) must be consistent with the SCP; and (3) must contain other content required by the procedure. Project participants are also required to perform technical reviews or revise Study Plans, using qualified staff. Any significant deviation from the SCP which is described in the Study Plan must be accompanied by an Interim Revision Notice (IRN). The TPO must submit approved Study Plans to the Director of the Project Office Regulatory and Site Evaluation Division (RSED). The Project Office must maintain documentation of the qualifications of PIs and reviewers.

Subsections 5.2 and 5.3 of AP-1.10Q describe the Project review of Study Plans, and contain several important requirements. Following an initial screening review, which focuses on format, content, and consistency with the SCP, the Project Office conducts management, regulatory, QA, and technical reviews according to established review criteria (see Sections 3 and 5.2 of AP-1.10Q). These reviews exceed the standard set by NNWSI 88-9, which does not require a regulatory review. The reviews are performed by qualified staff at the Project Office, T&MSS contractor, and other Project participants, and records are maintained of the qualifications of all reviewers. All comments are documented on comment resolution forms, which are returned to the Project Office. All comments are categorized as (1) mandatory, (2) nonmandatory, or (3) editorial. Mandatory comments are major technical concerns or inconsistencies with DOE policies or regulatory requirements, and must be resolved. Nonmandatory comments are suggestions to the author about the content or organization of the document, and are incorporated at the discretion of the author. Comments may be resolved in writing, or at comment resolution meetings, which are attended by both reviewers and PIs. Resolutions to all comments are documented in writing and signed by both reviewers and the PIs. Irresolvable comments may be referred to the RSED Director, for disposition. The RSED Director may seek a resolution based on compromise or independent technical review. Revised Study Plans are submitted to the Project by the responsible TPO with completed comment resolution forms. Reviewers are required to verify the resolution of comments prior to approval by the RSED Director, the Project Quality Manager, and the Project Manager (see AP-1.10Q).

AP-1.10Q also contains a description of the project role in the DOE/HQ (i.e., the OCRWM) review of Study Plans, and specifies responsibilities and qualifications for Project participants, the Project Office, PIs, and reviewers. A complete record of comments and resolutions must also be compiled and maintained, for the DOE/HQ review, and verification of the adequate resolution of all comments is required. A further discussion of DOE/HQ review appears below.

The Project response to NRC review of Study Plans is also defined by AP-1.10Q in Section 5.6. The procedure requires that the Project Office document NRC comments on comment resolution forms. The Project Office and the PI must work with DOE/HQ to develop proposed responses. If text revision is needed, the revision will be completed according to approved DOE procedures.

Revisions to Study Plans are, in general, covered by the same review and approval process used for initial drafts. In addition, AP-1.10Q requires that Study Plans be maintained and controlled according to AP-1.5Q and QMP-06-02, entitled "Document Control." Therefore, procedures applicable to controlled documents also apply to Study Plans.

In summary, AP-1.10Q is a detailed procedure designed to implement the requirements of the Project QAP for the preparation, review, and approval of Study Plans. As such, the procedure contains specific responsibilities and requirements, including the following:

1. Study Plans must be written and reviewed by qualified personnel.

2. Study Plans must conform to the format and content guidance of the DOE/NRC Agreement.

3. Study Plans must be consistent with the SCP.

4. The process of development, review, revision, and approval of Study Plans must be controlled according to specified procedures.

5. Records documenting that all requirements have been fulfilled must be maintained.

In addition to AP-1.10Q, several other Project-level procedures contain requirements that apply to the preparation, review, and approval of Study Plans. For example, as noted above, AP-1.10Q requires that Study Plans be prepared and reviewed by qualified staff. For the Project Office, qualification of personnel is controlled by QMP-02-01, entitled "Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Personnel." This procedure requires that the qualifications of all employees be evaluated by their managers against the requirements of the position, and that proficiency be evaluated yearly. In addition, QMP-02-01 requires indoctrination and training of employees, as appropriate, prior to the performance of activities that affect quality. Managers are responsible for checking and certifying that all necessary training has been conducted.

Two procedures for the issuance of controlled documents apply to Study Plans. AP-1.5Q describes the general requirements and responsibilities for controlled document distribution, and provides guidance for ensuring that individuals on the controlled document distribution list have current copies of approved documents. QMP-06-02 contains the detailed procedures used by the Project Office Document Control Center to implement the requirements of the NNWSI/88-9 and AP-1.10Q. As noted earlier, Section VI of the NNWSI/88-9 imposes numerous requirements on the Document Control system.

For Study Plans, Items 2, 3, and 4 in the list above are implemented through AP-1.10Q (in accordance with QMP-06-02, which stipulates that preparation, review, and approval shall be done according to appropriate procedures). The remainder of the requirements and the detailed procedures used for distribution and revision of controlled documents are described in QMP-06-02.

2.2.2 DOE/HQ PROCEDURES

The DOE/HQ Interim Procedure for the review of Study Plans (Enclosure 3, effective date: September 9, 1988) defines the responsibilities of DOE/HQ in the Study Plan process. The procedure focuses on the process of the review, and does not contain explicit guidance for the preparation of a Study Plan. However, it does clearly state that Study Plans will be evaluated for consistency with the SCP, and for consistency with the requirements of the DOE/NRC Agreement, which is included as Appendix A to the procedure.

The procedure requires an acceptance review by the DOE/HQ Regulatory Compliance Branch following Project Office submission of a draft Study Plan. The intent of the acceptance review is to check the plan for consistency with the SCP, and to compare the level of detail in the plan against the requirements of the DOE/NRC Agreement. Results of the acceptance review are documented in a memo and on an acceptance review checklist. Any concerns documented in the acceptance review are incorporated in the technical review comments. Following completion of the acceptance review, DOE/HQ initiates an integration and technical review. The transmittal letter initiating the review provides review criteria and specific guidelines for comparison of the Study Plan to the requirements of the DOE/NRC Agreement. The Director of the Office of Quality Assurance (OQA) is required to participate in reviews, as needed, and to ensure that the review process is audited, as appropriate.

All comments developed during the formal review are documented on comment resolution forms. The procedure also requires that reviewers provide proposed resolutions for each comment. After completion of all individual reviews, DOE/HQ is required to consolidate all comments, and distribute them to the Project Office for resolution. Final agreement on the proposed resolution of comments should be reached at a comment resolution meeting between reviewers and the Study Plan authors and/or PIs.

Verification of the adequacy of the actual resolutions of comments must be completed (and documented) by DOE/HQ following the revision and re-submission of the Study Plan by the Project Office. The final disposition of the comments is documented on the comment resolution forms and the completed (signed) comment resolution forms are maintained as part of the permanent record for the Study Plan. When the resolution of all DOE/HQ comments is judged adequate, the Study Plan will be approved and forwarded to the NRC for review. Approval requires the signatures of the Directors of the OQA, Office of Facility Siting and Development (OFS&D), and Office of Systems Integration and Regulations (OSI&R). The OSI&R Director is responsible for transmitting Study Plans to the NRC.

2.2.3 PROJECT PARTICIPANT PROCEDURES

Table 2-2 summarizes the procedures that are currently in place at Los Alamos National Laboratory (Los Alamos), Sandia National Laboratories (SNL), and the U.S. Geological Survey (USGS) to control Study Plan development. Copies of each of the Study Plan specific procedures are included in Enclosures 4, 5, and 6. The Project T&MSS Contractor uses Project Office procedures.

Table 2-2. Project Participant Procedures

Organization	Procedure
Los Alamos National Laboratory	TWS-QAS-QP-02.1, R0, NNWSI Personnel Selection, Training, and Certification (effective date: 3/29/88)
	R1, effective date: 12/7/88
	TWS-QAS-QP-07, R0, Procedure for Technical Review of Publications (effective date: 8/2/82)
	R1, effective date: 3/4/85
	R2, effective date: 5/11/88
Sandia National Laboratories	DOP 2-2, R0, Study Plan Requirements (effective date: 12/1/86)
	RA, effective date: 5/13/88
	RB, effective date: 11/11/88
	DOP 6-2, R0, Reviewing, Approving, and Issuing Technical Information Documents (effective date: 1/20/87)
	RA, effective date: 12/23/88
	DOP 2-6, R0, Qualification and Certification of Project personnel (effective date: 7/30/86)
U.S. Geological Survey	Study Plan Desk Procedure (effective date: 11/16/87)
	NNWSI-USGS-QMP-3.07, R0, Technical Review Procedure (effective date: 10/27/86)
	R1, effective date: 11/04/88
	NNWSI-USGS-QMP-2.03, R0, Certification of USGS and USGS Contractor personnel for the NNWSI Project (effective date: 10/27/86)

The Los Alamos procedure for technical review (TWS-QAS-QP-07, R2, Enclosure 3) requires independent technical review, formal comment resolution, and maintenance of the complete document review package as a QA record. The procedure does not specify independent documentation of the reviewer's

qualifications and does not provide criteria for the review or a definition of technical review. However, the Los Alamos procedure for qualification of personnel (TWS-QAS-QP-02.1, R1, Enclosure 4) establishes the requirements for the selection, indoctrination, certification, qualification, and evaluation of all Los Alamos personnel performing activities that affect quality on the Project. The procedure also requires the maintenance of records documenting that all the requirements have been satisfied.

The SNL procedure, Study Plan requirements (Enclosure 5) provides requirements for Study Plan preparation, including the annotated outline for Study Plan format and content from the DOE/NRC Agreement. The current revision requires internal review in accordance with Department Operating Procedure (DOP) 6-2, Revision 0 (see Table 2-2, Enclosure 5). DOP 6-2 requires an independent and documented technical review by a qualified reviewer and identifies QA records that must be maintained during the review process. DOP 2-6, Revision 0 (Enclosure 5), specifies the requirements for qualification and certification of SNL personnel.

The USGS approved a "desk procedure" for the control of Study Plans on November 16, 1987 (Table 2-2, Enclosure 6). This desk procedure is an informal procedure implemented by direction of the USGS Technical Project Officer. While this procedure was informally reviewed by the technical and QA staff, it was not approved through formal USGS procedure. The procedure describes USGS responsibilities and procedures for the preparation, review, and approval of Study Plans before they are submitted to the Project Office. Originators of Study Plans are required to develop them in accordance with the guidance contained in the DOE/NRC Agreement. The procedure also calls for a USGS review in accordance with NNWSI-USGS-QMP-3.07 (Enclosure 6), entitled "Technical Review Procedure." NNWSI-USGS-QMP-3.07 requires a documented technical review by a qualified reviewer who is independent of the work being reviewed. A USGS procedure for certification of personnel (NNWSI-USGS-QMP-2.03) has been in effect since October 1986 (Enclosure 6).

2.2.4 SUMMARY OF THE ADEQUACY OF CURRENT CONTROLS

Although minor inconsistencies in the implementation of AP-1.10Q, and the other applicable Project, OCRWM, and Project participant procedures have been identified during this review (see Section 3.2), the procedures do provide instructions to effectively implement the requirements of NNWSI/88-9. These inconsistencies do not affect the technical adequacy of the document. They have been or will be corrected by the technical staff through response to Project QA Observation No. YMP-SR-88-019-01 and revisions to appropriate plans (see Section 4.2). AP-1.10Q, together with the other Project procedures it references or requires, was designed to fully implement NNWSI/88-9, and it meets that goal. The OCRWM review provides additional confidence that all requirements have been satisfied. We therefore conclude that Study Plans that have been developed in accordance with existing procedures do meet all major QA requirements which apply, and should be adequate for NRC review.

2.3 HISTORY/EVOLUTION OF QUALITY CONTROLS FOR STUDY PLANS

This section describes the procedures and guidance issued by the DOE to control the development and approval of Study Plans between May 1986 and the implementation of the current controls. The key documents referred to in this discussion are contained in the Enclosures.

At the DOE/NRC Meeting, the DOE agreed to prepare SCP Study Plans according to the format and content guidance that was agreed to during the meeting. Documentation of the actions initiated by the DOE (see enclosures) includes letters from the DOE to the Project participants, as well as earlier versions of implementing procedures.

One month after the DOE/NRC Meeting, on June 5, 1986, the Project Office issued the DOE/NRC content requirements for descriptions of SCP studies in Study Plans to the Project participants (USGS, Los Alamos, Lawrence Livermore National Laboratory, SNL, and Science Applications International corporation) to facilitate the preparation of Study Plans (Enclosure 7). The transmittal letter noted that, although formal guidance on the preparation of Study Plans had not been issued by the DOE, the enclosed outline from the DOE/NRC Meeting would probably become the formal guidance. At an August 27 and 28, 1986, meeting of the SCP Management Group, the Project agreed to prepare Study Plans in accordance with the DOE/NRC Agreement. Additional clarification of content requirements has been provided in several subsequent letters (Enclosure 8), as well as in meetings of the TPOs of the Project participants.

During the fall of 1986, the Project also requested guidance from DOE/HQ on the review and approval process for Study Plans. DOE/HQ issued a draft procedure for DOE/HQ approval of Study Plans on December 11, 1986. This procedure instructed the Project to prepare Study Plans in accordance with the DOE/NRC Agreement and to submit the Study Plans to DOE/HQ for review and approval as soon as possible. The following sections describe the evolution of Project Office and DOE/HQ procedures for the control of Study Plan development and review. Figure 2-1 is a graphic representation of the development of the procedures during the preparation of the five ESF Study Plans. The processes used to control the studies were defined by the approved procedures at the time. On December 4, 1987, the Project distributed the Project QA Level II assignment sheet for the Study Plan process to the affected Project participants. This QA level includes documentation of the set of NQA-1 criteria that was applicable to the process.

2.3.1 YUCCA MOUNTAIN PROJECT QUALITY CONTROLS

Because Study Plans are subordinate documents to the SCP, the Project Office initially considered their preparation and review to be subject to the same controls that apply to the SCP. These controls are described in the SCPMP. It should be noted that the SCPMP is a quality-affecting document, approved by the Project Quality Manager, as well as the Project Manager and the Project Office Division Director responsible for preparation of the SCP.

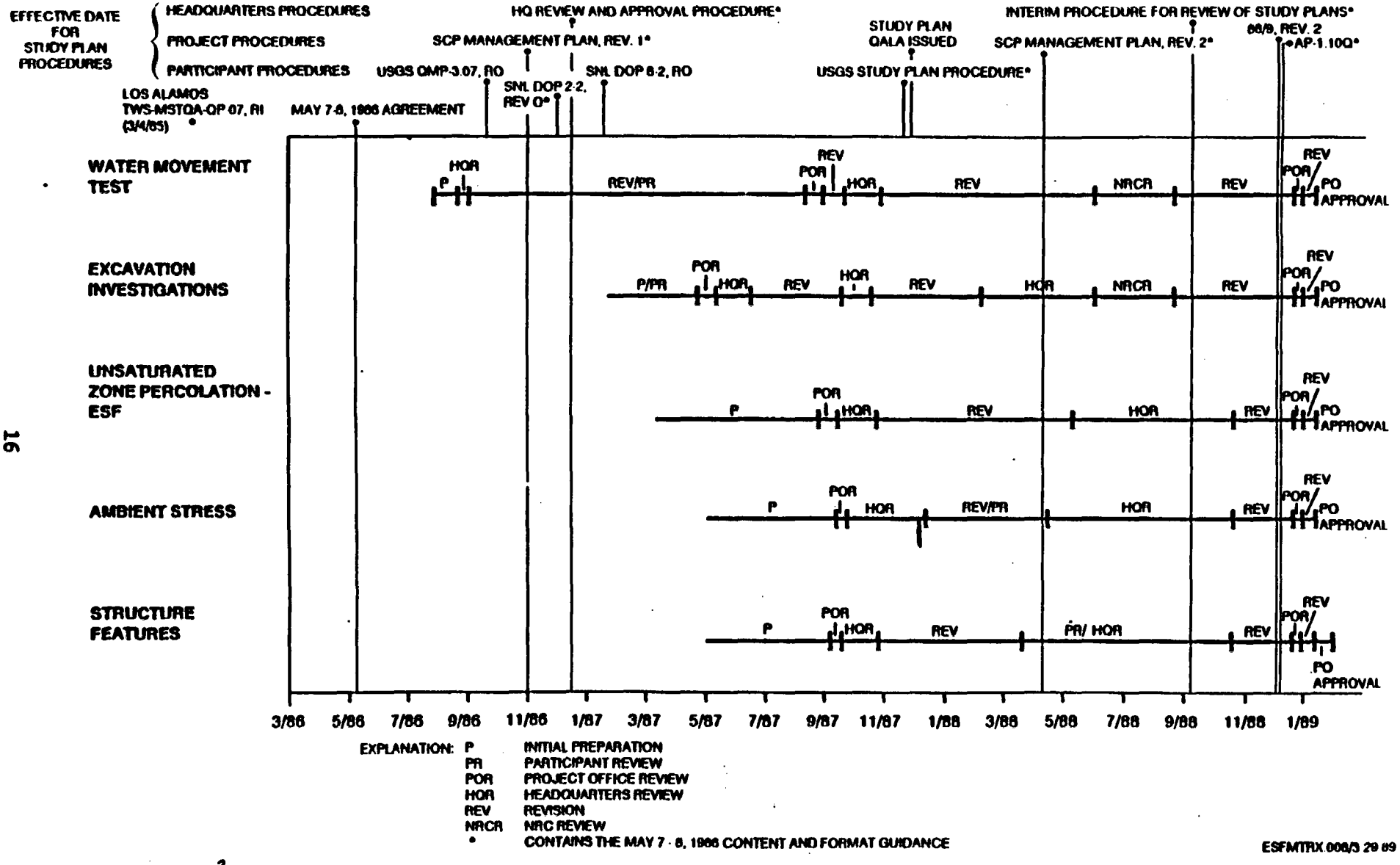


Figure 2-1. Matrix Showing Preparation and Review Procedures and the Review and Approval Process for the ESF Construction Phase Study Plans.

The purpose of the SCPMP is to define (1) organizational responsibilities and authorities of the Project participants for preparation and review of the SCP; (2) the approach and procedures to be used in the preparation, review, and revision of the SCP; and 3) the schedule for SCP preparation.

In order to explicitly incorporate Study Plans in the SCP process, the Project issued Revision 1 to the SCPMP on November 4, 1986. Revision 1 included an appendix containing the DOE/NRC Agreement (Enclosure 9). The SCPMP thus contained formal instructions to the Project participants on the format and content requirements for SCP Study Plans. In addition, each Project participant identified a Study Plan Coordinator to work with the PIs to ensure that the Study Plans were prepared in accordance with the DOE/NRC Agreement.

As the first drafts of several Study Plans were written and reviewed in the Project Office, it became apparent that it would be difficult to ensure adequate control of the quality of Study Plans without specific Project Office procedures to guide the process. The review process described in the Project Office's standard procedure for document review and approval (QMP-06-03) did not specifically include Study Plans, and the requirements of Study Plan review were not easily accommodated by the procedure. In addition, although the Project conducted a technical review of each Study Plan as it was submitted, there was no requirement to do so. QMP-06-03 required only DOE management and QA reviews, so the DOE/HQ review was the only technical review mandated by the existing DOE procedures. Project Office management therefore determined that a Project technical review should be required in order to ensure full integration of the Study Plans with the SCP, and to ensure that all information needs specified in the SCP would be met by the Study Plan. For this reason, Revision 2 of the SCPMP was issued on April 5, 1988 (Enclosure 9). The purpose of the SCPMP was expanded to describe the organization, process, and schedule by which the SCP, supporting Study Plans, and SCP progress reports would be completed. This revision formally committed the Project to reviews of Study Plans in parallel with, or prior to, the DOE/HQ review; defined specific review criteria; and defined a process for documentation and control of the review.

Section 2 of the SCPMP, Revision 2, described the organizational responsibilities and authorities for SCP and Study Plan preparation and review. Section 3 summarized the requirements for format and content of SCP Study Plans and referenced Appendix A, which contains the complete guidance on Study Plan format and content from the DOE/NRC Agreement.

Section 6 of the SCPMP identified Study Plans as Project participant documents developed by the PI at the Project participant organization following the format and content requirements described in Section 3. The SCPMP required that the preparation and review of the initial draft Study Plan be completed under the quality controls of the Project participant QA Programs. It required a record of revision in front of the Study Plan and an approval page to document Project participant technical and QA approvals. Section 6 also established Project Review Teams, with suggested reviewers selected on the basis of their technical expertise, along with review responsibilities.

Section 6 required that reviews be initiated by a transmittal letter defining the scope, emphasis, purpose, and schedule for each review. The section required an informal screening of each Study Plan (prior to initiation of a formal review) against the guidance from the DOE/NRC Agreement. Reviewers were required to document all comments on comment resolution forms and to distinguish between major and minor technical concerns. The PI was required to ensure that text modifications accurately reflected review team agreements. Following revision of the Study Plan, comment resolutions were required to be verified and documented on the comment resolution form. Later revisions to the Study Plan were subjected to the same level of review as the initial draft.

On December 1, 1987, the Project QA staff proposed a Standard Deficiency Report (Enclosure 10) against the preparation and review process for four of the five Exploratory Shaft Construction Phase Study Plans because these Study Plans were being prepared and reviewed without the benefit of approved Project procedures. The Standard Deficiency report was rejected by the Project QA Manager because these documents were being prepared within the overall framework and guidance established by the SCPMP.

In the summer of 1988, representatives of the Project QA staff completed a surveillance on Study Plan activities (Enclosure 11). This surveillance was limited to records available at the Project Office. Based on the observations presented in the surveillance, Project QA recommended the following actions:

1. Delete instructions relating to the Study Plan review process from the SCPMP.

2. Prepare an administrative procedure with instructions for Study Plan review, including:

   a. The use of written criteria to direct the technical review.

   b. Provisions for qualification of technical reviewers.

   c. Provisions of resolution of disputes.

   d. Provisions for traceable records maintenance.

3. Revise the definition of technical review in Appendix A of NNWSI/88-9 to eliminate references to "... expertise at least equivalent to those who performed the original work" because this requirement is unrealistic and unnecessary.

4. Collect all records of Study Plan reviews prior to April 21, 1988, and review these records to ascertain the extent to which these records meet current requirements.

These actions are currently being addressed by the technical staff (see Section 4.0).

2.3.2 DOE/HQ OCRWM QUALITY CONTROLS

The initial DOE/HQ procedures (Enclosure 12) for Study Plan review and approval were management procedures, signed by the Director, Engineering and Geotechnology Division, Office of Geologic Repositories, OCRWM, and were not reviewed or approved by the QA Division.

In response to a request from the Project Offices, DOE/HQ issued a draft procedure for DOE/HQ approval of SCP Study Plans. The procedure required that a Study Plan be prepared in accordance with the guidance for format and content specified in the DOE/NRC Agreement. The procedure also required an acceptance review against these criteria. If the format and content of a Study Plan was judged acceptable, the procedure required a review by DOE/HQ reviewers. DOE/HQ reviewers were trained in the implementation of the procedure. However, as noted in the March 31 and April 3, 1989, DOE/HQ internal surveillance, these procedures did not include appropriate quantitative and qualitative acceptance criteria for performance of the technical review.

Comments generated during this review were to be documented on comment resolution forms. A resolution to each comment was to be formulated in a comment resolution meeting with the Project. The procedure required the revision of the plan to address the comments and specified that the actual disposition of each comment was to be documented on the comment resolution forms. After the submission of the revised Study Plan to DOE/HQ, the procedure required verification of the comment resolutions, prior to approval of the Study Plan.

On April 14, 1987, a revised Final Procedure for DOE/HQ approval of Study Plans supporting the SCP was issued (Enclosure 12). This revision contained the requirements described above for the draft procedure, and added a requirement that the Project Office consider a draft Study Plan complete and ready for review prior to submittal to DOE/HQ for review. It also provided, in Attachment B to the procedure, additional guidance and requirements for the preparation of Study Plans. These requirements include consistency between Study Plan numbers and titles and SCP numbers and titles, and controlled issuance of Study Plans.

DOE/HQ issued a clarification of its Final Procedure on July 26, 1987 (Enclosure 12). The clarification specified the nature of the DOE/HQ review (stating that it was a technical review), and provided a definition of the scope of the review. It also assigned responsibility for controlled distribution of Study Plans to the Project.

2.3.3 PROJECT PARTICIPANT QUALITY CONTROLS

Table 2-1 summarizes the status and evolution of Project participant procedures that apply to the preparation and review of Study Plans. In particular, procedures for document review, Study Plan preparation and review, and personnel qualification are cited.

At the time that the Study Plan for Water Movement Tests (Study Plan 8.3.1.2.2.2) was prepared, the Los Alamos procedure for technical review (see Table 2-1, Enclosure 4) required an independent, documented technical review of the Study Plan. Revision 1 of the SCPMP provided requirements for format and content of Study Plans. However, Los Alamos had not yet issued its procedure for the qualification of personnel.

During the preparation of the Study Plan for Excavation Investigations (Study Plan 8.3.1.15.1.5), SNL had procedures in effect for the qualification of personnel and for Study Plan Preparation (see Table 2-1, Enclosure 5). In addition, SNL had a technical review procedure that required independent and documented technical and QA reviews.

During USGS preparation of its three ESF Study Plans (Study Plan 8.3.1.4.2.2 entitled "Characterization of Structural Features in the Site Area," Study Plan 8.3.1.2.2.4 entitled "Characterization of Percolation in the Unsaturated Zone - Exploratory Shaft Facility Studies," and Study Plan 8.3.1.15.2.1 "Characterization of Site Ambient Stress Conditions"), the USGS procedure for technical review of plans and technical procedures governed by the USGS QAP required a documented, independent review by a qualified reviewer. At that time, Study Plans were governed by DOE procedures rather than the USGS QAP (Enclosure 6). The USGS desk procedure for Study Plan preparation and review, which was approved on November 16, 1987, requires that Study Plans be prepared in accordance with the DOE/NRC Agreement guidance. The desk procedure also requires that Study Plans be reviewed in accordance with the USGS technical review procedure (see Table 2-1). The USGS procedure for the qualification of personnel was in effect throughout preparation and review of the three USGS Study Plans.

3.0 EVALUATION OF THE FIVE ESF STUDY PLANS

This section presents an evaluation of the process used to develop the five ESF construction phase Study Plans. The section is divided into two parts. Section 3.1 describes, in narrative, the history and documentation of the preparation, review, revision, and approval of each of the five plans. Section 3.2 contains an evaluation of the adequacy (when compared to current requirements of NNWSI/88-9) of the completed reviews in terms of QA requirements.

3.1 DESCRIPTION OF THE FIVE ESF STUDY PLAN REVIEWS

3.1.1 EXCAVATION INVESTIGATIONS (Study Plan 8.3.1.15.1.5)

In March 1987, SNL submitted an initial draft of the Excavations Investigations Study Plan to the Project Office. The Study Plan was written and reviewed using approved SNL procedures (see Table 2-1). The SCPMP, Revision 1, provided DOE/NRC Agreement guidance for preparation of the document. In April 1987, the Project Office conducted informal technical reviews of the Study Plan to determine whether the document was sufficiently developed to begin OCRWM review. The document was submitted to the OCRWM for review in April 1987. On May 12, 1987, the OCRWM completed an acceptance review, and concluded that the Study Plan was sufficiently consistent with the requirements of the DOE/NRC Agreement to begin a detailed technical review. The review was completed in accordance with the OCRWM procedure for review and approval of SCP Study Plans.

The Excavation Investigations Study Plan was reviewed by 17 OCRWM reviewers, who generated 221 comments. The qualifications of the OCRWM reviewers are summarized in Table 3-1. A comment resolution meeting was held with the Project on June 8 and 9, 1987. During this meeting, each comment was discussed and a proposed resolution was developed and documented on a comment resolution form.

SNL revised the Study Plan and resubmitted it to the Project Office on September 1, 1987. The Project Office reviewed the actual disposition of each comment against the revised text. Because it was determined that the revised Study Plan adequately addressed the OCRWM comments, the Project Office resubmitted the Study Plan to the OCRWM for review on September 22, 1987. In October 1987, the OCRWM provided a second set of 37 comments for the Project Office to address. SNL revised the Study Plan to address these comments and resubmitted it to the Project Office on February 11, 1988. The Project Office reviewed the revised Study Plan to verify comment resolution and resubmitted it to the OCRWM for approval on March 22, 1988.

On May 27, 1988, the Study Plan was approved by the Project Office and the OCRWM and transmitted the NRC for review. The NRC began an acceptance review of the subject Study Plan. On August 5, 1988, the NRC transmitted a letter to the DOE requesting additional information on the Study Plan prior to beginning its start work review. The Project Office provided written

Table 3-1. Qualifications of Study Plan Reviewers for Excavation Investigations (Page 1 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers				
R. L. Bastian	PNL	M.S. Mining Engineering 1985	Mining Engineering	4
Ched Bradley	DOE/HQ	M.S. Regional Planning 1976	Regional Planning	9
Charles Dowding	Northwestern	Ph.D. Rock Mechanics 1971	Rock Mechanics, Soil Mechanics	17
Paul Gnirk	RE/SPEC Inc.	Ph.D. Rock Mechanics 1966	Rock Mechanics	25
Robert Lundquist	Ohio State University	Ph.D. Mining Engineering 1973	Mining Engineering	23
M. A. Mahtrab	H.K. School of Mines Columbia University	Ph.D. Mining Engineering 1970	Mining Engineering	13
James Russell	Oak Ridge Nat'l. Lab.	Ph.D. Theoretical and Applied Mechanics 1966	Mining Engineering	22
Charles Schwartz	Univ. of Maryland	Ph.D. Structural Mechanics 1979	Structural Mechanics	10
Steve Singal	DOE/HQ	M.S. Civil Engineering	Civil Engineering	9
Dean Stucker	DOE/HQ	B.S. Mining Engineering 1975	Mining Engineering	8
Charles Voss	PNL	M.S. Geoengineering 1980	Geotechnical Engineering	8

Table 3-1. Qualifications of Study Plan Reviewers for Excavation Investigations (Page 2 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers (continued)				
William M. McClain	Weston	Ph.D. Mining Engineering and Rock Mechanics 1963	Rock Mechanics, Mining Engineering	25
Miguel Lugo	Weston	M.S. Civil Engineering 1983	Civil Engineering, Licensing	14
Derrick Wagg	Weston	B.S.(Equiv) Mining Engineering	Mining Engineering	8
Victor Montenyohl	Weston	Ph.D. Rock Mechanics 1975	Rock Mechanics	12
Robert Robinson	Weston	M.S. Mining Engineering 1969	Mining Engineering	22
James Ash	Weston	M.S. Mining Engineering 1960	Mining Engineering	27
Initial Project Technical Reviewers				
Collin Stewart	SAIC	M.S. Mining Engineering 1978	Geotechnical, Mining Engineering	16
Mike Voegele	SAIC	Ph.D. Geological Engineering 1978	Rock Mechanics	16

Table 3-1. Qualifications of Study Plan Reviewers for Excavation Investigations (Page 3 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
Project AP-1.10Q Reviewers				
Harry Perry	SAIC	M.S. Geology 1971	Hydrology, Drilling	17
Ken Wolverton	SAIC	B.S. Business 1975	Quality Assurance	12
Sid Ailes	SAIC	B.A. Physics and Mathematics 1978	Software Quality Assurance	10
Peter Karnoski	SAIC	B.S. Mechanical Engineering 1956, PE	Nuclear Power Design Quality Assurance	29 8
Jack Kepper	SAIC	Ph.D. Geology 1969	Economic Geology Structure/Stratigraphy	20
Keith Schwartztrauber	SAIC	B.S. Mechanical Engineering 1964 M.S. Environmental Science 1966	Nuclear Engineering Quality Assurance	20 3
Michael Glora	SAIC	B.A. Zoology 1959	Licensing, Regulatory Compliance	15

[a] PNL: Pacific Northwest Laboratories
SAIC: Science Applications International Corporation

instructions to SNL on the revisions necessary to address the NRC concerns on November 25, 1988.

On December 14, 1988, AP-1.10Q was issued by the Project Office. The Project Office therefore initiated an AP-1.10Q review of the Study Plan. A technical review was not completed in this review cycle because the plan had received extensive technical reviews in accordance with the OCRWM procedure. The AP-1.10Q review of the Study Plan generated ten comments (one management, four regulatory, five QA) from seven project reviewers. The qualifications of the reviewers are summarized in Table 3-1. No inconsistencies with the Statutory SCP were noted in the AP-1.10Q review. A proposed resolution to each comment was developed during a teleconference with SNL representatives. The Study Plan was revised to address the NRC concerns and the comments generated during the AP-1.10Q review. The plan was approved by the Project Office on January 9, 1989, and submitted to the OCRWM for approval.

Project reviewers verified the resolution of their comments, and signed the comment resolution forms to document that their comments had been adequately resolved. All completed comment resolution forms (Project and DOE/HQ) and revisions of the Study Plan are maintained as part of the the QA record for the Excavation Investigations Study Plan.

3.1.2 WATER MOVEMENT TEST (Study Plan 8.3.1.2.2.2)

Los Alamos submitted an initial draft of the Water Movement Test Study Plan to the Project in August 1986. The Study Plan was informally technically reviewed by the Project Office and the OCRWM and found to adequately follow the DOE/NRC format and content requirements. Minor revisions were made to the Study Plan and it was resubmitted to the Project Office formally on September 23, 1987, after internal review in accordance with Los Alamos procedure TWS-QAS-QP-07. The Project Office submitted the Study Plan to the OCRWM on September 25, 1987. The OCRWM completed its acceptance review of the document on October 14, 1987, and concurred that the Study Plan met the requirements of the DOE/NRC Agreement. The OCRWM then initiated its technical review of the Study Plan. The Study Plan was reviewed by eight OCRWM reviewers who generated 61 comments. Qualifications of reviewers are summarized in Table 3-2. The OCRWM and Project Office held a comment resolution meeting on October 30, 1987, to review the OCRWM comments and reach agreement on a proposed resolution.

Los Alamos submitted a revision of the Water Movement Test Study Plan to the Project Office on December 9, 1987. The Study Plan was forwarded to the OCRWM for review on January 14, 1988. The OCRWM completed its review and requested a few additional minor changes to complete the comment resolution process. Los Alamos provided page insertions to the Project Office and the Study Plan was resubmitted to the OCRWM for approval on April 11, 1988. The Project Office and the OCRWM approved the Study Plan and submitted it to the NRC for review on May 27, 1988. Completed comment resolution forms and all revisions of the Study Plan are maintained as part of the QA record for the study.

Table 3-2. Qualifications of Study Plan Reviewers for Water Movement Test (Page 1 of 2)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers				
Chalon Carnahan	LBL	Ph.D. Hydrology and Geohydrology 1975	Hydrology, Geohydrology	18
Glen Faulkner	DOE/HQ	M.A. Geology 1950	Hydrology	22
Kenneth Czyscinski	Weston	Ph.D. Geochemistry 1975	Hydrochemistry/Mineralogy Low-Temperature Geochemistry	10
Harold Wollenberg	LBL	M.S. Engineering Science 1962	Engineering Geology	17
Patrick Domenico	Texas A&M	Ph.D. Hydrology 1967	Hydrology	27
Ralph Cady	DOE/HQ	Ph.D. Hydrology 1989	Hydrology	14
Sam Panno	Weston	M.S. Geology 1978	Geochemistry	8
Ched Bradley	DOE/HQ	M.S. Regional Planning 1976	Regional Planning	9
Initial Project Technical Reviewer				
Dwayne Chestnut	SAIC	Ph.D. Physical Chemistry 1963	Reservoir Engineering	25

Table 3-2. Qualifications of Study Plan Reviewers for Water Movement Test (Page 2 of 2)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
Project AP-1.10Q Reviewers				
Dave Dobson	YMP	Ph.D. Geology 1984	Economic Geology	12
Tom Bjerstedt	YMP	Ph.D. Geology 1986	Stratigraphy, Paleontology	1
Robert Ramsgate	Westinghouse	B.S. Civil Engineering 1968	Quality Assurance	8
Tom Higgins	SAIC	Ph.D. Physics 1971	Environmental Physics/ Engineering Quality Assurance	10 4
Martha Mitchell	SAIC	Ph.D. Applied Earth Science 1976	Material Science	20
Jack Kepper	SAIC	Ph.D. Geology 1969	Economic Geology Structure/Stratigraphy	20
Keith Schwartztrauber	SAIC	B.S. Mechanical Engineering 1964 M.S. Environmental Science 1966	Nuclear Engineering Quality Assurance	20 3
Sid Ailes	SAIC	B.A. Physics and Mathematics 1972	Software Quality Assurance	10
Michael Glora	SAIC	B.A. Zoology 1959	Licensing, Regulatory Compliance	15

[a]LBL: Lawrence Berkeley Laboratory
SAIC: Science Applications International Corporation
YMP: Yucca Mountain Project

The NRC completed an acceptance review of the Study Plan. On August 5, 1988, the NRC transmitted a letter to the DOE requesting additional information before initiation of the start work review. The Project Office provided written instructions to Los Alamos on revisions necessary to address the NRC concern on November 11, 1988.

On December 14, 1988, the Project Office issued AP-1.10Q. The Project Office initiated an AP-1.10Q review of the Study Plan. Because the Study Plan had received extensive technical review through the OCRWM reviews, the Project Office did not complete an additional technical review of the document. The AP-1.10Q review of the Study Plan generated 29 comments (nine management, one regulatory, and 19 QA) from nine Project reviewers. The qualifications of the reviewers are summarized in Table 3-2. A proposed resolution for each comment was developed during a teleconference between reviewers and Los Alamos staff.

Los Alamos revised the Study Plan to address both the NRC concerns and the Project comments from the AP-1.10Q review, and resubmitted it to the Project Office on January 4, 1989. The Project Office reviewed the Study Plan to verify resolution of the NRC concerns and the comments from the AP-1.10Q review. The AP-1.10Q management review included comments on consistency with the testing strategy in the Statutory SCP and updated SCP section numbers. Project reviewers verified the resolution of their comments, and signed the comment resolution forms to document that their comments had been resolved. All comment resolution forms and revisions of the Study Plan are maintained as part of the permanent QA record for the study. The Project Office approved the Study Plan and submitted it to the OCRWM for approval on January 9, 1989.

3.1.3 CHARACTERIZATION OF PERCOLATION IN THE UNSATURATED ZONE—EXPLORATORY SHAFT FACILITY STUDIES (Study Plan 8.3.1.2.2.4)

The USGS submitted an early draft of this Study Plan to the Project Office for review in July 1987. The Project Office then began working informally with the USGS to technically review early drafts of this Study Plan and two others (see Sections 3.1.4 and 3.1.5) against requirements of the DOE/NRC Agreements. On July 16 and 17, 1987, the Project Office met with the USGS to discuss the Study Plans that were in preparation. Members of the working group agreed that, although the Study Plan met most of the requirements of the DOE/NRC Agreement, substantial revision would be required to produce a document of the desired technical quality. The Project Office and the USGS agreed to work together closely during revision of the Study Plan in order to produce a model Study Plan for other USGS PIs to use in developing future plans. The principal purpose of this collaboration was to establish the appropriate level of detail required in descriptions of the rationale for and application of results for this Study Plan.

After revising the Study Plan in accordance with the Project Office/USGS working group recommendations, the USGS submitted the first formal draft of the Study Plan to the Project Office on September 9, 1987. The Project Office submitted the draft Study Plan to the OCRWM on September 11, 1987, and initiated a Project technical review. The OCRWM completed an acceptance review on September 28, 1987; determined that the Study Plan adequately met the requirements of the DOE/NRC Agreements; and began their technical review.

The Study Plan was reviewed by 12 OCRWM reviewers who generated 151 comments. Qualifications of each of the reviewers are summarized in Table 3-3. A Project Office/OCRWM comment resolution meeting was held on October 19 and 20, 1987, to reach agreement on proposed resolutions to the OCRWM comments. The proposed resolutions were documented and the Study Plan and comment resolution record was returned to the USGS. The USGS revised the Study Plan to address all OCRWM and Project Comments using the USGS desk procedure for preparing and reviewing Study Plans.

On April 18, 1988, the USGS submitted the revised Study Plan to the Project Office. The Project Office verified the resolution of the OCRWM comments and forwarded the revised Study Plan to the OCRWM for their audit review. The OCRWM then conducted a review of the revised Study Plan, and met with representatives of the Project Office to suggest additional revisions to more fully resolve their comments, and to recommend additional modification for consistency with the testing strategies in the Statutory SCP.

During completion of the SCP, a new activity (the drilling of multi-purpose boreholes near the exploratory shafts) was added to this study. In October 1988, the USGS revised the Study Plan to include the multipurpose borehole (MPBH) activity, to be consistent with the SCP. The OCRWM completed its review of all previous comment resolutions to verify that they had been addressed. They also provided additional comments relating to consistency with the current testing strategy in the Statutory SCP. A revised Study Plan (containing the MPBH description) was submitted to the DOE early in November. The OCRWM, Project Office, and USGS met on November 8 and 9, 1988, to provide comments on the revised Study Plan and to discuss the results of the OCRWM review. On November 18, 1988, the USGS formally submitted another revision of the Study Plan to the OCRWM. The OCRWM then formally reviewed the MPBH activity and held a teleconference on December 13, 1988, with the Project Office and USGS to resolve the OCRWM comments.

On December 14, 1988, AP-1.10Q was issued by the Project Office. The Project Office initiated a review of the Study Plan in accordance with the procedure on December 20, 1988. A technical review was not completed in this review cycle because the Study Plan had received extensive technical review under the OCRWM procedure. The AP-1.10Q review generated 16 comments (1 management, 1 regulatory, 14 QA) from eight Project reviewers. The qualifications of the project reviewers are summarized in Table 3-3. Proposed resolutions to the comments were developed during a teleconference between USGS representatives and Project Office reviewers, and were documented on the comment resolution sheets. The USGS revised the Study Plan to address the comments generated by the OCRWM review and resubmitted it to the Project Office on December 20, 1988. The USGS revised the Study Plan to address comments generated by the AP-1.10Q review and resubmitted it on January 4, 1989. The Project Office approved the Study Plan and submitted it to the OCRWM for approval on January 9, 1989. All comment resolution forms (with proposed and actual resolutions) and all revisions of the Study Plan are maintained as part of the QA record for this study.

Table 3-3. Qualifications of Study Plan Reviewers for Characterization of the Yucca Mountain Unsaturated-Zone Percolation—Exploratory Shaft Facility Studies (Page 1 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers				
Iraj Javendel	LBL	Ph.D. Civil Engineering 1968	Hydrology, Hydrologic Modeling	19
Glen Faulkner	OCRWM	M.A. Geology 1950	Hydrology	22
Karen Albrecht	Weston	M.S. Soil Physics 1985	Hydrology, Soil Science	3
Kenneth Czyscinski	Weston	Ph.D. Geochemistry 1975	Hydrochemistry, Mineralogy, Low Temperature Geochemistry	10
David Back	Weston	M.S. Geology 1985	Hydrology, Hydrologic Modeling	4
T. L. Jones	PNL	M.S. Soils 1983	Hydrology, Soil Science	1
Ralph Cady	OCRWM	Ph.D. Hydrology 1989	Hydrology	14
Chin-Fu Tsang	LBL	Ph.D. Physics 1969	Hydrology	7
Patrick Domenico	Texas A&M	Ph.D. Hydrology 1967	Hydrologic Modeling, Hydrology	27
Victor Montenyohl	Weston	Ph.D. Rock Mechanics 1977	Rock Mechanics	12
Chalon Carnahan	LBL	Ph.D. Hydrology and Hydrogeology 1975	Hydrology, Geohydrologic Modeling	18

Table 3-3. Qualifications of Study Plan Reviewers for Characterization of the Yucca Mountain Unsaturated-Zone Percolation—Exploratory Shaft Facility Studies (Page 2 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers (continued)				
Ched Bradley	DOE/HQ	M.S. Regional Planning 1976	Regional Planning	9
Initial Project Technical Reviewer				
Ralph Peters	SNL[b]			
Project AP-1.10Q Reviewers				
Russ Dyer	YMP	Ph.D. Geology 1983	Structural Geology Tectonics	10
Sid Ailes	SAIC	B.A. Physics and Mathematics 1972	Quality Assurance	10
Martha Mitchell	SAIC	Ph.D. Applied Earth Science 1976	Material Science	20
Steven Nolan	SAIC	Extensive QA/QC ASME training and ANSI Certifications, 1977-84	Quality Assurance	14
Tom Higgins	SAIC	Ph.D. Physics 1971	Environmental Physics/ Engineering Quality Assurance	10 4
Peter Karnoski	SAIC	B.S. Mechanical Engineering 1956, PE	Nuclear Power Design Quality Assurance	29 8

Table 3-3. Qualifications of Study Plan Reviewers for Characterization of the Yucca Mountain Unsaturated-Zone Percolation—Exploratory Shaft Facility Studies (Page 3 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
Project AP-1.10Q Reviewers (continued)				
Keith Schwartztrauber	SAIC	B.S. Mechanical Engineering 1964 M.S. Environmental Science 1966, PE	Nuclear Engineering Quality Assurance	20 3
Michael Glora	SAIC	B.A. Zoology 1959	Licensing, Regulatory Compliance	15

[a]LBL: Lawrence Berkeley Laboratory
PNL: Pacific Northwest Laboratories
YMP: Yucca Mountain Project
SAIC: Science Applications International Corporation
[b]Qualifications available at SNL

3.1.4 CHARACTERIZATION OF THE STRUCTURAL FEATURES IN THE SITE AREA (Study Plan 8.3.1.4.2.2)

The USGS submitted an early draft of this Study Plan for review. In July 1987, the Project Office began working informally with the USGS to technically review early drafts of this Study Plan and two other USGS ESF Study Plans (see Sections 3.1.3 and 3.1.5) against the requirements of the DOE/NRS Agreement. After revising the Study Plan in accordance with the Project Office/USGS working group recommendations, the USGS submitted the first formal draft of the Study Plan to the Project Office on September 4, 1987. The Project Office submitted this version of the Study Plan to the OCRWM for review on September 14, 1987. The OCRWM completed an acceptance review of the Study Plan on September 28, 1987, concluding that the Study Plan was sufficiently consistent with the DOE/NRC Agreement to begin a detailed technical review. The Study Plan was reviewed by 10 OCRWM reviewers, who generated 105 comments. Qualifications of the reviewers are summarized in Table 3-4. The OCRWM held a comment resolution meeting with the Project on October 21 and 22, 1987, to reach agreement on proposed resolutions to OCRWM comments.

The USGS revised the Study Plan to resolve the OCRWM comments and resubmitted it to the Project Office on March 25, 1988. The Project Office verified the adequacy of comment resolution and documented the actual disposition of each comment on the OCRWM comment resolution forms. The Project Office then sent the revised Study Plan to the OCRWM on April 13, 1988. On October 19, 1988, the OCRWM provided the Project with the results of its evaluation of the adequacy of the comment resolutions, and requested additional revisions to the Study Plan to make the planned testing consistent with the Statutory SCP. The OCRWM held a meeting with the USGS and the Project Office to discuss the results of the review on November 29, 1988. The USGS revised the Study Plan to complete the comment resolution process.

On December 14, 1988, the Project Office issued AP-1.10Q. The Project Office implemented a review on the Study Plan in accordance with the procedure on December 20, 1988. A technical review was not completed in this review cycle because the Study Plan had received extensive technical reviews under the OCRWM procedure. The AP-1.10Q review generated 28 comments (11 management, 2 regulatory, 15 QA) from seven project reviewers. Qualifications of the reviewers (one management, one regulatory, five QA) are summarized in Table 3-4.

The USGS revised the Study Plan to resolve both the final OCRWM review comments and the Project comments and resubmitted the Study Plan to the Project Office on January 10, 1989. Comment resolutions were verified by the reviewers, and the Project Office approved the Study Plan and submitted it to the OCRWM on February 3, 1989. All comment resolution forms (both Project and OCRWM), with proposed and final comment resolutions, and all revisions of the Study Plan are maintained at the Project Office as part of the QA record for this study.

Table 3-4. Qualification of Study Plan Reviewers for Characterization of Structural Features in the Site Area (Page 1 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers				
Kathleen Mihm	DOE/HQ	M.S. Geology 1985	Geology	3
M. G. Foley	PNL	Ph.D. Geology 1976	Geology, Remote Sensing	9
J. R. Eliason	PNL			
T. V. Jennings	ANL	Ph.D. Geotectonics, Structural Geology 1967	Geology, Remote Sensing	4
Ina Alterman	DOE/HQ	Ph.D. Geology 1971	Structural Geology	12
Dave Fenster	Weston	M.S. Geology 1975	Structural Geology	12
Ched Bradley	DOE/HQ	M.S. Regional Planning 1976	Regional Planning	9
Deborah Jerez	Weston	M.A. Geology 1986	Structural Geology, Volcanology	4
Dan Haymond	Weston	M.S. Economic Geology 1980	Structural Geology, Volcanology	13
Victor Montenyohl	Weston	Ph.D. Rock Mechanics 1975	Rock Mechanics	12

Table 3-4 Qualification of Study Plan Reviewers for Characterization of Structural Features in the Site Area (Page 2 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
Initial Project Technical Reviewers				
Ernest Hardin	SAIC	M.S. Earth Science 1978	Geomechanics/Geophysics	10
Ralph Peters[b]	SNL	—	—	—
Project AP-1.10Q Reviewers				
Thomas Bjerstedt	YMP	Ph.D. Geology 1986	Stratigraphy Paleontology	1
Mike Glora	SAIC	B.A. Zoology, 1959	Licensing, Regulatory Compliance	15
Sid Ailes	SAIC	B.A. Physics and Mathematics 1972	Software Quality Assurance	15
Peter Karnoski	SAIC	B.S. Mechanical Engineering 1956, PE	Nuclear Power Design Quality Assurance	29 8
Steven Nolan	SAIC	Extensive QA/AC ASME training and ANSI Certifications, 1977-84	Quality Assurance	14

Table 3-4 Qualification of Study Plan Reviewers for Characterization of Structural Features in the Site Area (Page 3 of 3)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
Project AP-1.10Q Reviewers (continued)				
Martha Mitchell	SAIC	Ph.D. Applied Earth Science 1976	Material Science	20
Jack Kepper	SAIC	Ph.D. Geology 1969	Economic Geology Structure Stratigraphy	20
Keith Schwartztrauber	SAIC	B.S. Mechanical Engineering 1964 M.S. Environmental Science 1966	Nuclear Engineering Quality Assurance	20 3

[a]PNL: Pacific Northwest Laboratories
ANL: Argonne National Laboratory
SAIC: Science Applications International Corporation
YMP: Yucca Mountain Project
[b]Qualifications available at SNL

3.1.5 CHARACTERIZATION OF THE SITE AMBIENT STRESS CONDITIONS (Study Plan 8.3.1.15.2.1)

The USGS informally submitted an early draft of this Study Plan to the Project Office for preliminary review. In July 1987, the Project Office began working with the USGS to technically review early drafts of this Study Plan and two other Study Plans (see Section 3.1.3 and 3.1.4) against the requirements of the DOE/NRC Agreement. After revising the Study Plan in accordance with the Project Office/USGS working group recommendations, the USGS submitted the first formal draft of the Study Plan to the Project Office on September 22, 1987. The Project Office submitted the Study Plan to the OCRWM on September 25, 1987 for technical review. The OCRWM completed its acceptance review of the Study Plan on October 14, 1987; determined that the Study Plan adequately met the requirements of the DOE/NRC Agreements and began a technical review. The Study Plan was reviewed by seven OCRWM reviewers who generated 98 comments. Qualifications of the reviewers are summarized in Table 3-5.

A Project Office/OCRWM comment resolution meeting was held on December 3 and 4, 1987, to reach agreement on the resolution of the OCRWM comments. Five comments remained unresolved when the workshop adjourned. The USGS revised the Study Plan and resubmitted it to the Project Office on February 23, 1988. The Project Office reviewed the revised Study Plan and documented the actual disposition of each comment on the OCRWM comment resolution forms. The Project Office then forwarded the revised Study Plan and comment resolution forms to the OCRWM.

The OCRWM completed an evaluation of the revisions to the Study Plan on August 16, 1988. The OCRWM found that the revised Study Plan did not adequately resolve the comments and offered to provide additional written guidance to help resolve the concerns. On October 12, 1988, the OCRWM provided the Project Office with a list of general technical concerns, followed by a proposed revision of the Study Plan. This revision generated 37 additional comments, with proposed text revisions. The OCRWM reviewers, Project Office representatives, and USGS met on November 28 - 30, 1988, to discuss the proposed revision of the Study Plan. This revision included updating the Study Plan to be consistent with testing strategies in the Statutory SCP. Revisions agreed to at the meeting were documented on the comment resolution forms. The USGS revised and resubmitted the Study Plan to the Project Office on December 5, 1988.

On December 14, 1988, the Project Office issued AP-1.10Q. The Project Office initiated a review of the Study Plan in accordance with the procedure. Because the plan had received extensive technical review under the OCRWM procedure for Study Plan review and approval, the Project Office did not conduct an additional technical review of the plan. The AP-1.10Q review of the Study Plan generated 17 comments (2 management, 2 regulatory, 13 QA) by six Project reviewers (one management, one regulatory, four QA). Qualifications of all reviewers are summarized in Table 3-5.

The Study Plan was revised and resubmitted on December 20, 1988, to incorporate changes required by AP-1.10Q and again on January 9, 1989, to reflect format requirements. Project reviewers then verified the resolutions of their comments, and assessed the adequacy of the resolutions to OCRWM

Table 3.5. Qualifications of Study Plan Reviewers for Characterization of Site Ambient Stress Conditions (Page 1 of 2)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
OCRWM Reviewers				
Victor Montenyol	Weston	Ph.D. Rock Mechanics 1977	Rock Mechanics	12
Charles Dowding	Northwestern	Ph.D. Rock Mechanics 1971	Rock Mechanics	17
Larry Meyer	LBL	Ph.D. Engineering 1977	Geological Engineering	12
Ina Alterman	DOE/HQ	Ph.D. Geology, 1971	Structural Geology	12
Kenneth Czyscinski	Weston	Ph.D. Geochemistry 1975	Hydrochemistry/Mineralogy	10
Charles Schwartz	Univ. of Maryland	Ph.D. Structural Mechanics	Structural Mechanics	10
Charles Voss	PNL	M.S. Geoengineering 1980	Geotechnical Engineering Rock Mechanics	8
Initial Project Technical Reviewers				
Ernie Hardin	SAIC	M.S. Earth Science 1986	Geomechanics/Geophysics	10
Ray Finley[b]	SNL	—	—	—

Table 3-5 Qualifications of Study Plan Reviewers for Characterization of Site Ambient Stress Conditions (Page 2 of 2)

Name	Professional Affiliation[a]	Academic Training	Expertise	Years Experience
Project AP-1.10Q Reviewers				
Martha Pendleton	SAIC	M.S. Geology 1973	Carbonate Petrology, Critical Facility Siting	14
Steven Nolan	SAIC	Extensive QA/QC ASME training and ANSI Certifications, 1977-84	Quality Assurance	14
Jack Kepper	SAIC	Ph.D. Geology 1969	Economic Geology Stratigraphy/Structure	20
Sid Ailes	SAIC	B.A. Physics and Mathematics 1978	Software Quality Assurance	10
Keith Schwartztraber	SAIC	B.S. Mechanical Engineering 1964 M.S. Environmental Science 1966, PE	Nuclear Engineering Quality Assurance	20 3
Michael Glora	SAIC	B.S. Zoology 1959	Licensing, Regulatory Compliance	15

[a]LBL: Lawrence Berkeley Laboratory
PNL: Pacific Northwest Laboratories
SAIC: Science Applications International Corporation
[b]Qualifications available at SNL

comments. The Project approved the Study Plan and submitted it to the OCRWM for approval on January 11, 1989. All comment resolution forms, with proposed and actual dispositions of comments, and all revisions of the Study Plan are maintained in the Project Office as part of the QA record for this study.

3.2 EVALUATION OF THE ADEQUACY OF THE QUALITY CONTROLS IN PLACE DURING THE REVIEW AND APPROVAL OF THE Study Plans

As noted in Section 2.2, the DOE believes that the controls currently in place for Study Plan preparation, review, and approval (NNWSI 88-9, AP-1.10Q, and other procedures, as necessary) are adequate to ensure that the plans meet all applicable requirements, if the controls are properly implemented. Therefore, in order to demonstrate that the existing plans are acceptable, it must be shown that the program used to control the development of these plans was substantially equivalent to the current program, and that the plans are substantially the same as they would have been if the current program had been in place.

For DOE/HQ reviews, the memoranda initiating the reviews (see Enclosure 9) provided the following technical review criterion: technical reviews should focus on the content of the Study Plan, particularly whether that content meets the requirements of the DOE/NRC Agreement. The SCPMP, Revision 2, provided the following criteria: (1) consistency with performance assessment and design requirements; (2) consistency with Project schedules, milestones, and QA level assignments; and (3) technical adequacy. In addition, the initial screening in the SCPMP review criteria were (1) consistency with the DOE/NRC Agreement guidance; (2) technical level of detail; and (3) consistency with the SCP.

The conclusion to Section 2.1 of this report stated that the required controls for the development, review, and approval of Study Plans could be summarized in four categories. Analysis of the five ESF construction phase Study Plans, together with the procedures and records supporting their preparation and review, indicates that each of these basic requirements has been met and that the Study Plans are technically adequate. The general rationale for this conclusion is discussed immediately below. Nevertheless, some inconsistencies have been identified between the processes implemented and current requirements, as defined by AP-1.10Q, and NNWSI/88-9. These inconsistencies (discussed in Section 3.2) do not impact the technical quality of the Study Plans.

3.2.1 EVALUATION OF THE REQUIREMENTS FOR CONTROL OF THE Study Plan PROCESS

This section evaluates the adequacy of the process used to control Study Plans in comparison with the four categories of general requirements defined in Section 2.1:

Study Plans must be prepared and reviewed by qualified personnel.

Although early guidance and procedures issued by the DOE for Study Plan review and preparation did not specify qualification standards or training requirements, all personnel working on the Project were required to meet the basic Project requirements for qualifications. For PIs and Project reviewers of Study Plans, the qualifications required for their positions have been evaluated as part of this assessment. They were determined to be generally sufficient to meet the requirements of AP-1.10Q. During the early development and review of the Study Plans, no Project training on Study Plan preparation or review was thought necessary, because the DOE/HQ guidance to the Project was clear. However, all reviewers during the last Project review were trained in AP-1.10Q (and were required to verify by signature that they had read and understood the procedure). Qualifications of all Project employees and records of supervisors' statements of qualification are maintained by the Project participants, as part of the Project QA record.

For DOE/HQ reviewers of Study Plans who are not project employees, the initial procedures did not contain particular standards for qualification or training for Study Plan reviewers. DOE/HQ reviewers did, however, receive informal training on the implementation of their reviews. In addition, the qualifications of past Study Plan reviewers have been evaluated as part of this assessment. Documentation of the qualifications of all DOE/HQ reviewers has been compiled and evaluated (see Tables 3-1 through 3-5 for a summary). No unqualified reviewers have been identified.

Study Plan format and content must meet all applicable requirements, including specific provisions for technical, regulatory, and quality-related content.

The current requirement, defined in AP-1.10Q, specifies that Study Plans must be prepared in accordance with the content guidance that resulted from the DOE/NRC Agreement. Similar guidance was issued by the Project Office in June and September 1986, and has been formally in effect for the Project since November 1986, when Revision 1 of the SCPMP was issued. Thus, all Study Plans developed by the Project have met the requirement. AP-1.10Q also contains additional content requirements derived from NNWSI/88-9 and other sources (e.g., Study Plans shall contain an appendix containing certain QA information). Although some of these requirements were added after the writing of the initial drafts of the plans, the plans have been modified as necessary during reviews, so that they meet all current content requirements. All changes to the plans, including the addition of new sections, are documented on comment response forms, which are maintained as part of the permanent QA records for the Study Plans.

Each phase of the review of the Study Plans has addressed whether the studies met the requirements of the DOE/NRC Agreement. The reviews included a check for consistency with the SCP (for example, the final DOE/HQ verification review included review against the Statutory SCP text). Consistency with the DOE/NRC agreement was fundamental to all DOE/HQ reviews, as discussed previously, and it has been explicitly required by Project procedures since the issuance of Revision 2 of the SCPMP in April 1988. In summary, adequate guidance was in place, both during the preparation and review of the plans, to ensure that the format and content of the plans meets applicable requirements.

The process of preparation, review, approval, issuance, and revision of Study Plans must be controlled.

As discussed extensively in Section 2 of this report, the preparation of the five ESF Study Plans was controlled by written guidance from the DOE (contained in Revision 1 of the SCPMP). In addition, as described in Sections 2.2, 2.3, and 3.1, reviews of all the plans were carefully controlled and documented. Since the implementation of NNWSI/88-9, and AP-1.10Q, the process for approval and issuance has been controlled according to appropriate Project procedures. It should be noted, however, that the uncontrolled distribution of the two Study Plans previously released to the NRC would have been in violation of current procedures.

AP-1.10Q (with references to other procedures, as appropriate) currently provides all requirements for control of the review, approval, and issuance of Study Plans. The review of the five ESF Study Plans that was performed in December 1988 (immediately following implementation of AP-1.10Q), was intended to ensure that all requirements specified in the currently approved program had been met. A technical review was not performed during that cycle, because it was determined that previous DOE/HQ, Project Office, and Project participant technical reviews more than satisfied the requirements (see Section 3.1) of AP-1.10Q. With that exception, the December review was comprehensive, and demonstrated that the five Study Plans (after revision in response to the comments) were in compliance with all major requirements of the current program.

Records documenting that all requirements have been met must be maintained.

There are two critical areas that require the maintenance of current documentation: (1) personnel qualifications, and (2) records of reviews, revisions, and approvals of the plans. As stated in previous sections of this report, all records relating to the review, revision, and approval of the Study Plans have been maintained in accordance with all existing procedures since the submission of the first formal drafts in early to mid-1987.

Records of the qualifications of all Project participants in the Study Plan process have been maintained as part of the standard statements of qualification for Project employees. Specific statements of qualifications relative to Study Plan preparation and review have been maintained since the issuance of AP-1.10Q in December 1988. The qualifications of DOE/HQ reviewers of Study Plans were not evaluated prior to their performing reviews, as is required by procedures. However, their qualifications have been compiled and evaluated as part of this assessment. No unqualified reviewers have been identified, and the files of qualifications are now current and complete.

3.2.2 INCONSISTENCIES IDENTIFIED IN THE STUDY PLAN PROCESS FOR THE FIVE ESF STUDY PLANS

The discussion below details the inconsistencies identified in the Study Plan process as a result of this assessment and the Project QA Study Plan surveillance (Enclosure 9). Two types of inconsistencies are described. The first includes those inconsistencies between the program used to control the

Study Plans, and the current program, which has been judged to provide sufficient controls of the Study Plan process. For these inconsistencies, an evaluation is required to assess the effect on the technical adequacy of the Study Plans (and any consequences), but no revision of the current program is required. The second type of problem identified involves cases where aspects of the past or current program are not in compliance with NNWSI/88-9 and some further revision of current controls may be necessary.

3.2.2.1 Yucca Mountain Project Quality Controls

During the preparation and review of the five ESF Study Plans, the Yucca Mountain Project QAP was revised and issued four times: March 9, 1987; May 19, 1988; August 26, 1988; and December 12, 1988. The adequacy of the Project quality controls for development of Study Plans was assessed against the current revision of the Project QAP (NNWSI/88-9), because this is the first revision that has been reviewed and accepted by the NRC.

Revision 1 of the SCPMP provided the requirements of DOE/NRC as guidance for Study Plan preparation, but did not provide procedures for, or require, Project review of Study Plans. The requirement, and procedure, for Study Plan review was added to Revision 2 of the SCPMP. A draft of Revision 2 of the SCPMP began review on September 17, 1987, but the revision was not issued until April 5, 1988. Therefore, initial Project reviews were conducted according to the DOE/HQ procedure for Study Plan reviews, without a specific Project procedure defining the review.

Revision 2 of the SCPMP, which defined the Project review of Study Plans between April and December 1988, was inconsistent with NNWSI/88-9 in a few areas. The inconsistencies are summarized below, with a brief description of how each identified problem was resolved:

1. Paragraph 1.3.2 of Section III of NNWSI/88-9 requires the appropriate Branch Chief and the Project Quality Manager to review and approve scientific investigation planning documents (including Study Plans), and specifies, technical, QA, and management reviews in Section 1.1.

   Revision 2 of the SCPMP required review for consistency with performance assessment and design requirements; consistency with Project schedules, milestones, and QA Level Assignments; and technical adequacy. The requirements of the SCPMP therefore exceeded the requirements of the NNWSI/88-9.

2. The NNWSI/88-9 requires Study Plan preparation in accordance with a Project administrative procedure.

   The SCPMP did not meet this requirement, but AP-1.10Q does.

3. The NNWSI/88-9 requires documented qualification and training for PIs and reviewers.

The SCPMP required qualified personnel, but did not specifically require that the documentation be maintained, although general project procedures for the maintenance of records on personnel were assumed to apply. AP-1.10Q does specifically require that the qualifications of all Study Plan authors and reviewers be maintained.

Training in the implementation of Project procedures was not performed prior to the approval of AP-1.10Q, but the Project Office did issue the SCPMP, Revision 2, which defined the preparation of Study Plans and the criteria for the review, to the Project participants as a controlled document. The process of resolving comments contained in the procedure was explained and implemented at the comment resolution meetings attended by both authors and reviewers. Similarly, the DOE/HQ procedures were distributed to their reviewers, and the process of comment resolution was explained and implemented at comment resolution meetings. In addition, DOE/HQ also conducted a reviewer training session on a draft of its current procedure, entitled "Interim Procedure for the Review of Study Plans," in June 1988.

4. The QAP requires that the process for development, review, approval, and issuance of Study Plans be controlled.

   The SCPMP did not provide for controlled issuance and distribution, although AP-1.10Q does. The first two Study Plans were approved by the Project and DOE/HQ and submitted to the NRC as uncontrolled documents. That distribution would not have been authorized under NNWSI/88-9 and AP-1.10Q.

5. The SCPMP did not require that the reviewers sign or initial comment resolution forms to document that their comments had been adequately addressed in the revised Study Plan.

   Comment resolutions were required to be verified and signed by representatives of the DOE in accordance with the SCPMP and existing DOE/HQ procedures. AP-1.10Q does require the signature of both reviewers and Study Plan authors on the comment resolution sheets.

6. The SCPMP, Revision 2, required the review of Study Plans, and verification by signature, by Project participant QA organizations.

   This requirement does not appear in NNWSI/88-9 or AP-1.10Q, which incorporate QA requirements within the Project Office review. The requirement was not uniformly implemented for the ESF Study Plans, which were prepared and reviewed by the Project participants prior to implementation of the SCPMP.

One identified inconsistency in the current program (AP-1.10Q) has not been resolved. That is, the NNWSI/88-9 defines a technical reviewer as one who has "expertise at least equivalent to those who performed the work."

Neither the SCPMP or AP-1.10Q used this definition directly. Both the SCPMP and AP-1.10Q required the use of qualified reviewers, but did not contain additional criteria for the identification of the reviewers. Procedures for the qualification of personnel were assumed to apply (see Section 2 of this report). The NNWSI/88-9 should be modified to make the definition of a "qualified technical reviewer" consistent with the definition in AP-1.10Q..

3.2.2.2 DOE/HQ Quality Controls

The DOE/HQ procedures were reviewed in comparison with the current requirements of the NNWSI/88-9, which has been reviewed and accepted by the NRC. The following inconsistencies have been resolved by later revisions of the DOE/HQ or Project procedures, or by other actions:

1. The initial DOE/ HQ procedures did not require qualification of reviewers.

   As noted above, the qualifications of all reviewers have been checked as part of this review, and were found to be acceptable (see Tables 3-1 through 3-5). Current procedures require documentation of qualifications prior to the performance of quality-related work, and periodic evaluation of proficiency.

2. The initial management procedures emphasized the review process and schedule, rather than the type and scope of the review.

   The latest revision of the DOE/HQ procedure has mitigated this concern.

3. The initial procedure required a review, but did not specify the type of review. The checklist for technical review and the memorandum initiating the reviews (Enclosures 14 and 15), however, specified a technical review.

   The latest revision of the DOE/HQ procedure has mitigated this concern.

4. The initial DOE/HQ procedures for Study Plan Review did not include appropriate quantitative and qualitative acceptance criteria for performance of the technical review.

   The latest revision of the DOE/HQ procedure has mitigated this concern. In addition, the DOE/HQ technical comments were reviewed against current acceptance criteria and it was concluded that these comments constitute an adequate detailed technical review.

5. The initial DOE/HQ procedures were management procedures, not formally reviewed or approved by the QA division.

The latest revision of the DOE/HQ procedure has mitigated this concern.

A few aspects of the DOE/HQ interim procedure should be revised to provide more complete QA records. These are summarized below, with recommendations for resolution of the inconsistencies:

1. Both the past and current procedure for Study Plan review provides for a documented review, but does not require the reviewers to sign or initial the comment resolution forms to document that their comments have been adequately resolved.

   Verification of comment resolution is currently provided by a representative of the DOE, but the DOE/HQ procedure should be modified to specify that Study Plan authors and reviewers, as well as a DOE representative, should sign the comment resolution forms, verifying the resolutions.

2. The DOE/HQ procedure does not identify SCP Study Plans as Project participant, or DOE/HQ level documents, and it is not clear what responsibilities each organization had in the process.

   The procedure should be modified to clarify responsibilities of each organization (DOE/HQ, the Project Office, and the Project participants).

DOE/HQ procedures are currently being revised in accordance with the OCRWM program and will be consistent with a fully qualified program. These procedures must be consistent with the DOE/HQ QA Manual.

3.2.2.3 Project Participant Quality Controls

Because the principal focus of this assessment was to evaluate the process used by the DOE to control Study Plan development and review, this report does not include a review of the documentation supporting the procedures developed by the Projects participants for Study Plan preparation and review. Instead, the adequacy of the Project participant procedures was assessed.

Los Alamos National Laboratory

The Los Alamos procedure for technical review was in place prior to Los Alamos internal review of the Water Movement Test Study Plan. This procedure was consistent with the requirements of NNWSI/88-9, which requires a documented, independent technical review of Scientific Investigation Plans, including Study Plans. Recognized deficiencies in the Los Alamos QA program include:

1. Los Alamos did not implement a procedure for personnel qualification and certification until March 1988. Therefore, initial preparation of the Study Plan was completed without proper certification of the personnel involved.

Because the qualification requirements have now been met, this should not affect the Study Plan. For future Study Plans, qualifications should be established prior to the initiation of the activity.

2. Los Alamos does not have a separate procedure for Study Plan preparation.

   Requirements for Study Plan preparation were available in the SCPMP (Revisions 1 and 2), and in AP-1.10Q, but Los Alamos should take steps to ensure that the requirements of AP-1.10Q for Study Plan preparation are incorporated in its QA Program.

Sandia National Laboratories

SNL had procedures in place for preparation and review of Study Plans and for qualification of personnel prior to starting the development of the Excavation Investigations Study Plan. There are no apparent deficiencies in SNL quality controls for Study Plan development.

U.S. Geological Survey

The USGS had procedures in place for technical review and for qualification of personnel before it developed its three ESF Study Plans (see Section 2.3.3). However, two deficiencies have been identified:

1. The USGS desk procedure for Study Plan preparation was not issued until November 16, 1987. This procedure was approved by the TPO but was not reviewed and approved by QA.

   Revision 1 of the SCPMP (and later Revision 2 and AP-1.10Q) provided the DOE/NRC requirements for format and content of SCP Study Plans. The USGS desk procedure was an informal procedure but did provide the required guidance, after November 1987. This procedure is being revised and will be reviewed and approved by USGS QA.

2. AP-1.10Q, and the USGS desk procedure for Study Plan preparation requires documented and independent technical review of the Study Plan by the USGS in accordance with the USGS technical review procedure. For Study Plan 8.3.1.2.2.4, this review was not completed.

   At the time this Study Plan was initially written, NNWSI-USGS-QMP-3.07 required performing and documenting technical reviews of the USGS technical procedures and plans governed by the USGS QA program; Study Plans were governed by DOE procedures and not by the USGS QA program at that time. For all future Study Plans, AP-1.10Q requires each Project participant to conduct a technical review of the Study Plans prior to their submission to the DOE. In addition, the USGS QAP is being revised to include requirements for Study Plans.

4.0 GENERAL SUMMARY

4.1 CONCLUSIONS

The DOE believes that the reviews of the five ESF Study Plans according to AP-1.10Q, which implements the NRC-reviewed and accepted controls described by NNWSI 88-9 demonstrates that the plans do meet all major requirements.

In addition, the results of this assessment indicate that the five ESF Study Plans were developed, reviewed, and approved in accordance with quality controls that were substantially equivalent to those which would be found in a QA Level I program. Moreover, evaluation of the Study Plans indicates that the content of the Study Plans would not have changed in any substantive way if the plans had been developed completely within an approved QA program, because the guidelines and criteria used for preparation, review, and approval were essentially identical to the those in use in the current, NRC-approved program. The Study Plans were prepared by qualified staff and reviewed by multiple qualified reviewers; the review process above supports the technical merits of these plans.

Nevertheless, numerous minor inconsistencies with current QA requirements have been identified as a result of this assessment. No deficiencies were noted in the technical content of the documents. The inconsistencies have resulted from a variety of causes, such as the fact that the development and review of these Study Plans has been accomplished over a two-year period, during which there have been four revisions of the project QAP, three revisions of the DOE/HQ procedure for review and approval, and two revisions of the Project Office procedures that control the plans. As a consequence, some aspects of the initial preparation and review were done according to a QA program which would not meet all current QA requirements. However, these inconsistencies do not impact the technical quality of the Study Plans.

4.2 RECOMMENDATIONS

Several remaining inconsistencies in the current system of controls on the development, review, and approval of SCP Study Plans have been noted as a result of this assessment. These inconsistencies, described in Section 3.2 of this report, should be resolved as soon as possible. They include the following:

1. The Project Office should modify the definition of a technical reviewer in NNWSI 88-9. The current definition is overly restrictive and could result in the disqualification of most qualified technical peers, if strictly applied.

2. The Project Office should delete the second sentence from Section 1.3.2 of NNWSI/88-9. This sentence specifies that the WMPO PQM returns planning documents to the responsible organization's TPO after WMPO approval. This level of detailed instruction is inappropriate for the QAP and contradicts DOE/HQ guidance. The

DOE/HQ guidance requires that Study Plans, which are DOE documents, be approved and issued by the Project Office as controlled documents.

3. Los Alamos should determine whether its QA Program must be modified to clearly incorporate the requirements of AP-1.10Q for Study Plan preparation. For instance, QP-07, Revision 2, does not provide criteria for the review or a definition of technical review.

4. The DOE/HQ Interim Procedure should be modified to require the signature of reviewers and Study Plan authors on comment resolution sheets, and to more clearly identify the responsibilities of the organizations involved.

5. For all organizations, qualification and evaluation of personnel involved in the Study Plan process should be completed prior to the performance of work, and adequate documentation of the qualifications must be maintained.

6. Affected Project participants that are preparing Study Plans and DOE/HQ should revise their programs to comply with and implement the current Study Plan requirements.

5.0 REFERENCES

Project Site Characterization Plan, Yucca Mountain Site, Nevada Research and Development Area (DOE/RW-0199, December, 1988).

Project Quality Assurance Plan, Revision 2 (NNWSI/88/9, December, 1988)

Project SCP Management Plan (NNWSI/88-13)

Project Administrative Procedure (AP)-1.5Q, Issuance and Maintenance of Controlled Documents.

Project AP-1.10Q, Preparation, Review, and Approval of SCP Study Plans.

Project AP-5.9Q, Acceptance of Data and Data Interpretations not developed under NNWSI Project QA Program.

Project Office Quality Management Procedure (QMP)-01-01, Organization.

Project Office QMP-02-02, Qualification, Proficiency, Indoctrination, and Training of Waste Management Project Personnel.

Project Office QMP-06-02, Document Control.

Project Office QMP-06-03, Document Review/Acceptance/Approval.

10 CFR Part 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

10 CFR Part 60, Subpart G, Quality Assurance.

List of Enclosures

Enclosure 1.....Relevant sections of the Yucca Mountain Quality Assurance Plan

Enclosure 2.....Administrative Procedure 1.10Q

Enclosure 3.....DOE/HQ Interim Procedure for review and approval of Study Plans

Enclosure 4.....LANL Procedures for Personnel Selection, Training and Certification and for Technical Review

Enclosure 5.....SNL Procedures for Study Plan Requirements; Reviewing, Approving, and Issuing Technical Information Documents; and Qualification and Certification of Project Personnel

Enclosure 6.....USGS Procedures for Technical Review; Certification of USGS and USGS Contractor Personnel for the NNWSI Project; and Study Plan Preparation

Enclosure 7.....June 5,1986, letter from Blanchard to the project participants transmitting the DOE/NRC content requirements for Study Plans

Enclosure 8.....Letters providing the project participants additional guidance on the content requirements for Study Plans

Enclosure 9.....Relevant Sections of revisions 1 and 2 of the SCPMP

Enclosure 10.....WMPO Standard Deficiency Report No. 099, Revision 0

Enclosure 11.....Observation Number YMP-SR-88-019-01

Enclosure 12.....DOE/HQ procedures for Study Plan Review and Approval

Enclosure 13.....DOE/HQ memorandum initiating Study Plan reviews

Enclosure 14.....DOE/HQ Checklist for Study Plans

Enclosure 1: Relevant sections of the Yucca Mountain Quality Assurance Plan

The procedures shall identify the types of documents to be submitted for review and approval, assign responsibility for review, and identify the methods for documenting review and approval action. Reviews of QA program documentation shall be recorded on checklists or other forms that specify the criteria for acceptability and indicate conformance or nonconformance.

4.0 MANAGEMENT ASSESSMENT

4.1 FREQUENCY OF MANAGEMENT ASSESSMENTS

Management assessments are to be conducted at least annually for determining (1) the effectiveness of the system and management controls that are established to achieve and assure quality, and (2) the adequacy of resources and personnel provided to the QA program. Management is to verify that the QA program is being effectively implemented and that personnel are trained to the QA requirements of the program.

4.2 PERFORMANCE OF MANAGEMENT ASSESSMENTS

Management assessments are to be performed by the WMPO and each NNWSI Project Participant. Each organization is to develop its internal procedures for planning, organizing, performing, and documenting the management assessment conducted, including the analysis and reporting of the results and the tracking of recommendations. Copies of all management assessments are to be provided to the Project Manager, WMPO and the WMPO PQM. The Project Manager, WMPO will make appropriate submittals of management assessment reports to OCRWM. Management above or outside the QA organization shall be responsible for the management assessment activity.

5.0 PERSONNEL SELECTION, INDOCTRINATION, AND TRAINING PROCEDURES

5.1 ESTABLISHMENT OF REQUIREMENTS

All NNWSI Project participants shall establish requirements for the selection, indoctrination, and training of personnel performing or verifying activities that affect quality. The requirements shall establish position descriptions that set forth minimum personnel qualifications and provide for appropriate indoctrination or training or both, prior to initiation of activities that affect quality. In addition to the following requirements for indoctrination and training, personnel performing activities that specifically require certification by applicable codes and standards (e.g., lead auditors, inspectors, testers, nondestructive examiners, etc.) shall be certified in accordance with the detailed requirements specified in Appendix C, D, or F, as applicable.

5.1.1 POSITION DESCRIPTION

Minimum education and experience requirements shall be established and documented in position descriptions for each position involved in the performance of activities that affect quality.

5.1.2 PERSONNEL QUALIFICATION EVALUATION

Personnel selected shall have education and experience commensurate with the minimum requirements specified in the position description. Relevant education and experience shall be verified. This verification shall be documented. The initial capabilities of an individual shall be based upon an evaluation of their education, experience, and training and compared to those established for the position. Evaluations shall be documented by managers or supervisors responsible for the activities to be performed.

5.1.3 INDOCTRINATION

Prior to assigning personnel to perform activities affecting quality, they shall be indoctrinated as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the work to be accomplished. Indoctrination may be accomplished by the use of a mandatory reading list, by group classroom presentations, by video presentation, or other instructional methods.

- QAPP's
- Implementing Procedures and Work Instructions (applicable to the individual's responsibilities).
- Regulations
- Project level Documents

5.1.4 TRAINING

Prior to assigning personnel to perform quality affecting activities training, if needed, shall be conducted to gain the required proficiency. The training (in-depth instruction) shall include the principles, techniques, and requirements of the activity. Such in-depth instruction may be internal or external classroom sessions, classroom sessions supplemented by hands-on workshops, on-the-job training, other instructional methods, or combinations thereof.

5.1.5 PROFICIENCY EVALUATION

After the initial personnel qualification evaluation, the job proficiency of personnel who perform activities affecting quality shall be evaluated and documented at least annually. Proficiency evaluations may be performed in conjunction with periodic or day-to-day employee performance evaluations. Proficiency evaluations shall be performed by managers or supervisors who have responsibility for the activities being performed or verified.

5.1.6 RECORDS

Records of personnel qualification evaluations, indoctrination, training, and proficiency evaluations shall be retained as lifetime QA records. These records shall include, as a minimum, the items listed below.

5.1.6.1 Personnel Qualification Evaluation Records

Records of the verification and evaluation of a candidate's education, experience, and training, compared to those required for the position.

5.1.6.2 Indoctrination Records

Records of indoctrination which include the objective and content of the indoctrination, date or dates of indoctrination, and other applicable information.

5.1.6.3 Training Records

Records of training which include the objective(s) and content of the training, name of the instructor, attendees, dates of attendance, and result of proficiency evaluations (where applicable), and other applicable information.

5.1.6.4 Proficiency Evaluation Records

Records of proficiency evaluation shall include, as a minimum, the name of the evaluated employee, the evaluator, evaluation results, date of evaluation, and the activities covered by the evaluation.

SECTION III

SCIENTIFIC INVESTIGATION CONTROL AND DESIGN CONTROL

1.0 SCIENTIFIC INVESTIGATION CONTROL

1.1 PREPARATION OF PLANS

1.1.1 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

Prior to the start of any scientific investigation, the responsible Principal Investigator (PI) shall develop a scientific investigation planning document for that investigation. Scientific investigations categorized as site characterization activities as defined in the Nuclear Waste Policy Act (as amended) shall utilize study plans as the scientific investigation planning document. The WMPO shall conduct a technical, QA, and management review of scientific investigation planning documents and approve the document prior to implementation. Study plans shall also be reviewed and approved by OCRWM prior to implementation. Such planning documents shall contain or shall reference the following:

1.1.1.1 Description of Work to be Performed

A description of the work to be performed in the scientific investigation and the proposed methodology for accomplishing the work including a discussion of the overall purpose for the work shall be provided in the scientific investigation planning document. References to any applicable regulations, requirements, performance criteria, key issues, issues, information needs, higher level scientific investigation planning documents, or Work Breakdown Structure (WBS) items, for which the work is to be performed shall also be provided. This discussion shall identify all of the factors and concerns that are important for the planning or the performance of the scientific investigation including identification, explanation, and justification for areas where scientific notebooks are to be used.

1.1.1.2 Description of previous work

A description of any previous work which will be used in support of the scientific investigation, including the identification of the Quality Assurance Levels, or Quality Assurance (QA) controls, under which that previous work was performed. Note: This requirement does not apply to study plans.

1.1.2 PLANNING DOCUMENTS

The scientific investigation planning document shall contain a level of detail which would enable an independent reviewer to determine the appropriate QA Level to be applied to the investigation. For Site Characterization activities, the purpose and key milestones of study plans is described in the SCP. The format and content of study plans shall meet the requirements of Appendix K of this QA Plan.

1.2 ASSIGNMENT OF QUALITY ASSURANCE LEVELS

1.2.1 ASSIGNMENT

Once a scientific investigation planning document, as specified in Paragraph 1.1.1 of this section has been developed, the Quality Assurance Levels for all of the items and activities which are associated with that work, may be assigned. It may be necessary in some cases to assign Quality Assurance Levels to the items and activities within a plan that was prepared earlier.

Therefore, the Quality Assurance Level assignments are not a part of the planning documents themselves, even though they would normally accompany those planning documents and go through the same review and approval process.

1.2.2 CONFORMANCE

Scientific investigation planning documents shall be prepared and Quality Assurance Levels shall be assigned in accordance with the methods specified in the Nevada Nuclear Waste Storage Investigations (NNWSI) Project Administrative Procedures Manual.

1.3 REVIEW AND APPROVAL PROCESS

1.3.1 RESPONSIBILITY

The responsible Participating Organization shall conduct a technical review of the scientific investigation planning document. This review shall be performed by any qualified individual(s) other than those who developed the original planning document. In exceptional cases, the originator's immediate supervisor can perform the review if the supervisor is the only technically qualified individual, and if the need is individually documented and approved in advance with the concurrence of the QA manager of the originating organization. The results of this technical review, and the resolution of any comments by the reviewer or reviewers, shall be documented, and shall become a part of the QA records.

1.3.2 WASTE MANAGEMENT PROJECT OFFICE REVIEW

The WMPO Project Quality Manager and the appropriate WMPO Branch Chief shall review and approve the scientific investigation planning document prior to implementation. The WMPO PQM shall return the planning document to the responsible organization's TPO upon completion of the WMPO review and approval cycle. Study plans shall also be reviewed and approved by OCRWM prior to implementation.

1.3.3 PEER REVIEW

A peer review of the scientific investigation planning document will be conducted when deemed necessary by the WMPO.

1.4 SCIENTIFIC INVESTIGATION DATA INTERPRETATION AND ANALYSIS

1.4.1 INTERPRETATION/ANALYSIS DOCUMENTS

Interpretation/analysis shall be performed in a planned, controlled, and documented manner. Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.

1.4.2 DOCUMENTATION OF INTERPRETATION/ANALYSIS

Documentation of interpretation/analysis shall include the following:

- o Definition of the objective of the interpretation/analysis.
- o Definition of input and their sources.
- o A listing of applicable references.
- o Results of literature searches or other background data
- o Identification of assumptions
- o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.
- o Signatures and dates of review and approval by appropriate personnel.

1.5 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subsection 3.0 and Appendix H of this QA Plan. The documentation and control measures shall be consistent with the guidance contained in NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management."

1.6 THE USE OF SCIENTIFIC NOTEBOOKS VERSUS THE USE OF TECHNICAL IMPLEMENTING PROCEDURES

1.6.1 DOCUMENTATION

There are two methods which can be used for the quality assurance, documentation and control of scientific work. These are the scientific notebook system and the technical implementing procedure system.

The scientific notebook system will generally be used by qualified individuals who are using a high degree of professional judgment, trial and error methods, or developing the methodology by which an activity will be accomplisned. When the scientific notebook system is used, the study plan or scientific investigation planning document shall be the controlling document used to perform the activity since it describes the proposed approach or general procedure for accomplishing the work. Alternatively, the technical implementing procedure system will generally be used when qualified personnel are performing repetitive work which does not include the use of a high-degree of professional judgment or trial and error methods in the performance of the work. Detailed technical implementing procedures are required when it is not possible to deviate from a prescribed sequence of actions, without endangering the validity of the results that will be obtained from the work. Modifications may be made to these procedures as detailed in Para. 1.6.2. Logbooks or appropriate forms or both are used, particularly in repetitive work, to document the performance of the work according to the technical implementing procedure, and to maintain absolute control over all other aspects of the work.

1.6.2 TECHNICAL IMPLEMENTING PROCEDURES

Detailed technical implementing procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive. Such technical implementing procedures shall be developed in accordance with the requirements given in Section V of this document and reviewed for compliance with the requirements of this section of the QA Plan. Modifications may be made to the technical aspects of technical implementing procedures by the individual utilizing the procedure. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.

Requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.

Technical procedures utilized for scientific investigations shall provide for the following as appropriate:

- Requirements, objectives, methods and characteristics to be tested or observed.
- Acceptance limits, if applicable, contained in applicable documents, including precision and accuracy.
- Prerequisites such as calibrated instrumentation, adequate and appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions shall

be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the scientific investigation.

- Mandatory verification points.
- Acceptance and rejection criteria, including required levels of precision and accuracy (NOTE: "Accept/reject criteria" means those features or characteristics of a procedure that make it possible to determine whether the work has been, or is being, performed in such a way that it produces the intended results. A data acquisition task produces output that, in itself, cannot be characterized as acceptable or unacceptable. However, the task of acquiring the data is acceptable if all specified prerequisites were met and the work was accomplished in the specified manner. In that instance, the "accept/reject criteria" are simply the conditions and methods stated in the procedure.)
- Methods of documenting or recording data and results, including precision and accuracy.
- Methods of data reduction.
- Provision for ensuring that prerequisites have been met.
- Special training or qualification requirements for personnel performing the scientific investigation.
- Personnel responsibilities.

1.6.2.1 Procedures shall be complete to the extent that another qualified individual may, at a later date, reproduce the results.

1.6.2.2 The potential sources of uncertainty and error in technical implementation procedures which must be controlled and measured to assure that scientific investigations are well controlled shall be identified. Parameters that need to be measured and/or controlled to minimize such uncertainties or error, and to ensure adequate control, shall be addressed explicitly in test procedures.

1.6.2.3 For instrumentation and/or equipment used in data collection consideration shall be given to whether failure or malfunction of the instrumentation during scientific investigation will be detectable, either during data collection or by examination of the data. Where ability to detect such failure or malfunction is questionable, procedures will include any special provisions for equipment/instrumentation configuration, installation, and use that can further reduce risk of undetectable failure or malfunction.

1.6.2.4 Any procedural deviations or nonconformances, encountered during activities shall be documented, reported, and evaluated for significance.

1.6.3 SCIENTIFIC NOTEBOOKS

Scientific notebooks along with other appropriate documents may be used to document scientific investigations and experiments. In such cases this documentation shall be sufficient such that another qualified scientist can use the notebook to retrace the investigation and confirm the results, or repeat the experiment and achieve the same results without recourse to the PI.

1.6.4 FORMAT FOR DOCUMENTATION

Documentation of scientific work i.e. experiments and research shall be performed using bound logbooks or notebooks to provide written record of the experiment or research.

1.6.4.1 Initial Entries

Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, shall be made

- Title of the experiment or research.
- Name of the qualified individual or individuals performing the experiment or research.
- Description of the experiment's objective or objectives and the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work.
- Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any needed characterization of starting material.
- Calibration requirements.
- Dated signature of the individual or individuals making the initial entries.
- Special training or qualification requirements.
- Documentation of suitable and controlled environmental conditions, if applicable.
- Required levels of precision and accuracy shall be identified.
- The potential sources of uncertainty and error in scientific investigations which must be controlled and measured to assure the investigations are well controlled shall be identified.

The initial entries described above are considered to be a "general" procedure and shall be entered into the scientific notebook prior to beginning an investigation. Modifications may be made by the individual performing the investigation. If the change or modification is not within the scope of the study plan or scientific investigation plan, and the investigation is not repeatable, or the change could potentially impact the waste isolation capability of the site, or interfere with other site characterization activities, approval shall be obtained from an appropriately qualified reviewer.

1.6.4.2 In-process Entries

Entries to be made during the experiment or research, daily or as appropriate, shall be sufficiently detailed so that another competent experimenter/researcher could repeat the experiment or research, and shall include:

- Date and name of individual making the entry.
- Provisions for assuring prerequisites have been met.
- Description of the experiment or research attempted, including detailed step-by-step process followed; either by reference to implementing procedure or by actual entry into the notebook.
- Description of any conditions which may adversely affect the results of the experiment or research.
- Identification of samples used and any additional equipment and materials not included as part of the initial entries prescribed by Paragraph 1.6.4.1 of this section.
- All data taken and a brief description of the results, to include notation of any unaccepted results.
- Any deviations from the planned experiment or research.
- Any interim conclusions reached, as appropriate.

1.6.4.3 Final Entries

The final entries in the record shall have, as a minimum, the signature of the experimenter and the signature of a competent technical reviewer.

1.6.4.4 Final Results

Final results and a summary of the outcome of the experiment or research shall be documented (e.g. in a technical report). This shall include a discussion of whether the experiment's objectives as outlined in the initial entries (Paragraph 1.6.4.1) were achieved. This documentation shall become part of the QA records of the activity.

1.7 CHANGE CONTROL

All changes in scientific investigation planning documents shall go through the same review and approval process as specified in Paragraph 1.3 of this section. The Participating Organization shall be responsible for evaluating the impacts of such changes on the associated Quality Assurance level assignments.

1.8 INTERFACE CONTROL

1.8.1 COORDINATION

Internal and external scientific investigation interfaces shall be identified and scientific investigation efforts shall be coordinated among and within Participating Organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within Participating Organizations for the review, approval, release, distribution and revision of documents involving scientific investigation interfaces. Interfaces within a participating organization shall be coordinated according to procedures developed by that participating organization. Interfaces between scientific investigations, or between a scientific investigation and any other Project activity including design activities, shall be coordinated among Project participants in accordance with administrative procedures established by the WMPO. Interfaces between Participating Organizations and their suppliers shall be controlled in accordance with procedures established by the Participating Organization. Ongoing field or laboratory scientific investigations shall be identified to preclude inadvertent interruption and to ensure operational compatability. Such identification shall be clearly evident at the location at which the scientific investigation is being performed. Field investigations shall identify the location of the investigation.

1.8.2 TRANSMITTAL

The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces shall be documented.

1.9 VERIFICATION OF SCIENTIFIC INVESTIGATIONS

1.9.1 VERIFICATION PLANNING

Planning for verification activities shall be accomplished and documented via verification procedures, instructions, or checklists. Verification procedures, instructions, or checklists shall provide for following:

- o Identification of characteristics and activities to be verified.
- o A description of the method of verification.
- o Identification of the individuals or groups responsible for performing the verification.

- Acceptance and rejection criteria.
- Identification of required procedures, drawings, and specifications (including revisions).
- Recording identification of the verifier and the results of the verification.

1.9.2 VERIFICATION HOLD POINTS

Mandatory verification hold-points shall be established as necessary. When such hold points are established, work may not proceed without the specific consent of the responsible representative. These hold points shall be indicated in appropriate documents controlling the activity. Consent to waive any specified hold point shall be documented before work can be continued beyond the designated hold point.

1.9.3 REPORTING INDEPENDENCE OF PERSONNEL

Verification shall be performed by personnel who do not report directly to the immediate supervisor(s) who is/are responsible for performing the activity being verified. If these personnel are not part of the formal QA organization, they shall have sufficient authority, access to work areas, and organizational freedom to (1) identify quality problems; (2) initiate, recommend, or provide solutions to quality problems through designated channels; (3) verify implementation of solutions; and (4) assure that further processing, delivery, installation or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. When these persons or organizations who perform the verification activities are not part of the formal QA organization (i.e., part of line management), then the quality assurance organization shall overview and monitor the verification activity.

1.10 SURVEILLANCE OF SCIENTIFIC INVESTIGATIONS AND EXPERIMENTS

1.10.1 LOGISTICS OF SURVEILLANCE

The QA organization within the Participating Organization shall perform surveillances of all scientific investigations, as may be deemed appropriate for the purposes and the complexity of the work. The QA surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel. The timing and the number of surveillances shall be determined by the QA surveillance team that is formed for this work. Surveillances will be performed in accordance with the requirements specified in Section XVIII of this document.

1.10.2 SURVEILLANCE TEAM

The technical member or members of the QA surveillance team shall be familiar with the plan for the scientific investigation.

1.11 REPORTS, CONCLUSIONS, AND RECOMMENDATIONS

The Participating Organization shall have implementing procedures for the technical review and approval of the results of scientific investigations. These procedures shall include the WMPO in the review and approval cycle of the Final report.

1.12 CLOSE-OUT VERIFICATION

The Participating Organization shall perform a close-out verification upon the completion of any scientific investigation to assure that the QA records for that investigation are adequate and complete. This will be done because it may be a considerable period of time after the work is completed and before the investigation is used in the licensing process. Close-out verifications shall be performed by a team consisting of qualified technical personnel as well as QA personnel.

2.0 DESIGN CONTROL

2.1 GENERAL

2.1.1 DEFINITION

The design shall be defined, controlled, and verified. The term design refers to specifications, drawings, design criteria, and component performance requirements for the natural and engineered components of the repository system. Design information and design activities refer to data collection and analyses activities that are used in supporting design development and verification. This includes general plans and detailed implementing procedures for data collection and analyses and related information such as test results and analysis. The data collection activities result from scientific investigations and produce design input. Data analysis includes the initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

It is the policy of the NNWSI Project that a completed or final design of a facility or item evolves from a sequential order of design activities (or phases) wherein each phase becomes more detailed in nature than the preceding phase. It is recognized that the number and length of design phases required to produce a completed or final design of any particular item or facility may vary, among organizations responsible for design, according to the timeliness and availability of pertinent information and the complexity of the item or facility. It is also recognized that all Project design activities, although undertaken by different organizations, which may progress at different rates, are dependent on and require an interface with each other to produce a unified facility design.

2.1.2 QUALITY ASSURANCE LEVEL ASSIGNMENT

All design phases shall be assigned a Quality Assurance Level prior to execution in accordance with the methods specified in the NNWSI Project Administrative Procedures Manual.

2.1.3 QUALIFICATION OF PERSONNEL

Personnel performing design work shall be indoctrinated, trained, and qualified in accordance with the requirements of Section II of this document. Instructions, procedures and drawings for design work shall be in accordance with the requirements of Section V of this document.

2.1.4 PEER REVIEW

For design activities including design output documents which involve use of untried or beyond state-of-the-art testing and analysis procedures and methods, or where detailed technical criteria and requirements do not exist or are being developed, a peer review shall be conducted. The peer review shall meet the requirements of Paragraph 4.0 of this section of the NNWSI Project Quality Assurance Plan (QAP).

2.2 DESIGN INPUT

2.2.1 IDENTIFICATION, REVIEW AND APPROVAL OF INPUT

Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements. The design input shall be specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

2.2.2 CHANGES TO DESIGN INPUT

Changes to approved design input, including the reason for the changes, shall be identified, documented, approved, and controlled by the responsible design organization.

2.2.3 CONSIDERATIONS FOR DESIGN INPUT

Considerations for design inputs as they apply to specific items or systems are contained in Appendix B of this document.

2.3 DESIGN ANALYSIS

2.3.1 DESIGN ANALYSIS DOCUMENTS

Design analyses shall be performed in a planned, controlled, and documented manner. Design analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, design input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject (including structure, system, or component) originator, reviewer, and date.

2.3.2 DOCUMENTATION OF DESIGN ANALYSES

Documentation of design analysis shall include the following:

- Definition of the objective of the analysis.
- Definition of design input and their sources.
- A listing of applicable references.
- Results of literature searches or other background data.
- Identification of assumptions and indication of those which require verification as the design proceeds.
- Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the bases of application to the specific problem.
- Signatures and dates of review and approval by appropriate personnel including QA Personnel. The purpose of the QA review is to assure that the documentation is prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.3.3 USE OF COMPUTER PROGRAMS

Computer programs that are used to support a license application shall be documented and controlled as specified in Section III, Subparagraph 3.0 and Appendix H of this QA Plan.

2.4 DESIGN VERIFICATION

2.4.1 IDENTIFICATION AND DOCUMENTATION

Design control measures shall be applied to verify the adequacy of design and verification shall be performed in a timely manner. The responsible design organization shall identify and document the verification method used, the results of the verification, and the verifier.

2.4.2 TIMING OF VERIFICATION

Verification of the adequacy of design shall be performed prior to release for procurement, manufacture, construction, or release to another organization for use in other design activities. In those cases, where this timing can not be met, the portion or portions of design which have not been verified shall be identified and controlled. In all cases, the verification shall be completed prior to relying on the component, system, or structure to perform its function.

2.4.3 EXTENT OF VERIFICATION

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Where the design has been subjected to a verification process in accordance with Paragraph 2.4 of this section, the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standardized or previously proven designs and their effects on other features shall be considered. The original design and associated verification measures shall be adequately documented and referenced in the files of subsequent application of the design.

2.4.4 CHANGES TO VERIFIED DESIGNS

Changes to previously verified designs shall require verification including evaluation of the effects of those changes on the overall design.

2.4.5 PERSONNEL PERFORMING VERIFICATION

Design verification shall be performed in accordance with the requirements of Paragraph 2.4.6 of this Section by any competent, certified individual or individuals or certified group or groups other than those who performed the original design. This includes the following:

2.4.5.1 Individuals or groups from the originator's same organization.

2.4.5.2 Individuals or groups from other organizations contracted for this purpose.

2.4.5.3 The originator's supervisor providing all of the following requirements are met:

- The supervisor is the only individual in the organization competent to perform verification.
- The supervisor did not establish the design input used, specify a singular design approach, or rule out certain design considerations.

- The rationale for satisfying the two requirements above is documented and approved by management superior to the supervisor. The QA manager shall also concur with this rationale.

2.4.6 METHODS OF DESIGN VERIFICATION

Design verification shall be accomplished by any one or a combination of the following: design reviews, alternate calculations, qualification testing, or peer review.

2.4.6.1 Design Reviews

Design reviews are detailed critical reviews to provide assurance that the design is correct and satisfactory. At a minimum, the items below shall be considered during the review and the results of such deliberations shall be documented.

- Were the design inputs correctly selected?
- Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?
- Was an appropriate design method used?
- Were the design inputs correctly incorporated into the design?
- Is the design output reasonable compared to design inputs?
- Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures or instructions?
- Are computer programs used for analysis identified and verified in accordance with the methods specified in paragraph 3.0 of this Section.

2.4.6.2 Alternate Calculations

Alternate calculations are a form of analysis which may be used to determine the adequacy of the original analyses. The use of alternate calculations shall include a review of the appropriateness of assumptions, inputs and computer programs or other calculation method used.

2.4.6.3 Qualification Tests

Qualification tests that involve actual physical testing of systems, structures, or components may be used to verify the adequacy of design. Where design adequacy is to be verified by qualification tests, the tests shall be identified. The test configuration shall be clearly defined and documented.

Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Test results shall be documented and evaluated by the responsible design organization to assure that test requirements have been met. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification shall be documented and the item modified and retested or otherwise verified to assure satisfactory performance. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design work.

2.4.6.4 Peer Review

Peer review is an acceptable method of design verification when the design is beyond state-of-the-art and other methods of design verification are not feasible.

2.5 DESIGN CHANGE CONTROL

2.5.1 CHANGES TO APPROVED DESIGNS

Changes to approved designs, including field changes, shall be justified and subjected to design control measures commensurate with those applied to the original design and approved by the same affected groups or organizations which reviewed and approved the original design documents; except where an organization which originally was responsible for approving a particular design document is no longer responsible, then the WMPO shall designate a new responsible organization. The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design. Errors and deficiencies in approved design and design information documents shall be documented, and action taken to assure that all errors and deficiencies are corrected. Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

2.6 DESIGN INTERFACE CONTROL

2.6.1 IDENTIFICATION AND RESPONSIBILITY

Internal and external design interfaces shall be identified and controlled and design efforts shall be coordinated among and within responsible design organizations. Interface controls shall include the assignment of responsibility and the establishment of procedures among and within responsible design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

2.6.3 INFORMATION TRANSMITTED ACROSS INTERFACES

Design information transmitted across interfaces shall be documented and controlled. Transmittals shall identify the status of the design information or document provided and, where necessary, identify incomplete items which require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

2.7 DESIGN OUTPUT REQUIREMENTS

2.7.1 DESIGN OUTPUT DOCUMENTS

Design output documents shall:

2.7.1.1 Relate to the design input by documentation in sufficient detail to permit design verification.

2.7.1.2 Identify assemblies or components or both that are part of the item being designed. When such an assembly or component part is a commercial grade item that, prior to its installation, is modified or selected by special inspection or testing or both, to requirements that are more restrictive than the Supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.

2.7.1.3 Show evidence that the required review and approval cycle has been achieved prior to release for procurement, construction, or release to another organization for use in other design activities. As a minimum, the review and approval cycle shall include the participation of the technical and QA elements of both the responsible design organization and the WMPO. The purpose of the QA review is to assure that the documents are prepared, reviewed and approved in accordance with documented procedures and quality assurance requirements.

2.8 DESIGN DOCUMENTS AS QA RECORDS

Design documentation, including design inputs, analyses, drawings, specifications, approved changes thereto, evidence of design verification and records confirming interface control shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document.

3.0 SOFTWARE QUALITY ASSURANCE REQUIREMENTS

3.1 COMPUTER SOFTWARE DOCUMENTATION AND CONTROL

For a geologic repository, computer software used to perform analysis in support of the license application shall be controlled to the same level of

requirements as software used to perform direct design analysis. Auxiliary software used to support primary analysis software shall be controlled at a level commensurate with the complexity of that software.

Where commercial auxiliary software is used, all available documentation from the software supplier shall be obtained. It is recognized that source code is generally not available and controls are limited to unique version identification and user-related manuals. Supplemental, detailed requirements for the development, maintenance, and security of computer software based on the life cycle model are contained in Appendix H to this QA Plan.

3.1.1 Each organization participating in the NNWSI Project shall prepare a description of their software design, test and configuration management system, and submit it to the next higher program organizational level for review and approval. The description shall:

- Provide criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository.
- Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code.
- Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use.
- Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software.
- Specify the process to be used for verification and validation of the software developed or applied to geologic repository design analysis.
- Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action.

3.1.2 Software shall be placed under configuration management as each baseline element is approved. Software baseline elements shall be uniquely identified to assure positive control of all revisions; the identification of each code version shall be directly related to the associated documentation.

3.1.3 Changes to software shall be systematically evaluated, coordinated, and approved to assure that the impact of a change is carefully assessed prior to updating the baseline, required action is documented, and the information concerning approved changes is transmitted to all affected organizations.

Changes to computer software shall be subject to the same level of approval, verification, and validation as the original software.

3.1.4 Computer programs developed and/or modified shall be documented in accordance with the applicable elements of NUREG-0856, Final Technical Position on Documentation of Computer Codes for High-Level Waste Management. This requirement may be met in part by existing documentation if properly referenced and related to the NUREG-0856 requirements.

3.1.5 Testing of software, including new or modified software, shall be performed for those inputs and conditions necessary to exercise the software, identify boundary conditions and to provide a suitable benchmark or sample problem for installation. The goal of testing is to develop a set of test cases that have highest probability of detecting the most errors in order to identify under what conditions the software does not perform properly.

3.1.6 Verification and validation of computer software shall be performed prior to the use of such software to perform technical calculations in support of site-characterization, performance assessment analyses, and the design, analysis, and operation of repository structures, systems, and components. In those cases where this requirement cannot be met, the portion or portions of software which have not been verified and validated shall be identified and controlled. In all cases, the verification and validation of software shall be completed prior to relying on the software to support the license application.

3.1.7 Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

3.1.8 Existing software shall be qualified for use. This qualification shall be based on the ability of the software to provide acceptable results for specific applications and compliance with the requirements of this section. Software that has not been developed in accordance with this QA Plan may be qualified for use provided the software is verified and validated, a software baseline established, and applicable documentation prepared to support the software in accordance with the provisions of this section.

3.1.9 Methods for determining the applicability of requirements and managing interfaces involving the documentation, configuration management, change, qualification, verification, and validation of software, shall be described in each organizations software QA Plan and procedures.

3.2 DOCUMENTATION OF COMPUTER SOFTWARE

Documentation of scientific and engineering software shall include the following, as a minimum:

- Software requirements specification;
- Software design and change documentation;

- Description of mathematical models and numerical methods;
- Software verification and validation documentation;
- User documentation;
- Code assessment and support;
- Continuing documentation and code listings; and
- Software summary.

This documentation is considered to be a QA Record and is subject to the requirements of Section XVII of this QA Plan. Appendix H to this QA Plan provides detailed requirements on the content of the documentation for this software and other computer software used on the NNWSI Project.

3.3 SOFTWARE CONFIGURATION MANAGEMENT

All Participating Organizations and NTS Support Contractors shall institute a software configuration management program appropriate to the projects they conduct and shall provide documentation of this program to the Records Management System (RMS). The minimum requirements for this configuration management program shall be: (1) the inclusion of a unique identification, including software version numbers whenever feasible, in the output; (2) listings of the software; and (3) a brief chronology of the software versions, including descriptions of the changes made between versions.

4.0 PEER REVIEWS

All Participating Organizations and NTS Support Contractors shall institute a peer review process, when applicable, to provide adequate confidence in the work being reviewed. Peer reviews shall meet the requirements of NUREG-1297 "Peer Review for High-Level Nuclear Waste Repositories" (Feb. 1988). These requirements are contained in Appendix J to this QA Plan.

5.0 TECHNICAL REVIEWS

When technical reviews are required, they shall be conducted in accordance with procedures that contain specific criteria for the performance of the technical review.

SECTION V

INSTRUCTIONS, PROCEDURES, PLANS AND DRAWINGS

1.0 GENERAL

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings, of a type appropriate to the circumstances except as noted in paragraph 3.0 of this Section. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Instructions and procedures shall include a section which identifies the QA records which are generated during implementation of the document. If plans are used in lieu of procedures, then these plans shall also include or reference appropriate acceptance criteria and identify the QA records which are generated. These documents, including drawings, shall be controlled as required in Section VI of this document.

2.0 REVIEWS

An independent review of all instructions, procedures, plans and drawings shall be performed by the originating organization to assure technical adequacy and inclusion of appropriate quality requirements. If applicable, this review shall consider whether or not the activities are repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

3.0 INSTRUCTIONS FOR SCIENTIFIC NOTEBOOKS

The Participating Organizations shall prepare instructions for the control of scientific notebooks, plans and the other documentation that will be used in scientific investigations. When scientific notebooks are used to document scientific investigations, the requirements of Section III, paragraph 1.6 shall prevail over the requirements of this Section. Scientific notebooks shall be collected, controlled, stored, and maintained as QA records in accordance with procedures which meet the requirements of Section XVII of this document.

4.0 DISTRIBUTION

Each Participating Organization and Nevada Test Site (NTS) Support Contractor shall maintain and provide the WMPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager with controlled distribution of all implementing procedures, plans and instructions used for QA Level I and II activities.

SECTION VI

DOCUMENT CONTROL

1.0 DOCUMENT PREPARATION, REVIEW, APPROVAL, AND ISSUANCE

1.1 METHODS

The preparation, review, approval, and issuance of documents such as instructions, procedures, plans and drawings, including changes thereto, shall be controlled through the implementation of methods that assure that only correct documents are used. Document control shall be applied to the following:

- Documents containing or specifying quality requirements.
- Documents that prescribe activities affecting quality.

The document control system shall be documented, and the QA organization shall provide the appropriate review, resolution of comments, and concurrence with respect to quality-related aspects of the documents.

1.2 IMPLEMENTATION

Implementation of document control shall provide for the following:

- Identification of documents to be controlled.
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents.
- Review of documents for technical adequacy, completeness, correctness, and inclusion of appropriate quality requirements, prior to approval and issuance.
- A method for the removal or marking of obsolete or superseded documents to prevent inadvertent use.
- A method for assuring that the correct and applicable documents are available at the location where they are to be used.
- A master list or equivalent to identify the correct and updated revisions of documents.
- Coordination of interface documents.

2.0 DOCUMENT CHANGES

2.1 MAJOR CHANGES

Changes to documents, other than those defined below as minor changes are considered as major changes and shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are specifically designated by the organization responsible for the document. The reviewing organization shall have access to pertinent background data or information upon which to base their approval and, if applicable, shall specifically consider whether or not the activities being changed are repeatable, have the potential to impact the waste isolation capability of the site or interfere with other site characterization activities.

2.2 MINOR CHANGES

Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.

3.0 DISTRIBUTION OF DOCUMENTS

3.1 DOCUMENT CONTROL SYSTEM

The document control system shall assure that documents requiring verification are not released prior to verification or, if they must be released before verification, they are uniquely identified as such and controlled in accordance with Paragraph 1.2 of this section. A master list or equivalent used to identify the correct, current and updated versions of documents shall be submitted to the WMPO PQM and the SAIC/T&MSS Project Quality Assurance Department Manager.

Enclosure 2: Administrative Procedure 1.10Q

Title

AP-1.10Q PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS

1.0 PURPOSE AND SCOPE

This procedure defines the requirements and responsibilities for preparation, review, and approval of the Yucca Mountain Project Site Characterization Plan (SCP) Study Plans. This procedure implements the U.S. Department of Energy/U.S. Nuclear Regulatory Commission (DOE/NRC) Format and Content Requirements for SCP Study Plans (Exhibit 1).

2.0 APPLICABILITY

This procedure applies to all Study Plans developed by the Project participants to support the Yucca Mountain Project SCP.

3.0 DEFINITIONS

3.1 DOCUMENT REVIEW

A document review is a documented, traceable review of documents, material, or data that may consist of a technical review, Assistant Manager for Administration - Technical Publications (AMAT) review, regulatory review, quality assurance review, and/or management review.

3.2 INTERIM REVISION NOTICE (IRN)

An IRN is an approved and controlled document that is used to temporarily change an approved Study Plan prior to revising the affected plan in accordance with this procedure, or is used to temporarily change the Statutory SCP for consistency with an approved Study Plan.

3.3 MANAGEMENT REVIEW

A management review is an examination of a document to determine its compliance with requirements established by approved Yucca Mountain Project management plans, procedures, and DOE policies as described by the DOE/Nevada Operations Office and the Office of Civilian Radioactive Waste Management (OCRWM). This review includes an examination to determine if the document fulfills the established milestone criteria.

3.4 MANDATORY COMMENTS

Mandatory comments are those a reviewer determines represent significant technical concerns or inconsistencies with applicable DOE policies and regulatory requirements. Mandatory comments require resolution by the author(s) and reviewer. Reviewers must cite the applicable requirement, quality assurance provision, or technical rationale for changing the SCP Study Plan.

3.5 NONMANDATORY COMMENTS

Nonmandatory comments are those the reviewer designates as suggestions to the author(s) about the organization or content of the document. These comments do not constitute a significant weakness in the document. Nonmandatory comments are incorporated at the discretion of the author(s). All nonmandatory comments except editorial changes are resolved on comment response forms.

3.6 PRINCIPAL INVESTIGATOR (PI)

The PI is the individual who has the technical responsibility for a particular technical task. This responsibility includes, but is not limited to, planning and cost control, the day-to-day technical direction and control of the item or activity, and the assembly of a support team to accomplish the item or activity. This term may be synonymous with task leader or project engineer, depending on the Yucca Mountain Project participants.

3.7 QUALIFIED REVIEWER

Qualified reviewers are independent of the work performed and have demonstrated expertise in their area of review. Expertise can be established by the reviewer's job description, education, or other experience.

3.8 QUALITY ASSURANCE REVIEW

A quality assurance review is an examination of a document to determine its compliance with the DOE Order relating to Quality Assurance (DOE/NV 5700.6B), the Yucca Mountain Project Quality Assurance Plan (NNWSI/88-9), and Project quality-related administrative procedures.

3.9 REGULATORY REVIEW

A regulatory review is an examination of a document to determine consistency with the SCP and with applicable NRC requirements and agreements.

3.10 SCP STUDY PLAN

An SCP Study Plan is a DOE document that describes the studies, activities, tests, and analyses that constitute site characterization activities as defined by the Nuclear Waste Policy Amendments Act of 1987. The plan is consistent with the descriptions presented in Chapter 8 of the SCP or supplemented in SCP progress reports. The required level of detail, format, and content of the Study Plans are defined in the May 7 and 8, 1986, agreement between the NRC and the DOE (Exhibit 1).

3.11 TECHNICAL REVIEW

A technical review is a documented, traceable review performed by qualified personnel who are independent of those performing the work but have expertise in the work described. Technical reviews are in-depth, critical analyses and evaluations of documents, material, or data.

4.0 RESPONSIBILITIES

4.1 YUCCA MOUNTAIN PROJECT MANAGER

The Project Manager or a designee is responsible for final approval of the SCP Study Plans and for transmitting SCP Study Plans to the OCRWM for their approval.

4.2 DIRECTOR, REGULATORY AND SITE EVALUATION DIVISION (R&SED)

The Director, R&SED, or a designee is responsible for coordinating the preparation, review, and approval of SCP Study Plans in accordance with this procedure, including the resolution of comments generated by the OCRWM, the NRC, and the State of Nevada.

4.3 YUCCA MOUNTAIN PROJECT STUDY PLAN COORDINATOR (SPC)

The Yucca Mountain Project SPC is responsible for assisting the Director, R&SED, with coordination of the Study Plan preparation, review, revision, and approval. The SPC is responsible for all Yucca Mountain Project actions other than final approvals, letters of direction, and approval of mandatory comment resolutions, and coordinates Yucca Mountain Project Study Plan reviews among the divisions of the Yucca Mountain Project Office (Project Office). The Yucca Mountain Project SPC is a member of the Regulatory Interaction Branch of the R&SED.

4.4 TECHNICAL PROJECT OFFICERS (TPOS)

The TPOs and their designated technical staff are responsible for preparing and reviewing SCP Study Plans in their area of program responsibility in accordance with the Quality Assurance Plan (QAP) and the Work Breakdown Structure (WBS), for submitting approved Study Plans to the Yucca Mountain Project, for providing technical experts for independent Project technical reviews of SCP Study Plans, and for resolving comments from the Project, the OCRWM, and the NRC reviews.

4.5 TECHNICAL AND MANAGEMENT SUPPORT SERVICES (T&MSS) SPC

The T&MSS SPC is responsible for assisting the Project Office in review and approval of the SCP Study Plans, including technical, management, quality assurance, and regulatory reviews completed by the Project, the OCRWM, and the NRC, and for tracking the status of Study Plan preparation and review.

4.6 OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

The OCRWM is responsible for interfacing with the NRC and providing guidance to the Project Office in the area of Study Plan completion. The OCRWM reviews and approves SCP Study Plans.

5.0 PROCEDURE

5.1 STUDY PLAN PREPARATION

5.1.1 The TPOs designate a principal investigator or other technical staff to prepare Study Plans in accordance with the following requirements:

1. Plans must be editorially consistent with the OCRWM Production Guidance Manual (1985) to the extent practicable.

2. Plans must conform to level of detail, format, and content specified in the May 7 and 8, 1986, DOE/NRC agreement (Exhibit 1).

3. Plans must include an abstract provided in front of the table of contents.

4. Plans must include an appendix that provides additional information on the quality assurance measures that will be applied to Study Plan activities. The appendix must give quality assurance level assignments for activities.

5. Plans must be consistent with the descriptions of the study given in Section 8.3 of the Statutory SCP, unless an IRN (Exhibit 2) is provided.

5.1.2 Participating organizations perform technical reviews of Study Plans prepared or revised by them in accordance with their procedures.

5.1.3 The TPO or a designee ensures that the Study Plans meet the requirements given in paragraph 5.1.1 and that the plans are prepared and reviewed by qualified staff.

5.1.4 If the Study Plan differs from the Statutory SCP in purpose, goals, scope, or testing methods, then the TPO, or a designee, prepares an IRN (Exhibit 2) to request changes to the SCP.

5.1.5 The TPO or a designee submits the participant approved Study Plan, any IRN and the qualifications of the principal investigators to the Director, R&SED.

5.1.6 The Yucca Mountain Project SPC will maintain a list of qualified principal investigators and supporting documentation for the Director, R&SED.

5.2 PROJECT REVIEW OF STUDY PLAN

5.2.1 The Yucca Mountain Project SPC, or a designee, documents completion of major steps in the Project review process on the Checklist for Review of Study Plans (Exhibit 3).

5.2.2 Upon receipt of a draft Study Plan, the Division Director, R&SED, or a designee initiates through the T&MSS SPC a screening review of the Study Plan for overall format and content consistency with the SCP and for completeness of any Study Plan IRNs.

5.2.3 The T&MSS SPC documents the result of the screening review in a memo to the Director, R&SED.

5.2.4 If significant deficiencies are identified, the Director, R&SED, returns the Study Plan to the TPO with instructions for revision.

5.2.5 When no significant deficiencies are identified, the Director, R&SED, or a designee prepares a written request for management, quality assurance, regulatory, and technical reviews of the Study Plan in accordance with this procedure. The written request establishes the review criteria, the proposed reviewers, and the schedule for completing the review. The review criteria must be consistent with the definitions of review given in this procedure and may include additional review criteria, if necessary.

5.2.6 Reviews of Study Plans are performed only by qualified staff. Qualifications of reviewers will be completed internally by participant organizations and provided to the Yucca Mountain Project SPC by the TPO prior to initiation of the Project review. The Yucca Mountain Project SPC maintains a list of qualified Study Plan reviewers, principal investigator(s), and supporting documentation.

5.2.7 Review criteria should be consistent with the definitions of reviews given in this procedure and may be supplemented by the Director, R&SED, if necessary.

5.2.7.1 The management reviewers examine the study plan for consistency with DOE policies and programmatic interfaces, including as a minimum SCP schedules and milestones, technical integration, and environmental permitting. The management reviewers also ensure that quality assurance level assignments have been completed and satisfy the applicable provisions of NNWSI/88-9.

5.2.7.2 The quality assurance reviewers examine the document for consistency with the quality assurance requirements of the Project, including as a minimum the quality assurance level assignments for the planned work.

5.2.7.3 The technical reviewers examine the document for consistency with the technical program described in the SCP. They evaluate the technical adequacy of the Study Plan, including as a minimum the descriptions of proposed tests and analyses, interrelationships with other studies, ties to performance and design issues, consideration of alternative test methods, and quality assurance level assignments.

5.2.7.4 The regulatory reviewers examine the Study Plan for consistency with applicable NRC requirements and agreements.

5.2.8 Reviewers document all comments on comment resolution forms (CRFs, Exhibit 4) and categorize comments as mandatory or nonmandatory (see Sections 3.4 and 3.5). A proposed resolution should be included. Reviewers record editorial comments on the text and attach the text to the set of CRFs. Editorial comments marked on the text will not become part of the permanent comment-response record. After completing the review, reviewers return the completed CRFs to the Director, R&SED.

5.3 COMMENT RESOLUTION

5.3.1 The Yucca Mountain Project SPC compiles a complete set of CRFs and forwards this set to the responsible TPO. After the principal investigator(s) reviews the comments, a comment resolution meeting may be scheduled to resolve mandatory comments. As a minimum, the principal investigator(s), the Yucca Mountain Project SPC or a designee, and reviewers will attend the meeting.

5.3.2 If the principal investigator(s) and reviewers are unable to resolve a mandatory comment, the Director, R&SED, develops a final disposition. The final disposition is based on an agreeable compromise, an independent technical review, or a peer review. The responsible TPO coordinates revision of the Study Plan to address mandatory comments and completion of the final disposition column on the CRFs. The responsible TPO submits the revised Study Plan and completed CRFs to the Director, R&SED.

5.3.3 The Yucca Mountain Project SPC or a designee distributes the revised Study Plan and CRFs for mandatory comments to the reviewers.

5.3.4 The reviewers will verify resolutions of their mandatory comments. If their mandatory comments have been resolved, the reviewers sign and return their CRFs to the Director, R&SED.

5.3.5 If the mandatory comment resolution is inadequate, the reviewer notifies the Director, R&SED. The Director, R&SED, returns the package to the responsible TPO with instructions for revision.

5.3.6 When comment resolution is finalized, the Director, R&SED, will sign the review checklist (Exhibit 2).

5.4 YUCCA MOUNTAIN PROJECT APPROVAL

Upon completion of the management, quality assurance, regulatory, and technical reviews, a copy of the revised Study Plan and the comment resolution record is submitted to the Director, R&SED, for approval. The Director, R&SED, signs the Yucca Mountain Project approval form (Exhibit 5) and forwards the form to the Project Quality Manager and the Project Manager for signature.

5.5 OCRWM REVIEW AND APPROVAL

5.5.1 The OCRWM reviews SCP Study Plans in parallel with or following the Project review. The Director, R&SED, provides the lead Branch Chief, OCRWM, ten copies of the Study Plan and any SCP IRNs. The OCRWM review of the Study Plan is completed in accordance with their procedures.

5.5.2 After the OCRWM has completed their Study Plan review and consolidated their comments on OCRWM CRFs, a comment resolution meeting may be scheduled to discuss the OCRWM mandatory comments and to reach agreement with the Project on the proposed resolutions. As a minimum, the principal investigator(s) and the Yucca Mountain Project SPC or a designee participate in the comment resolution meeting.

5.5.3 If the participants in the OCRWM comment resolution meeting are unable to resolve a mandatory comment, then the lead OCRWM Branch Chief and the Director, R&SED, develop a final resolution based on an agreeable compromise, an independent technical review, or a peer review. If resolution cannot be obtained at this level, the appropriate Headquarters Division Director and the Yucca Mountain Project Manager are consulted to facilitate comment resolution.

5.5.4 The Director, R&SED, directs the responsible TPO to initiate resolution of the comments and revision of the Study Plan. The responsible TPO submits the revised text and completed OCRWM CRFs to the Yucca Mountain Project SPC.

5.5.5 The Yucca Mountain Project SPC or a designee reviews the revised Study Plan to verify the adequacy of the changes to the text and advises the

Director, R&SED, of the results. If the OCRWM comment resolution is incomplete, the Director, R&SED, returns the Study Plan to the responsible TPO for additional revision. If the resolution of OCRWM comments is deemed to be adequate, the Director, R&SED, Project Quality Manager, and Project Manager approve the Study Plan (Exhibit 5). The Director, R&SED, forwards the Study Plan to the OCRWM for approval.

5.6 NRC REVIEW

5.6.1 After OCRWM approval, the OCRWM forwards the Study Plan to the NRC for review and to the State of Nevada for their information. The OCRWM also forwards a copy of the completed OCRWM CRFs to the Director, R&SED, for the Project file.

5.6.2 The Yucca Mountain Project SPC or a designee documents written comments received from the NRC on CRFs (Exhibit 4). The Yucca Mountain Project SPC and the principal investigator(s) work with the OCRWM to develop proposed resolutions to the NRC written comments. This may include meetings with the NRC for clarification of the written comments and for discussion of proposed resolutions to the written comments.

5.6.3 The TPO or a designee revises the Study Plan according to the proposed resolutions to address major NRC and State of Nevada comments and submits the revised Study Plan and completed CRFs to the Director, R&SED.

5.6.4 The Yucca Mountain Project SPC reviews the revised Study Plan to verify that the NRC comments have been adequately addressed. If the comment resolution is incomplete, the Director, R&SED, returns the Study Plan to the responsible TPO for revision. If the comment resolution is adequate, the Director, R&SED, Project Quality Manager, and Project Manager sign the approval sheet (Exhibit 5). The Project Manager forwards the Study Plan to the OCRWM for their approval.

5.7 REVISION OF APPROVED STUDY PLANS

If revisions to approved Study Plans prove to be necessary, proposed revisions are incorporated by the principal investigator or a designee as directed by the Project Office. Revisions may be initiated by the principal investigator(s), the TPO, or representatives of the Yucca Mountain Project.

5.7.1 Revision and review of major changes to the purpose, scope, testing strategy, test methods, and quality assurance level assignments follow the procedures outlined in Sections 5.2 and 5.3 for the preparation and review of the original Study Plan.

5.7.2 To implement minor revisions to an approved Study Plan, the TPO or a designee prepares an IRN (Exhibit 2) as a temporary method to identify these

changes. The responsible TPO approves the IRN and submits the signed IRN to the Director, R&SED, for review and approval.

5.7.3 The Director, R&SED, evaluates the scope of the IRN and, if necessary, prepares a transmittal letter to initiate a Project review of the IRN. A Project review is only required if the Director, R&SED, does not consider the proposed revisions to be minor. The transmittal letter will define the types of review required for IRN approval.

5.7.4 The reviewer(s) documents all comments on the IRN and proposed resolutions to the comments on CRFs (see Section 5.2.8).

5.7.5 The Director, R&SED, compiles a complete set of CRFs and forwards this set to the responsible TPO. Comment resolution follows the procedures established in Section 5.3 of this procedure.

5.8 DISTRIBUTION OF SCP STUDY PLANS AND IRNs

Study Plans and IRNs are maintained and controlled in accordance with QMP-06-02, Document Control. Study Plans and IRNs are distributed by the T&MSS Information Management Division to individuals designated by the Director, R&SED.

6.0 REFERENCES

Nuclear Waste Policy Amendments Act of 1987, December 21, 1987, in Omnibus Budget Reconciliation Act of 1987. Public Law 100-203, December 22, 1987.

U.S. Department of Energy, Office of Civilian Radioactive Waste Management, 1985. Production Guidance Manual.

U.S. Department of Energy, Nevada Operations Office, June 26, 1981. Quality Assurance Plan, NNWSI/88-9 (Revision 1), Las Vegas, Nevada.

U.S. Department of Energy, Yucca Mountain Project Office, 1988 (in preparation). QMP-06-02, Document Control (Revision 0).

7.0 APPLICABLE FORMS

Exhibit 2. Interim Revision Notice.

Exhibit 3. Checklist for Review of Study Plans.

Exhibit 4. Study Plan Comment Resolution Form.

Exhibit 5. Approval Form for Study Plans.

8.0 QUALITY ASSURANCE RECORDS

1. Document submitted for review.
2. Transmittal letter initiating Project review.
3. Reviewer qualifications documents.
4. Complete copy of the comment resolution record.
5. Completed Study Plan checklist.
6. Approved revisions of the Study Plan.

1. Purpose and Objectives of Studies:

1.1 Objectives of the Study

Describe the information that will be obtained in this study. Briefly discuss how this information will be used; and

1.2 Regulatory Rationale and Justification

Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

2. Rationale for Selected Study:

2.1 Technical Rationale and Justification

Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and

Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify

Exhibit 1. DOE/NRC Requirements for Format and Content of SCP Study Plans.

reasonable alternatives; summarize reasons for not selecting these alternatives, and reference, if available, reports which evaluate alternatives considered.

2.2 Constraints on the study

Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:

- Potential impacts on the site from testing;
- Whether the study needs to simulate repository conditions;
- Required accuracy and precision of parameters to be measured with test instrumentation;
- Limits of analytical methods that will use the information from the tests;
- Capability of analytical methods to support the study;
- Time required versus time available to complete the study;
- The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;
- Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and
- Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information).

3. Description of Tests and Analyses:

o Since studies are comprised of tests and analyses, provide for each type of test:

- Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESF elements, repository layout, stratigraphic units, depth, and test location);

Exhibit 1. DOE/NRC Requirements for Format and Content of SCP Study Plans (continued).

- Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA Level 1. Reference the applicable specific QA requirements that will be applied to the test;
- Specify the tolerance, accuracy, and precision required in the test, where appropriate;
- Indicate the range of expected results of the test and the basis for those expected results;
- List the equipment required for the test and describe briefly any such equipment that is special;
- Describe techniques to be used for data reduction and analysis of the results;
- Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;
- Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests, and
- Relationship of the test to the set performance goals and confidence levels.

o For each type of analysis:

- State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;
- Describe the methods of analysis, including any analytical expressions and numerical models that will be employed;
- Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality

Exhibit 1. DOE/NRC Requirements for Format and Content of SCP Study Plans (continued).

assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA Level 1. Reference the applicable QA requirements;
- Identify the data input requirements of the analysis;
- Describe the expected output and accuracy of the analysis; and
- Describe the representativeness of the analytical approach (e.g., with respect to spatial variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

4. Application of Results:

Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies);

4.1 Resolution of Design and Performance Issues

For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;

For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

4.2 Interfaces with other site characterization studies

For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

Exhibit 1. DOE/NRC Requirements for Format and Content of SCP Study Plans (continued).

5. Schedules and Milestones:

- Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing, data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;

- Describe the timing of this study relative to other studies and other program activities that will affect, or will be effected by, the schedule for completion of the subject study; and

- Dates for activities or milestones, including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5. of the SCP.

Exhibit 1. DOE/NRC Requirements for Format and Content of SCP Study Plans (continued).

INTERIM REVISION NOTICE
SCP AND SCP STUDY PLANS

T-AD-086
11/88

IRN NUMBER:	EFFECTIVE DATE:	PAGE of

APPLIES TO:

SCP Section Number _____

Title _____

or

Study Plan Number _____ Revision _____

Title _____

REQUIRED CHANGES:

SECTION/PAGE NUMBER:	CHANGE TO:

APPROVALS:

Technical Project Officer _____ Date: _____

Director, R&SED _____ Date: _____

Yucca Mountain Project Manager* _____ Date: _____

OCRWM: Chief, Siting and Geoscience* _____ Date: _____

*If required

Exhibit 2. Interim Revision Notice.

Title

AP-1.10Q PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS

INTERIM REVISION NOTICE CONTINUATION SHEET
SCP AND SCP STUDY PLANS

T-AD-086
11/88

IRN NUMBER:	EFFECTIVE DATE:	PAGE of

APPLIES TO:

REQUIRED CHANGES:

SECTION/PAGE NUMBER:	CHANGE TO:

Exhibit 2. Interim Revision Notice (continued).

CHECKLIST FOR REVIEW OF STUDY PLANS T-AD-007 11/88

Study Plan Title _____

Study Plan Number _____

Revision Number/Date _____

Principal Investigator/Organization _____

Study Plan Coordinator or Designee shall sign and date when completed:

Action	Signature	Date
TPO Approved Study Plan received		
Screening Review completed		
Letter sent to reviewers to initiate review		
Reviewer qualifications received		
All CRFs returned to the Project		
CRFs sent to principal investigator		
Revised Study Plan/completed CRFs returned to the Project		
Resolution to all mandatory comments verified		

The above review steps have been completed in accordance with Administrative Procedure, AP-1.10Q

Director, R&SED _____ Date _____

Exhibit 3. Checklist for Review of Study Plans.

STUDY PLAN COMMENT RESOLUTION FORM

T-AD-089
11/88

Comment Number ____ of ____

Type of Review
Management ____ Quality Assurance ____
Technical ____ Regulatory ____

1. Reviewer _____
2. Organization _____
3. Study Plan No. _____
4. Title _____
5. Revision No/Date _____
6. Section _____
7. Page _____
8. Paragraph _____
9. Category _____ (mandatory/non-mandatory)

10. Comment

11. Proposed Resolution

12. Actual Disposition

13. Concurrence

Principal investigator or designee _____ Date _____
Reviewer _____ Date _____
Project SPC or designee _____ Date _____

Exhibit 4. Study Plan Comment Resolution Form.

YUCCA MOUNTAIN PROJECT

T-AD-08B
10/88

Study Plan Number _____

Study Plan Title _____

_____

Revision Number _____

Prepared by:

Date:

_____
Director, Regulatory and Site Evaluation Division

_____
Project Quality Manager Date

_____
Project Manager Date

UNCONTROLLED

Exhibit 5. Approval Form for Study Plan.

Enclosure 3: DOE/HQ Interim Procedure for review and approval of Study Plans

DOE F 1325.8
(12-84)

United States Government | Department of Energy

memorandum

DATE: SEP 09 1988

REPLY TO ATTN OF: RW-20

SUBJECT: Interim Procedure for the Review of Study Plans

TO: Lake Barrett, RW-3

The interim procedure for the review of DOE study plans is attached to this memo (Attachment I). This interim procedure has been prepared to supply further detail on the manner in which study plans will be reviewed, and is intended to implement the technical review process described in the draft Quality Assurance Administrative Procedure (QAAP) dealing with technical review. While the QAAP for technical review is being finalized, this interim procedure will be used for study plan review, so that the reviews can be continued and carried out in accordance with written Quality Assurance requirements (this interim procedure) that fulfill the intent of the governing QAAP. This interim procedure may be issued as a Quality Assurance Implementing Procedure (QAIP) after the QAAP is finalized, and further guidance is provided on the format for writing implementing procedures.

If you have any questions, please call Ina B. Alterman of my staff on 586-9274.

S. H. Kale

Stephen Kale
Acting Associate Director for
Facilities Siting and Development

Attachment

cc: M. Frei, RW-22
R. Stein, RW-30
[redacted], YMPO
M. Blanchard, YMPO
D. Dobson, YMPO
D. Alexander, RW-332
S. Brocoum, RW-221
I. Alterman, RW-221
S. Singal, RW-332

ACTION YMPO
INFO
AMA
AMESH
AMOE
OER

ACTION
GERTZ
WILMOT
BLANCHARD
DOBSON
LKOUSEN
HUGHES
CLANTON
PETRIE
WATERS
MANGUM/MONKS
PENDLETON
FILES IN YMPO
9/15/88
FOR YOUR COPY

investigation

NNI.880915.0068

INTERIM PROCEDURE FOR THE REVIEW OF STUDY PLANS

I. Purpose

The purpose of this procedure is to describe the method for HQ-OCRWM technical review and final approval of Project Office Study Plans which support the Site Characterization Plan (SCP).

II. Scope

This procedure applies to the review of study plans submitted by the Project Office for HQ-OCRWM approval.

III. QA References

A. OGR QA Plan - OGR/B-3
B. QIP 3.2 Technical Reviews
C. QIP 2.1 Indoctrination and Training
D. QIP 17.0 Quality Assurance Records
E. QIP 18.4 Internal Audits

IV. General

A. References A and B require that technical reviews be performed to verify the technical adequacy of data and documents, including study plans, which are related to items and activities important to safety or waste isolation.

B. This procedure complies with the requirements of Reference B and provides specific details for HQ-OCRWM review and approval of Project Office Study Plans.

C. The emphasis of the HQ-OCRWM review will be on the following:

1) Integration between the study plan and the Site Characterization Plan

2) A management-level technical overview

3) A detailed technical evaluation, if required.

D. As a minimum, HQ-OCRWM will perform a management-level technical overview. This overview requires review of the study plan for the appropriateness of the scope of work, schedule considerations and integration with the Site Characterization Plan.

E. The Project Office has the primary responsibility for assuring the technical completeness and adequacy of study plans. HQ-OCRWM, however, retains the option of performing a detailed technical review of any, or all, study plans submitted by the Project Office. Whether an overview or a detailed technical review is conducted, the applicable sections of this procedure shall apply.

F. The responsible HQ-OCRWM Branch Chief shall ensure that the reviewers are independent of the work being reviewed but have demonstrated expertise in the subject area equivalent to that of those who performed the work. Expertise can be demonstrated by the reviewer's job position or other education and experience.

G. The responsible HQ-OCRWM Branch Chief shall verify that the HQ-OCRWM reviewers have received documented indoctrination and training in accordance with Reference C or, in the case of contractors or other program participants, a similar training program. The training for the review of study plans may be either by classroom instruction or by reading applicable documents.

V. Responsibilities

A. The Associate Director of the Office of Facilities Siting and Development (OFS&D) is responsible for assuring that the review is conducted and for approving the study plan prior to issuance to the NRC.

B. The Associate Director of the Office of Systems Integration and Regulations (OSI&R) is responsible for the acceptance review and for providing the OCRWM-approved study plan to the NRC for review and to the State of Nevada and affected parties for information.

C. The Director of the Siting & Facilities Technology Division (S&FTD), through the Siting and Geosciences Branch Chief, is responsible for coordinating, directing and reporting the results of the review.

D. Reviewers are responsible for conducting the review in a timely and professional manner.

E. The Director of the Office of Quality Assurance (OQA) is responsible for participating in the review process, as needed, and for assuring that QA audits (Reference E) and surveillances are conducted on the review process.

VI. Procedure

A. When the study plan is considered to be complete and ready for HQ-OCRWM review, the Project Office shall transmit by memo ten (10) copies to the Siting and Geoscience Branch Chief of the S&FTD.

B. The Siting and Geoscience Branch Chief shall transmit by memo a copy of the study plan to the Regulatory Compliance Branch Chief of the OSI&R for an acceptability review.

C. The Regulatory Compliance Branch shall perform a preliminary review of the study plan for acceptability of content and format and for level-of-detail consistent with the DOE/NRC level-of-detail agreement from the May 7-8, 1986 DOE/NRC meeting. A copy of the level-of-detail agreement, or a summary in the form of a checklist, shall be used to verify acceptability during this preliminary review.

D. The Regulatory Compliance Branch shall document the results of this preliminary review in a memo to the Siting and Geosciences Branch Chief with a recommendation to either distribute the study plan for HQ-OCRWM review or to return it to the Project Office for further development.

E. The Siting and Geosciences Branch Chief shall consider the recommendation of the Regulatory Compliance Branch and act accordingly.

F. When the study plan is found acceptable for review, the Siting and Geosciences Branch Chief will assign the lead responsibility for HQ-OCRWM review and will coordinate the review efforts.

G. The Siting and Geosciences Branch Chief shall provide copies by memo to the DOE reviewers from the HQ-OCRWM lead branch and also shall provide support (2 to 3 Non-DOE reviewers most often) to the review efforts as needed. The memo shall identify the scope of the review (e.g., whether a management-level overview or a detailed technical review).

H. The HQ-OCRWM review shall focus on the following:

1) Integration between the Site Characterization Plan and the study plan.

2) Appropriateness of the scope of activities.

3) Schedule relationships.

4) Adequacy of recognition and discussion of constraints on the study.

5) QA levels and QA requirements assigned including a matrix of how the study plan complies with each applicable criterion of the 18 criteria of NQA-1.

I. If a detailed technical review is performed by HQ-OCRWM, the study plan shall be reviewed for technical adequacy and completeness relative to the content description given in the DOE/NRC level-of-detail agreement. A summary of the level-of-detail agreement is provided in Appendix A and should be used as guidance. In addition, any non-standard or modified technical procedures shall be identified in the study plan and shall be submitted to HQ-OCRWM for review and approval after approval by the Project Office.

J. All concerns and specific recommendations for resolution shall be documented on a Study Plan Review Comment Sheet (Appendix B). Suggested wording or clarifications should be made, if possible.

K. The lead HQ-OCRWM Branch Chief, or designee, shall conduct a comment consolidation meeting with the lead HQ-OCRWM reviewer and the Regulatory Compliance Branch, to discuss all HQ-OCRWM comments and to develop a consolidated set of comments. During this meeting, the comments will be prioritized into categories as described below.

L. The comments will be assigned to either of two categories: mandatory or non-mandatory. Guidance for determining the category is identified in Appendix C.

   1) Mandatory comments must be resolved to HQ-OCRWM's satisfaction.

   2) Non-Mandatory comments suggest revisions which might improve the clarity of the study plan but are to be implemented at the discretion of the Project Office.

   3) The classification of the comments as either mandatory or non-mandatory will be indicated on the comment sheet in the "Priority" block.

M. Both mandatory and non-mandatory comments shall address technical concerns or matters of SCP/study plan integration. Editorial changes are the responsibility of the Project Office.

N. Guidance for review of schedule integration is identified in Appendix D.

O. After the mandatory and non-mandatory comments have been determined and consolidated, the comments shall be numbered sequentially.

P. The consolidated comments shall be transmitted by memo through the Siting and Geosciences Branch Chief to the Project Office.

Q. A comment resolution meeting if necessary will be scheduled by the Siting and Geosciences Branch at the earliest time when the Project Office representatives, study plan authors, and HQ-OCRWM reviewers (or designees) can be present. This meeting should be held no earlier than five(5) days after the transmittal of the consolidated comments in order to give the Project Office reasonable time to review the comments.

R. HQ-OCRWM may elect to hold a teleconference instead of a meeting if the nature of the comments do not require more extensive interaction between reviewers and authors. Results of teleconferences shall be documented.

S. The proposed comment dispositions, agreed to by HQ-OCRWM and the Project Office, shall be documented on the Study Plan Review Comment Sheet. The dispositions shall receive the concurrence of the lead HQ-OCRWM Branch Chief and the lead Project Office representative, or their designees, and documented by their initials and date on the concurrence block of the Comment Sheet.

T. Unresolved mandatory comments will be resolved by the lead HQ-OCRWM Branch Chief. If resolution cannot be obtained at this level, the appropriate HQ Division Director shall be consulted to resolve any contentious issues.

U. Upon disposition of the comments, the Project Office shall revise the study plan, as appropriate, and resubmit it by memo to the Siting and Geosciences Branch for an audit review within an agreed-upon time limit. The purpose of the audit review is to verify that the actual dispositions of the comments have been incorporated into the study plan.

V. If mandatory comments have not been satisfactorily resolved, the Siting and Geosciences Branch Chief shall inform the Project Office by memo, or other appropriate means, of the revisions needed to resolve the comment.

W. After the audit review is successfully completed and the final concurrence blocks on the comment sheet (Actual Disposition) are initialled and dated by the lead HQ-OCRWM Branch Chief and the lead Project Office representative, or their designees, the Associate Director, OFS&D shall issue a memo, indicating approval, to the Associate Director, OSI&R.

X. Upon receipt of the approved study plan, the Associate Director, OSI&R, or designee, shall prepare a cover letter and transmit the study plan to the NRC for review, and to the State of Nevada and affected parties for information.

Y. After receipt of the NRC comments following the NRC review, HQ-OCRWM and the Project Office will confer to determine how the comments will be addressed. If the NRC identifies any major concerns or objections, during this review, the lead HQ-OCRWM Branch Chief and lead Project Office representative will jointly evaluate the concerns and meet with the NRC, if necessary, to reach an appropriate resolution. This resolution will be incorporated into the final study plan.

Z. The Project Office shall revise the study plan as deemed appropriate in response to the NRC comments.

AA. The Project Office shall transmit the revised study plan by memo to the Siting and Geosciences Branch Chief for final review and approval by the Associate Director, OFS&D. This memo shall identify how the NRC comments were addressed.

BB. The Associate Director, OFS&D shall forward the final study plan by memo to the Associate Director, OSI&R, for transmittal to the NRC, and to the State of Nevada and affected parties for information.

CC. A Tracking Sign-off Sheet for Technical Reviews of Study Plans (Appendix E) shall be used to document completion of required steps during the review process.

DD. Revisions to HQ-OCRWM approved study plans shall be reviewed by HQ-OCRWM using the same process that was used during the original study plan review.

VII. Records

A. Records for the technical reviews of study plans are lifetime records and as such shall be maintained in accordance with Reference D.

B. As a minimum, the following records shall be maintained:

1) The Memo from the Project Office transmitting the study plan to HQ-OCRWM.

2) The memo to the Regulatory Compliance Branch from the Siting and Geosciences Branch requesting an acceptability review.

3) The Memo to the Siting and Geosciences Branch from the Regulatory Compliance Branch identifying results of the acceptability review.

4) Documentation of the HQ-OCRWM Comment Consolidation Meeting including identification of reviewers and the consolidated comments.

5) Documentation of the HQ-OCRWM and Project Office Comment Resolution Meeting (or teleconference) including a list of attendees and the proposed dispositions to comments.

6) Results of the HQ-OCRWM audit review and Actual Disposition and Comment Sheets.

7) Transmittal Letters to the NRC, the State of Nevada and affected parties.

8) Transmittal letters from the NRC documenting the results of their review.

9) Disposition of NRC comments.

10) Tracking Sign-off Sheets.

VIII. Appendices

Appendix A Summary of Level-of-Detail Agreement
Appendix B Study Plan Review Comment Sheet
Appendix C Guidance for Identifying Mandatory Comments for Study Plan Review
Appendix D Guidance for Review of Budget and Schedule Integration.
Appendix E Tracking Sign-Off sheet for the Technical Review

Appendix A

Summary of Level-of-Detail Agreement (May 7-8, 1986)

A. Purpose and Objectives of Studies:

1. Describe the information that will be obtained in this study. Briefly discuss how this information will be used.

2. Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); and 3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and the higher level goal.

B. Rationale for Selected Study:

1. Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options.

2. Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives; summarize reasons for not selecting these alternatives; and reference, if available, reports which evaluate alternatives considered.

3. Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:

   (a) Potential impacts on the site from testing;

   (b) Whether the study needs to simulate repository conditions;

   (c) Required accuracy and precision of parameters to be measured with test instrumentation;

(d) Limits of analytical methods that will use the information from the tests;

(e) Capability of analytical methods to support the study;

(f) Time required versus time available to complete the study;

(g) The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field;

(h) Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference; and

(i) Interrelationships involving significant interference among tests and ESF design and construction, as appropriate (refer to Section 8.4 of the SCP or its references for specific ESF design information).

C. Description of Tests and Analyses:

1. Since studies are comprised of tests and analyses, provide for each type of test;

(a) Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, ESF elements, repository layout, stratigraphic units, depth, and test location);

(b) Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;

(c) Specify the tolerance, accuracy, and precision required in the test, where appropriate;

(d) Indicate the range of expected results of the test and the basis for those expected results;

(e) List the equipment required for the test and describe briefly any such equipment that is special;

(f) Describe techniques to be used for data reduction and analysis of the results;

(g) Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;

(h) Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests; and

(i) Relationship of the test to the set performance goals and confidence levels.

2. For each type of analysis:

(a) State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

(b) Describe the methods of analysis, including any analytical expressions and numerical models that will be employed;

(c) Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA level 1. Reference the applicable QA requirements;

(d) Identify the data input requirements of the analysis;

(e) Describe the expected output and accuracy of the analysis; and

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

D. Application of Results:

1. Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies);

2. For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) that will use the information produced from the studies described above, and refer to any use of the results for model validation;

3. For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development, and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

4. For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

E. Schedule and Milestones:

1. Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing, data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;

2. Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and

3. Dates for activities or milestones, including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section\8.5 of the SCP.

Appendix B
(Attached)

Appendix B

STUDY PLAN REVIEW COMMENT SHEET **COMMENT NO.** _____

A. REVIEWER

1. NAME: _____
2. ORGANIZATION: _____
3. PHONE NO: _____
4. DATE: _____

B. COMMENT IDENTIFICATION

5. STUDY PLAN NUMBER: _____
6. STUDY PLAN TITLE: _____
7. SECTION: _____
8. PAGE: _____
9. PARAGRAPH: _____
10. PRIORITY: _____

C. COMMENT AND DISPOSITION

11. COMMENT AND PROPOSED RESOLUTION:

12. PROPOSED DISPOSITION (FROM COMMENT RESOLUTION WORKSHOP):

13. CONCURRENCE: HQ _____ PO _____ DATE _____

14. ACTUAL DISPOSITION:

15. CONCURRENCE: HQ _____ PO _____ DATE _____

Appendix C

Guidance Criteria for Identifying Mandatory Comments during Study Plan Review

C.1 The following outline provides guidance criteria to be used in identifying review comments for which HQ-OCRWM considers resolution to be mandatory. These comments must be resolved to the satisfaction of HQ-OCRWM before the study plan is approved and forwarded to the NRC.

C.2 The criteria, placed under heading I-V corresponding to the major divisions of the study plan content descriptions in the DOE/NRC level-of-detail agreement (May 7-8, 1986), are focused on identifying comments that would be of sufficient importance to constitute a mandatory revision of the study plans.

C.3 In reviewing study plans from the perspective of program integration with the Site Characterization Plan, headings, I, IV and V are most important and headings II and III to a lesser extent. A technical overview, and detailed technical review, would emphasized headings II and III.

I. Purpose and Objectives of Study

1) The study plan does not fulfill the objectives as described in the SCP. The study scope may be either too large or too small. Schedule adjustments may be required to remedy the problem.

2) The study does not collect all the data called for in the list of performance and design parameters given in the SCP, or expands the list beyond that in the SCP without giving an acceptable justifications.

II. Rationale for Selected Study

1) The technical approach or methodology is inconsistent with that in the SCP or the data may not be defensible for the applications described.

2) Alternate approaches and methods are likely to produce significantly more defensible data or shorten the activity durations (such as different phasing of the work).

III. Description of the Tests and Analysis

1) The work described is inconsistent with previously approved approaches or methods in other study plans, peer reviews or strategy documents.

IV. Application of Results

1) The study plan does not include all the applications of the data given in the SCP and consequently the scope of the work may be inadequate.

V. Schedule & Milestones

1) The schedule does not show the ties to other studies, either as information feeds to other studies, or constraints from other studies (sample or data availability, etc.).

2) Decision points and alternative paths are not shown where needed.

Appendix D

Guidance for Review of Budget and Schedule Integration in Study Plan

D.1 One of HQ-OCRWM's concerns is the integration of study plan activities with the program budget and schedule. To assure that the level-of-effort for individual study plans is consistent with the program budget, either of two options can be used for the study plan review process.

I. The Project Manager can certify that the budget figures for the study, as contained in the most recent budget submission to HQ-OCRWM, are consistent with the level-of-effort described in the study plan. This certification assures that the level-of-effort planned for the study has been incorporated into project budget and schedule planning.

To allow review of the proposed level-of-effort for the study, an estimate of the study plan level-of-effort in terms of staff-years/yr should be provided.

II. When this certification is not provided, cost per year and FTE figures must be supplied with the study plan, along with an estimate of the percentage of capital equipment costs. Reviewers will then be asked to judge whether the level-of-effort projection for the study is consistent with work described in the study plan itself. The cost figures of interest are those for the collection and assessment of data, not the costs associated with drilling or other activities accounted for under another budget element. Should the cost figures for the study be in sharp contrast to the estimates made by the reviewers based on the description of the study, the Project Office and HQ-OCRWM would be alerted that a potential budget/schedule problem exists.

D.2 The information requested in Options I or II shall be supplied in the cover letter transmitting the study plan to HQ-OCRWM for review and approval, not in the study plan itself.

Appendix E

DOE/HQ Study Plan QA Tracking & Sign-Off Sheet
NNWSI Study Plan Number
Study Plan Title
Date of Last Revision
Name of Preparing Organization

DOE HQ Review Basis	SCP Integration	Technical Overview	Detailed Tech Review
	X	X	X

Approval Block

1. Study Plan received from WMPO	Chief, Siting & Geoscience	Date	Rev. #
2. Acceptance Review Completed	Chief, Reg. Compliance Branch	Date	Rev. #
3. Comment Resolution Mtg. Compl.	Chief, Siting & Geoscience Branch	Date	Rev. #
4. Audit Review Completed	Chief, Siting & Geoscience Branch	Date	Rev. #
5. DOE/HQ approval	Director, QA	Date	Rev. #
	Director, OFS&D	Date	Rev. #
	Director, OSI&R	Date	Rev. #

Reviewed and Approved according to QA procedure HQ/OCRWM-QIP-3.2, RQ

Reviewers

Enclosure 4: LANL Procedures for Personnel Selection, Training and Certification and for Technical Review

PROCEDURE FOR PERSONNEL SELECTION, INDOCTRINATION, AND QUALIFICATION

Effective Date: 12/20/88

James George
James J. George
Quality Assurance Support

12/07/88
Date

H P Nunes
H. P. Nunes
Quality Assurance Project Leader

12/09/88
Date

Kevin A. West for
D. T. Oakley
Technical Project Officer

12/12/88
Date

UNCONTROLLED

PROCEDURE FOR PERSONNEL SELECTION, INDOCTRINATION, AND QUALIFICATION

1.0 PURPOSE

The purpose of this procedure is to establish the requirements used for the selection, indoctrination, certification, qualification, and evaluation of Los Alamos National Laboratory (LANL) personnel performing activities that affect quality on the Yucca Mountain Project (YMP or Project).

2.0 SCOPE

This procedure applies to all Project personnel assigned to perform, manage, or verify activities affecting quality. The procedure establishes and characterizes the requirements for position descriptions that set forth minimum personnel qualifications, including formal education and experience, and the appropriate indoctrination required before performing or initiating activities affecting quality. In addition, personnel performing activities that specifically require certification by applicable codes and standards shall be certified in accordance with the requirements specified in the involved codes or standards.

For purposes of this Project, the scope of this procedure does not include requirements for the training of personnel performing or verifying activities that affect quality.

3.0 REFERENCES

LANL-YMP-Quality Assurance Program Plan (QAPP).
TWS-QAS-QP-02.2, Procedure for Personnel Training.
TWS-QAS-QP-18.1, Procedure for Audits.

4.0 DEFINITIONS

4.1 Activities Affecting Quality

Activities affecting quality include deeds, actions, work, or performance of a specific function or task. The quality assurance (QA) program applies to activities affecting the quality of all Project systems, structures, and components important to safety, to the design and characterization of barriers important to waste isolation, and to the characterization of the Yucca Mountain site.

4.2 Position Description

A position description is used to establish, identify, and document the minimum personnel qualifications, including education and experience, and responsibilities for each position involved in the performance of activities that affect quality.

4.3 Indoctrination

Indoctrination includes required reading, classroom or other methods of instruction provided to personnel, who perform activities affecting quality, to familiarize them with programmatic and work-oriented documents applicable to the assigned activity.

4.4 Qualification Evaluation (of Personnel)

The evaluation of an individual's capabilities is based on a documented verification of the individual's relevant education and experience as compared to the minimum requirements established and specified in the position description.

5.0 RESPONSIBILITIES

Responsibilities of the Project employees, Principal Investigators (PI), supervisors, Technical Project Officer (TPO), Quality Assurance Project Leader (QAPL), Quality Assurance Liaisons (QAL), and Quality Assurance Support (QAS) staff are delineated in the procedure.

6.0 PROCEDURE

Responsibility	Action
6.1 Preparation of Position Descriptions	
Division Leader	1. Prepare position description for TPO.
Technical Project Officer	2. Prepare position description for the QAPL.
Quality Assurance Project Leader	3. Prepare position descriptions for the QALs and QAS staff positions.
Division and/or Group Leaders or their Designee(s)	4. Prepare descriptions for the PI positions.
Principal Investigators and/or their Supervisors or their Designees	5. Establish descriptions for each position, involved in the performance of activities affecting quality, such as scientific investigators, Resident File Custodian, technical support staff, and any other position the PI supervises. The position descriptions shall establish the minimum education and experience requirements necessary for the performance of the Project activities.
Quality Assurance Project Leader and/or Quality Assurance Liaison	6. May assist PIs in establishing position requirements that set forth the minimum personnel qualifications.

Responsibility	Action
Quality Assurance Support Staff	7. If required, assist the QAPL prepare position descriptions for Project activities affecting quality. After initial preparation, the position description will be changed only if position responsibilities or definitions change.
6.2 Personnel Selection	
Yucca Mountain Project Personnel	8. Each Project employee shall complete, with the relevant correct information, and sign the Project Resume Form (Attachment 1, Parts A and B). The employee will update the resume as necessary.
Supervisor(s) of Yucca Mountain Project Personnel	9. Supervisors are responsible for determining and documenting that personnel selected have relevant education and experience commensurate with the minimum requirements specified in the position description. Supervisors are responsible for contacting the personnel department to verify that it has performed a background verification of education and experience for selected personnel. This verification is documented concurrently with step 10 by signing and dating the Project Resume Form.
6.3 Personnel Qualifications	
Supervisor(s) of Yucca Mountain Project Personnel	10. Verify resumes of employees or potential employees for accuracy and conformance to position description requirements, by reviewing the Project resume against the position description, and document verification of relevant education and experience by signing and dating the Project Resume Form (Attachment 1). Send the original to QAS Files, one copy to the group

Responsibility	Action
	Resident File, and two copies to the Records Processing Center (RPC) for dual records storage.
	11. Verify resume updates for accuracy and conformance to position requirements and document verification by signing and dating the updated Project Resume Form. Send the original to QAS files, one copy to the group Resident File, and two copies to RPC to be attached to either the original or the copy of the most recent resume.
Quality Assurance Project Leader	12. The QAPL will ensure that personnel performing activities specifically requiring certification by applicable codes and standards (auditors and lead auditors, inspectors, etc.) shall be certified in accordance with the applicable detailed requirements.
6.4 Indoctrination	
Principal Investigator and/or Responsible Supervisor	13. Before assigning personnel to perform activities affecting quality, coordinate with the QAL and/or the QAS to determine and establish the initial orientation, indoctrination, and training requirements an employee must meet to accomplish Project activities. Refer to QP-02.2, Procedure for Personnel Training, for examples of minimum training requirements matrix.
Quality Assurance Liaisons and/or Quality Assurance Support Staff	14. Before Project personnel perform activities affecting quality, provide indoctrination as to the purpose, scope, methods of implementation, and applicability of the following documents (including changes thereto), as a minimum, as they relate to the Project work to be accomplished by the employee:

Responsibility	Action
	• LANL-YMP-QAPP; • Federal regulations, guidelines, and DOE Orders (e.g., 40 CFR 191; 10 CFR 960; 10 CFR 60; 10 CFR 50, Appendix B; 5700.6B); • industry standards (e.g., ANSI/ASME-NQA-1); • DOE Project-level documents (e.g., Site Characterization Plan; Systems Engineering, Configuration, Records, Exploratory Shaft Facility, and Training Management Plans; Advanced Acquisition or Assistance, Environmental Safety and Health Protection Implementation, QA and Financial and Performance Measurement Application Plans); • quality and technical procedures applicable to individual's responsibilities (see QP-02.2, Procedure for Personnel Training); and • orientation to the purpose and scope of the Yucca Mountain Project. NOTE: Indoctrination may be accomplished by using mandatory reading lists, classroom presentations, video presentations, or combinations thereof.
6.5 Certification	
Quality Assurance Liaison/Quality Assurance Support	15. Enter a record of personnel indoctrination, which includes the objective, content of indoctrination, date(s) of indoctrination, and other applicable information, on the Yucca Mountain Project Indoctrination Form (Attachment 2).

Responsibility	Action
	16. Enter a record of personnel indoctrination (and training as per QP-02.2, Procedure for Personnel Training) on the Yucca Mountain Project Certification Form (Attachment 3, Part A). If mandatory reading lists are used, they shall be referenced on and attached to Attachment 3.
Project Personnel	17. Acknowledge receipt and understanding of initial indoctrination (and training as per QP-02.2) by signing and dating the Yucca Mountain Project Indoctrination Form (Attachment 3) and the Yucca Mountain Project Certification Form (Attachment 3, Part B).
Quality Assurance Liaison/Quality Assurance Support	18. Forward completed Indoctrination and Certification Forms (Attachments 2 and 3) to the Project employee's supervisor.
Supervisor of Project Personnel	19. Review records of indoctrination and certification and, if acceptable, sign and date Yucca Mountain Project Certification Form (Attachment 3, Part B). Send original Indoctrination and Certification Forms (Attachments 2 and 3) to the QAS files, one copy to the group Resident File, and two copies to the RPC for dual records storage.
Quality Assurance Project Leader	20. Ensure that all Project personnel have been indoctrinated and trained in the scope, purpose, and objective of their assignment and have been certified before they initiate activities affecting quality.

Responsibility	Action
6.6 Proficiency Evaluation	
Supervisors of Project Personnel	21. After the initial determination of personnel qualifications, evaluate and document at least annually the job proficiency of personnel who perform activities affecting quality. Proficiency evaluations may be performed in conjunction with periodic or daily employee performance evaluations. The supervisor documents verification of the employee's satisfactory proficiency evaluation by completing and signing the Yucca Mountain Project Certification Form. Distribution of the completed evaluation is the same as in step No. 19.
Quality Assurance Liaison	22. Assist Project personnel supervisors in the performance of the annual proficiency evaluation and preparation of the annual Certification and Training Forms. The QAL may solicit internal input from the PI, supervisor, and employee as to the QP and DP training necessary for certification of the employee. If documents have not been revised during the evaluation period, retraining need not be performed as long as the individual is determined to be proficient in these documents' requirements.
Quality Assurance Support	23. Provide assistance as required by the QAPL.
	24. Maintain original files of all qualification evaluations, indoctrination, training (as per QP-02.2), and proficiency evaluations.

7.0 QUALITY ASSURANCE REQUIREMENTS

7.1 Records

Copies of all original documentation of personnel selection, indoctrination, certification, qualification, and evaluation shall be sent to the QAS files and a copy maintained in the group Resident File.

Responsibility	Action
Quality Assurance Support	25. Maintain originals of the following records: • personnel resumes and updates, • position description, • indoctrination (and training per QP-02.2) forms, • certification forms, and • Annual Proficiency Evaluation Forms.
Resident File Custodian(s)	26. Maintain copy of all records listed in No. 25.
Records Processing Center	27. Maintain 2 copies of all records listed in No. 25 in dual storage facilities.

8.0 ATTACHMENTS

Attachment 1	Project Resume Form, Parts A and B
Attachment 2	Project Indoctrination Form
Attachment 3	Certification Form, Parts A and B

Los Alamos

YUCCA MOUNTAIN PROJECT RESUME

PARTICIPANT DATA *(PLEASE PRINT)*

NAME _____

OCCUPATION _____ WORK PHONE _____

RELEVANT EDUCATIONAL BACKGROUND

(BEGIN WITH MOST RECENT EDUCATION)

SCHOOL	LOCATION	MAJOR FIELD	DATES	DEGREE

EMPLOYMENT RECORD

(BEGIN WITH MOST RECENT RELEVANT EMPLOYMENT)
(LIST RELEVANT PAST EMPLOYMENT)
(USE ADDITIONAL SHEET IF REQUIRED)

MOST RECENT EMPLOYER _____ FROM _____ TO _____

ADDRESS _____

NAME AND TITLE OF SUPERVISOR _____

POSITION HELD _____

RESPONSIBILITIES _____

LOS ALAMOS NATIONAL LABORATORY

YUCCA MOUNTAIN PROJECT RESUME

(CONCLUDED)

GENERAL INFORMATION:

LIST PROFESSIONAL/SCIENTIFIC YUCCA MOUNTAIN PROJECT-RELEVANT PUBLICATIONS OF WHICH YOU ARE AUTHOR OR CO-AUTHOR OR PATENTS THAT YOU HOLD.

LIST RELEVANT PROFESSIONAL OR TRADE LICENSES, GIVING TYPE OF LICENSE, DATE ISSUED, AND EXPIRATION DATE.

LIST ADDITIONAL TRAINING, GIVING NAME AND DATE OF TRAINING.

APPROXIMATE TOTAL OF RELEVANT YEARS OF EXPERIENCE _____

I HEREBY CERTIFY THE CORRECTNESS OF THE ABOVE INFORMATION AND AUTHORIZE ITS RELEASE AS REQUIRED BY THE YUCCA MOUNTAIN PROJECT AND APPLICABLE CODES AND STANDARDS.

_____ _____

EMPLOYEE'S SIGNATURE DATE

I HAVE REVIEWED AND VERIFIED RELEVANT EDUCATION AND EXPERIENCE OF _____ AND FIND HIM/HER QUALIFIED TO PERFORM HIS/HER YUCCA MOUNTAIN PROJECT JOB ASSIGNMENT AS DELINEATED IN THE APPLICABLE POSITION DESCRIPTION.

_____ _____

SIGNATURE DATE

Los Alamos

YUCCA MOUNTAIN PROJECT

INDOCTRINATION / TRAINING FORM

OBJECTIVE: _____

TITLE / CONTENT: _____

_____

DURATION: _____ DATE: _____

INSTRUCTOR: _____ ORG: _____ PHONE: _____

SIGNATURE: _____ DATE: _____

ATTENDEES

PRINT NAME	SIGNATURE	GROUP	PHONE

Los Alamos

YUCCA MOUNTAIN PROJECT
CERTIFICATION FORM

THE COMPLETION OF THIS FORM, TOGETHER WITH PREVIOUSLY COMPLETED FORMS FOR _____, DOCUMENTS THAT HE/SHE HAS RECEIVED APPROPRIATE ORIENTATION, INDOCTRINATION, AND TRAINING TO THE ADMINISTRATIVE AND TECHNICAL PROCEDURES THAT ARE REQUIRED IN THE PERFORMANCE OF ACTIVITIES THAT AFFECT QUALITY ON THE YUCCA MOUNTAIN PROJECT.

QUALITY ASSURANCE TRAINING

PROCEDURE #	TITLE

TECHNICAL PROCEDURES NECESSARY TO PERFORM JOB ASSIGNMENT

PROCEDURE #	TITLE

(USE ADDITIONAL SHEETS IF NECESSARY)

LOS ALAMOS NATIONAL LABORATORY
YUCCA MOUNTAIN PROJECT
CERTIFICATION FORM
(CONCLUDED)

_____ HAS BECOME FAMILIAR WITH THE DOCUMENTS LISTED ON THIS FORM THROUGH IMPLEMENTATION, ON-THE-JOB TRAINING, AND TRAINING AS SPECIFIED ON THE ENCLOSED PROJECT TRAINING FORMS. FURTHER TRAINING WILL BE DOCUMENTED ON PROJECT TRAINING FORMS AND INCLUDED WITH THIS FORM.

I HEREBY ACKNOWLEDGE THAT THE ABOVE TRAINING HAS BEEN RECEIVED AND AUTHORIZE THE RELEASE OF THE ABOVE INFORMATION AS REQUIRED BY THE YMP AND APPLICABLE CODES AND STANDARDS _____.

PROFICIENCY EVALUATION INDICATES _____ PERFORMANCE OF YMP ACTIVITIES.

SUPERVISOR'S SIGNATURE _____ DATE _____

_____
PRINT SUPERVISORS NAME

LOS ALAMOS NATIONAL LABORATORY

NNWSI PROJECT

PROCEDURE FOR TECHNICAL AND POLICY REVIEW OF PUBLICATIONS

Effective Date May 11, 1987

QA Support H. P. Nunes, QAS	2/3/87 Date
QA Implementation Manager P. R. Guthals, WM	2/5/87 Date
Technical Project Officer D. T. Oakley, WM	2/6/87 Date

LOS ALAMOS NATIONAL LABORATORY

NNWSI PROJECT

PROCEDURE FOR TECHNICAL AND POLICY REVIEW OF PUBLICATIONS

1.0 PURPOSE

The purpose of this procedure is to ensure that technical publications resulting from the LANL NNWSI Project, including revisions, are reviewed by authorized personnel for technical adequacy and approval for submittal to WMPO for review prior to release. This procedure details the appropriate quality requirements intended by the Document Control Procedure, TWS-QAS-QP-03, paragraph 13.2.

2.0 SCOPE

The process shall apply to technical reports of work required for fulfillment of Los Alamos responsibilities for NNWSI and to other reports, articles, papers, and abstracts that deal with technical aspects of the LANL NNWSI Project if those reports, articles, papers, or abstracts report results of work performed by LANL.

This QA requirement is not intended to infringe on the right of individual Los Alamos researchers to submit scientific findings for publication in the open literature. Rather it is intended to ensure that reports of work identified or identifiable as supported by NNWSI have been reviewed for technical content and programmatic (policy) concerns.

3.0 RESPONSIBILITY

The Group Leader or his designee (to be designated in writing) is responsible for initiating Publication Traveler (Attachment 1) and Technical Review Form (Attachment 2) and assigning the technical reviewer(s). The principal author is responsible for tracking the attachments and for ensuring that the document review package is complete and in the NNWSI Resident File before public dissemination of the document.

The NNWSI Editor is responsible for initiating the Policy Review form (Attachment 3) to ensure that the publication is reviewed by the TPO and transmitted to WMPO/NV for policy review.

4.0 PROCEDURE

Figure 1 shows a flow chart of the steps in the procedure for technical and policy review.

The LANL NNWSI Publications Traveler (Attachment 1) will be attached to documents going through the review procedure, in order to control the sequence of routing for review.

4.1 Formal Technical Review

4.1.1 The Group Leader(s) or his designee (or Division Leader if a Group Leader is an author) of the originating group(s) shall designate one (or more) reviewer(s) for each document at the time of final draft, from a list of reviewers approved by the Division Leader and the TPO. The reviewer(s) shall not be directly involved in the same research activities in the LANL NNWSI Project.

4.1.2 The final findings of the reviewer(s) shall be noted on Attachment 2, the LANL NNWSI Technical Review Form for Publications. The package consisting of Attachment 2 and the document under review will be returned by the reviewer to the author.

4.1.3 The author(s) will resolve all comments submitted by the reviewer(s). In the event that the author(s) and reviewer(s) cannot reach agreement, the Group Leader(s) or his designee and/or the TPO or his designee will resolve the issue in the most appropriate way consistent with the intent of this QA requirement. Any action taken will be documented on Attachment 2. The procedure in item 4.2 will then be followed. Before a reviewer formally submits his comments, the reviewer may discuss the publication with the author or authors, who may wish to modify the manuscript. Such informal discussions do not need to be documented.

4.2 Policy Review

4.2.1 When the principal author and Group Leader (or designee) agree that the technical review process is complete and that the package is ready for WMPO/NV review, the principal author will submit the copy of the document package, including Attachments 1 and 2, to the Editor for NNWSI publications. The Editor will review the publication to ensure that it follows Project policy guidelines and will initiate a Policy Review form (Attachment 3) to record any comments on Attachment 3, the LANL NNWSI Policy Review Form.

4.2.2 When the Editor for NNWSI and the TPO agree that the publication is complete and complies with policy guidelines, but before preparation of the final version, the Editor will submit the publication through the TPO to WMPO/NV.

4.2.3 The written response from WMPO/NV will be sent by the TPO to the principal author, the Editor for NNWSI, and the QAS/QAIM. Completed Attachments 1, 2, and 3 shall be returned to the author by the Editor. The WMPO/NV concerns must be addressed before the final version is prepared by the principal author. Disagreements will be resolved as in 4.1.3, except that the reviewer will be designated by WMPO/NV.

4.2.4 When all WMPO/NV concerns have been resolved, and the publication approved by WMPO/NV, it will be released in accordance with Laboratory requirements.

5.0 RECORDS

A copy of the completed document and all attachments will be maintained by the author in the Resident File, and the author will send a copy of the complete document review package to the LANL NNWSI Records Center Manager. A copy of the list of approved reviewers shall be maintained in the Project office records file.

6.0 REFERENCES

6.1 NNWSI Administrative Procedure, AP-1.3, Publication Review and Clearance.

6.2 LANL NNWSI TWS-QAS-QP-03, Document Control Procedure.

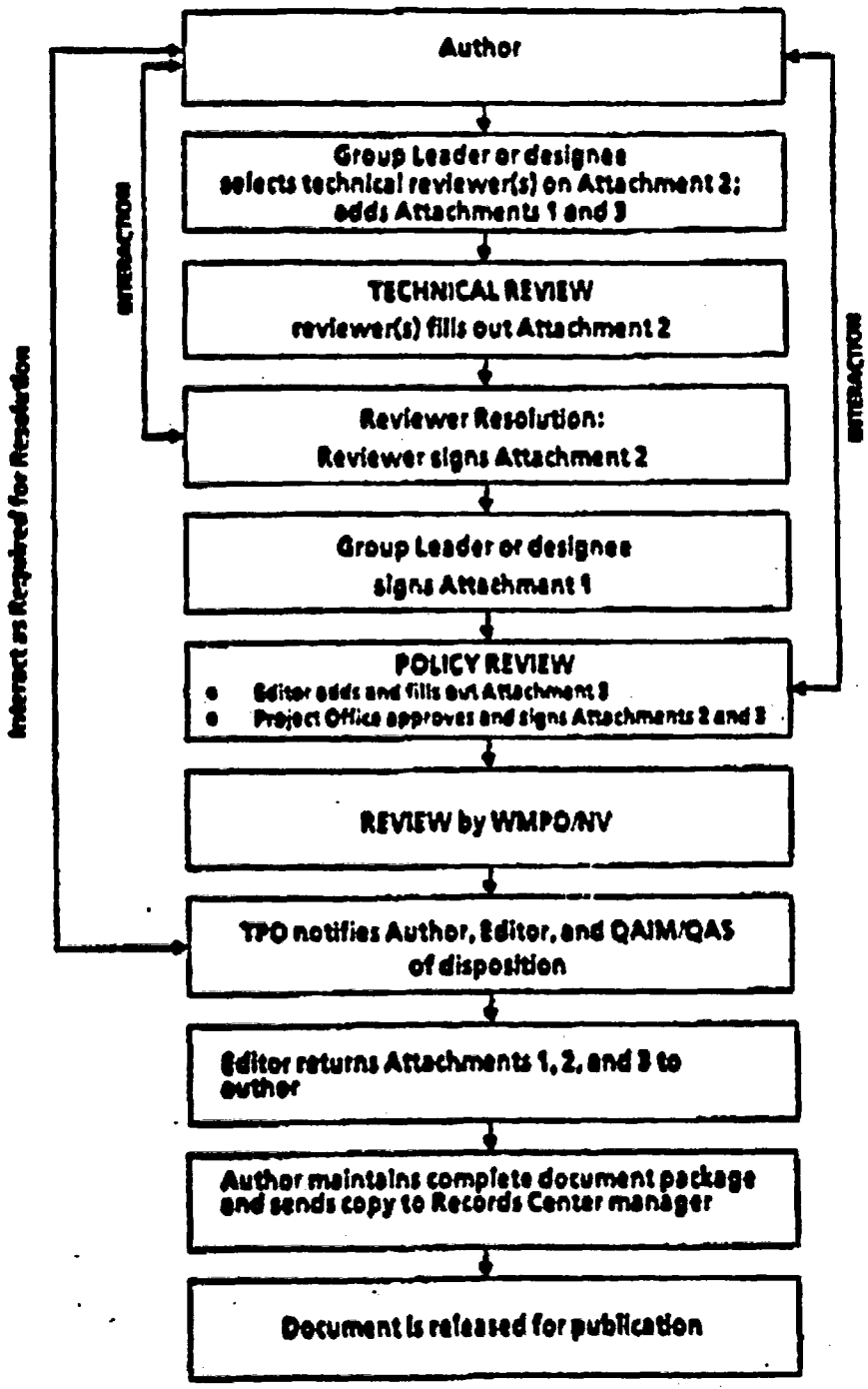


FIGURE 1: Flow Chart of Procedural Steps for Technical and Policy Review

ATTACHMENT 1
LANL NNWSI PUBLICATIONS TRAVELER

Title:

Principal Author:

TWS Number:

Los Alamos Report Number:

Sequence		Signature	Date
Formal Technical Review Completed by Reviewer	Author		
Review Comments Resolved and Completed	Group Leader or Designee		
TPO Policy Review	TPO		
WMPO/NV Policy Comments Received	Editor		
WMPO/NV Comments Resolved and Document Released for Publication	TPO		

ATTACHMENT 2
LANL NNWSI TECHNICAL REVIEW FORM FOR PUBLICATIONS

Title of Paper:

Type of Paper:

Authors:

Reviewers:

Selection of Reviewers Approved: _____ _____
Group Leader or Designee — Date

Recommendation:

Publish as is.

Publish with minor revisions as noted below.

Publish only with major revisions and re-review.

Not suitable for publication.

Other (To be specified)

Comments:

Resolution:

_____ _____
Reviewer or TPO Signature — Date

Reviewer's signature indicates that the pertinent comments have been resolved to the reviewer's satisfaction.

ATTACHMENT 3
LANL NNWSI POLICY REVIEW FORM

TWS Number:

Los Alamos Report Number:

Destination (if other than LA-series):

Title:

Authors:

This document received its policy review on _____

_____ **Approved as is.**

_____ **Approved with suggested changes/additions as listed below.**

_____ **Approved, but with changes/additions as listed below.**

_____ **Not approved, reasons listed below.**

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Project Office (signature and date) _____

Enclosure 5: SNL Procedures for Study Plan Requirements; Reviewing, Approving, and Issuing Technical Information Documents; and Qualification and Certification of Project Personnel

SNL Yucca Mountain Project
Department 6310 Operating Procedure

Study Plan Requirements

Page	1	2	3	4	5	6	7
Rev	B	B	B	B	B	B	B

Approved by:

B. M. Schwartz, 6313
Author — 11/11/88 Date

for R. R. Richards, 6310
Quality Assurance Coordinator — 11/11/88 Date

T. E. Blejwas, 6313
Division Supervisor — 11/11/88 Date

J. E. Stiegler (acting) 6310
SNL YMP Technical Project Officer — 11/11/88 Date

1.0 PURPOSE

The purpose of this Department Operating Procedure (DOP) is to state the minimum requirements for writing a Study Plan (SP) for the Yucca Mountain Project (YMP).

2.0 SCOPE

This DOP defines the format and sign-off requirements and revision procedures to be used by SNL Department 6310 staff writing or using SPs for the YMP.

3.0 DEFINITIONS

3.1 Study Plan: a document that provides details for studies, experiments, tests, and analyses that are listed in the Site Characterization Plan (SCP). A study may involve single or multiple experiments, tests, or analyses, or combinations of these categories.

3.2 Experiment and Equipment Test Procedure (EP and ETP): a document that provides detailed written requirements and provides primary control for implementation of experiments and equipment-tests listed in the SP.

3.3 Technical Procedure (TP): a document detailing implementing procedures that define technical requirements, constraints, and the procedural steps in support of EPs.

3.4 Experiment-Data Gathering: an activity conducted to establish characteristics or values not previously known.

3.5 Equipment Test: process of exposing an item of hardware to some defined parameter change or operational sequence to determine its acceptability.

3.6 Analyses: calculations or other evaluations needed to assess site characteristics, to support design activities, or to support experiment designs and evaluations.

4.0 PROCEDURES

4.1 Organization of the Study Plan. An SP should be prepared by a Principal Investigator (PI) or Task Leader (TL) in response to SCP needs following a standard outline. Appropriate headings are

I. Purpose and Objectives of Studies
II. Rationale for Selected Study
III. Description of Experiments, Tests, and Analyses
IV. Application of Results
V. Schedule and Milestones

4.1.1 Purpose and Objectives of Studies. The following should be considered in preparing the purpose and objectives:

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used.

- Provide the rationale and justification for the information to be obtained by the study. It can be justified by 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and the higher level goals.

4.1.2 Rationale for Selected Study. The following should be considered in preparing the rationale for the study:

- Provide the rationale and justification for the selected experiments, tests, and analyses (including standard tests). Indicate the alternative measurement concepts and analytical methods from which they were selected, including options for type of measurement, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitation of the various options.

- Provide the rationale for the selected number, location, duration, and timing of experiments and tests with consideration to various sources of uncertainty (e.g., test method, location, interference with other tests, and estimated parameter variability). When the achievement of quantitative statistical confidence levels for experiment results necessitates a designed experiment or test, include the experiment design in this rationale. This rationale should also identify reasonable alternatives, summarize reasons for not selecting these alternatives, and reference, if available, reports that evaluate alternatives considered.

- Describe the constraints that exist for the study, and explain how these constraints affect selection of experiment and test methods and analytical approaches. Factors to be considered include the following:

  - Potential impacts on the site from the measurement activities.
  - Whether the study needs to simulate repository conditions.
  - Required accuracy and precision of parameters to be measured with instrumentation.
  - Limits of analytical methods that will use the information from the experiments and tests.
  - Capability of analytical methods to support the study.
  - Time required versus time available to complete the study.

- Statistical relevance of data and data trends to performance goals and confidence limits. Where appropriate, the experiments or tests will be designed for replications necessary to achieve the quantitative statistical confidence level required (by performance allocation) of the parameter under study. Such experiment design will be described in the SP. In cases where experiments or tests are conducted for demonstration purposes or proof-of-concept approaches, statistical experimental design may not be appropriate or applicable as will be explained in the SP.

- The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field.

- Interrelationships of experiments and tests involving significant interference with other similar activities and how studies have been designed or sequenced to address such interference.

- Interrelationships involving significant interference among experiments, tests, and exploratory shaft facility design and construction (as appropriate, refer to Section 8.4 of the SCP or its references for specific exploratory shaft facility design information such as design drawings or specifications).

4.1.3 Description of Experiments, Tests, and Analyses. The following should be considered in preparing a description of experiments, tests and analyses:

o Because studies are composed of experiments, tests, and analyses, provide for each

- a description of the general approach that will be used. Describe key parameters that will be measured and the experimental conditions under which the measurements will be conducted. Indicate the number of measurements and their locations (e.g., spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units depth, and test location);

- a summary of the EPs or ETPs. If EPs are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any experiments or tests that are not judged to be QA Level I. Reference the applicable specific QA requirements that will be applied;

- specification of the tolerance, accuracy, and precision required, where appropriate;

- indications of the range of expected results and the basis for those expected results;

- lists of the equipment required and a brief description of any special equipment needed;

1.0 PURPOSE

The purpose of this Department Operating Procedure (DOP) is to state the minimum requirements for writing a Study Plan (SP) for the Yucca Mountain Project (YMP).

2.0 SCOPE

This DOP defines the format and sign-off requirements and revision procedures to be used by SNL Department 6310 staff writing or using SPs for the YMP.

3.0 DEFINITIONS

3.1 Study Plan: a document that provides details for studies, experiments, tests, and analyses that are listed in the Site Characterization Plan (SCP). A study may involve single or multiple experiments, tests, or analyses, or combinations of these categories.

3.2 Experiment and Equipment Test Procedure (EP and ETP): a document that provides detailed written requirements and provides primary control for implementation of experiments and equipment-tests listed in the SP.

3.3 Technical Procedure (TP): a document detailing implementing procedures that define technical requirements, constraints, and the procedural steps in support of EPs.

3.4 Experiment-Data Gathering: an activity conducted to establish characteristics or values not previously known.

3.5 Equipment Test: process of exposing an item of hardware to some defined parameter change or operational sequence to determine its acceptability.

3.6 Analyses: calculations or other evaluations needed to assess site characteristics, to support design activities, or to support experiment designs and evaluations.

4.0 PROCEDURES

4.1 Organization of the Study Plan. An SP should be prepared by a Principal Investigator (PI) or Task Leader (TL) in response to SCP needs following a standard outline. Appropriate headings are

I. Purpose and Objectives of Studies
II. Rationale for Selected Study
III. Description of Experiments, Tests, and Analyses
IV. Application of Results
V. Schedule and Milestones

4.1.1 Purpose and Objectives of Studies. The following should be considered in preparing the purpose and objectives:

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used.

- Provide the rationale and justification for the information to be obtained by the study. It can be justified by 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and the higher level goals.

4.1.2 Rationale for Selected Study. The following should be considered in preparing the rationale for the study:

- Provide the rationale and justification for the selected experiments, tests, and analyses (including standard tests). Indicate the alternative measurement concepts and analytical methods from which they were selected, including options for type of measurement, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitation of the various options.

- Provide the rationale for the selected number, location, duration, and timing of experiments and tests with consideration to various sources of uncertainty (e.g., test method, location, interference with other tests, and estimated parameter variability). When the achievement of quantitative statistical confidence levels for experiment results necessitates a designed experiment or test, include the experiment design in this rationale. This rationale should also identify reasonable alternatives, summarize reasons for not selecting these alternatives, and reference, if available, reports that evaluate alternatives considered.

- Describe the constraints that exist for the study, and explain how these constraints affect selection of experiment and test methods and analytical approaches. Factors to be considered include the following:

  - Potential impacts on the site from the measurement activities.

  - Whether the study needs to simulate repository conditions.

  - Required accuracy and precision of parameters to be measured with instrumentation.

  - Limits of analytical methods that will use the information from the experiments and tests.

  - Capability of analytical methods to support the study.

  - Time required versus time available to complete the study.

- Statistical relevance of data and data trends to performance goals and confidence limits. Where appropriate, the experiments or tests will be designed for replications necessary to achieve the quantitative statistical confidence level required (by performance allocation) of the parameter under study. Such experiment design will be described in the SP. In cases where experiments or tests are conducted for demonstration purposes or proof-of-concept approaches, statistical experimental design may not be appropriate or applicable as will be explained in the SP.

- The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field.

- Interrelationships of experiments and tests involving significant interference with other similar activities and how studies have been designed or sequenced to address such interference.

- Interrelationships involving significant interference among experiments, tests, and exploratory shaft facility design and construction (as appropriate, refer to Section 8.4 of the SCP or its references for specific exploratory shaft facility design information such as design drawings or specifications).

4.1.3 Description of Experiments, Tests, and Analyses. The following should be considered in preparing a description of experiments, tests and analyses:

o Because studies are composed of experiments, tests, and analyses, provide for each

- a description of the general approach that will be used. Describe key parameters that will be measured and the experimental conditions under which the measurements will be conducted. Indicate the number of measurements and their locations (e.g., spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units depth, and test location);

- a summary of the EPs or ETPs. If EPs are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any experiments or tests that are not judged to be QA Level I. Reference the applicable specific QA requirements that will be applied;

- specification of the tolerance, accuracy, and precision required, where appropriate;

- indications of the range of expected results and the basis for those expected results;

- lists of the equipment required and a brief description of any special equipment needed;

- descriptions of techniques to be used for data reduction and analysis of the results;

- discussions of the representativeness of the measurements including why the results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results;

- illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of experiments and tests;

- a discussion of the relationships of the measurements to the set performance goals and confidence levels; and

- a discussion of statistical methods used to evaluate data and data trends and an explanation as to the validity of the results.

o For each type of analysis provide

- statements as to the purpose of the analysis, indicating the experiment, testing, or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set of performance goals and confidence levels;

- a description of the methods of analysis, including any analytical expressions and numerical models that will be employed;

- a reference to the Problem Definition Memo (PDM) that will apply to the analysis (If PDMs are not yet available, indicate when they will be available. Indicate the level of Quality Assurance (QA) that will be applied to the analysis and provide a rationale for any analyses that are not judged to be QA Level 1. Reference the applicable QA requirements);

- identification of the data input requirements of the analysis;

- a description of the expected output and accuracy of the analysis; and

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

4.1.4 Applications of Results. The following should be considered regarding applications of the results

o Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies).

- For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) which will use the information produced from the studies described above, and refer to any use of the results for model validation.

- For design uses, refer to, or describe, where the information from the study described above will be used in equipment design and development and engineered system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals).

- For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

4.1.5 Schedule and Milestones. The schedule and milestones should be established according to the following:

- provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of EPs, TPs, data analyses, and preparation of reports), and indicate the key milestones including decision points associated with the study activities;

- describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and

- give dates for activities or milestones, including durations and interrelationships, for the SPs (These should reference the master schedules provided in Section 8.5 of the SCP).

4.2 Document Changes. SPs can be revised as needed to

1) comply with changes to YMP policy;
2) reflect changes in SNL policy; and
3) reflect changes in scope or technical content of the SP that have impacts on EPs.

5.0 REQUIREMENTS

5.1 General

5.1.1 QA Levels. SPs will define the quality assurance (QA) level(s) for each activity to be performed in support of the SP. If the activities described are of differing QA levels, the SP will use the highest QA level that are defined on file codes used for distribution to the SNL Department 6310 Local Records Center.

5.1.2 Initiating a Study Plan. The responsible PI shall prepare study plans to comply with YMP requirements negotiated between SNL and the DOE Project Office. The author of the SP is responsible for ensuring that SPs are compatible with the agreements between DOE, NRC, and the State of Nevada.

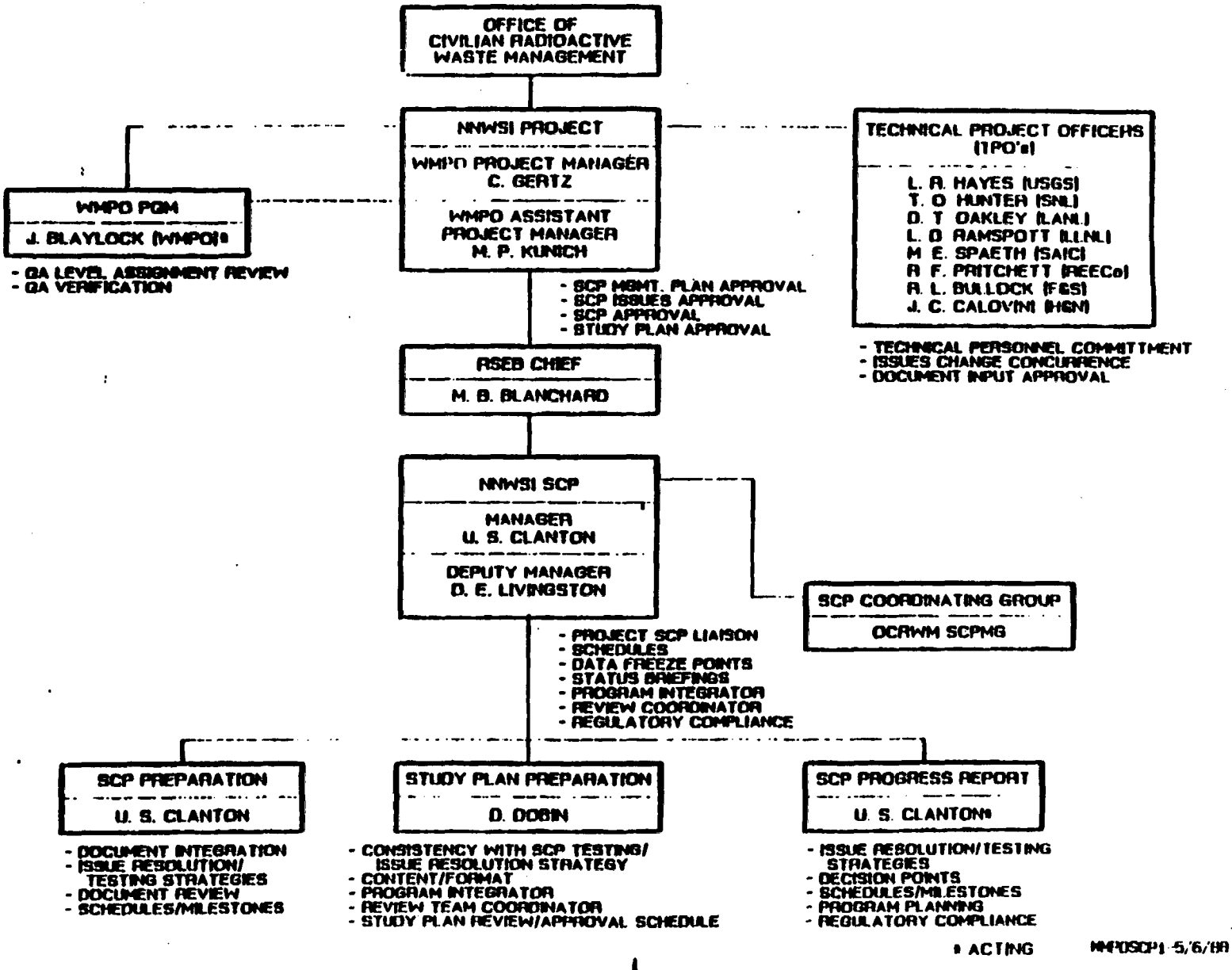
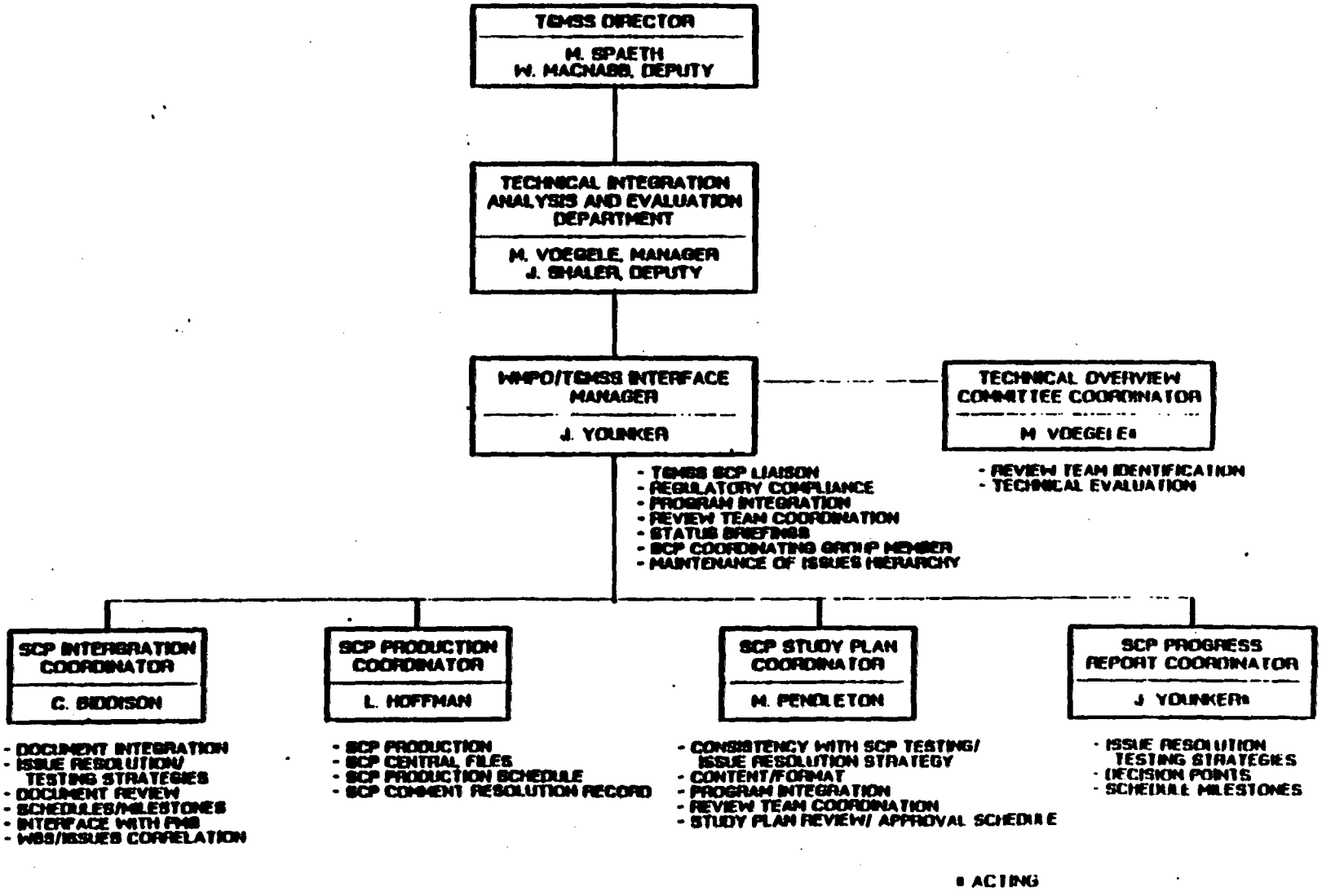


FIGURE 2-1. WMPO SCP ORGANIZATION



2-2. T&MSS SCP ORGANIZATION

WM-88372-9/16/87 VA

2.2.1 Management Responsibilities

2.2.1.1 WMPO Project Manager

The WMPO Project Manager retains ultimate responsibility for delivery of the NNWSI Project SCP, SCP Study Plans, and input to SCP Progress Reports to the OCRWM. To deliver high quality documents by the specified date and in accordance with applicable budgetary constraints, the WMPO Project Manager has delegated appropriate responsibility and authority for preparation of the SCP, SCP Study Plans, and input to SCP Progress Reports to the Branch Chief, Regulatory and Site Integration Branch (R&SEB). The Project Manager will receive technical assistance and resource commitments from the NNWSI Project Technical Project Officers (TPOs). The WMPO Project Manager will retain authority for final approval of the SCP Management Plan, the SCP and the supporting Study Plans, and SCP Progress Reports.

2.2.1.2 WMPO Assistant Project Manager

The WMPO Assistant Project Manager will act as manager in the absence of the WMPO Director.

2.2.1.3 Branch Chief (R&SEB)

The Branch Chief, R&SEB, directs preparation and ensures coordination and review of documents such as the SCP, supporting Study Plans, SCP Progress Reports, SCP Issues Hierarchy, and demonstrating compliance with the applicable NRC regulations. The Branch Chief, R&SEB, also ensures coordination of technical meetings between the NNWSI Project and the NRC and is a member of OGR's SCP Coordinating Group and OGR's SCP Overview Committee (SOC). The Branch Chief, R&SEB, has delegated the responsibility for completing the provisions of this management plan to the SCP Manager.

2.2.1.4 Technical Project Officers

The TPOs will have the following responsibilities and authority relative to the SCP, SCP Study Plans, and SCP Progress Reports:

1. Recommendations and approval for the Project review committee membership.

2. Approval and commitment of personnel within their organization for SCP review and revision, Study Plan preparation, review and revision, input to SCP Progress Reports, and participation in technical meetings with the NRC and the State on SCP related topics.

2.2.1.5 SCP Management Group

The SCPMG will be called into action at the request of the SCPMG Manager. The SCPMG will be composed of personnel who, as a group, will be responsible for the following:

1. Change control for the SCP Management Plan including schedules, milestones, and deliverables.

2. Initiation of change recommendations to the AO and the SCP Production Guidance Manual for the OCRWM SCP Coordinating Group (SCPCG).

3. Initiation of change recommendations relative to the SCP Issues Hierarchy.

4. Evaluations of staffing requirements for SCP, SCP Study Plan, and SCP Progress Report preparation and review.

5. Working with the OCRWM SCPCG to develop format and content guidance for SCP progress reports.

6. Supporting technical meetings between the NNWSI Project and the NRC and the State on SCP related topics.

The SCPMG has been formed to ensure communications throughout the SCP organization and to address problems in an efficient and timely manner. To

accomplish this, the following people have been identified as members of the SCPMG:

1. SCP Manager.

2. SCP Assistant Manager.

3. WMPO T&MSS Interface Manager.

4. WMPO Project Quality Manager.

5. Technical Overview Committee Coordinator.

6. SCP Integration Coordinators.

7. SCP Production Coordinator.

8. SCP Study Plan Coordinators.

9. SCP Progress Report Coordinators.

The responsibilities and authority of the SCPMG members are described in the remainder of this section and in sections 4.0, 5.0, 6.0, and 7.0.

2.2.1.6 SCP Manager

The SCP Manager will be responsible to the R&SEB Chief for preparation of the SCP, SCP Study Plans and input to SCP progress reports in accordance with guidance given in this plan and in accordance with applicable budget and time constraints. To accomplish this task, the SCP Manager will have the responsibility and authority to direct the SCPMG staff as to their responsibility, authority, and interactions relative to the SCP. The SCP Manager's specific responsibilities include the following:

1. Managing the overall development of the NNWSI Project SCP, SCP Study Plans, and input to SCP Progress Reports.

2. Acting as NNWSI Project liaison with the OCRWM SCPCG and with SCP-related participant organizations, and acting as NNWSI Project spokesperson for SCP-related communications outside the NNWSI Project, including the NRC.

3. Ensuring overall technical adequacy and quality of the SCP, SCP Study Plans and input to SCP Progress Reports;

4. Resolving conflicts related to the preparation of the SCP, SCP Study Plans and input to SCP Progress Reports, except as noted under the responsibilities of the WMPO Project Manager, WMPO Assistant Project Manager, and the R&SEB Chief, including authority to seek resolution at the OCRWM or NNWSI Project management levels.

5. Providing schedules and establishing data freeze points.

6. Instituting corrective action to maintain the necessary levels of quality assurance.

7. Preparing OCRWM Project Managers' status briefings.

8. Ensuring that the review and approval of the SCP, SCP study plans and input to SCP progress reports is in accordance with this plan and the NNWSI QAP, NVO-196-17.

9. Participating in the OGR-SCP Coordinating Group.

2.2.1.7 SCP Assistant Manager

The SCP Assistant Manager will act as the SCP Manager in the absence the SCP Manager.

2.2.1.8 WMPO Project Quality Manager

The WMPO Project Quality Manager (PQM) will provide quality assurance guidance to the SCPMG Manager. The WMPO PQM will ensure that each NNWSI Project participant contributing to the SCP follows the controls outlined in

this SCPMP, the NNWSI QAP, NVO-196-17, and their respective Quality Assurance Program Plans (QAPPs).

2.2.2 Technical Responsibilities

2.2.2.1 WMPO T&MSS Interface Manager

The SCP technical and management interface between the WMPO and the T&MSS Contractor will be through the WMPO T&MSS Interface Manager, who will have the following specific responsibilities:

1. Assuring overall technical adequacy and quality of the SCP, SCP Study Plans, and input to SCP Progress Reports.

2. Acting as T&MSS SCP Liaison.

3. Managing project review activities.

4 Assuring regulatory compliance, coordination, and evaluation associated with the SCP.

5. Assigning QA levels to the SCP in accordance with NNWSI SOP-02-02.

6. Assuring consistency with other NNWSI Project technical plans.

7. Maintenance of the SCP Issues Hierarchy.

8. Supporting technical meetings with the NRC and the State on SCP related topics.

2.2.2.2 SCP Technical Overview Committee

The SCP Technical Overview Committee (TOC) will be composed of NNWSI Project personnel who will support the SCPMG by providing reviews of the SCP and SCP Study Plans. Individuals for the TOC will be selected by the TOC Coordinator in consultation with the SCPMG Manager. The focus and level of review will be defined by the SCPMG Manager and the T&MSS Interface Coordinator in advance of each review. Individuals from the TOC may also be called upon to assist the T&MSS Interface Coordinator in resolving differences of opinion among NNWSI Project organizations and between the NNWSI Project and U.S. Department of Energy Headquarters (DOE/HQ) as well as to provide advice on other policy or technical issues.

2.2.2.3 Working Groups

Two working groups will be used to review and revise the SCP text for compliance with the OCRWM SCP AO and produce to the SCP: (1) the SCP Integration Working Group will be responsible for review, revision, and integration

of Chapters 1 through 8, and (2) the Production Working Group will be responsible for the production and editorial review of the SCP and will manage the SCP supporting records and documents.

The responsibilities of the SCP Integration Coordinator and the Production Coordinator include supervising the work activities of their respective groups and ensuring that the SCP is written according to the OCRWM SCP AO and the SCPMP. The SCP Integration Coordinator will assist the WMPO T&MSS Interface Manager in coordinating Project Reviews, in the preparation of review packages and transmittal letters for distribution to reviewers and for coordinating document submittals to production with the Production Coordinator. The responsibilities of the SCP Working Group members are further defined in Sections 4.0 and 5.0.

The SCP Integration Working Group will include Permanent Internal Review Committees (PIRCs) and Project Overview Committees (POCs). The SCP PIRCs will be composed of NNWSI Project personnel and DOE/HQ representatives who will support the SCPMG by serving as technical reviewers to review and revise the SCP data and design chapters and the issues and plans chapter. Each PIRC will be managed by a PIRC Chairman (see Section 4.0). Each PIRC Chairman is responsible for coordinating review and revision of their PIRC package including scheduling PIRC reviews, consolidating PIRC comments, comment resolutions, and revising the text according to the resolved comments.

The SCP POCs were formed in a TPO meeting on November 6, 1986 in response to an OGR request to accelerate the SCP preparation process. Because there was insufficient time to conduct a comprehensive technical

5.1.3 Distribution. SPs will be produced as a Sandia National Laboratories letter report (SLTR) or a SAND report, or both, and distribution prepared by the PI or his designee.

5.1.4 Content. PIs shall consider all items in Section 4.1 and apply those that are appropriate.

5.2 Specific

5.2.1 Approval Requirements. The SP, written as an SLTR or a SAND Report, will be reviewed, approved (including approval by the SNL Department 6310 QA Coordinator), and issued in accordance with DOP 6-2. In addition, each page of an SP that is written as an SLTR will contain reference to the SLTR Number, revision, and page.

5.2.2 Revisions. The revised SP is subject to the approval requirements specified in Section 5.2.1. As a minimum, the revision will be issued and distributed to the same individuals and files as the previous version.

6.0 RECORDS

Completed SPs, together with their manuscript review sheet(s) and other supporting documentation (peer review comments), will be filed in the SNL Department 6310 LRC under the appropriate file codes for SLTR or SAND Reports and in the files for SPs. The current master listing of file codes should be used to determine the proper file codes.

7.0 REFERENCES

- DOP 6-2 Reviewing, Approving, and Issuing Technical Information Documents.

SANDIA NATIONAL LABORATORIES

NUCLEAR WASTE REPOSITORY TECHNOLOGY PROJECT

DEPARTMENT 6310 OPERATING PROCEDURE

REVIEWING, APPROVING, AND ISSUING TECHNICAL INFORMATION DOCUMENTS

Page	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	App A	App B	App C
Revision	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	0A	0A	0A

Page	App D	App E	App F
Revision	0A	0A	0A

RAR 1/3/89

Author: _____ Carl Mora — 12/22/88 Date

Approved: _____ Division Supervisor — 12/22/88 Date

Approved: _____ SNL QA — 12/23/88 Date

Approved: _____ J. E. Stiegler, SNL TPO (Actg.) — 12/23/88 Date

SNL NNWSI DEPARTMENT 6310
CONTROLLED DOCUMENT
NCDN 000048
Copy Number: _____
RETURN TO 6310 RECORDS CENTER
WHEN NO LONGER NEEDED.

DEPARTMENT 6310 OPERATING PROCEDURE FOR REVIEWING, APPROVING, AND ISSUING TECHNICAL INFORMATION DOCUMENTS

1.0 PURPOSE

The purpose of this procedure is to detail the method for reviewing, approving, and issuing official technical information documents produced by Department 6310, by its contractors, and by other Sandia organizations for Department 6310. Such documents include SAND reports, abstracts, conference papers, journal articles, and letter reports (SLTRs). Other types of documents are covered separately in other QAPs and DOPs.

2.0 SCOPE

2.1 The procedures herein apply to all such documents to be distributed outside of Sandia National Laboratories. This procedure (DOP 6-2) supersedes entirely QAP III-1, adopted in May 1983 and QAP VI-2, November 1985.

2.2 Paragraph 4.2, "Documents Authored by Department 6310 Personnel," provides a detailed description of the method of reviewing, approving, and issuing formal technical documents written by members of Department 6310.

2.3 Paragraph 4.3, "Documents Authored by Other Sandia Organizations for Department 6310," provides a detailed description of the method of reviewing, approving, and issuing formal technical documents written by Sandia employees outside of Department 6310.

2.4 Paragraph 4.4, "Contractor Documents for Department 6310," provides a detailed description of the method of reviewing, approving, and issuing formal technical documents written by outside firms under contract to Department 6310.

2.5 Paragraph 4.5, "Letter Reports (SLTRs)," defines what a letter report is and describes the method of reviewing, approving, and issuing it.

3.0 DEFINITIONS

3.1 Technical Review

A documented traceable review performed by qualified personnel who are independent of those who performed the work but who have technical expertise at least equivalent to those who performed the original work. Technical reviews are in-depth, critical reviews, analyses, and evaluations of documents,

material, or data that require technical verification and/or validation for applicability, correctness, adequacy, and completeness.

3.2 Independent Technical Reviewer

Any individual who is knowledgeable in the technical area to be reviewed but who did not perform the original work that resulted in the report. The author's supervisor can be an independent technical reviewer only if the supervisor is the only technically competent, certified individual available and that fact is documented by the 6310 Department Manager per DOP 2-6. For technical documents resulting from QA Level I activities, the independent technical reviewers must also be certified in accordance with DOP 2-6 in the technical area to be reviewed.

3.3 SLTR

A letter report containing results of Department 6310 activities. It is assigned a log number by the Department 6310 technical reports editor and entered into the Records Management System. An SLTR is non-referenceable in SAND reports.

4.0 REQUIREMENTS AND PROCEDURES

4.1 General

In the case of documents authored by Department 6310 personnel, it is the responsibility of the primary author to see that the procedure is followed and that the document receives complete review and approval before it is printed and/or distributed. In the case of documents authored by contractors and by other Sandia organizations, the Department 6310 employee assigned to monitor the work has that responsibility.

No abstract, conference paper, or journal article covered by this DOP can be submitted outside of Sandia unless it has been reviewed and approved by Dept. 6310, the Department of Energy's Yucca Mountain Project (DOE/YMP), and Sandia according to the procedures outlined in this procedure. To be processed, such documents must be submitted for review and approval no later than 15 working days (for abstracts) and 30 working days (papers and articles) before they are due. These requirements apply to both Sandia personnel and all contractors.

Technical review comments and resolutions, including those of supervisors and QA personnel, shall be documented on the Document Review and Comment sheet (DRC), Appendix F, for each technical review. For Department of Energy/YMP reviews, either the DRC sheet or a comparable DOE/YMP form may be used. When

all comments have been resolved and signed off by reviewers and by the responsible author or comment resolver, the DRC sheet(s) shall be entered in the Records Management System.

Any supporting input documents (e.g., SLTR, DIM, or PDM) used in the preparation of a SAND report shall be identified in the introduction.

The Quality Assurance level or levels under which the activities were carried out which led to the writing of the SAND report shall be identified on page ii following the title page.

4.2 Documents Authored by Department 6310 Personnel (Figure 1)

4.2.1 Editorial Review

Author sends three copies of draft document to Department 6310 technical reports editor (hereafter "editor," c/o Division 6311), who will conduct, or arrange for, an editorial review, examining it to determine if it is complete, in the proper format, and otherwise ready for review. If not, draft will be returned to the author for modifications.* (Note: Author's division supervisor has the authority to waive editorial review requirement if there is a compelling reason to do so. The Manuscript Review Sheet contains a signature block for this.)

4.2.2 Technical Review

When editor has an acceptable draft, author will ask his/her division supervisor to select two independent technical reviewers who are qualified** and available to technically review the document. The editor then sends a copy of the draft document and Department 6310 Manuscript Review Sheet (Appendix A) and DRC sheet (Appendix F) to each independent technical reviewer.

4.2.3 Technical reviewers return written review comments and manuscripts to the author and initial the Manuscript Review Sheet. Author resolves problems and questions, incorporates changes into a revised draft, and sends document to the editor.

4.2.4 Author works with technical and editorial reviewers and gets final approval signatures on Manuscript Review Sheet and DRC

*Writing and rewriting assistance is available through the Department 6310 technical reports editor.

**See Section 3.0, "Definitions," for qualifications.

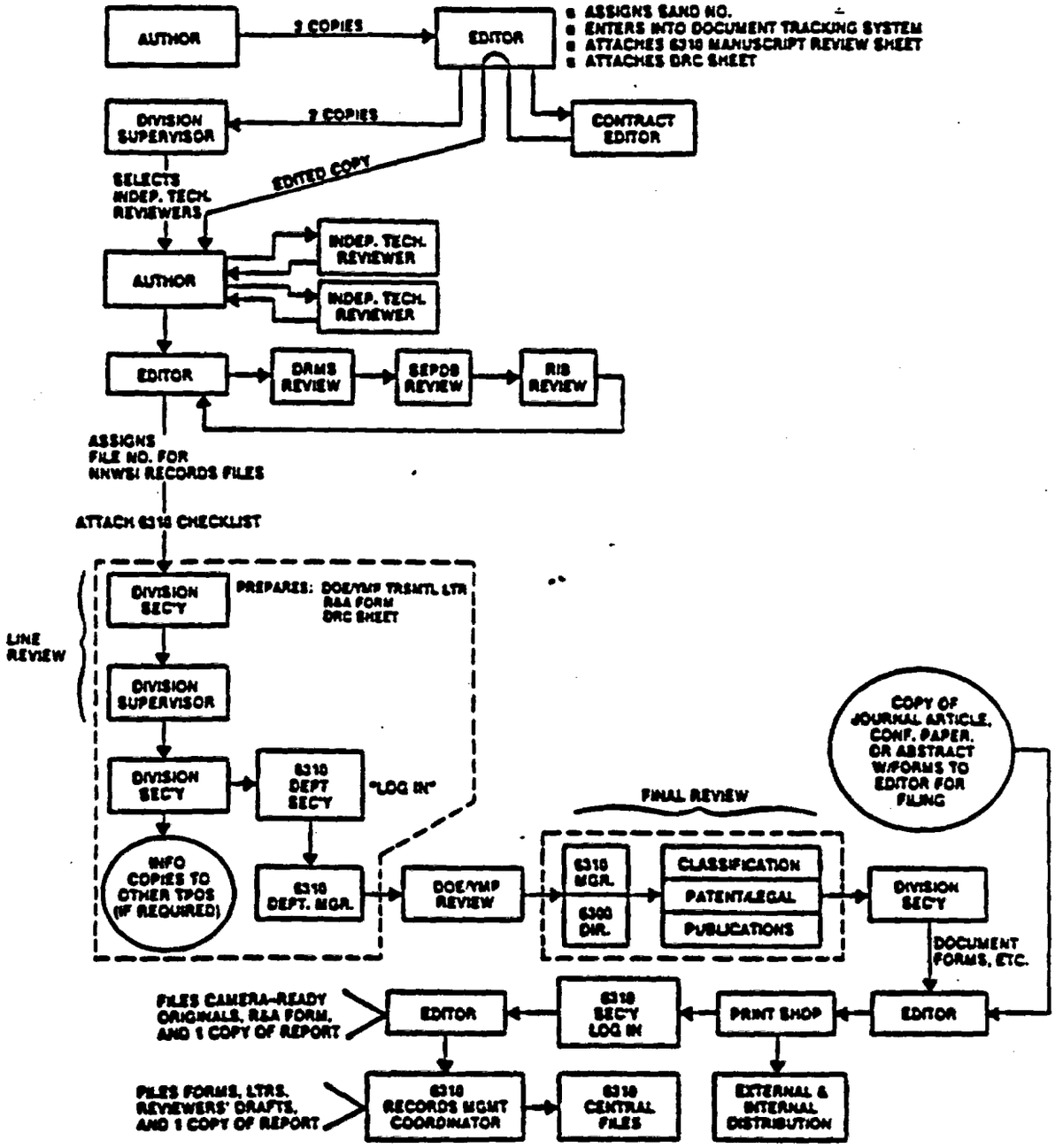


Figure 1. Documents Authored by 6310 Personnel.

sheet(s) from technical and editorial reviewers.* Author sends two copies of revised manuscript to the editor, along with the DRC sheet(s) and Manuscript Review Sheet completed by reviewers.

4.2.5 The editor will forward a copy of the document to the Department 6310 Data Records Management System (DRMS) representative who will review the document and appropriate DRMS data set notebooks to determine if all data and supporting documents for the reported data have been placed in the DRMS. If the DRMS data set notebooks are incomplete relative to the data, the representative will so inform the author. The author will provide to the DRMS representative the required documents to complete the DRMS notebook. The representative will sign the 6310 Manuscript Review Sheet when all the data and supporting documents are placed into the appropriate DRMS data set notebook. The representative then returns the draft document and review sheet to the editor.

4.2.6 The editor sends draft to the Site and Engineering Properties Data Base (SEPDB) representative to ensure that appendices identifying SEPDB candidate information are considered for future entry. If draft sent to the SEPDB representative contains the appendix for the SEPDB comparison and the latter is acceptable, the representative will sign the Department 6310 Manuscript Review Sheet, and the draft and sheet will be returned to the editor. If draft is unacceptable from this standpoint, the SEPDB representative will work with the author to solve the problems and produce an acceptable draft.

4.2.7 The editor sends the draft to the Reference Information Base (RIB) representative for examination. If draft sent to the RIB representative contains an acceptable appendix for the RIB comparison, the representative will sign the Department 6310 Manuscript Review Sheet, and the draft and sheet will be returned to the editor. If draft is unacceptable from this standpoint, the RIB representative will work with the author to solve the problems and produce an acceptable draft.

4.2.8 The editor, after ascertaining that the manuscript is ready for line review, attaches the Department 6310 Technical Publication Checklist (Appendix C), and sends the packet to the author's division secretary who prepares the transmittal letter** to

---

*If differences cannot be resolved between the author and a reviewer, the author's division supervisor may sign in lieu of the reviewer. If supervisor does this, he must document the unresolved differences and how he handled them; a copy must be sent to the Department 6310 QA Coordinator and the reviewer involved.

**If applicable, the transmittal letter to DOE/YMP shall include the sentence: "This draft document satisfies Milestone #_____."

DOE and the SNL Review and Approval form (SF 1003) (Appendices D and E) that accompanies the document through the remainder of the Sandia review process. The secretary gives Manuscript Review Sheet, Review and Approval form, DRC sheet(s), and manuscript to division supervisor.

4.2.9 The division supervisor completes his review. After any problems are resolved with author and an acceptable draft document exists, the supervisor signs Review and Approval form. The supervisor determines if the document has direct application to other DOE/YMP participant organizations. If so, the supervisor sends an information copy of the document to the TPO at appropriate organization(s).

4.2.10 Supervisor has secretary send two copies of the draft document, Manuscript Review Sheet, Review and Approval form, DRC sheet(s), and transmittal letter to Department 6310 secretary who "logs in" the document, files copies of the abstract and Manuscript Review Sheet, and gives document and all forms to Department 6310 manager.

4.2.11 Department 6310 manager examines the document. If it is satisfactory, he has department secretary send one copy of the draft document, DRC sheet(s), and transmittal letter to DOE/YMP for "policy review."

4.2.12 NVO/YMP performs policy review and returns any comments to Department 6310 manager. Department secretary updates log and files a copy of DOE comments and/or approval letter. Comments requiring resolution are forwarded to author.

4.2.13 After DOE/YMP comments are resolved and a revised draft is prepared (if necessary), reviews are conducted by department manager and 6300 director. The document, together with the Review and Approval form, is sent through the remaining steps in the final review process--classification, patent/legal, and publication policy reviews.

4.2.14 Document and forms are returned to appropriate division secretary who notifies author that document has final approval. Secretary forwards original manuscript and all forms and letters to editor to arrange for printing, if document is to be published by Sandia. If document is a journal article, conference paper, or abstract, secretary forwards original manuscript and copies of forms to author who submits manuscript to appropriate place; at the same time secretary sends a copy of the manuscript and original forms to editor.

4.2.15 Department 6310 secretary notes in log when a printed copy of a document is received.

4.2.16 After document is printed, editor transmits copy of SAND report and all forms, letters, and DRC sheets (all QA levels) to SNL RMS for filing.

4.3 Documents Authored by Other Sandia Organizations for Department 6310 (Figure 2)

4.3.1 Author has draft document reviewed by two independent technical reviewers. (Department 6310 contact's* division supervisor selects two qualified independent technical reviewers.** At least one reviewer should be a Department 6310 staff member.) At the same time, author should send a draft to the Department 6310 contact who will forward a draft to the Department 6310 technical reports editor (c/o Division 6311), hereafter referred to as "editor," who will conduct, or arrange for, an editorial review and get a SAND number assigned if the author has not done so. (Note: if author expects considerable suggestions and changes from the peer reviewers, author may choose to have the editorial review done after the independent technical reviewers' comments have been resolved and incorporated into a revised draft. Monitor's division supervisor has the authority to waive editorial review requirement if there is a compelling reason to do so... The Manuscript Review Sheet contains a signature block for this.)

4.3.2 Technical and editorial reviewers return written review comments and manuscripts and initial the Manuscript Review Sheet. Author resolves problems and questions and incorporates changes into a revised draft.

4.3.3 Author works with technical and editorial reviewers and gets final approval from them.*** Reviewer signatures are required on the Department 6310 Manuscript Review Sheet (Appendix A) and DRC sheet (Appendix F) to indicate final approval.

4.3.4 Author sends two copies of revised manuscript together with Manuscript Review Sheet and DRC sheet(s) to 6310 contact who

---

*In most cases, a Sandia author outside Department 6310 will have been assigned a contact within 6310. The author should work closely with the contact and keep his/her informed about the status of the document throughout the review process.

**See Section 3.0, "Definitions," for qualifications.

***If differences cannot be resolved between the author and a reviewer, the author's division supervisor may sign in lieu of the reviewer. If supervisor does this, he must document the unresolved differences and how he handled them; a copy must be sent to the Department 6310 QA Coordinator and the reviewer involved.

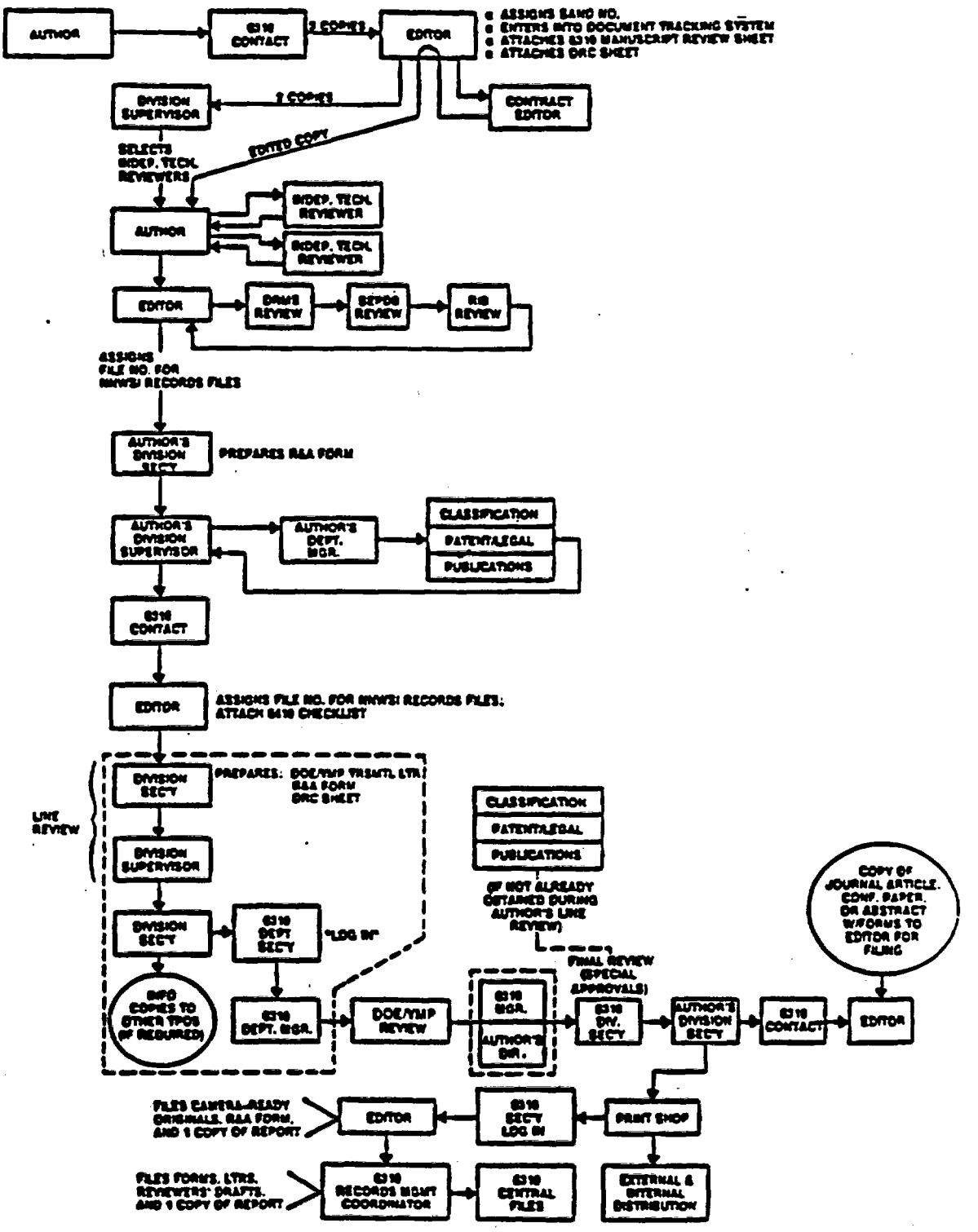


Figure 2. Documents Authored by Other Sandia Organizations for Department 6310.

forwards them to the 6310 editor. The editor forwards a copy of the document to the Department 6310 Data Records Management System (DRMS) representative, who will review the document and appropriate DRMS data set notebooks to determine if all data and supporting documents for the reported data have been placed in the DRMS. If the DRMS data set notebooks are incomplete relative to the data, the representative will so inform the author (through the Department 6310 contact). The author will provide the required documents to the 6310 contact who will then forward them to the DRMS representative to complete the DRMS notebook. The representative will sign the 6310 Manuscript Review Sheet when all the data and supporting documents are placed into the appropriate DRMS data set notebook. The representative then returns the draft document and review sheet to the editor.

4.3.5 The editor sends draft to the SEPDB representative to ensure that appendices identifying candidate information for the SEPDB are considered for future entry. If draft sent to the SEPDB representative contains the appendix for the SEPDB comparison and the latter is acceptable, the representative will sign the Department 6310 Manuscript-Review Sheet, and the draft and sheet will be returned to the editor. If draft is unacceptable from this standpoint, the SEPDB representative will work with the 6310 contact to solve the problems and produce an acceptable draft.

4.3.6 The editor sends the draft to the RIB representative for examination. If draft sent to the RIB representative contains an acceptable appendix for the RIB comparison, the representative will sign the Department 6310 Manuscript Review Sheet, and the draft and sheet will be returned to the editor. If draft is unacceptable from this standpoint, the RIB representative will work with the 6310 contact to solve the problems and produce an acceptable draft document.

4.3.7 The editor then sends two copies of the manuscript to the author's division secretary, along with the Manuscript Review Sheet completed by reviewers. Author's division secretary prepares Review and Approval form (SF 1003) (Appendices D and E) that accompanies the manuscript through remainder of Sandia review process. Secretary gives Manuscript Review Sheet, DRC sheet(s), Review and Approval form, and both copies of the manuscript to author's division supervisor.

4.3.8 Author's division supervisor and department manager conduct their reviews. After any problems are resolved with author, the supervisor and manager sign the Review and Approval form. The manuscripts and forms are sent to the author's Department 6310 contact, who will ensure that everything is in order and complete. The contact sends two copies of the revised manuscript to the editor, along with the Manuscript Review Sheet completed by reviewers. The editor, after ascertaining that

the manuscript is ready for line review, attaches the Department 6310 Technical Publication Checklist (Appendix C) and sends the packet to the contact's division secretary.

4.3.9 The division supervisor completes his review. After any problems are resolved with author (through the Department 6310 contact) and an acceptable draft document exists, the supervisor signs Review and Approval form under "Special Approvals." The Supervisor determines if the document has direct application to other DOE/YMP participant organizations. If so, the supervisor sends an information copy of the document to the TPO at appropriate organization(s).

4.3.10 Division supervisor's secretary prepares transmittal letter* to DOE/YMP and sends the two copies of the document, Manuscript Review Sheet, Review and Approval form, DRC sheet(s), and transmittal letter to Department 6310 secretary who "logs in" the document, files copies of the abstract and manuscript review sheets, and gives document and all forms to Department 6310 manager.

4.3.11 Department 6310 manager examines the document. If it is satisfactory, he has department secretary send one copy of the draft document and transmittal letter to DOE/YMP for "policy review."

4.3.12 DOE/YMP performs policy review and returns comments to Department 6310. Secretary updates log and files a copy of DOE/YMP comments and/or approval letter. Comments requiring resolution are forwarded to author.

4.3.13 After DOE/YMP comments are resolved and a revised draft is prepared (if necessary), reviews are conducted by Department 6310 manager, who signs under "special approvals." The document, together with the Review and Approval form, is then sent through remaining steps in the final review process--classification, patent/legal, and publication policy reviews (if author's organization has not already obtained these approvals prior to sending R & A form to 6310 contact). If author's organization is to arrange for printing, the packet is returned to author; if publication is to be done by Department 6310, the packet is forwarded to the editor.

4.3.14 Document and forms are returned to contact who forwards original manuscript and all forms and letters to editor to arrange for printing, if document is to be published by Department 6310. If document is a journal article, conference paper, or abstract, author submits manuscript to appropriate place.

---

*If applicable, the transmittal letter to DOE/YMP shall include the following sentence: "This draft document satisfies Milestone #_____."

4.3.15 Department 6310 secretary notes in log when a printed copy of the document is received.

4.3.16 After document is printed, editor transmits copy of SAND report and all forms, letters, and DRC sheets (all QA levels) to SNL RMS for filing.

4.4 Contractor Documents for Department 6310 (Figure 3)

4.4.1 Contractor conducts internal review of draft document, updates and submits five copies of typed, double-spaced document to Department 6310 employee assigned to monitor contract. The 6310 monitor examines draft to determine if it is acceptable.

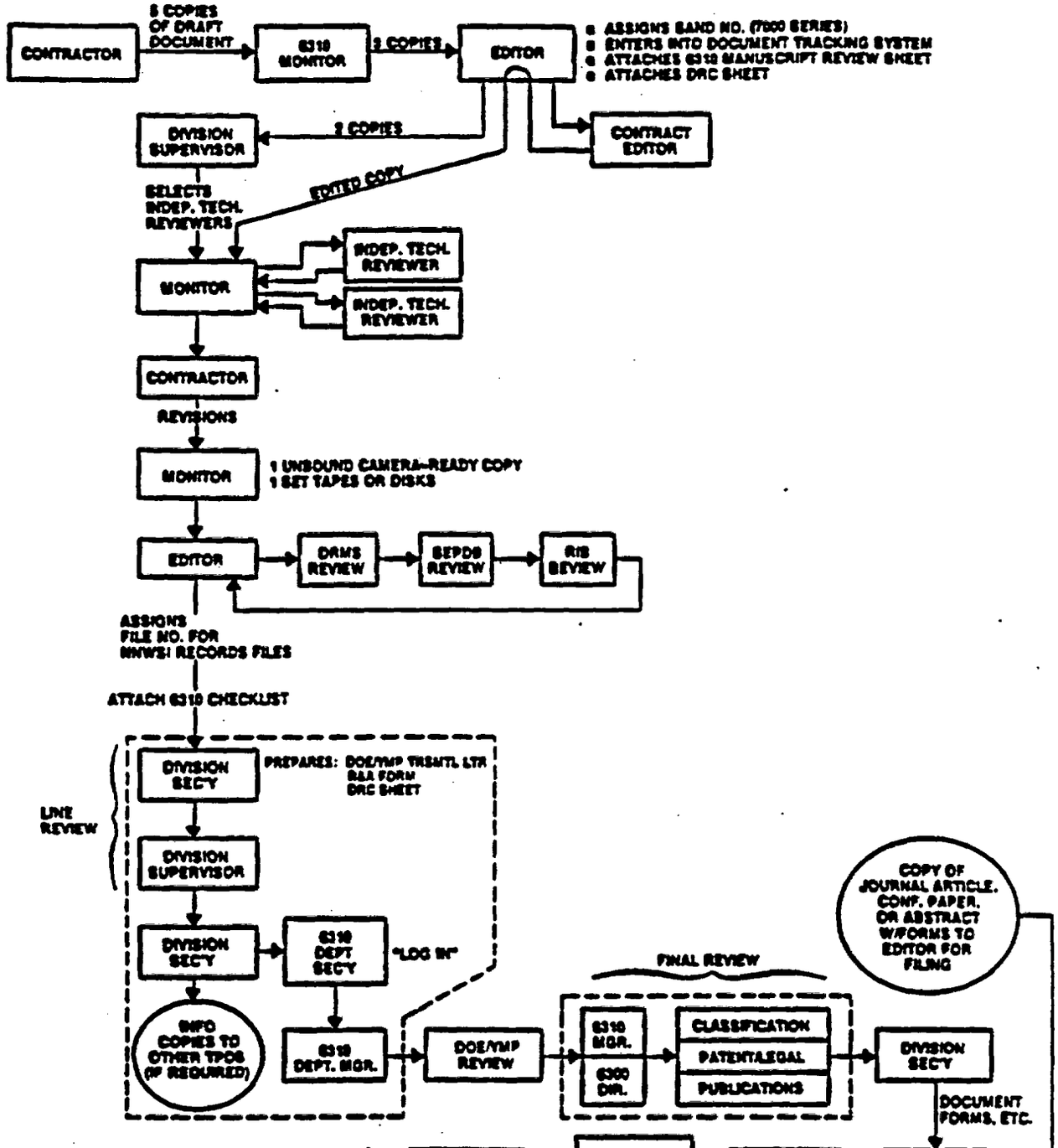
4.4.2 When monitor is satisfied with draft, he or she should send three copies to Department 6310 technical reports editor (hereafter, "editor") who will assign a SAND number (7000 series). The editor will work with the monitor to ensure that the document is in the proper format and condition for independent technical review. The editor will then forward the draft to the appropriate division 6310 supervisor, who examines it to determine if it is ready for review. If not, draft is returned to monitor, who works with contractor to get an acceptable draft. After division supervisor determines that draft is ready, he selects the qualified independent technical reviewers and returns manuscript to monitor.* Monitor sends a copy of the draft and a copy of the Department 6310 Manuscript Review Sheet (Appendix A) and DRC sheet(s) (Appendix F) to each independent technical reviewer. At same time, monitor sends a draft to editor, c/o Division 6311, who will conduct, or arrange for, and editorial review. (Note: monitor's division supervisor has the authority to waive editorial review requirement if there is a compelling reason to do so. The Manuscript Review Sheet contains a signature block for this.)

4.4.3 Technical and editorial reviewers return written review comments and manuscripts and initial the Manuscript Review Sheet. Monitor resolves problems and questions and incorporates changes into a revised copy.

4.4.4 The monitor returns the revised copy to the contractor for necessary revisions to the manuscript and artwork. Contractor makes revisions and, if document is a technical report, provides the following to the monitor: one unbound "camera-ready" copy of the document (now single-spaced) and a set of tapes or disks containing the complete text of the document. (The tapes or disks should be compatible with Sandia's word-processing equipment in case Sandia needs to make adjustments to the final copy.)

---

*See Section 7.0, "Definitions," for qualifications.


5 COPIES OF DRAFT DOCUMENT
CONTRACTOR
6318 MONITOR
2 COPIES
EDITOR
ASSIGNS SAND NO. (7000 SERIES)
ENTERS INTO DOCUMENT TRACKING SYSTEM
ATTACHES 6318 MANUSCRIPT REVIEW SHEET
ATTACHES DRC SHEET
DIVISION SUPERVISOR
2 COPIES
CONTRACT EDITOR
EDITED COPY
SELECTS INDEP. TECH. REVIEWERS
MONITOR
INDEP. TECH. REVIEWER
INDEP. TECH. REVIEWER
CONTRACTOR
REVISIONS
MONITOR
1 UNBOUND CAMERA-READY COPY
1 SET TAPES OR DISKS
EDITOR
DRMS REVIEW
SEPDS REVIEW
RIS REVIEW
ASSIGNS FILE NO. FOR NNWSI RECORDS FILES
ATTACH 6318 CHECKLIST
LINE REVIEW
DIVISION SEC'Y
PREPARES: DOE/YMP TRSMTL LTR
B&A FORM
DRC SHEET
DIVISION SUPERVISOR
DIVISION SEC'Y
6318 DEPT SEC'Y
"LOG IN"
INFO COPIES TO OTHER TPOS (IF REQUIRED)
6318 DEPT. MGR.
DOE/YMP REVIEW
FINAL REVIEW
6318 MGR.
6300 DIR.
CLASSIFICATION
PATENT/LEGAL
PUBLICATIONS
DIVISION SEC'Y
COPY OF JOURNAL ARTICLE, CONF. PAPER, OR ABSTRACT W/FORMS TO EDITOR FOR FILING
DOCUMENT FORMS, ETC.

4.4.5 Monitor checks manuscript and gets final approval signatures on Manuscript Review Sheet from technical and editorial reviewers. The monitor sends two copies of the revised manuscript to the editor, along with the Manuscript Review Sheets completed by reviewers.

4.4.6 The editor forwards a copy of the document to the Department 6310 Data Records Management System (DRMS) representative, who will review the document and appropriate DRMS data set notebooks to determine if all data and supporting documents for the reported data have been placed in the DRMS. If the DRMS data set notebooks are incomplete relative to the data, the representative will so inform the monitor. The monitor will provide to the DRMS representative the required documents to complete the DRMS notebook. The representative will sign the 6310 Manuscript Review Sheet when all the data and supporting documents are placed into the appropriate DRMS data set notebook. The representative then returns the draft document and review sheet to the editor.

4.4.7 The editor sends draft to the SEPDB representative to ensure that appendices identifying candidate information for the SEPDB are considered for future entry. If draft sent to the SEPDB representative contains an acceptable appendix for the SEPDB comparison, the representative will sign the Department 6310 Manuscript Review Sheet, and the draft and sheet will be returned to the editor. If draft is unacceptable from this standpoint, the SEPDB representative will work with the monitor to solve the problems and produce an acceptable draft.

4.4.8 The editor sends the document to the RIB representative who examines it to see if data and assumptions agree with the Department RIB. If draft sent to the RIB representative contains an acceptable appendix for the RIB comparison, the representative will sign the Department 6310 Manuscript Review Sheet, and the draft and sheet will be returned to the editor. If draft is unacceptable from this standpoint, the RIB representative will work with the 6310 contact to solve the problems and produce an acceptable draft document.

4.4.9 The editor, after ascertaining that the manuscript is ready for line review, attaches the Department 6310 Technical Publication Checklist (Appendix C) and sends the packet to the monitor's division secretary.

4.4.10 Secretary prepares Review and Approval form (SF 1003) (Appendices D and E) and DRC sheet(s) that accompany the document

through remainder of Sandia review process and the transmittal letter* to DOE/YMP. Secretary gives DRC sheet(s), Review and Approval form, and document to division supervisor.

4.4.11 Division supervisor completes his review. After any problems are resolved with monitor and an acceptable draft document exists, supervisor signs Review and Approval form. Supervisor determines if the document has direct application to other DOE/YMP participant organizations. If so, the supervisor sends an information copy of the document to the TPO at appropriate organization(s).

4.4.12 If differences cannot be resolved between the monitor and a reviewer, the monitor's division supervisor may sign in lieu of the reviewer. If supervisor does this, he must document the unresolved differences and how he handled them; a copy must be sent to the Department 6310 QA coordinator and the reviewer involved.

4.4.13 Supervisor has division secretary send two copies of the document, Manuscript Review Sheet, Review and Approval form, and transmittal letter to Department 6310 secretary who "logs in" the document, files copies of the abstract and Manuscript Review Sheet, and gives document and forms to 6310 manager.

4.4.14 Department 6310 manager examines the document. If it is satisfactory, he has department secretary send one copy of the draft document and transmittal letter to DOE/YMP for "policy review."

4.4.15 DOE/YMP performs policy review and returns any comments to Department 6310 manager. Secretary updates log and files a copy of NVO/YMP comments and/or approval letter. Items requiring resolution are forwarded to monitor.

4.4.16 After DOE/YMP comments are resolved and a revised draft is prepared (if necessary), reviews are conducted by 6310 Department Manager and 6300 Director. The document, together with the Review and Approval form, is sent through remaining review steps--classification, DOE Albuquerque Operations patent/legal office, and publication policy reviews.

4.4.17 Document and forms are returned to appropriate division secretary who notifies monitor that document has final approval. Secretary forwards original manuscript and all forms and letters to editor to arrange for printing. Before the document is printed, the editor will work with the monitor to ensure that the contractor concurs with all changes made to the document as a result of the review process. If document is a

---

*If applicable, the transmittal letter to DOE/YMP shall contain the sentence: "This draft document satisfies Milestone #_____."

journal article, conference paper, or abstract, secretary forwards manuscript to contract monitor who then sends it to the contractor for submission to appropriate place; at same time secretary sends a copy of the manuscript and original forms to editor.

4.4.18 Department 6310 secretary notes in log when a printed copy of a document is received.

4.4.19 After document is printed, editor transmits copy of SAND report and all forms, letters, and DRC sheet(s) (all QA levels) to SNL RMS for filing.

4.5 Letter Reports (SLTRs)

4.5.1 A Letter Report (SLTR) is miscellaneous documentation that must be formally entered into the Records Management System and be made available expeditiously to DOE/YMP personnel and their contractors without going through the longer review and publication process required for SAND reports. SLTRs may be in various formats: engineering memos, correspondence, test data, etc., and should represent results of DOE/YMP activities such as design, analysis, or planning activities and/or other technical work.

4.5.2 SLTRs will be assigned numbers and logged by the Department 6310 editor.

4.5.3 An SLTR must be reviewed by two independent technical reviewers chosen by the author with the division supervisor's approval. DRC sheet(s) (Appendix F) shall be completed to document comments and resolutions. The independent technical reviewers will sign the Department 6310 Letter Report Review Sheet (Appendix B). The SLTR is then routed through DRMS, SEPDB, and RIB reviews. Finally it is reviewed by the division supervisor who signs the Letter Report Review Sheet. An editorial review is optional.

4.5.4 SLTRs will be archived in the Department 6310 Records Management Center, together with the Letter Report Review Sheet and any other supporting documentation.

4.5.5 SLTRs are not referenceable in SAND documents.

5.0 RECORDS MANAGEMENT

QA documents identified in this DOP are: (1) the Department 6310 Manuscript Review Sheet (Appendix A), (2) the Department 6310 Letter Report Review Sheet (Appendix B), (3) the SAND or SLTR document itself, (4) technical reviewer comments for all Quality Levels, (5) the Review and Approval forms (Appendices D and E), and DRC sheets (Appendix F). All are filed with the

documents they accompany and come under the codfng index for that document per the Master Index for Department 6310 Records Management System.

6.0 REFERENCES

Other procedures necessary for implementation of this document include:

DOP 2-6, Qualification and Certification of Project Personnel
DOP 3-13, Technical Reviews of Documents
DOP 3-12, Peer Reviews

7.0 APPENDICES

Appendix A Department 6310 Manuscript Review Sheet

Appendix B Department 6310 Letter Report Review Sheet

Appendix C Department 6310 Technical Publication Checklist

Appendix D Review and Approval for Release/Distribution of Official Sandia Reports

Appendix E Review and Approval Journal Articles, Conference Papers, Presentations (Oral or Written)

Appendix F Document Review and Comment Sheets

RRB
1/3/87

Appendix A

DEPARTMENT 6310 MANUSCRIPT REVIEW SHEET

Case No._____

Appendix A
to DOP 6-2
(Revised 08/18/86)

SAND _____ Date _____

Title _____

_____

Author(s) and Organization(s) _____

_____

If contractor report, name of Sandia contract monitor and organization _____

If author from outside 6310, name of Dept. contact _____

Type of Manuscript:
( ) SAND Report
( ) Journal Article _____
(name of journal)
( ) Conference/Meeting Abstract or Paper _____
(name of Conf./meeting)

Attach your comments, initial below, and return the package to the author/contract monitor/contact by _____. If you cannot complete your review by this date, please contact the author/monitor/contact as soon as possible. Do not complete the signature block until your comments and suggestions are resolved to your satisfaction; your signature indicates your final approval.[a] All signatures and other entries must be in black indelible ink.

[b] Ind. tech. reviewer _____ Org. _____ Initials _____
Signature (final approval): _____ Date: _____

[c] Ind. tech. reviewer _____ Org. _____ Initials _____
Signature (final approval): _____ Date: _____

[d] Editorial reviewer _____ Org. _____ Initials _____
Signature (final approval): _____ Date: _____
( ) Editorial review not required _____
Division supervisor signature

[e] QA reviewer _____ Org. _____ Initials _____
Signature (final approval): _____ Date: _____

The manuscript has been reviewed by a Data Records Management System (DRMS) representative. All appropriate data and testing information have been provided to and placed into the DRMS.

Data Set ID _____ Signature: _____ Date: _____

_____

The manuscript has been reviewed and approved for conformance with the Site Engineering Properties Data Base and the Reference Information Base.

SEPDB
Signature: _____ Date: _____

RIB
Signature: _____ Date: _____

Records Management System (DRMS) index code

Appendix B

DEPARTMENT 6310 LETTER REPORT REVIEW SHEET

Case No._____

Appendix B
to DOP 6-2
(Revised 08/15/88)

SLTR[a] _____ Date _____

Title _____

_____

Author(s) and Organization(s) _____

_____

PI/Contract Monitor/Contact (if applicable) _____

Attach your comments, initial below, and return the package to the author/monitor/contact by _____. If you cannot complete your review by that date, please contact the author/monitor/contact as soon as possible. Do not complete the signature block until your comments and suggestions are resolved to your satisfaction; your signature indicates your final approval. All signatures and other entries must be in black ink.[b]

[c] Ind. tech. reviewer _____ Org. _____ Initials _____

Signature (final approval): _____ Date: _____

[d] Ind. tech. reviewer _____ Org. _____ Initials _____

Signature (final approval): _____ Date: _____

[e] QA Reviewer _____ Org. _____ Initials _____

Signature (final approval): _____ Date: _____

Division Supervisor _____ Org. _____ Initials _____

Signature (final approval): _____ Date: _____

This Letter Report has been reviewed by a Data Records Management System (DRMS) representative. All appropriate data and testing information have been provided to and placed into the DRMS.

Data Set ID _____ Signature: _____ Date: _____

This Letter Report has been reviewed and approved for conformance with the Site Engineering Properties Data Base and the Reference Information Base.

SEPDB
Signature: _____ Date: _____

RIB
Signature: _____ Date: _____

[f] Records Management System (RMS) index code _____

Milestone number _____ Precursor for Level 1 Milestone _____

[a] To be assigned by Dept. 6310 Editor.
[b] If differences cannot be resolved between the primary author/PI/contract monitor/contact and the independent technical reviewers, the division supervisor of the author/monitor may sign in lieu of reviewers
[c] Should be PI, contract monitor/contact, or designee (for externally generated reports).
[d] To be chosen by division supervisor and should be someone outside of the division wherever possible.
[e] For Sandy Plain only.
[f] To be assigned by author/PI/contract monitor/contact.

Note. Neither independent technical reviewer should have been directly involved with the acquisition or interpretation of data reported in the manuscript.

PAR 10/85

Appendix C

DEPARTMENT 6310 TECHNICAL PUBLICATION CHECKLIST

TO: 1. _____, 63__ SAND_____
2. J.E. Stiegler, Actg., 6310

FROM: Carl Mora, 6311

DATE:

I have examined the technical report or other publication attached. It appears to be ready for your action. The following are noted:

_____ SAND number is correct.
_____ Is logged into the 6310 document tracking system.
_____ Independent technical review signoff sheets included.
_____ Correct review and approval form is included.
_____ Includes two appendices for RIB and SEPDB.
_____ The document has been reviewed for consistency with the RIB.
_____ The document has been reviewed for SEPDB candidate information.
_____ Has received an editorial review.
_____ Latest YMP standard distribution list enclosed, along with other distribution required by Sandia and suggested by author or monitor.
_____ If 6310 has seen the publication previously and requested changes, a copy of the request is included, and the current version of the document with all changes incorporated is included.
_____ The document does - does not (circle one) represent a milestone. If it does, the milestone number is _____ and the number has been noted on the NVO policy letter. Precursor for Level 1 milestone_____.
_____ A DRMS data set is - is not documented. If so, the data set identification is _____. B. M. Schwartz (6313) has been added to the distribution list, and all appropriate information provided to and accepted into the Data Records Management System.
_____ Accession numbers have been requested from NVO; references obtained, if required.
_____ Supporting input documents (SLTRs, DIMs, PDMs) identified.
_____ Quality level of activities identified.

THE FOLLOWING ITEMS SHOULD BE COMPLETED BY SUPERVISOR BEFORE SENDING TO DEPARTMENT 6310 MANAGER:

_____ Policy review letter to NVO is included. (If abstract or conference paper, state name, dates, and location of conference. If journal article, include name of journal.) Send information copies w/cy of transmittal letter to Max Blanchard, Larry Skousen, T&MSS TISD (SAIC), and a copy of the transmittal letter only to T&MSS Configuration Management Division (SAIC). For milestone documents, include copy of milestone sheet and add following to NVO policy review letter: "This draft document satisfies Milestone No. _____."

_____ The division supervisor named at the top of this form has examined the document to determine if it has direct application to other YMP participant organizations. It _____ does not have such application, and no information copies have been sent. It _____ does have such application, and an information copy has been sent to the TPO at the following organizations:
LANL _____, LLNL _____, USGS _____, SAIC _____ other _____

Appendix D

Do not enter Classified Information

REVIEW AND APPROVAL FOR RELEASE/DISTRIBUTION OF OFFICIAL SANDIA REPORTS

Use yellow form SF 1003-MF for journal articles, conference papers, and presentations.

1. IDENTIFICATION

Control Number _____ DOE Distribution Category Number _____ Case No. _____ Date _____

Unclassified Title _____

2. CLASSIFICATION LEVEL, CATEGORY AND EXTRA MARKINGS (To be completed by originating organization)

Title _____ Abstract _____ Total Report _____ Authorized Classifier _____

(Check when applicable) ☐ NWD ☐ Sigma ___ ☐ CNWDI Org. _____ Date _____

(Complete when applicable) ☐ NSI Declassify/Downgrade on _____

3. SPECIFIC CONTENTS REQUIRING ADDITIONAL APPROVALS *(see instructions on back of form)*

Unclassified controlled access information ☐ No ☐ Yes

Unclassified computer software ☐ No ☐ Yes

4. LIMITATIONS ON DISTRIBUTION State reason for limitation: _____

☐ **Unlimited Release**
In my judgment the unlimited release of the information in this document is not detrimental to the best interests of the United States.

☐ **Specified External Distribution Only**
Only those recipients external to SNL as listed under "Distribution" are authorized to receive copies of this document. They are not authorized to further disseminate this information without permission from the originator.

☐ **Internal Distribution Only**
This document is to be distributed within Sandia National Laboratories only.

Signature _____ (Author) Org. _____ Date _____

5. LINE SIGNATURES/APPROVALS THROUGH DIVISION

Author	E No.	Division Supervisor	Org.	Date

6. CLASSIFICATION REVIEW 3180 (8024)

Signature/Initials _____ Date _____

7. PATENT/LEGAL REVIEW 4050 (8024)

Patent Interest: ☐ no ☐ yes Signature/Initials _____ Date _____

8. PUBLICATION POLICY REVIEW 3151 (8265)

Signature/Initials _____ Date _____

9. LINE DEPARTMENT AND DIRECTOR APPROVAL

Department	Org.	Date	Department	Org.	Date
Director	Org.	Date	Director	Org.	Date

10. SPECIAL APPROVALS/CHECKS

11. COMPLETED FORM — In Albuquerque, return completed form to Division 3151 so that DOE reporting can be processed. In Livermore, include this form with the copies sent to 8265.

1/3/8

Appendix E

of research — *Do not enter classified information.*

Review and Approval
Journal Articles, Conference Papers, Presentations (Oral or Written)

1. IDENTIFICATION

Control Number _____ Case Number _____ Date _____

Send 3 Copies of Unclassified "C" cutfield material to Division 3151

Unclassified Title _____

Proposed for Publication in _____ (Name of Journal)

Proposed for Presentation at _____ (Name of meeting, conference, or symposium)

Date of Meeting _____ Location _____ Sponsoring Org _____

2. CLASSIFICATION LEVEL, CATEGORY AND EXTRA MARKINGS (To be completed by originating organization)

Title _____ Abstract _____ Manuscript _____ Authorized Classifier _____

(Check when applicable) ☐ NWD ☐ Sigma ___ ☐ CNWDI Org _____ Date _____

(Complete when applicable) ☐ NSI Declassify/Downgrade on _____

3. SPECIFIC CONTENTS REQUIRING ADDITIONAL APPROVALS *(see instructions on back of form)*

Unclassified controlled access information ☐ No ☐ Yes

Unclassified computer software ☐ No ☐ Yes

4. LIMITATIONS ON DISTRIBUTION State reason for limitation: _____

☐ **Unlimited Release**
In my judgment the unlimited release of the information in this document is not detrimental to the best interests of the United States

☐ **Specified External Distribution Only**
Only those recipients external to SNL as listed under "Distribution" are authorized to receive copies of this document. They are not authorized to further disseminate this information without permission from the originator.

☐ **Internal Distribution Only**
This document is to be distributed within Sandia National Laboratories only.

Signature _____ (Author) Org _____ Date _____

5. LINE SIGNATURES/APPROVALS THROUGH DIVISION

Author	E No.	Division Supervisor	Org.	Date

6. CLASSIFICATION REVIEW 3180 (8024)

Signature/Initials _____ Date _____

7. PATENT/LEGAL REVIEW 4080 (8024)

Patent Interest: ☐ no ☐ yes Signature/Initials _____ Date _____

8. DEPARTMENT AND DIRECTOR APPROVAL

Department	Org	Date	Department	Org	Date
Director	**Org**	**Date**	**Director**	**Org**	**Date**

9. SPECIAL APPROVALS/CHECKS

Signature _____ Date _____

10. TECHNICAL PUBLICATIONS REVIEW 3151 (8265)

☐ Abstract Release ☐ Full Paper Release

If full paper is preferred, it must be approved and reviewed before release.

Initials _____ Date _____

11. COMPLETED FORM — Return completed form to Division 3151 (8265)

RAL
1/3/67

Appendix F

SNL NWRT DEPARTMENT
DOCUMENT REVIEW AND COMMENT FORM

[1]Document Title:	[2]Document Number:	[3]Rev:

[4]Author/Review Requester:

[5]Independent Technical Reviewer: _____ [6]Organization: _____

[7]Requested Scope of Review/Criteria:

[8]Comment Location: _____ [9]Cmt. No. _____

[10]Comment:

[11]Resolution:

[12a]Accepted:		[12b]Not Accepted:	
Reviewer	Date	Reviewer	Date

Appendix F (concluded)

DOCUMENT REVIEW AND COMMENT FORM

Instructions

A. Document author or person requesting document review will complete blocks 1 through 7. Author/Requester will provide the Document Review and Comment (DRC) form, along with the document to be reviewed, to the independent technical reviewer (ITR).

B. ITR will review the subject document, applying criteria as noted in block 7. Comments will be recorded in blocks 8 through 10, one comment per DRC sheet. Return the DRCs to the author/requester.

C. Author or other person designated to resolve comments will develop resolutions which address the comments, and record them in block 11.

D. ITR will indicate acceptance or non-acceptance of comment resolution in block 12a or 12b. In the case of nonacceptance, additional information should be attached indicating reason for nonacceptance.

E. When completed, this form should be entered into the Records Management System by the author or review requester.

SANDIA NATIONAL LABORATORIES
NUCLEAR WASTE REPOSITORY TECHNOLOGY
DEPARTMENT OPERATING PROCEDURE

QUALIFICATION AND CERTIFICATION OF PROJECT PERSONNEL

Page	1	2	3	4	5	6
Revision	B	B	B	B	B	B

Author: Richard M. Baehr — SNL Author — 3/22/89 — Date

Approved: N/A — SNL Division Supervisor — Date

Approved: R R Richards — SNL QA Coordinator — 3/23/89 — Date

Approved: N/A — SNL NWRT Department Manager — Date

This revision consists of a minor, editorial changes. RR 3/23/89

SNL DEPARTMENT 6310
CONTROLLED DOCUMENT

Copy Number: 006

RETURN TO SNL 6310 RECORDS CENTER
WHEN NO LONGER NEEDED

1.0 Purpose

The purpose of this Department Operating Procedure (DOP) is to state the action(s)/requirement(s) necessary to determine the qualifications of YMP/NWRT personnel and to certify such personnel performing or verifying activities affecting quality.

2.0 Scope

The requirements of this DOP are applicable to personnel performing or verifying Quality Level I or II tasks. The Quality Level of tasks are identified in Quality Level Assignment Sheets recorded for such WBS elements. These requirements apply to all personnel assigned to perform and/or verify activities affecting quality, specifically including independent technical reviews, design verification, receipt inspection of non-Q-list items, and surveillance. Additional specific qualification requirements apply to "special processes," audit personnel, inspection and test personnel, and nondestructive examination personnel.

3.0 Definitions

See Appendix A of SNL NWRT QA Program Plan.

4.0 Qualification Requirements

4.1 Personnel Performing Technical or QA Functions

For personnel having position descriptions of either supervisor, task leader, principal investigator, or supporting staff, certification is required prior to the performance of technical functions affecting quality and/or performing QA functions. The following are the minimum qualifications for each of these job titles:

4.1.1 Supervisor/Manager. A supervisor or manager shall have the same minimum academic requirements, as determined by the SNL NWRT Department Manager, prescribed for a task leader. They will have the appropriate technical experience to manage the individuals performing technical functions affecting quality within their division. A supervisor will have actual management experience or demonstrated potential to perform project management functions as determined by the SNL NWRT Department Manager to assure that quality objectives can be achieved by the division staff.

4.1.2 Task Leader. A task leader will be designated from the SNL NWRT staff by the Technical Division Supervisor for each WBS element. They must have an academic background in a technical area that provides the basic concepts of mathematics, engineering, and the physical sciences to manage the task. The academic degree should

be related to the technical content of the task in the judgement of the designating technical supervisor or sufficient related technical experience must be demonstrated. Minimum degree requirements will be commensurate with those of the SNL position classification (MTS, MLS, TSA, etc.), established for the position. The initial hiring of the staff, the selection of staff for new or vacant positions, and the training of staff will be done by the supervisor in such a way to assure that individuals selected as task leaders have the commensurate academic background.

4.1.2.1 Task leaders will have appropriate technical experience for the tasks being performed. Actual project management experience or demonstrated potential to perform project management functions will be required in related technical activity. The supervisor will determine that the technical experience of the task leader is sufficiently related to the technical content of the task. Similarly, the supervisor will determine that the project management experience is sufficient to assure that quality objectives can be achieved.

4.1.3 Principal Investigator. Principal investigators (PI) will be designated from the SNL NWRT staff by the Technical Division Supervisor. PIs will generally be responsible for a major portion or all of an activity or task within a WBS element. The academic and experience requirements will be similar to that of task leaders, except that the level of project management experience does not need to be as extensive because the scope of a specific task is not generally as broad as that of an entire WBS element.

4.1.4 Supporting Staff. Various staff will be assigned to support principal investigators and task leaders. They must have an academic background or the equivalent in experience and practice in a technical area that provides the basic concepts of mathematics, engineering, and the physical sciences. The academic degree should be related to the technical content of the task in the judgement of the designating supervisor or sufficient related technical experience must be demonstrated. Minimum degree requirements will be commensurate with those of the SNL position classification (MTS, MLS, STA, etc.) established for the position. The initial hiring of staff, the selection of staff for new or vacant positions, and the training of staff will be done by the supervisor in such a way to assure that individuals designated as supporting staff have the commensurate academic backgrounds.

4.1.4.1 Supporting staff will have appropriate technical experience for the tasks being performed. The supervisor will determine that the technical experience is sufficiently related to technical conduct of the task. Project management experience is not a requirement for supporting staff personnel.

4.2 Personnel performing audits will be qualified and certified in accordance with QAP 2-7.

4.3 Personnel performing inspections, tests, and nondestructive examinations will be qualified and certified in accordance with Appendices B and C of NNWSI/88-9. While no such personnel are members of the SNL NWRT Department, qualification requirements will be implemented, as necessary, in procurement documents for suppliers.

4.4 Personnel performing special processes shall be qualified and certified in accordance with applicable codes, standards or other specifications. While no such personnel are members of the SNL NWRT Department, these qualification requirements will be implemented, as necessary, in procurement documents.

5.0 Personnel Selection and Periodic Evaluation

5.1 The supervisor assigned responsibility for the activities to be performed or verified shall select personnel with education and experience commensurate with the minimum requirements specified for the job in the SNL established position description. (The SNL Personnel Department verifies the education and experience of personnel during the hiring process, then maintains records of the education and experience gained while employed by SNL. These records are utilized by supervisors in selecting personnel.) The capabilities of an individual shall be based upon an evaluation of the candidate's education, experience, and training, compared to those established for the position.

5.2 Prior to requiring personnel to perform or verify activities affecting quality, the division supervisor assigned responsibility for the WBS activities to be performed shall ensure that those personnel are familiarize in the principles, techniques, QA Program, technical objectives, and requirements of the WBS activities being performed or verified (see SNL NWRT QAP 2-5). The supervisor shall so certify by signing the certification document (see Form DOP 2-6 (1)). Personnel reassigned within the YMP/NWRT Project shall be certified for their new assignments.

6.0 Documentation of Certification

The certification of personnel shall be documented on form DOP 2-6 (1) and include the following information: (see Appendix A)

a. Employer's name
b. Name of person being certified
c. Title or job function
d. Tasks certified for
e. Restriction or limitation to the certification

f. Education
g. Experience
h. Record of familiarization, including QA instruction
i. Date of certification
j. Expiration date (last day of month one year from date of certification)
k. Signature of division supervisor and department manager

This information shall be recorded on form DOP 2-6(1) with the signature of the responsible division supervisor and the signature of the NWRT department manager providing certification for project personnel. This certification document will be filed in the SNL Records Management System.

7.0 Recertification

The job performance of personnel who perform or verify activities important to quality shall be evaluated at least annually. This evaluation shall be performed by supervision assigned responsibility for the activities to be performed or verified and shall determine whether adequate proficiency has been maintained. The evaluation shall determine the need for additional training, retraining or replacement. The evaluation is conducted by the division supervisor with the concurrence and participation of the NWRT department manager. This evaluation is used in determining the eligibility for recertification of the individual.

If training is required, the supervisor shall arrange for completion of such training. Initiation of a new form DOP 2-6(a) shall serve to document that the evaluation required above has occurred and to recertify each individual. Supervisors shall initiate these documents.

8.0 Records

Completed certification forms and related documents are QA records and will be filed in the SNL NWRT Records Management System under the appropriate file codes. The current Master Listing of File Codes should be used to determine the proper file code.

9.0 Appendices

A. Certification of Qualifications Form (Form DOP 2-6(1)).

APPENDIX A

FORM DOP 2-6(1)

CERTIFICATION FOR YMP/NWRT PERSONNEL

Employer: _____

Name: _____

Job Title	WBS Element	PCA	PCA Title

Restrictions: _____

Basis for Certification:

Education and Experience Applicable to Job Function (resumes, etc. may be attached)

Education: _____

_____

Experience: _____

_____

_____

I certify that the above information is factual and understand it may become part of the public record.

_____ _____

Employee Date

Training: The subject individual has been familiarized in the purpose, scope, technical objectives, and requirements of the activities to be performed and instructed in the SNL NWRT QA Program, that is, the subject individual has completed an NWRT Project Familiarization Program.

_____ _____

Division Supervisor (Dept. 6310) Date

Based on the above record and information described in DOP 2-6, _____ _____ is qualified to perform or to verify activities that affect quality, including conducting independent technical reviews, participating in design verification, and performing surveillances in the above and related activities.

_____ _____

Department Manager 6310 Date

Date Certification Expires _____.

6310 _____
Division Supervisor

6310 R. M. Baehr
6310 90/1293/CRT/01
6310 YMP CRF

Enclosure 6: USGS Procedures for Technical Review; Certification of USGS and USGS Contractor Personnel for the NNWSI Project; and Study Plan Preparation

United States Department of the Interior
GEOLOGICAL SURVEY
BOX 25046 M.S. 421
DENVER FEDERAL CENTER
DENVER, COLORADO 80225

IN REPLY REFER TO

November 9, 1987

Memorandum

To: Bob Raup, Geologic Division, MS 913
William Wilson, Chief, Nuclear Hydrology Program, MS 421
David Harris, U.S. Bureau of Reclamation

From: Larry R. Hayes, Chief, Branch of NNWSI, MS 421

Subject: Study Plan Desk Procedure

The attached desk procedure for preparing draft study plans will become effective November 16. The procedure was prepared by Bill Langer (Branch Staff) and Dave Schleichar (GD), and has been informally reviewed by Martha Mustard (QA Office) and Bill Wilson (NHP). Any concerns you may have should be resolved with Bill Langer before the effective date. Please insure that all personnel under your purview who are responsible for preparing study plans, have a copy of this procedure.

Larry

Larry R. Hayes

Enclosures

cc: Carl Gertz, Project Manager, WMPO
Jack Fisher, ACH PC&TS
Joe Willmon, USGS QA Manager
Bob Wise, SAIC, Golden

LRH/WHL/jml

USGS STUDY PLANS--DESK PROCEDURE

1. PURPOSE. The USGS is required to prepare draft study plans as input to WMPO study plans. This document specifies USGS procedures for preparing, reviewing and approving those study plans before they are submitted to the Waste Management Project Office (WMPO). The purpose of this procedure is to ensure that the study plans are technically sound and well presented and that they meet the goals of the NNWSI Project.

2. SCOPE OF COMPLIANCE. These procedures apply to all study plans prepared by the USGS and to all USGS contributors to study plans prepared by other NNWSI participants. All investigators and their management responsible for these study plans shall comply with this procedure.

3. DEFINITION.
DIVISION COORDINATOR: The Chief, Nuclear Hydrology Program for the geohydrologic studies, and the Geologic Division NNWSI Coordinator for the geologic studies.

4. RESPONSIBILITIES.

4.1 The Chief, Branch of NNWSI, or his designee ensures that each study plan complies with overall project planning and that it complies with this procedure before it is transmitted to WMPO. He is also responsible for transmitting the study plan to WMPO. The Chief may delegate any or all of these responsibilities.

4.2 Division Coordinators are responsible for identifying necessary study plans and to inform the Chief, Branch of NNWSI of these study plans. They appoint study plan originators and technical reviewers for each study plan, and ensure that the study plans have been reviewed and revised as necessary for technical adequacy. They ensure that changes to the study plan resulting from the HQ review are adequately addressed, and if necessary, that the study plan is re-reviewed in regards to these changes. They ensure that the study plan originator and the technical reviewers have had appropriate training. Division coordinators may delegate any or all of these responsibilities.

4.3 The study plan originator prepares the study plan, submits it for review, and revises it on the basis of technical review comments.

4.4 The technical reviewer reviews the study plan for technical adequacy and documents the review.

5. PROCEDURE.

5.1 The study plan is prepared, reviewed, and approved for transmittal to WMPO in the following way:

5.1.1 The study plan originator develops the study plan containing the information called for in attachment B of attachment 4 of the May 7-8, 1986, agreement between DOE/HQ and the NRC (attached). The study plan should be in the format shown in the attached outline. The study plan is assigned the number and title that identify the study in the SCP; each revision of the study plan is assigned a unique number starting with Revision Ø. The study plan is covered by a signature sheet (similar to that attached) bearing the same number as the study plan.

5.1.2 The originator(s) and the principal investigator(s) (if other than the originators).sign and date the signature sheet indicating approval of their sections of the study plan and submit the study plan to their division coordinator for technical review.

5.1.3 The division coordinator assigns the study plan to one or more technical reviewers. The technical reviewer may be any qualified individual(s) other than those who developed the original study plan. The review shall be documented in accordance with NNWSI-USGS-QMP-3.07, or its equivalent NNWSI-USGS-AP.

5.1.4 The technical reviewer(s) either (a) sign and date the signature sheet to indicate their recommendation that the study plan be approved with minor revision or (b) initial and date the signature sheet to indicate their recommendation that the study plan be approved only after significant revision. The reviewer(s) then return the study plan, the signature sheet, and the review comments and suggested revisions to the division coordinator.

5.1.5 The division coordinator assesses the adequacy of the technical review. He then either returns it to the originators, or returns the study plan to the reviewer(s) for further review.

5.1.6 The originator(s) address all major comments beyond inconsequential editorial changes, sign and date the signature sheet, and return the revised study plan, the signature sheet, the review copy of the study plan, and the reviewer's comments to the division coordinator.

5.1.7 The division coordinator reviews the revised study plan to ensure that the study plan addresses program needs and to ensure that the originators have adequately responded to the technical review(s). He then either signs and dates the signature sheet and transmits the revised study plan and the signature sheet to the Chief, Branch of NNWSI, or returns the study plan to the originators for further revisions. Review and approval procedure for revisions to the study plan is identical to that for the original study plan.

5.1.8 The Chief, Branch of NNWSI reviews the study plan for compliance with overall Project planning and requirements and for compliance with this procedure. He then either signs and dates the signature sheet and forwards the study plan to WMPO for review and approval, or he returns the study plan to the division coordinator for further revisions. Review and approval procedure for the revisions to the study plan is identical to that for the original study plan. Signature sheets will be removed from approved study plans and retained by the Chief, Branch of NNWSI, before transmittal to WMPO.

5.2 After the study plan is reviewed by DOE, it may be returned to the USGS with comment response forms suggesting changes.

5.2.1 Upon receipt of review comments from the DOE review, the Chief, Branch of NNWSI reattaches the signature sheet and returns the study plan and comments to the appropriate division coordinator. The division coordinator returns the study plan and comments to the appropriate study plan originator(s).

5.2.2 After resolution of the comments, the originator(s) sign and date the signature sheet and submit the revised study plan to their division coordinator.

5.2.3 The division coordinator determines if the HQ review comments are adequately addressed. If the comments are adequately addressed, the division coordinator determines if the changes merit a second USGS review. If a review is deemed necessary the revised study plan follows the procedures outlined in sections 5.1.3 through 5.1.7. If a review is not necessary, the division coordinator signs and dates the signature sheet and forwards the study plan to the Chief, Branch of NNWSI. If the changes are not adequate he returns the study plan to the originator(s).

5.2.4 The Chief, Branch of NNWSI processes the study plan as described in section 5.1.8.

5.3 Quality assurance level assignments (QALA) are to be prepared during the preparation of a SIP in accordance with NNWSI-USGS QMP-3.02 or its equivalent NNWSI-USGS-AP.

5.3.1 Because the QALA's are separately controlled documents, they may be incorporated in the study plan by referenced control number only.

5.4 Change Control - The study plan may be changed (revised) as needed following sections 5.1 and 5.2 of this procedure.

5.4.1 Study plans containing multiple activities may be prepared as separate revisions containing detailed discussions of one or more activities. As other activities are detailed, the study plan shall be resubmitted. The standing study plan prevails in all aspects until notice of approval of the revised study plan has been provided from WMPO.

5.4.2 All revisions to study plans follow the same procedures as original study plan.

TECHNICAL REVIEWER SELECTION FORM

(To be completed by the Geologic Division Branch Chief, NHP Chief, or Chief, Branch of YMP responsible for technical reviewer selection.)

Document to be reviewed:

_____

_____

_____

Selection of technical reviewer:

Name of reviewer: _____

Title of reviewer: _____

Employer of reviewer: _____

Basis of qualification for technical reviewer:

Position description
OR
Basis described below:

_____

_____

_____

_____

_____

Independence of reviewer (check one - second option requires QA Manager's approval):

( ) This technical reviewer is independent of the development of the document, under review.

( ) Although this technical reviewer is or has been indirectly involved in the development of the document, he/she is the only technically qualified person available.

_____

QA Manager's signature Date

_____

Printed Name Title

_____

Signature Date

TECHNICAL REVIEW FORM

[For each topic, technical reviewer indicates either satisfactory, major comments (to be attached), or not applicable. Technical personnel responsible for the document under review indicates acceptance or rejection of each major comment. Appropriate official (Geologic Division Branch Chief, NHP Chief, or Chief, Branch of YMP) assures justification for rejection is adequate.]

Document reviewed: _____

Topic	Satis-factory	Major Comments	Not Applic.	Comments Accept	Comments Reject
1. Are the assumptions adequately described and reasonable?					
2. Were appropriate concepts, methods, or techniques selected and used?					
3. Are requirements such as equipment, calibrations, etc. adequately addressed?					
4. If required, are limitations, qualitative or quantitative criteria, or holdpoints addressed?					
5. Does this document adequately and clearly state the output requirements such as records, reports, maps, data or other pertinent work products?					
6. Does the plan or procedure contain sufficient information such that it appears capable of meeting the objective and purpose stated?					
7. Other considerations (list): _____ _____ _____					

_____

Signature of technical reviewer Date

ATTACHMENT 4

DOE/NRC AGREEMENT ON
LEVEL OF DETAIL TO BE PROVIDED
IN THE SCP

Attachment B

DOE CONTENT REQUIREMENTS FOR DESCRIPTIONS OF STUDIES IN 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; specific program; investigation; study; tests and analyses; and test procedures. Details for studies and tests and analyses, listed in Chapter 8 of the SCP, will be presented in study plans. Study plans will be separate from the SCP proper and will be issued periodically throughout site characterization. Individual test procedures will be referenced in the study plans.

The following outline describes the information on studies, tests and analyses that will be presented in the study plans. A study may involve a single test or a set of tests and analyses, as appropriate. The tests include those measurements of physical parameters, or observations of physical phenomena, that are performed in the field or in the laboratory. Test activities include preparation of procedures, test set-up, conduct of the test, data acquisition, and data reduction. The analyses include those calculations or other evaluations needed to assess site characteristics and support design activities.

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

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

I. Purpose and Objectives of Studies:

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used; and
- Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1.) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2.) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3.) a direct Federal, State, and other regulatory requirements for specific studies. Where relevant

performance or design goals actually apply at a higher level than the study (e.g. where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

II. Rationale for Selected Study:

- Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and

- Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g. test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives, summarize reasons for not selecting these alternatives and reference, if available, reports which evaluate alternatives considered (refer to NRC Observation 8).

- Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:

  - Potential impacts on the site from testing;
  - Whether the study needs to simulate repository conditions;
  - Required accuracy and precision of parameters to be measured with test instrumentation;
  - Limits of analytical methods that will use the information from the tests;
  - Capability of analytical methods to support the study; and
  - Time required versus time available to complete the study.
  - The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field.
  - Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference.
  - Interrelationships involving significant interferance

among tests and exploratory shaft facility design and construction (as appropriate, refer to Section 8.4 of the SCP or its references for specific exploratory shaft facility design information such as design drawings or specifications) (refer to NRC Observation 4).

III. Description of Tests and Analyses:

- Since studies are comprised of tests and analyses, provide for each type of test:
  - Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g. spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units, depth, and test location);
  - Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;
  - Specify the tolerance, accuracy, and precision required in the test, where appropriate;
  - Indicate the range of expected results of the test and the basis for those expected results;
  - List the equipment required for the test and describe briefly any such equipment that is special;
  - Describe techniques to be used for data reduction and analysis of the results;
  - Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results; and
  - Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests.

- Relationship of the test to the set performance goals and confidence levels.

o For each type of analysis:

- State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

- Describe the methods of analysis, including any analytical expressions and numerical models that will be employed;

- Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses which are not judged to be QA level 1. Reference the applicable QA requirements;

- Identify the data input requirements of the analysis;

- Describe the expected output and accuracy of the analysis; and

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

IV. Application of Results:

o Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies);

o For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) which will use the information produced from the studies described above, and refer to any use of the results for model validation;

o For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

o For characterization uses, refer to, or describe, where the

OUTLINE FOR STUDY PLANS

1.0 Purpose of study (purpose and objectives of studies)

2.0 Rationale for selected study

3.0 Activity plan(s) (description of tests and analyses)

3.1 1st activity

3.2 2nd activity

etc...

4.0 Application of results

5.0 Schedule and milestones

SIGNATURE SHEET

NNWSI PROJECT
USGS DRAFT STUDY PLAN
TITLE
NUMBER

Study Plan Originators DATE

Technical Reviewer DATE

Division Coordinator DATE

Chief, Branch of NNWSI DATE

SECTION BELOW ONLY TO BE COMPLETED IF STUDY PLAN IS RETURNED FROM DOE WITH COMMENT RESPONSE FORMS

Study Plan Originator(s) DATE

Technical Reviewer (if necessary) DATE

Division Coordinator DATE

Chief, Branch of NNWSI DATE

UNCONTROLLED

MANAGEMENT PROCEDURES MANUAL

CHAPTER 3 - SCIENTIFIC INVESTIGATION AND DESIGN CONTROL

SECTION 7 - TECHNICAL REVIEW PROCEDURE

1. PURPOSE. This procedure defines the requirements for performing and documenting technical reviews of the YMP USGS technical procedures and plans governed by the YMP-USGS Quality Assurance (QA) Program.

2. SCOPE OF COMPLIANCE. This procedure applies to the technical review of technical procedures and plans governed by the YMP-USGS QA Program. It does not apply to the review of USGS publications governed by QMP-3.04.

3. DEFINITIONS. None.

4. RESPONSIBILITIES.

4.1 The NHP Chief, the Geologic Division Branch Chiefs, and the Chief, Branch of YMP are responsible for the selection of qualified, independent technical reviewers of procedures and plans generated within their organizations, including their subcontractors. They also are responsible for settlement of comment resolution disputes.

4.2 The Quality Assurance (QA) Manager is responsible for approval of a technical reviewer's selection if that individual has been indirectly involved in the development of the document under review.

5. PROCEDURE.

5.1 Selection of Technical Reviewers: Qualified technical reviewers shall be selected by the appropriate official (Geologic Division Branch Chief, NHP Chief, or the Chief, Branch of YMP). This selection, including the reviewer's qualifications, and independence of the work to be reviewed, shall be documented on the Technical Reviewer Selection Form (Attachment 1) and signed by the selecting official. If the technical reviewer selected is, or has been, indirectly involved in the development of the document under review, the QA Manager's approval is required.

5.2 Documentation of Technical Review: The technical review shall be documented on the Technical Review Form (Attachment 2) and/or pertinent correspondence. The reviewer shall document his/her evaluation of the document under review in regard to each appropriate topic listed on the form. Comments shall be attached and designated either minor, indicating a suggestion or editorial comment, or major, indicating a comment requiring resolution.

5.3 Response to Technical Review: The technical personnel responsible for the document under review shall respond in writing to each major comment, clearly indicating acceptance of the comment or justification for rejection. Acceptance of comments may be documented by simply initialling the form; rejection of a major comment requires marginal notes, attached sheets, or separate correspondence.

QUALITY ASSURANCE MANUAL

CHAPTER 2 - QUALITY ASSURANCE PROGRAM

SECTION 3 - CERTIFICATION OF USGS AND USGS CONTRACTOR PERSONNEL FOR THE NNWSI PROJECT

1. PURPOSE. The purpose of this document is to describe the system used for the required certification of USGS technical, review, and staff personnel including USGS contractor personnel for the Nevada Nuclear Waste Storage Investigation Project of the USGS.

2. SCOPE OF COMPLIANCE. This procedure applies to all USGS technical, review and key staff personnel and to USGS contract employees who perform activities that affect the quality on the NNWSI Project.

3. POLICY. Personnel performing activities affecting quality shall be certified to show competence to perform their specific duties. The certification shall specify any restrictions and/or limitations to the certification and the documentation of certification shall identify the basis for certification.

4. RESPONSIBILITIES.

   4.1 Each technical, review and staff person performing activities NNWSI Project has the responsibility for completing the Personnel Certification USGS Nuclear Waste Management Project form (Attachment 1).

   4.2 The Branch or Unit Chief has the responsibility for reviewing and signing the completed Personnel Certification form(s) for each technical, review, and staff person in that Branch or Unit who is assigned responsibility on the NNWSI Project. This signature signifies the employee's certification.

   4.3 The Chief Branch of NNWSI has the responsibilty for signing the Personnel Certification form for those Branch or Unit Chiefs who require certification.

   4.4 The immediate functional supervisor of the QA Manager shall have responsibility for certifying the QA Manager.

5. PROCEDURE.

   5.1 Quality Assurance Training - Personnel assigned responsibility affecting quality on the NNWSI Project shall be given training in quality assurance as required by the USGS Quality Assurance Program Plan. Such training shall be documented and the documentation shall be filed in the QA Office per QMP 2.02 Indoctrination and Training.

   5.1.1 Receiving Inspection personnel shall also be qualified under this QMP. Appropriate criteria for certification of Receiving Inspection personnel include:

a) Employer's name;
b) Identification of person being certified;
c) Activities certified to perform;
d) Basis used for certification that includes such factors as:
   - Education, experience, and training (when necessary),
   - Test results (where applicable), and
   - Results of capability demonstration (i.e., visual acuity, colorblindness, etc.);
e) Results of periodic evaluation;
f) Results of physical examinations (when required);
g) Signature of employer's designated representative who is responsible for such certification; and
h) Dates of certification and certification expiration.

5.2 Certification Instructions for USGS Employees and Contractors - A USGS Nuclear Waste Management Project Personnel Certification form (see Attachment 1) shall be completed and signed by the Branch or Unit Chief for each technical, review and staff person in that Branch or Unit assigned responsibility affecting quality on Nuclear Waste Management projects.

5.2.1 The Branch or Unit Chief shall assess the qualifications as stated in comparison to the Chief's understanding of what minimum normal requirements are for the assigned task.

5.2.2 In the event the certification requires limitations or restrictions in capabilities or assigned scope of work, such limitations or restrictions shall be included on the Personnel Certification form.

5.2.3 The original of each form is sent to the USGS QA Office, and constitutes the required certification that the person is qualified to perform the assigned responsibilities.

5.2.4 If the Branch or Unit Chief requires certification, it is accomplished by the next higher supervisory level.

5.3 Certification Instructions for Fenix and Scisson (F&S) on USGS Work - The USGS Certification for Fenix & Scisson NNWSI Personnel form (see Attachment 2) shall be completed and signed by the supervisor (Senior Geologist) for each F&S person assigned responsibilities for the USGS assigned work or task.

5.3.1 The basic requirements of this procedure, with the exclusion of Para. 5.2 apply to completion of the F&S form. The original of this form shall be sent to the USGS QA Office. A copy shall be retained by F&S as evidence of the certification.

5.3.2 All provisions of this procedure apply to pertinent F&S employees except for the Paras. of 5.2.

5.3.3 Each individual shall have access to the completed certification form and shall be cognizant of the operations and procedures listed on the current certification.

5.4 Personnel Qualifications - Because each review, management or technical task requires specific qualifications, the technical, review, and staff personnel shall have work or educational experience or formal training in the area(s) to which they are assigned on the NNWSI Project. The certifying Chief (or supervisor for Fenix and Scisson) shall assure that documentation of pertinent education and work experience is included on the Personnel Certification form to provide support for the certification.

5.5 Recertification - Each certification shall be renewed yearly in January so long as an individual continues to participate in the Project. To recertify an individual, a Branch or Unit Chief (or supervisor for F&S) may simply complete a part of the Annual Recertification section of the original form, which will be sent to him for that purpose, provided:

a) The assigned job has not changed;
b) The credentials have not changed; and
c) The worker has demonstrated satisfactory job performance during the previous certification period.

In the event of a change in either the assignment or the credentials a new form shall be issued.

6. RECORDS MANAGEMENT. Records associated with this procedure shall be submitted to the USGS Records Processing Center in accordance with QMP-17.01. Records to be submitted include the completed Personnel Certification form.

7. REFERENCES. There are no references to materials external to this manual.

8. ATTACHMENTS.

Attachment 1. Personnel Certification USGS Nuclear Waste Management Project form.

Attachment 2. USGS Certification for Fenix & Scisson NNWSI Personnel.

9. EFFECTIVE DATE. This procedure shall become effective upon its approval as noted by completion of the following signatures.

NNWSI-USGS QA Manager	10/7/86 Date
Chief, Branch of NNWSI	10/7/86 Date
USGS Assistant Director For Engineering Geology	10/17/86 Date
Project Quality Manager DOE Waste Management Project Office	10/27/86 Date

PERSONNEL CERTIFICATION
USGS NUCLEAR WASTE MANAGEMENT PROJECT

This is to certify that _____, a _____
(Name) (Title)
_____ employed by the _____
is assigned to conduct and/or participate in scientific investigations, or to perform necessary duties associated therewith, for the NNWSI Project of the U.S. Geological Survey.

The following credentials of this investigator are pertinent to the NNWSI assignment for work in the area of _____

_____.

EDUCATION:

Degree/Cert.	Major	Date	Where

WORK EXPERIENCE:

From	To	Employer and description of work

Based on the above listed education, experience and the demonstrated performance of this individual, (i.e.; technical publications, papers, scientific contributions, etc.), I certify this employee for the assigned task(s).

CERTIFICATION: 1. _____ _____
Chief Date

_____
Branch or Unit

RECERTIFICATION:

2. _____ _____ 3. _____ _____
Chief Date Chief Date

_____ _____
Branch or Unit Branch or Unit

THIS CERTIFICATION IS VALID FOR ONE YEAR FROM DATE OF SUPERVISOR'S SIGNATURE

USGS CERTIFICATION FOR FENIX & SCISSON NNWSI PERSONNEL

This certifies that _____, a _____
(Name) (Title)
_____ employed by Fenix & Scisson is assigned to conduct and/or participate in scientific investigations, or to perform necessary duties associated therewith, for the NNWSI Project of the U.S. Geological Survey. Specific work assignment of operations, procedures or parts thereof pertinent to this certification are:

Procedure No.	Operation, task, or investigation title

The following credentials of this employee are pertinent to the NNWSI assignment for work as specified above.

EDUCATION:

Degree/Cert.	Major	Date	Where

WORK EXPERIENCE:

From	To	Employer and description of work

Based on the above listed education, experience and the demonstrated performance of this individual, (i.e.; technical publications, papers, scientific contributions, etc.), I certify this employee for the assigned task(s).

CERTIFICATION: (1)_____ _____
Supervisor (Sr. Geologist) Date

RECERTIFICATION:

(2)_____ _____ (3)_____ _____
Sr. Geologist Date Sr. Geologist Date

I hereby authorize the release of the above information as required by the NNWSI Program.

_____ _____
(Employee's Signature) Date

THIS CERTIFICATION IS VALID FOR ONE YEAR FROM DATE OF SUPERVISOR'S SIGNATURE

Enclosure 7: June 5, 1986, letter from Clanton to the project participants transmitting the DOE/NRC content requirements for Study Plans

SAIC/T & NSS
RECEIVED
JUN 05 1986
DUPLICATE

Department of Energy
Nevada Operations Office
P. O. Box 14100
Las Vegas, NV 89114-4100

JUN 05 1986

William W. Dudley, Jr., USGS, Denver, CO
Sheldon D. Murphy, F&S, Las Vegas, NV
Vincent Gong, REECo, Las Vegas, NV
Thomas O. Hunter, SNL, 6310 Albuquerque, NM
Donald T. Oakley, Los Alamos, NM
Lawrence D. Ramspott, LLNL, Livermore, CA
James P. Pedalino, H&N, Las Vegas, NV
James B. Wright, W, Mercury, NV
Michael E. Spaeth, SAIC, Las Vegas, NV

DEPARTMENT OF ENERGY (DOE) CONTENT REQUIREMENTS FOR DESCRIPTIONS OF STUDIES IN STUDY PLANS

A question about format and content for Scientific Investigation Plans (SIP) was raised at the May 21-22, 1986, Technical Project Officers (TPO) meeting. The Department of Energy/Headquarters (DOE/HQ) has established that the Site Characterization Plan (SCP) will provide an overall description and interpretation of the site characterization test program and that separate study plans will now provide the details of studies, tests, and analyses to be conducted as part of the test program. Formal guidance on content and format for the study plans has not been issued by DOE/HQ. However, an agreement has been reached with the Nuclear Regulatory Commission (NRC) (May 7-8, 1986, DOE/NRC meeting) on the appropriate level of detail to be provided in the study plans.

To facilitate preparation of the study plans, an outline is enclosed which reflects that agreement in terms of the content requirements, and prescribes a format for presenting the required information. DOE/HQ believes the content of SCP Section 8.3, together with the content of the study plans, as represented in this outline, is consistent with the requirements of the Annotated Outline for Section 8.3 and will provide the information requested by the NRC.

The enclosed outline, to a large degree, represents material furnished to DOE/HQ by the NNWSI Project. Basically, that outline, together with the information need write-ups in the SCP, still reflects the approach adopted by the NNWSI Project in late 1982. Generally, if the focus of written material is on an information need, it will be presented in the SCP. If the focus of the material is on specific testing, it will be presented in a study plan. We expect forthcoming DOE/HQ guidance to write study plans, not yet written, to a common format. We expect that the enclosed outline will become that guidance.

If you have any questions, please contact me or one of the Science Applications International Corporation (SAIC) staff.

Uel S. Clanton
Geologic Investigations Branch
Waste Management Project Office

WMPO:USC:1367

Enclosure:
As stated

cc w/encl:
V. J. Cassella, DOE/HQ (RW-22), FORS
P. L. Aamodt, Los Alamos, NM
A. E. Norris, Los Alamos, NM
D. T. Vaniman, Los Alamos, NM
M. S. Whitfield, USGS, Denver, CO
Parviz Montezar, USGS, Denver, CO
R. B. Scott, USGS, Denver, CO
W. L. Ellis, USGS, Denver, CO
R. M. Zimmerman, SNL, Albuquerque, NM
J. L. Yow, LLNL, Livermore, CA
D. B. Jorgenson, SAIC, Las Vegas, NV
M. D. Voegele, SAIC, Las Vegas, NV
M. D. Teubner, SAIC, Las Vegas, NV

ATTACH 4
DOE/NRC AGREEMENT OF MAY 7-8

DOE CONTENT REQUIREMENTS FOR DESCRIPTIONS OF STUDIES IN STUDY PLANS

The test program presented in Chapter 8 of the SCP will be subdivided into a hierarchy of increasing detail. The SCP test prog hierarchy will include (in increasing detail): generic program; specific program; investigation; study; tests and analyses; and tes procedures. Details for studies and tests and analyses, listed in Chapter 8 of the SCP, will be presented in study plans. Study plans will be separate from the SCP proper and will be issued periodicall throughout site characterization. Individual test procedures will b referenced in the study plans.

The following outline describes the information on studies, te and analyses that will be presented in the study plans. A study ma involve a single test or a set of tests and analyses, as appropriat The tests include those measurements of physical parameters, or observations of physical phenomena, that are performed in the field in the laboratory. Test activities include preparation of procedur test set-up, conduct of the test, data acquisition, and data reduction. The analyses include those calculations or other evaluations needed to assess site characteristics and support desig activities.

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

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

I. Purpose and Objectives of Studies:

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used; and
- Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1.) a performance goal and a confidence level in that goal (develope via the performance allocation process and results that will be described elsewhere in the SCP); 2.) a design goal and a confidence level in that goal (design goals beyond those relat to performance issues); 3.) a direct Federal, State, and other regulatory requirements for specific studies. Where relevant

performance or design goals actually apply at a higher level t the study (e.g. where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.]

II. Rationale for Selected Study:

- Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and

- Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g. test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives, summarize reasons for not selecting these alternatives and reference, if available, reports which evaluate alternatives considered (refer to NRC Observation 8).

- Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:

  - Potential impacts on the site from testing;
  - Whether the study needs to simulate repository conditions;
  - Required accuracy and precision of parameters to be measured with test instrumentation;
  - Limits of analytical methods that will use the information from the tests;
  - Capability of analytical methods to support the study; and
  - Time required versus time available to complete the study.
  - The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field.
  - Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference.
  - Interrelationships involving significant interference

among tests and exploratory shaft facility design and construction (as appropriate, refer to Section 8.4 of SCP or its references for specific exploratory shaft facility design information such as design drawings or specifications) (refer to NRC Observation 4).

III. Description of Tests and Analyses:

- Since studies are comprised of tests and analyses, provide for each type of test:
  - Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g. spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units, depth, and test location);
  - Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;
  - Specify the tolerance, accuracy, and precision required in the test, where appropriate;
  - Indicate the range of expected results of the test and the basis for those expected results;
  - List the equipment required for the test and describe briefly any such equipment that is special;
  - Describe techniques to be used for data reduction and analysis of the results;
  - Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results; and
  - Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests.

- Relationship of the test to the set performance goals and confidence levels.

o For each type of analysis:

- State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

- Describe the methods of analysis, including any analytical expressions and numerical models that will be employed;

- Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses which are not judged to be QA level 1. Reference the applicable QA requirements;

- Identify the data input requirements of the analysis;

- Describe the expected output and accuracy of the analysis; and

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

IV. Application of Results:

- Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, desi and characterisation studies);

- For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) wh will use the information produced from the studies described above, and refer to any use of the results for model validatio

- For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

- For characterisation uses, refer to, or describe, where the

information from the study described above will be used in planning other characterization activities.

V. Schedule and Milestones:

- Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing, data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;
- Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and
- Dates for activities or milestones, including durations and interrelationships, for the study plans will be provided. They should reference the master schedules provided in Section 8.5 of the SCP.

Copies to Cindy L.
Martha
Mike T.
Lynn H.

Department of Energy
Nevada Operations Office
P. O. Box 14100
Las Vegas, NV 89114-4100

SEP 02 1986

Lawrence D. Ramspott, LLNL, Livermore, CA
William W. Dudley, Jr., USGS, Denver, CO
Donald T. Oakley, LANL, Los Alamos, NM
Thomas O. Hunter, SNL, 6310, Albq., NM
Michael E. Spaeth, SAIC, Las Vegas, NV
James P. Pedalino, H&N, Las Vegas, NV
Vincent Gong, REECo, Mercury, NV
Sheldon D. Murphy, F&S, Las Vegas, NV
James B. Wright, W, Mercury, NV

CORRELATION OF DEPARTMENT OF ENERGY (DOE) CONTENT REQUIREMENTS FOR STUDY PLANS AND INVESTIGATIONS IN THE SITE CHARACTERIZATION PLAN

The attached enclosure (i.e. letter from Alexander, DOE, to Linehan, U.S. Nuclear Regulatory Commission (NRC), dated 8/11/86) describes DOE Headquarter's most recent revision of Attachment D of the DOE/NRC Agreement of May 7-8, 1986. This revised correlation chart is supposed to make Attachment D, B, C, and 4 of the May 7-8, 1986, Agreement consistent.

Maxwell B. Blanchard, Chief
Regulatory & Site Evaluation Branch
Waste Management Project Office

WMPO:MBB-1954

Enclosure:
As stated

cc w/encl:
V. J. Cassella, DOE/HQ (RW-221) FORS
M. D. Voegele, SAIC, Las Vegas, NV
J. L. Younker, ~~WMPO, DOE/NV~~ SAIC
D. L. Vieth, WMPO, DOE/NV
M. P. Kunich, WMPO, DOE/NV
U. S. Clanton, WMPO, DOE/NV
D. E. Livingston, WMPO, DOE/NV

Enclosure 8: Letters providing the project participants additional guidance on the content requirements for Study Plans

Copies to Cindy L 9/2/86 Martha Mike T Lynn H

Department of Energy
Nevada Operations Office
P. O. Box 14100
Las Vegas, NV 89114-4100

SEP 02 1986

Lawrence D. Ramspott, LLNL, Livermore, CA
William W. Dudley, Jr., USGS, Denver, CO
Donald T. Oakley, LANL, Los Alamos, NM
Thomas O. Hunter, SNL, 6310, Albq., NM
Michael E. Spaeth, SAIC, Las Vegas, NV
James P. Pedalino, H&N, Las Vegas, NV
Vincent Gong, REECo, Mercury, NV
Sheldon D. Murphy, F&S, Las Vegas, NV
James B. Wright, W, Mercury, NV

CORRELATION OF DEPARTMENT OF ENERGY (DOE) CONTENT REQUIREMENTS FOR STUDY PLANS AND INVESTIGATIONS IN THE SITE CHARACTERIZATION PLAN

The attached enclosure (i.e. letter from Alexander, DOE, to Linehan, U.S. Nuclear Regulatory Commission (NRC), dated 8/11/86) describes DOE Headquarter's most recent revision of Attachment D of the DOE/NRC Agreement of May 7-8, 1986. This revised correlation chart is supposed to make Attachment D, B, C, and 4 of the May 7-8, 1986, Agreement consistent.

Maxwell B. Blanchard, Chief
Regulatory & Site Evaluation Branch
Waste Management Project Office

WMPO:MBB-1954

Enclosure:
As stated

cc w/encl:
V. J. Cassella, DOE/HQ (RW-221) FORS
M. D. Voegele, SAIC, Las Vegas, NV
J. L. Younker, WMPO, DOE/NV ~~SAIC~~
D. L. Vieth, WMPO, DOE/NV
M. P. Kunich, WMPO, DOE/NV
U. S. Clanton, WMPO, DOE/NV
D. E. Livingston, WMPO, DOE/NV

Department of Energy
Washington, DC 20585

AUG 11 1986

John J. Linehan
Acting Branch Chief
Repository Projects Branch
Division of Waste Management
Office of Nuclear Materials
Safety and Safeguards
U. S. Nuclear Regulatory Commission
Silver Springs, MD 20555

Dear Mr. Linehan:

Enclosed please find a copy of a correlation table entitled "Comparison of DOE Content Requirements for Description of Study Plans and Investigations", which is a revised version of Attachment D included in the May 7-8, 1986 DOE-NRC advance meeting materials. Attachment D has been revised to be consistent with attachments B and C to Attachment 4 of NRC/DOE meeting summary. This revision to Attachment D satisfies DOE-NRC agreement number 2 from the meeting summary.

If there are any questions regarding the correlation table, please contact Carol Hanlon at 252-1224 or me at 252-1238.

Donald H. Alexander

Donald H. Alexander
Chief, Technology Branch
Engineering & Geotechnology Division
Office of Civilian Radioactive Waste
Management

cc: W. Purcell
R. Stein
J. Knight
D. Veith
O. Olson
J. Neff
C. Hanlon
S. Grodin
S. Echols
C. Borgstrom

ACTION _____
CC VIGH
CC. Blanchard
CC Lewis
CC Szymanski
CC _____
CC: _____
REC'D IN WMPO

ACTION WMPO
INFO _____
R.F. _____
AMA _____
AME&S ✓
AMO _____

WESTON

June 16, 1986
RFW-SD-DEL-01388/86

Dr. Donald H. Alexander
Chief, Technology Branch
Office of Geologic Repositories
U.S. Department of Energy
RW-24 (Forrestal) Room 8F-094
Washington, D.C. 20585

Subject: Revisions to Content Requirements Correlation Table from NRC-DOE Meeting, May 7-8, 1986. TDD #3002-24-09-1002

Dear Dr. Alexander:

Enclosed please find a copy of a correlation table entitled "Comparison of DOE Content Requirements for Descriptions of Study Plans and Investigations", which is a revised version of Attachment D included in the May 7-8, 1986 NRC-DOE advance meeting materials. Attachment D was revised to be consistent with Attachments B and C to Attachment 4 of NRC/DOE meeting summary. This revision to Attachment D satisfies NRC-DOE agreement number 2 from the meeting summary and should be forwarded to the NRC and the Project Officer.

If you have any questions please call me at 330-3761.

Sincerely,

ROY F. WESTON, INC.

Jeffrey W. Nelson,
SCP Task Manager
Siting Department

Approved by:

[redacted]
William F. Hewitt
Program Manager

cc: W. Purcell
T. Isaacs
R. Stein
J. Knight
H. Brandt
J. Fiore
R. Blaney
A. Jelacic
J. Frei
C. Head
S. Echols
C. Borgstrom
C. Heuloa
S. Grodin
R. Jackson
L. Skoblar

Comparison of DOE Content Requirements for Descriptions of Study Plans and Investigations

	Study Plans	Investigations
I. Purpose and Objectives	• Describe the information to be obtained in the study	• Describe the information t obtained in the investiga
	• Provide the rationale for information to be be obtained	• Provide the rationale for 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, identify relevant technical 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 the investigation affectin select on of studies, including interferences am studies and between studie 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 technical 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 procedu 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 Content Requirements for Descriptions of Study 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 Content Requirements for Descriptions of Study 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 re from investigation will used for support of othe investigations • Refer to specific perfor assessment studies • Indicate where informati from studies will be use construction equipment a engineering system, desi and development • Describe where informatic from studies will be use planning other character 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. 8.5 in SCP	• Show interrelationships a sequencing of (groups of) and analyses; use PERT ch to illustrate • List major milestones wh will result from studies • Present schedule for stud supporting the investigat providing beginning and e dates

ENCLOSURE 2.2.2:

DOE/HQ INTERIM PROCEDURE FOR REVIEW AND APPROVAL OF STUDY PLANS

Enclosure 9: Relevant Sections of revisions 1 and 2 of the SCPMP

NNWSI PROJECT

SUPERSEDED

SCP MANAGEMENT PLAN

Department of Energy
Nevada Operations Office
Waste Management Project Office

Approved By

D. L. Vieth
WMPO Director

November 5,1986
Date

UNCONTROLLED

SUPERSEDED

STUDY PLAN OUTLINE

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; specific program; investigation; study; tests and analyses; and test procedures. Details for studies and tests and analyses, listed in Chapter 8 of the SCP, will be presented in study plans. Study plans will be separate from the SCP proper and will be issued periodically throughout site characterization. Individual test procedures will be referenced in the study plans.

The following outline describes the information on studies, tests and analyses that will be presented in the study plans. A study may involve a single test or a set of tests and analyses, as appropriate. The tests include those measurements of physical parameters, or observations of physical phenomena, that are performed in the field or in the laboratory. Test activities include preparation of procedures, test set-up, conduct of the test, data acquisition, and data reduction. The analyses include those calculations or other evaluations needed to assess site characteristics and support design activities.

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

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

I. Purpose and Objectives of Studies:

- Describe the information that will be obtained in this study. Briefly discuss how this information will be used; and

- Provide the rationale and justification for the information to be obtained by the study. It can be justified by: 1) a performance goal and a confidence level in that goal (developed via the performance allocation process and results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (design goals beyond those related to performance issues); 3) a direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal.

II. Rationale for Selected Study:

- Provide the rationale and justification for the selected tests and analyses (including standard tests). Indicate the alternative test and analytical methods from which they were selected, including options for type of test, instrumentation, data collection and recording, and alternative analytical approaches. Describe the advantages and limitations of the various options; and

- Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives, summarize reasons for not selecting these alternatives and reference, if available, reports which evaluate alternatives considered.

- Describe the constraints that exist for the study, and explain how these constraints affect selection of test methods and analytical approaches. Factors to be considered include:

  - Potential impacts on the site from testing;

  - Whether the study needs to simulate repository conditions;

  - Required accuracy and precision of parameters to be measured with test instrumentation;

  - Limits of analytical methods that will use the information from the tests;

  - Capability of analytical methods to support the study; and

  - Time required versus time available to complete the study.

  - The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the applicability of studies conducted in the laboratory to the scale of the phenomena in the field.

  - Interrelationships of tests involving significant interference with other tests and how plans have been designed or sequenced to address such interference.

  - Interrelationships involving significant interference among tests and exploratory shaft facility design and construction (as appropriate, refer to Section 8.4 of the SCP or its references for specific exploratory shaft facility design information such as design drawings or specifications).

III. Description of Tests and Analyses:

o Since studies are comprised of tests and analyses, provide for each type of test:

- Describe the general approach that will be used in the test. Describe key parameters that will be measured in the test and the experimental conditions under which the test will be conducted. Indicate the number of tests and their locations (e.g., spatial location relative to the site, exploratory shaft facility elements, repository layout, stratigraphic units, depth, and test location);

- Summarize the test methods. Reference any standard procedures (e.g., ASTM, API) to be used. If any of the procedures to be used are not standard, or if a standard procedure will be modified, summarize the steps of the test, how it will be modified, and reference the technical procedures that will be followed during the test. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance and provide a rationale for any tests which are not judged to be QA level 1. Reference the applicable specific QA requirements that will be applied to the test;

- Specify the tolerance, accuracy, and precision required in the test, where appropriate;

- Indicate the range of expected results of the test and the basis for those expected results;

- List the equipment required for the test and describe briefly any such equipment that is special;

- Describe techniques to be used for data reduction and analysis of the results;

- Discuss the representativeness of the test including why the test results are considered representative of future conditions or the spatial variability of existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results; and

- Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests.

- Relationship of the test to the set performance goals and confidence levels.

o For each type of analysis:

- State the purpose of the analysis, indicating the testing or design activity being supported. Indicate what conditions or environments will be evaluated and any sensitivity or uncertainty analyses that will be performed. Discuss the relationship of the analysis to the set performance goals and confidence levels;

- Describe the methods of analysis, including any analytical expressions and numerical models that will be employed;

- Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a rationale for any analyses which are not judged to be QA level 1. Reference the applicable QA requirements;

- Identify the data input requirements of the analysis;

- Describe the expected output and accuracy of the analysis; and

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

IV. Application of Results:

o Briefly discuss where the results from the study will be used for the support of other studies (performance assessment, design, and characterization studies);

o For performance assessment uses, refer to specific performance assessment analyses (described in Section 8.3.5 of the SCP) which will use the information produced from the studies described above, and refer to any use of the results for model validation;

o For design uses, refer to, or describe, where the information from the study described above will be used in construction equipment design and development and engineering system design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and

o For characterization uses, refer to, or describe, where the information from the study described above will be used in planning other characterization activities.

V. Schedule and Milestones:

o Provide the durations of and interrelationships among the principal activities associated with conducting the study (e.g., preparation of test procedures, test set-ups, testing, data analyses, preparation of reports), and indicate the key milestones including decision points associated with the study activities;

- Describe the timing of this study relative to other studies and other program activities that will affect, or will be affected by, the schedule for completion of the subject study; and

- Dates for activities or milestones, including durations and interrelationships, for the study plans will be provided. These should reference the master schedules provided in Section 8.5. of the SCP.

NNWSI PROJECT

SCP MANAGEMENT PLAN

U.S. Department of Energy
Nevada Operations Office
Waste Management Project Office

Approved By

4/21/88

C. P. Gertz
Project Manager, WMPO

4/5/88

WMPO Project Quality Manager

4/5/88

Regulatory & Site Evaluation Branch

UNCONTROLLED

SCP MANAGEMENT PLAN

RECORD OF REVISIONS

REVISION NUMBER	REVISION	DATE
1	Revision #1 to the Site Characterization Management Plan (SCPMP) reflects a major revision to the 4-9-85 SCPMP, Rev. 0. This revision reflects modifications to the SCP preparation and review process to focus on review and integration of sections of Chapter 8. Changes in the process for producing the SCP were necessary to increase the speed and effectiveness with which the Internal Review Committee (IRC) process incorporated comments and generated revised versions of the individual chapters so that the DOE/HQ schedule would be met. This revision replaces the 7 IRCs with 17 Permanent Internal Review Committees (PIRCs) and establishes a Technical Overview Committee for internal project review of the SCP. The revision was also necessary to accommodate the May 7 and 8, 1986, agreement between the DOE and the NRC which obligates the NNWSI Project to additional activities, such as the completion of additional study plans and a report of on-going studies to the State. These activities were not considered in the development of the SCPMP, Revision 0.	11-05-86
2	Revision #2 to the SCPMP constitutes a major revision to the 11-5-86 SCPMP, Rev. 1, to reflect changes to the approach the Project is using to produce the SCP and SCP Study Plans. Some of these changes include technical reviews by a Project Overview Committee (POC), utilizing a Site Characterization Overview Committee (SOC) during comment resolution meetings with DOE/HQ to produce written agreements to incorporate DOE/HQ changes to the SCP, revised schedules for delivery of the SCP to DOE/HQ for concurrence and subsequent release to the public. Also plans and schedules for the development of SCP Study Plans have been addressed.	

1.0 INTRODUCTION

The Nevada Nuclear Waste Storage Investigations (NNWSI) Project Site Characterization Plan (SCP) will be the initial vehicle for interaction with the U.S. Nuclear Regulatory Commission (NRC) before submission of a license application upon which an NRC construction authorization will be based in accordance with Section 114 of the Nuclear Waste Policy Act (NWPA). The SCP will describe the basis for the NNWSI Project's site characterization program. Additional detail on the planned site characterization activities, described in Chapter 8 of the SCP, will be provided in SCP Study Plans as required by the DOE/NRC May 7-8, 1986, agreement. Study Plans will be issued as needed during site characterization. The purpose of this SCP Management Plan (SCPMP) is to describe the organization, process, and schedule by which the NNWSI Project SCP, supporting Study Plans, and SCP Progress Reports will be completed.

To meet the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) schedule, this revised management plan focuses on the review and integration of the SCP and the preparation and review of SCP Study Plans. Working schedules will be issued periodically to update progress towards finalizing these objectives.

The SCP, SCP Study Plans, and SCP Progress Reports will be subject to extensive review and comment within the NNWSI Project and by the NRC, the State of Nevada, the public, and affected Indian tribes. The SCP preparation processes described in this plan will ensure that the SCP and SCP Study Plans are produced and reviewed in a controlled sequence. SCP Progress Reports (as required by Federal Register, Vol. 50, #12, January 17, 1985) will be

prepared semiannually as new information is developed and analyses are performed during site characterization. The SCPMP will be revised to include coordination of SCP Progress Reports.

Approval of this revised plan by the Waste Management Project Office (WMPO) Project Manager constitutes direction to initiate SCP review and revision and the development and review of SCP Study Plans. This revised plan will be updated as needed to ensure that it represents the process by which the SCP and SCP Study Plans are being prepared. The approved document will be treated as an NNWSI Project baseline document. Changes to this plan will be made in accordance with the procedures described in Section 1.3. Any deficiencies in regard to the implementation of this plan shall be documented and processed in accordance with the NNWSI QAP, NVO-196-17 and the respective participants QAPP, as appropriate.

1.1 PURPOSES OF THE SCP MANAGEMENT PLAN

The purposes of the SCPMP are to describe and establish the following:

1. The organizational structure and the responsibilities and authority of the NNWSI Project participants in the preparation of the SCP, SCP Study Plans, and input to SCP progress reports.

2. The approach to be used in review and revision of the SCP, SCP Study Plans, and input to SCP Progress Reports.

3. The schedule of events from approval of this plan through the U.S. Department of Energy Nevada Operations Office (DOE/NV) submission of the SCP, SCP Study Plans, and input to SCP Progress Reports to the OCRWM.

1.2 FORMAT AND CONTENT OF THE MANAGEMENT PLAN

This plan is divided into eight additional sections as described in the following paragraphs.

Section 2.0, Organization and Responsibilities, describes the organizational structure and the functions of the organization's component parts and identifies the key personnel and their responsibilities and authority.

Section 3.0, Approach, summarizes the applicable guidance on the format and content of the SCP and SCP Study Plans.

Section 4.0, SCP Integration, describes the SCP Integration Working Group and Project review responsibilities and provides guidance on review and revision of the data and conceptual design chapters (Chapters 1-7) and the Issues and Plans chapter (Chapter 8).

Section 5.0, SCP Production, describes the Production Working Group responsibilities, the SCP production process, and records and document control.

Section 6.0, Study Plan Development, describes the Study Plan Working Group responsibilities and provides guidance on preparation, review, and approval of SCP Study Plans.

Section 7.0, SCP Progress Reports, describes the SCP Progress Report Working Group.

Section 8.0, Quality Assurance (QA), describes quality assurance responsibilities and authorities applicable to the preparation of the SCP.

Section 9.0, Schedule, presents the schedule and major milestones for SCP and SCP study plan preparation, review, and approval.

1.3 CHANGES TO THE MANAGEMENT PLAN

Revisions (changes) to the SCPMP will be initiated by the SCPMG Manager and will require the concurrence of the WMPO Project Manager and the WMPO Project Quality Manager. Significant revisions may be the result of any of the following four occurrences:

1. Modification of SCP schedule as a result of legislative, regulatory, or OCRWM decisions.

2. Modification of SCP format and content as a result of legislative, regulatory or OCRWM decisions.

3. Changes in organization that would affect responsibility or authority.

4. Modification of the review, production, and document control processes set forth in the plan, or of quality assurance requirements.

The SCPMP will be maintained as a controlled document. A revision form record will be maintained at the front of this plan.

2.0 ORGANIZATION AND RESPONSIBILITIES

Responsibilities and authorities of key positions within the management and technical organizations are described in this section.

2.1 ORGANIZATION

The WMPO SCP organization is illustrated in Figure 2-1. This figure indicates three functional responsibilities: SCP preparation, SCP Study Plan preparation, and development of input to SCP Progress Reports. Figure 2-2 illustrates the T&MSS organization whose purpose is to assist NNWSI Project personnel in completing the provisions of this management plan.

2.2 RESPONSIBILITIES AND AUTHORITY

Principal responsibility for the development of the SCP rests with the SCP Manager with assistance from the SCP Management Group (SCPMG). The SCPMG is composed of NNWSI Project personnel (Figures 2-1 and 2-2) whose purpose is to ensure that the provisions set forth in this plan are accurately and efficiently completed in accordance with pertinent guidance, such as the OCRWM SCP Annotated Outline (AO), and within schedule and budget constraints identified in the NNWSI Project Monitoring System (PMS). Specific management and technical responsibilities are described in the following sections.

review of the SCP, POC members were to perform reviews of sections of the SCP for which they provide specific expertise, rather than a comprehensive technical review of the total document. These reviews focused on (1) DOE and NNWSI Project policies, (2) topical areas where sensitive technical issues exist within the Project, and (3) clarity of the text. Each POC was managed by at least one chairman who was responsible for producing a markup of the pertinent SCP sections.

Two additional Working Groups are also being used to coordinate preparation, review and approval of SCP Study Plans, and input to SCP Progress Reports. The responsibilities of these working groups are defined in Sections 6.0 and 7.0.

relative to the content requirements and level of detail for Study Plans was developed by and received concurrence from the DOE and the NRC in the May 7-8, 1986, SCP level-of-detail meeting (see Appendix A). It should be noted that whereas the information in the SCP will be formatted according to the OCRWM SCP AO, a common format (such as that in the OCRWM SCP AO) has not been developed for SCP Study Plans. This allows flexibility in the preparation of Study Plans to accommodate variability in differing types of studies.

3.4.1 DOE content requirements for SCP Study Plans

As specified in the May 7-8, 1986, DOE/NRC agreement, the test program presented in Chapter 8 of the SCP will be subdivided into a hierarchy of increasing detail including: generic program, specific program, investigation, study, tests and analyses, and test procedures. In addition to the above, the NNWSI Project SCP includes an additional level in the hierarchy between studies and tests and analyses, termed activities. Details for studies, activities, tests and analyses, listed in Chapter 8 of the SCP, will be presented in Study Plans. Study Plans will be separate from the SCP proper and will be issued as needed throughout site characterization. Individual test procedures will be referenced in the study plans.

The DOE/NRC outline summarized in Section 3.4.1.2 describes the information relative to studies, activities, tests, and analyses that will be presented in the Study Plans as outlined in the May 7 and 8, 1986, DOE/NRC meeting on level-of-detail in SCP and SCP study plans. A study may involve

one or more activities composed of a single test or a set of tests and analyses, as appropriate. The tests include those measurements of physical parameters or observations of physical phenomena that are performed in the field or in the laboratory. Test activities include preparation of procedures, test set-up, conduct of the test, data acquisition, and data reduction. The analyses include those calculations or other evaluations needed to assess site characteristics and support design activities.

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

In some instances, tests and analyses may be planned for later stages of a study for which detailed plans depend on the results of earlier tests and analyses. Under these circumstances, it will not be possible to provide the same level of detail for all tests and analyses at the time the Study Plan is first issued. In such instances, the initial Study Plans will present complete descriptions of the tests and analyses that occur early in the study and less detailed information for tests and analyses that occur later.

3.4.2 Study Plan outline

The following section summarizes the content requirements of SCP Study Plans as specified in the May 7-8, 1986 DOE/NRC agreement. Appendix A of the

SCPMP provides the detailed annotated outline that was developed for Study Plan format and content by the DOE and the NRC.

3.4.2.1 Section 1 - Purpose and Objectives

This section will describe the information that will be obtained in the study and how the information will be used. It will also provide a justification for the information to be obtained.

3.4.2.2 Section 2 - Rationale

This section will provide a rationale for the selected tests and analyses. The discussion may include a discussion of alternative methods, the rationale for the number, location, and duration of the proposed tests as well as any constraints that exist for the study.

3.4.2.3 Section 3 - Description of Tests and Analyses

This section will describe the general approach that will be used in the test, including a summary of test methods and applicable Quality Assurance

levels for each test. For each analysis, the purpose of the analysis will be discussed along with the methods of analysis.

3.4.2.4 Section 4 - Application of Results

This section will provide a brief discussion of where the results of the study will be used in support of other studies (performance assessment, design, and characterization studies).

3.4.2.5 Section 5 - Schedules and Milestones

This section will provide durations of and interrelationships among the principal activities conducted in the study. It will also discuss the interrelationships with other studies that feed information to this study or require input from the results of this study.

3.5 SCP PROGRESS REPORT CONTENT

Guidance for the content and format of SCP Progress Reports will be developed by the SCP Progress Report Working Group in concert with OCRWM.

6.0 SCP STUDY PLAN DEVELOPMENT

6.1 RESPONSIBILITIES

The SCP Study Plan Coordinators will coordinate the preparation and review of NNWSI Project SCP Study Plans. Initial draft text will be developed by the participating organizations using the format and content guidance developed by the OCRWM in consultation with the NRC (see Section 3.4.1). The T&MSS Study Plan Coordinator will maintain a working schedule to document study plan preparation, review, and revision. NNWSI Project reviews will be completed by Project review teams selected from the SCP TOC. Table 6-1 presents a proposed list of review team members and individual Study Plan review responsibilities. A current list of review team members will be maintained by the T&MSS Study Plan Coordinator.

The responsibilities of the SCP Study Plan Coordinators include the following:

1. Coordinating review and approval of NNWSI Project SCP Study Plans, including Study Plan revisions.

2. Ensuring consistency between SCP Study Plans and related sections of Chapter 8 of the SCP.

3. Participating, as directed by the WMPO SCP Manager, in NNWSI Project and OCRWM Program committees and Study Plan comment resolution workshops.

Table 6-1. NNWSI Project Study Plan Review Teams (page 1 of 5)

	Study plans	Suggested review team members
Team 1	8.3.1.2.1.1 - Meteorology for Regional Hydrology 8.3.1.2.1.2 - Runoff and Stream Flow 8.3.1.9.2.2 - Water Resource Assessment 8.3.1.9.3.2 - Effects of Natural Resource Extraction on Hydrology 8.3.1.12.2.1 - Meteorology Data Collection 8.3.1.16.1.1 - Flood Potential	Buqo, Jablonski, Glancy, Langer, Matthusen, Giampaoli, Snyder, Clanton
Team 2	8.3.1.2.2.1 - Unsaturated Zone Infiltration 8.3.1.2.2.2 - Water Movement Tracer Tests 8.3.1.2.2.3 - Percolation in the UZ-surface 8.3.1.2.2.4 - Percolation in the UZ-BS 8.3.1.2.2.5 - Diffusion Tests in the BS 8.3.1.2.2.6 - Flux within the Paintbrush 8.3.1.2.2.7 - Gaseous-phase movement in the UZ 8.3.1.2.2.8 - Hydrochemical Characterization of the UZ 8.3.1.2.2.9 - UZ Flow and Transport Modeling 8.3.1.2.2.10 - UZ System Analysis and Integration 8.3.1.16.3.1 - Preclosure Hydrology of the UZ	Goings, Canepa, Chestnut, Cullen, Wilson, Klavetter, Sinnock, Peters, Dobson, Norris
Team 3	8.3.1.2.1.3 - Regional Ground-Water Flow System 8.3.1.2.1.4 - Regional Hydrologic System Synthesis and Modeling 8.3.1.2.3.1 - Saturated Zone Ground-Water Flow System 8.3.1.2.3.2 - Saturated Zone Hydrochemistry 8.3.1.2.3.3 - Saturated Zone System Synthesis and Modeling 8.3.1.16.3.1 - Adequate Water Supply	Goings, Cullen, Sinnock/Klavetter, Wilson/Langer, Chestnut, Robison, Canepa, Szymanski, Echart/ Cederberg
Team 4	8.3.1.3.1.1 - Ground-Water Chemistry 8.3.1.3.2.1 - 3-Dimensional Mineral Distribution 8.3.1.3.2.2 - Mineralogic and Geochemical Alteration	Mattson, Spengler/Raup, Leedom, Perry, Canepa, Glassley, Livingston, Rutland

Table 6-1. NNWSI Project Study Plan Review Teams (page 2 of 5)

	Study plans	Suggested review team members
Team 4 (continued)	8.3.1.3.3.1 - Natural Analog of Hydrothermal Systems 8.3.1.3.3.2 - Kinetics/Thermodynamics of Mineral Evolution 8.3.1.3.3.3 - Conceptual Model of Mineral Evolution	
Team 5	8.3.1.3.4.1 - Batch Sorption Studies 8.3.1.3.4.2 - Biological Sorption and Transport 8.3.1.3.4.3 - Development of Sorption Models 8.3.1.3.5.1 - Dissolved Species Concentration Limits 8.3.1.3.5.2 - Colloid Behavior 8.3.1.3.6.1 - Dynamic Transport Column Experiments 8.3.1.3.6.2 - Diffusion 8.3.1.3.7.1 - Retardation Sensitivity Analysis 8.3.1.3.7.2 - Applicability of Laboratory Data to Transport Calculations 8.3.1.3.8.1 - Gaseous Radionuclide Transport Calculations	Livingston, Canepa, Glassley, Park, Eggert, Dobson, Rutland
Team 6	8.3.1.4.2.1 - Vertical and Lateral Distribution of Stratigraphic Units 8.3.1.4.2.2 - Structural Features 8.3.1.4.2.3 - 3-Dimensional Geologic Model 8.3.1.4.3.1 - Systematic Acquisition of Subsurface Information 8.3.1.4.3.2 - 3-Dimensional Rock Characteristics Model	Hurley, Ziegler, Sinnock/Rautman, Eppler, Spengler/Raup, Dobson, Hughes, Vanniman/Broxton
Team 7	8.3.1.5.1.1 - Modern Regional Climate 8.3.1.5.1.2 - Paleoclimate Study 8.3.1.5.1.3 - Climatic Implications of Terrestrial Paleoecology 8.3.1.5.1.4 - Paleoenvironmental History of Yucca Mountain	Moore, Leedom, Wilson, Fox/Whitney, Thompson, Vanniman, Levy, Matthusen

Table 6-1. NNWSI Project Study Plan Review Teams (page 3 of 5)

	Study plans	Suggested review team members
Team 7 (continued)	8.3.1.5.1.5 - Paleoclimate-paleoenvironment Synthesis 8.3.1.5.1.6 - Future Regional Climate 8.3.1.5.2.1 - Quaternary Regional Hydrology 8.3.1.5.2.2 - Future Regional Hydrology due to Climate	
Team 8	8.3.1.6.1.1 - Present and Past Erosion 8.3.1.6.2.1 - Effect of Climate on Erosion 8.3.1.6.3.1 - Effects of Tectonics on Erosion 8.3.1.6.4.1 - Effects of Erosion on Hydrology, Geochemistry and Rock Characteristics 8.3.1.9.1.1 - Effects of Erosion on Surface Markers	Giampaoli, Schleicher, Matthusen, Sinnock, Clanton, Harrington
Team 9	8.3.1.8.1.1 - Probability of Volcanic Eruption 8.3.1.8.1.2 - Effects of Volcanic Eruption 8.3.1.8.2.1 - Waste Package Rupture 8.3.1.8.3.1 - Effects of Tectonics on Flux Rates 8.3.1.8.3.2 - Effects of Tectonics on Water Table 8.3.1.8.3.3 - Effects of Tectonics on Fracture Permeability and Porosity 8.3.1.8.4.1 - Effects of Tectonics on Rock Geochemical Properties 8.3.1.8.5.1 - Volcanic Features 8.3.1.8.5.2 - Igneous Intrusive Features 8.3.1.8.5.3 - Folds on Miocene and Younger Rocks 8.3.1.9.1.1 - Effects of Tectonics on Marker System	King, Raup, Sinnock/Klavetter, Grant, Crowe, Wilson, Frazier, Fox, Eppler
Team 10	8.3.1.14.2.1 - Exploration Program 8.3.1.14.2.2 - Laboratory Tests/Material Properties 8.3.1.14.2.3 - Geophysical Field Measurements	Schleicher, Sublette, Stevens/Dennis, Raup, Stewart, Perry

Table 6-1. NNWSI Project Study Plan Review Teams (page 4 of 5)

	Study plans	Suggested review team members
Team 11	8.3.1.15.1.1 - Laboratory Thermal Properties 8.3.1.15.1.2 - Laboratory Thermal Expansion Tests 8.3.1.15.1.3 - Mechanical Properties of Intact Rock 8.3.1.15.1.4 - Mechanical Properties of Fractures 8.3.1.15.1.5 - Excavation Investigations 8.3.1.15.1.6 - In Situ Thermomechanical Properties 8.3.1.15.1.7 - In Situ Mechanical Properties 8.3.1.15.1.8 - In Situ Design Validation 8.3.1.15.2.1 - Site Ambient Stress Conditions 8.3.1.15.2.2 - Site Ambient Thermal Conditions	Hardin, Voegele, Stevens, Stewart, Spengler, Barbour, Blejwas
Team 12	8.3.1.17.1.1 - Potential for Ash Fall 8.3.1.17.2.1 - Fault Potential 8.3.1.17.3.1 - Earthquake Sources 8.3.1.17.3.2 - UNE Sources 8.3.1.17.3.3 - Ground Motion from Earthquakes and UNEs 8.3.1.17.3.4 - Effects of Local Geology on Motion 8.3.1.17.3.5 - Ground Motion from Seismic Events 8.3.1.17.3.6 - Probabilistic Seismic Hazards Analysis 8.3.1.17.4.1 - Historic and Current Seismicity 8.3.1.17.4.2 - Faulting Potential Near S.P. 8.3.1.17.4.3 - Quaternary Faulting within 100 km 8.3.1.17.4.4 - Quaternary Faulting within NE-trending Faults 8.3.1.17.4.5 - Detachment Faults 8.3.1.17.4.6 - Quaternary Faults within the Site Area 8.3.1.17.4.7 - Subsurface Geometry, Quaternary Faults 8.3.1.17.4.8 - Stress Field within the Site Area 8.3.1.17.4.9 - Tectonic Geomorphology 8.3.1.17.4.10 - Geodetic Leveling	Clanton, King, Grant, Fox, Rogers, Raup, Sinnock, Mattson, Frazier, Dobson, Crove

Table 6-1. NNWSI Project Study Plan Review Teams (page 5 of 5)

	Study plans	Suggested review team members
Team 12 (continued)	8.3.1.17.4.11 - Regional Lateral Crustal Movement 8.3.1.17.4.12 - Tectonic Models and Synthesis	
Team 13	8.3.4.2.4.1 - Chemical and Mineralogic Changes - Post-emplacement environment 8.3.4.2.4.2 - Hydrologic Properties - Waste Package Environment 8.3.4.2.4.3 - Thermal and Mechanical Attributes - Waste Package 8.3.4.2.4.4 - Engineered Barrier System Field Tests 8.3.3.2.2.1 - Seals Materials	Park, Dymmel, Morissette, Skousen, Dennis, Wilder, Canepa, Livingston, Eggert

4. Assisting the WMPO, as directed by the R&SEB or the WMPO Project Manager, in interfacing with related activities, including: licensing, environmental permitting, criteria letter development, budget revisions, schedule and milestone revisions and quality assurance reviews.

Members of the Study Plan coordinating group are shown in Table 6-2.

6.2 STUDY PLAN PREPARATION

Study Plans are participant documents that require WMPO and OGR approval. The initial draft text of a Study Plan will be developed by the principal investigator at the participating organization following the guidance on format, content, and level of detail as agreed to in the May 7 and 8, 1986, DOE/NRC Meeting (see Appendix A). Preparation and internal review of the initial draft text will be completed under the quality controls of the participating organization's Quality Assurance Program. A revision record will be maintained at the front of the Study Plan. In addition, an approval page will be provided to document participant technical and QA approvals. Signature blocks will also be provided for WMPO Chief of R&SEB or Technology Development and Engineering Branch (TDED), the WMPO Project Quality Manager and the Director, Engineering and Geotechnology Division, OCRWM (see Figure 6-1).

TITLE

NNWSI - USGS - SP 8.3.1.2.2.4, RO

EFFECTIVE DATE _____

_____	_____		
PRINCIPAL INVESTIGATOR	DATE		
_____	_____	_____	_____
PARTICIPANT TECHNICAL	DATE	PARTICIPANT QUALITY ASSURANCE	DATE
_____	_____	_____	_____
WMPO*	DATE	WMPO QUALITY ASSURANCE	DATE

_____ _____

DIRECTOR, ENGINEERING AND TECHNOLOGY DIVISION DATE

* REGULATORY AND SITE EVALUATION BRANCH OR TECHNOLOGY DEVELOPMENT BRANCH AS APPROPRIATE

FIGURE 6-1 EXAMPLE STUDY PLAN SIGNATURE PAGE

Table 6-2. SCP Study Plan Working Group

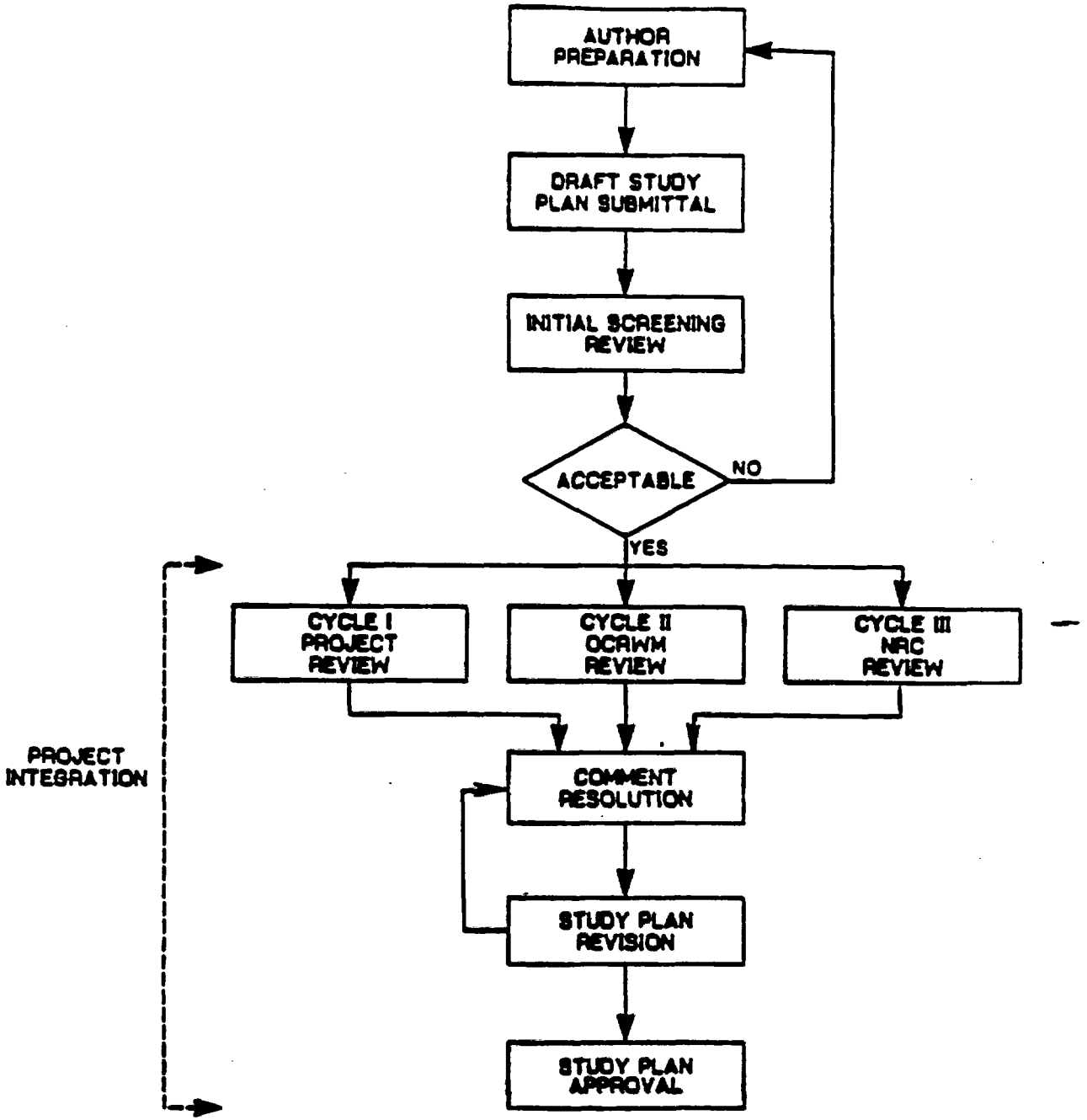
Working Group Coordinators	D. Dobson, WMPO M. Pendleton, SAIC
Participant Study Plan Coordinators	J. Canepa, Los Alamos D. Emerson, LLNL T. Blejwas, SNL B. Langer, USGS D. Schleicher, USGS
Study Plan Integration Coordinators:	
Environmental Permitting	E. McCann, SAIC
Quality Assurance	J. Estella, SAIC
Technical Integration and Support	D. Jorgenson, SAIC
Schedules and Milestones	S. Bozarth, SAIC*
Licensing	M. L. Brown, SAIC

*Acting

The OCRWM style guide may be used as a reference for preparation of initial draft text, but there is no program requirement for standardizing typographical format and editorial style. All references cited in the study plan that are not listed in the SCP/CD reference list should be provided to the WMPO prior to study plan approval.

6.3 STUDY PLAN REVIEW

The participating organization will submit clean, typed initial draft text that is consistent with the required format (Section 3.4) to the WMPO for review (see Figure 6-2). The initial draft text will be reviewed internally at the participating organization according to their own procedures.


AUTHOR PREPARATION
DRAFT STUDY PLAN SUBMITTAL
INITIAL SCREENING REVIEW
ACCEPTABLE
NO
YES
CYCLE I PROJECT REVIEW
CYCLE II OCRWM REVIEW
CYCLE III NRC REVIEW
COMMENT RESOLUTION
STUDY PLAN REVISION
STUDY PLAN APPROVAL
PROJECT INTEGRATION

6.3.1 Initial screening review

The Study Plan Coordinating Group will complete an initial informal review of the draft Study Plan. This review will focus on consistency with the OCRWM guidance on format and content (Section 3.4), technical level-of-detail, and consistency with the NNWSI SCP (see Figure 6-2) to verify that the Study Plan is sufficiently mature for Project and for OGR technical reviews. Depending on the results of this informal review, the Study Plan will either be returned to the participant for revision or, if sufficiently mature, forwarded for Project review.

6.3.2 Project Study Plan Review (Cycle 1)

A Project Study Plan review will be completed in advance of or in parallel with the OCRWM review cycle (see Figure 6-2) depending on schedule constraints defined by the OCRWM. A request for review will be provided to Study Plan reviewers by the Study Plan Working Group Coordinators in the form of a transmittal letter. The transmittal letter will define the scope, emphasis, purpose, and schedule for each review. The review includes the following:

1. Consistency with performance assessment and design requirements.

2. Consistency with Project schedules, milestones, and Quality Assurance Level Assignments.

3. Technical adequacy.

Project Review Teams will be established and given the responsibility for review and revision of the SCP Study Plans. Table 6-1 identifies the SCP Study Plans, the Study Plan Review teams, and suggested reviewers. Each team will include an author representative, WMPO staff, SAIC staff, performance assessment staff (if required) and Project technical reviewers. Each reviewer will be selected on the basis of his/her technical expertise.

The WMPO and T&MSS Study Plan Coordinators will be responsible for coordinating Study Plan review activities, for recognizing conflicts among reviewers, and for working with review team to develop plans for resolution of problems due to differences of technical opinion or schedule conflicts. Conflicts that cannot be resolved by a specific review team will be elevated to the WMPO SCP Manager for resolution. Members of the SCP POC may be called upon to assist the WMPO SCP Manager in the resolution of difficult issues.

Reviewers will record all technical comments on CRFs (see Figure 6-3); editorial comments will be recorded on marked up text and addressed at the discretion of the author. After the Study Plan is reviewed, the Study Plan Coordinator will contact each reviewer to schedule a comment resolution workshop, if necessary.

Reviewers are responsible for categorizing their comments into minor technical comments (Category 1) that can be resolved with minor revisions to the text and major technical comments (Category 2) that require discussion. If Category 2 comments are accepted and require significant revisions to the

STUDY PLAN CRF

1. REVIEWER NAME/ORGANIZATION _____ DATE _____

2. STUDY PLAN TITLE NUMBER AND ORIGINATING ORGANIZATION _____

3. CONCURRENCE AUTHOR REPRESENTATIVE _____ DATE _____ STUDY PLAN COORDINATOR _____ DATE _____

COMMENT NO./ CATEGORY/ PAGE NO.	COMMENT	PROPOSED RESOLUTION	FINAL DISPOSITION

PAGE ___ OF ___

FIGURE 6-3. STUDY PLAN COMMENT RESOLUTION FORM

STUDY PLAN CRF CONTINUATION SHEET

STUDY PLAN TITLE

COMMENT NO./ CATEGORY/ PAGE NO.	COMMENT	PROPOSED RESOLUTION	FINAL DISPOSITION

PAGE ___ OF ___

FIGURE 6-3, CON'T

Study Plan, the review team will agree to a plan and schedule for revision. The Study Plan author will ensure that text modifications accurately reflect review team agreements.

In some cases, the review team may not be able to resolve all comments. These unresolved comments will be classified as Category 3 and may require management attention for resolution. The review team will be responsible for providing a consolidated markup of the draft Study Plan, completed CRFs, an agreed-upon schedule for resolution of comments that cannot be completed during the comment resolution meeting, and a list of Category 3 comments that require management attention to the T&MSS Study Plan coordinator. If OCRWM schedule constraints require that the Project review is completed in parallel with the OCRWM Study Plan review (Section 6.3.4), revision to the Study Plan may be completed after the OCRWM comments have been addressed.

Project Study Plan reviewers may be required to participate in OCRWM comment resolution meetings (see Section 6.4). As a minimum, the Study Plan author representative, a WMPO representative, and a T&MSS technical reviewer will participate in the OCRWM comment resolution meeting. The T&MSS technical reviewer will be responsible for maintaining the comment resolution record in the OCRWM comment resolution meeting.

6.3.3 Project integration

When a Study Plan is received from a participating organization, copies of the Study Plan will be distributed to the Study Plan Integration Coordinators (Table 6-2). The Study Plan Integration Coordinators will ensure that Project activities, such as environmental permitting, Quality Assurance Level Assignments, criteria letter development, and budget and scheduling activities, are proceeding in parallel with Study Plan development and are consistent with the requirements of the activities described in the Study Plans.

6.3.4 OCRWM review and approval

The OCRWM Study Plan approval process (Formal Procedures for HQ Approval of Study Plans Supporting the SCP, April 14, 1987) will consist of a one-cycle review to be accomplished within approximately seven weeks of receipt of the Study Plan at the OCRWM. To achieve this goal, OCRWM staff and the NNWSI Project will work in close cooperation throughout the review and approval process.

The steps for OCRWM review and approval, outlined in the Final Procedure for HQ approval, are as follows:

1. During preparation of Study Plans, the Project will brief DOE/HQ staff at least bimonthly on their progress toward completing the Study Plans and any problems that may have arisen.

2. When the Study Plan is considered by the the Project Office to be complete and ready for review, 10 copies of the Study Plan will be submitted to the Technology Branch for DOE/HQ approval.

3. Upon receipt of a Study Plan, the Technology Branch will review it for acceptability of content, level of detail, for compliance with the May 7-8, 1986 DOE/NRC agreement, and to identify the branch with lead responsibility for DOE/HQ review.

4. Upon determining that the Study Plan is acceptable for review and within one week of its receipt, the OGR Technology Branch will provide copies to the Engineering Branch; Geosciences Branch; Project Management Branch; Siting, Licensing, and Quality Assurance Division; Office of Environment, Safety and Health; Office of General Counsel; Weston; and technical reviewers at the National Laboratories for comment. Reviewers will have two weeks to review and comment on the Study Plan. All concerns and specific recommendations for resolution of the concerns will be documented on comment sheets, as has been done throughout the SCP review process.

5. On the last day of the two-week comment period, the lead branch will conduct a comment consolidation meeting to discuss all DOE/HQ comments relative to the Study Plan and develop a consolidated set of comments.

6. Within one week of the comment consolidation meeting, the lead branch will conduct a comment resolution workshop with the NNWSI

Project to resolve all DOE/HQ comments. The Director, Engineering and Geotechnology Division, and the NNWSI Project Manager will be available, if necessary, to resolve any contentious issues.

7. Within two weeks after the comment resolution workshop, the NNWSI Project will revise the Study Plan and resubmit it to the Technology Branch for a comment resolution audit.

8. After the audit review is successfully completed, the Director, Engineering & Geotechnology Division, will approve the Study Plan. After approval, the Director, Siting, Licensing, and Quality Assurance Division, will provide the Study Plan to the NRC for its review and to the State and affected Indian tribes for their information.

9. The NRC will identify major concerns, if any, during the first three months of its six-month review period.

10. If major concerns are identified by the NRC in a Study Plan, the NNWSI Project and DOE/HQ will jointly evaluate the concerns and meet with the NRC to discuss them, if necessary, and determine the appropriate resolution.

11. After receipt of the NRC comments following its six-month review, the NNWSI Project will meet with DOE/HQ to determine how comments will be addressed. The NNWSI Project will revise Study Plans, within three weeks.

12. Revised Study Plans will be forwarded to the NRC, and information copies will be provided to State and affected Indian tribes.

6.4 Schedule for study plan approval

The OCRWM has assigned SCP Study Plans to four categories: (1) Exploratory Shaft Construction Phase, (2) plans for first year studies, (3) plans for subsequent studies, and (4) plans for pre-SCP studies.

6.4.1 Exploratory Shaft Construction Phase study plans

The NRC will not begin their review of the NNWSI SCP until they have received the Exploratory Shaft Construction Phase study plans. Therefore, the NNWSI Project should provide acceptable high-quality draft Study Plans to the OCRWM for their review and approval at least seven weeks in advance of the issuance of the NNWSI Project SCP.

6.4.2 First year study plans

To be consistent with the DOE/NRC May 7 and 8, 1986, agreements, Study Plans for first year studies should be provided to the NRC as soon as

possible following SCP issuance. The NRC will notify the DOE of major concerns relative to a Study Plan during the first three months of availability. Major concerns of the NRC must be received before work can be initiated on an individual study, although the OCRWM will consider exceptions, on a case-by-case basis.

6.4.3 Second year and beyond

For studies that will be initiated more than one year after SCP issuance, the OCRWM will provide the Study Plans to the NRC at least six months in advance of the start of the study. Therefore, the NNWSI Project will provide Study Plans for out-year activities to the OCRWM for review and approval at least eight months in advance of the start of a study.

6.4.4 Pre-SCP studies

Study Plans for the surface-based investigations initiated before construction of the ESF should be provided to the NRC for review six months in advance of study initiation, where practicable. For studies where this is not practicable, study plans will be provided to the NRC three months before initiation of the study. Therefore, the NNWSI Project should provide pre-ESF study plans five to eight months before initiating work, to allow for the

OCRWM approval. Exemptions will be considered by the OCRWM on a case-by-case basis.

6.4.5 Study plan revisions

Guidelines for the revision of Study Plans during site characterization are contained in the OCRWM procedure for review and approval. The Project procedures described in this section are consistent with that guidance.

Proposed changes to Study Plans may be initiated by the participant, WMPO, or OCRWM in response to comments generated within, or from outside, the NNWSI Project. However, all changes to the text will be made by the author(s) at the participating organizations. Review of the revised text will initially focus on whether suggested changes are minor or major in scope. According to the OCRWM procedure, major changes are interpreted as those involving a completely new approach to a study or an activity which could result from a change in licensing strategy, changes in test scale or duration that will result in significant schedule delays or budget impact, or changes in testing that potentially could impact the performance of the site.

The WMPO Study Plan Coordinator will distribute copies of all proposed changes to the chairman of the original review team, to the Study Plan Integration Coordinators and to OCRWM. For changes which WMPO and OCRWM agree are minor, resolution of comments on the CRFs may be agreed upon by teleconference and confirmed by signed CRFs. Minor revisions will be made by

issuance of approved replacement pages to the original text. A complete record of the approval of revisions, signed by the WMPO Study Plan Coordinator and by the designated OCRWM representative, will be kept in the Project T&MSS files. A list of current revisions will also be maintained in the files and a revision record form will be maintained at the front of each Study Plan.

For changes which the WMPO and OCRWM designate as major, the revised Study Plan will be reviewed according to the procedure from initial review and approval of SCP Study Plans (see Section 6.3). The review should focus on new or revised text. During the review of major revisions, the OCRWM procedure specifies that work stoppage is required only for those activities undergoing revisions and not for all activities described in the Study Plan.

Following approval of any revisions to a Study Plan, copies of the revisions will be sent to OCRWM, the review team chairman, the Study Plan integration coordinators and the Project files. Notification of approved revisions may also be published in the SCP Progress Reports.

8.0 QUALITY ASSURANCE

The QA requirements for ensuring that all the activities defined in the SCPMP are accomplished in accordance with the QA program for the NNWSI Project are specified in the general QA plan for the Project (NVO-196-17), which summarizes the QA policy and program for the Project. This general plan is implemented through the QAPP for the WMPO (NVO-196-18) and the QAPP for each Project participant. These QAPPs specify the quality criteria, practices, and procedures required to achieve the necessary quality for the Project.

The process by which the SCP and SCP study plans will be developed has been evaluated and assigned QA Level II in accordance with NVO-196-17 and NNWSI-SOP-02-02, Assignment of QA Levels to NNWSI Project Activities. Activities summarized with the individual SCP study plans shall be assigned a QA level by the NNWSI Project participant responsible for the respective activity.

8.1 SCPMG QUALITY ASSURANCE RESPONSIBILITIES

The management program set forth in this plan is designed to provide the necessary assurance that the data upon which the SCP, SCP study plans, and SCP progress reports are based are adequate relative to their associated confidence or uncertainty, that alternative data or data interpretations are

incorporated appropriately, and that necessary documentation and traceability are maintained by providing the following:

1. A documented review process to provide independent technical and regulatory input as the SCP evolves.

2. A system of implementing procedures to maintain traceability and control.

3. Control of references relative to both technical acceptability and subsequent file maintenance.

Additional guidance is provided by the following:

1. The OCRWM AO, which provides technical guidance for the preparation of the SCP.

2. The OCRWM Production Guidance Manual, which provides editorial guidance for the preparation of the SCP.

3. The OCRWM final procedures for HQ Approval of Study Plans Supporting the SCP.

It is the responsibility of the Branch Chief, R&SEB, to ensure that the activities set forth in the SCPMP are conducted in accordance with this plan and the overall QA program for the NNWSI Project.

8.2 QUALITY ASSURANCE RESPONSIBILITIES

8.2.1 WMPO SCP activities

Overall responsibility for verifying implementation of the controls outlined in the SCPMP rests with the WMPO QA Coordinator. These responsibilities include the following:

1. Reviewing and approving the SCPMP to ensure compliance with QA requirements.

2. Monitoring the SCPMP documentation and records systems.

3. Monitoring compliance with the established implementing procedures and instructions, and documenting findings or recommendations.

4. Monitoring independent reviews and disposition of comments.

5. Recommending corrective measures to the SCPMG.

The WMPO QA Coordinator, with assistance from the WMPO QA, will provide the SCPMG Manager with guidance in QA matters and will ensure that each NNWSI Project participant contributing to the SCP is following both the controls outlined in this plan.

8.2.2 NNWSI Project participants

The development of the individual NNWSI Project participant's input to the SCP (e.g., technical data chapters, technical procedures, and study plans) will be controlled appropriately. Each participant is required to evaluate his SCP activities in accordance with NNWSI QAP, NVO-196-17, QAPP Requirements for the respective Participating Organizations and NTS Support Contractors, and to assign an appropriate QA level to his activity in accordance with NNWSI- SOP-02-02. Based on the assigned QA level and scope of work, appropriate quality assurance requirements will be applied in accordance with the WMPO's QAPP and associated implementing procedures. WMPO's QA organization will monitor the SCP activities to ensure compliance with the established quality assurance requirements.

ENCLOSURE 2.3.2:

DOE/HQ FINAL PROCEDURE AND CLARIFICATION

Enclosure 10: WMPO Standard Deficiency Report No. 099, Revision 0

Department of Energy
Nevada Operations Office
P. O. Box 98518
Las Vegas, NV 89193-8518

JUL 19 1988

Michael E. Spaeth
Technical Project Officer
for NNWSI
ATTN: Steve Nolan
Science Applications International
Corporation
The Valley Bank Center
101 Convention Center Drive
Suite 407
Las Vegas, NV 89109

WASTE MANAGEMENT PROJECT OFFICE (WMPO) QUALITY ASSURANCE (QA) STANDARD DEFICIENCY REPORT (SDR) NO. 099, REVISION 0

The enclosed SDR is being returned in accordance with the previsions of Paragraph 5.2.2.4 of QMP 16-03 of March 27, 1987.

Study plans are prepared as an extension of the Site Characterization Plan Management Plan (SCPMP). The Study Plans cited in the subject SDR were prepared and approved within the overall framework and guidance established by the SCPMP.

James Blaylock
Project Quality Manager
Waste Management Project Office

WMPO:REM-2933

Enclosure:
SDR No. 099, Revision 0

cc w/encl:
J. Estella, SAIC, Las Vegas, NV
R. E. Monks, WMPO, NV

cc w/o encl:
V. J. Cassella, HQ (RW-123) FORS
E. L. Wilmot, WMPO, NV

Enclosure 11: Observation Number YMP-SR-88-019-01

WMPO STANDARD DEFICIENCY REPORT

N-QA-038
3/87

Completed by Originating QA Organization

1 Date December 1, 1987 | 2 Severity Level ☐ 1 ☒ 2 ☐ 3 | Page 1 of 2

3 Discovered During	3a Identified By	3b Branch Chief Concurrence Date	4 SDR No.
N/A	S. Nolan		099 Rev. 0

5 Organization	6 Person(s) Contacted	7 Response Due Date is 20 Working Days from Date of Transmittal
WMPO	M. Pendleton	

8 Requirement (Audit Checklist Reference, if Applicable) NVO-196-17, Rev. 5, Section V
Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, and drawings of a type appropriate to the circumstances.

9 Deficiency
The following study plans have been prepared and reviewed by NNWSI Project Participants and WMPO staff personnel without the benefit of the preparation and reviews being performed in accordance with an approved Project document (cont'd)

10 Recommended Action(s): ☐ Remedial ☐ Investigative ☒ Corrective

See Page 2

Aprvl.

11 QAE/Lead Auditor Date	12 Branch Manager Date	13 Project Quality Mgr. Date
Steven P. Nolan 12.9.87	J. W. Estella 12/9/87	

Completed by Organization in Block 5

14 Remedial/Investigative Action(s)

15 Effective Date _____

16 Cause of the Condition & Corrective Action to Prevent Recurrence

17 Effective Date _____

18 Signature/Date

Comp. by Orig. QA Org.

19 Response	☐Accept ☐Reject ☐Amended Response	QAE/Lead Auditor/Date	Branch Manager/Date
20 Amended Response	☐Accept ☐Reject	QAE/Lead Auditor/Date	Branch Manager/Date
21 Verification	☐Satisfactory ☐Unsatisfactory	QAE/Lead Auditor/Date	Branch Manager/Date

22 Remarks VOIDED PER LTR. BLAYLOCK TO SPAETH DTD. 7/15/88

23 QA CLOSURE	QAE/Lead Auditor/Date	Branch Manager/Date	PQM/Date

Block 9 - Deficiency (cont'd)

and/or instruction. These study plans have also been submitted to DOE/HQ for comment consolidation meetings/workshops:

Examples Are:

Study Plan#	Subject
8.3.1.4.2.2	Characterization of Structural Features Within the Site Area
8.3.1.2.2.4	Characterization of Yucca Mountain Unsaturated Zone Percolation Test ESF
8.3.1.2.2.2	Water Movement Tracer Tests Using Chlorides and Chlorine 36
8.3.1.15.2.1	Characterization of the Site Ambient Stress Conditions

Block 10 - Recommended Actions

1. Initiate action to stop the preparation and review of NNWSI study plans until the required controls have been developed, approved, and issued or devise an interim plan to control this activity until such time that required controls are in place.
2. Develop and issue the required documents to control the preparation and review of NNWSI study plans.
3. Investigate to determine the specific study plans affected to date that were prepared and/or reviewed without the proper controls in place.
4. Upon development and issuance of required documents, determine whether the study plans developed and reviewed to date require a re-review and if not, provide proper justification for this determination.
5. Provide training to personnel assigned responsibility for the preparation, review, and issuance of study plans.
6. Determine cause and provide action that will be taken to prevent recurrence.

WMPO OBSERVATION NO. YMP-SR-88-019-01

N-QA-012
8/88

Completed by Originating QA Organization

Noted During:	Identified By:	Date:
YMP-SR-88-019	T. Higgins/J. Jardine	1/27/89
Organization: Project Office	**Person(s) Contacted:**	Response Due Date is 20 Days from Date of Transmittal

Discussion: The following observations resulted from the surveillance of the Study Plan review process as documented on review comment forms and correspondence among management authors and reviewers in the Project Office and at the Project Participant sites:

1. Review of revisions 0 and 1 to the SCP Management Plan and of QMP-06-03 indicates that none of these documents included instructions for the review of Study Plans. Revision 2 of the SCPMP (effective 4/21/88) was the first document in the Project that specified instructions for the review of Study Plans. None of the twelve Study Plans currently available entered the review process

QAE/Lead Auditor	Date	Branch Manager	Date
[signature]	1/27/89	[signature]	1/29/89

Completed By Respondee

Response:

The following steps have been taken to address the recomendations of the surveillance team in WMPO Observation No. YPM-SR-88-019-01:

1. The SCPMP has been revised to exclude all instructions relating to the review process for Study Plans.

2. An Administrative Procedure (AP-1.10Q) was prepared and approved (effective date, 12/14/88). This procedure provides a complete set of instructions for the preparation and review of Study Plans. It provides for 1) written criteria for technical review, 2) provision for documentation of reviewer's qualifications, 3) provisions for the resolution of disputes, and 4) provisions for maintenance of records that document the review process.

Signature: [signature] **Date:** 5/20/89

Completed By QA Org.

Response Receipt Verified/Closed ☐

QAE/Lead Auditor	Date	Branch Manager	Date

Remarks:

after the issuance of Rev. 2 of the SCPMP. Consequently, part of the review process for all twelve Plans was conducted without benefit of an approved procedure.

2. Attempts to locate and understand the documentation relating to the review of the twelve Study Plans were hindered by the lack of a coordinated record system. Two sources of information were identified during the surveillance, namely: the Correspondence Control Facility and the working files of the T&MSS Study Plan Coordinator. Neither source nor a combination of the two sources provide a clear record of the review process employed prior to Rev. 2 of the SCPMP.

3. The review comment forms employed are often not completed so that review completeness and reviewer identity can be shown unambiguously. Based on the sample examined:

   - o Reviewer's organization is usually not indicated
   - o Reviewer identification usually appears only on the first page.
   - o Reviewers did not sign their review package
   - o Reviewers rarely initial the individual pages of their review
   - o The document title often does not appear on continuation pages
   - o Pages are often unnumbered
   - o Total page count is rarely indicated

Based on the observations given in this report the surveillance team recommends that the following steps be taken:

1. Revise the SCPMP to exclude all instructions relating to the review process for Study Plans.

2. Prepare an Administrative Procedure that displays a level of detail sufficient to describe in a qualitative and/or quantitative manner the complete set of instructions for the review of Study Plans. Emphasis must be placed on compliance with the provisions of the NNWSI QAP, 88-9, Rev. 1 with particular attention to:

   - o The use of written criteria that directs the technical review of study plans.
   - o Provisions to assure that all technical reviewer's have adequate education and experience to understand and critically review Study Plans from a technical perspective.

- o Explicit provisions for the resolution of disputes.

- o Provisions for the collection and maintenance of records in a manner that lends traceability to the review process.

3. Collect all records pertaining to the review of Study Plans prior to 4/21/88 and assemble packages that provide evidence of the review process employed prior to 4/21/88. Review these packages to ascertain the extent to which the review process complies with current requirements for such reviews. Particular emphasis should be placed on all aspects of the conduct of technical reviews.

Response, continued:

3. All records pertaining to the review of the 5 Exploratory Shaft construction phase Study Plans have been collected and assessed to ascertain the extent to which the review process complies with current requirements for reviews of Study Plans. The results of this assessment are documented in the Study Plan Assessment which is currently under QMP-06-03 review. Records of Study Plan reviews are being reviewed for completeness.

For the record, we believe that the third observation is overstated. While we agree that the comment resolution forms were not always complete (especially for the reviews that were ongoing), we do not believe that this was often the case).

Enclosure 12: DOE/HQ procedures for Study Plan Review and Approval

Department of Energy
Nevada Operations Office
P. O. Box 14100
Las Vegas, NV 89114-4100

January 21, 1987

Ralph Stein, Director, Engineering & Geotechnology Division, Office of Geologic Repositories, (RW-23), FORS

PROCEDURE FOR DEPARTMENT OF ENERGY HEADQUARTERS (HQ) APPROVAL OF SITE CHARACTERIZATION PLAN (SCP) STUDY PLANS

The Nevada Nuclear Waste Storage Investigations (NNWSI) Project has reviewed the proposed procedure for HQ approval of SCP study plans. We consider the proposed review process to be of concern in two important areas. First, study plans would not receive DOE/HQ approval until after review and consultation with the Nuclear Regulatory Commission (NRC). We believed that the study plans would be Project documents that would receive HQ approval before they are sent to the NRC. Second, the HQ review appears to us to be extensive and to require an extended period for completion. Our analysis indicates that the proposed comprehensive review and revision may require up to approximately eight months to complete after a study plan has been prepared and reviewed internally by the Project (see enclosure 1). It is not clear how the proposed review and approval can be completed in the time frame outlined in your letter of December 11, 1986. An alternative approach would be for HQ reviewers to participate in the Project review of study plans.

Specific comments are listed below:

- The guidance appears to reiterate the requirement that the Exploratory Shaft Facility (ESF) study plans and study plans for activities to be initiated six months to one year after issuance of the SCP be provided to the NRC with the SCP. This requirement appears to go beyond the agreements of the May 7-8, 1986, NRC/DOE meeting on the level of detail of site characterization plans. According to the May NRC/DOE agreements, study plans for studies to be initiated within six months after issuance of the SCP should be given to the NRC before issuance of the SCP; study plans for ongoing studies which will continue past SCP issuance should accompany the SCP. It appears that there may be some timing conflicts.

- Many of proposed reviewers have already reviewed summaries of the study plans during the SCP review and concurrence process. Therefore, it is not clear why HQ organizations, outside of OGR (such as the Office of General Council and the Office of Environmental Guidance), are included in the review and approval cycle for technical study plans. We are interested to know the role the other organization will play in the regulatory review process.

- Study plans address tests and activities to be conducted over the entire period of site characterization. As additional data are acquired and analysed, revisions to study plans will be issued sequentially throughout site characterization. The proposed review and approval procedure does not address procedures for revisions to approved study plans.

- The performance allocation process should lead to the resolution of strong differences as to what information will be needed to resolve performance and design issues for license application. Because of the accelerated SCP preparation process, these differences were not completely resolved during the SCP review and approval process. The reviews of the study plans should be structured to focus on resolving the difference regarding the information believed to be necessary to meet the performance and design needs of the Project.

- OGR might want to reconsider the sequence of events that are necessary before initiating site characterization activities. The review and approval procedure implies that a study cannot be initiated until step 11, final approval, is completed. It is the Project's view that this sequence of events will lead to extensive delays and cause increased cost to the program. For example, if the NRC does not identify serious concerns within the first three months of their review, then the Project should be allowed to begin an activity. After the final NRC comments are received and resolved, the Project could issue a revised study plan. As an indication of potential delay, we should consider the recent comments received from NRC on December 23, 1986 regarding the final EA. It was supposed to be timely input for the SCP. It was not.

- The review and approval procedure does not discuss NRC and State consultations in detail (NRC/DOE Agreement and Action Item #2, Summary of the NRC/DOE Meeting on the level of detail for Site Characterization Plans and Study Plans, May 7-8, 1986). Specifically, no mechanism is provided for addressing and resolving comments from the State and Tribes.

In conclusion, the Project encourages OGR to consider adopting a more streamlined review procedure with their staff participating in internal project reviews of the study plans. Given the requirement for extensive inter-actions with the NRC and the States/Tribes during the development of the study plans, an efficient mechanism to produce approved study plans in a timely manner should be developed. We believe that approval of study plans by HQ should be given prior to sending study plans to the NRC.

If you have any questions or need clarification of the concerns noted above, please contact Maxwell B. Blanchard at (FTS) 295-1091 or Uel S. Clanton at (FTS) 295-1589.

Donald L. Vieth, Director
Waste Management Project Office

WMPO:MBB-767

Enclosure:
As stated

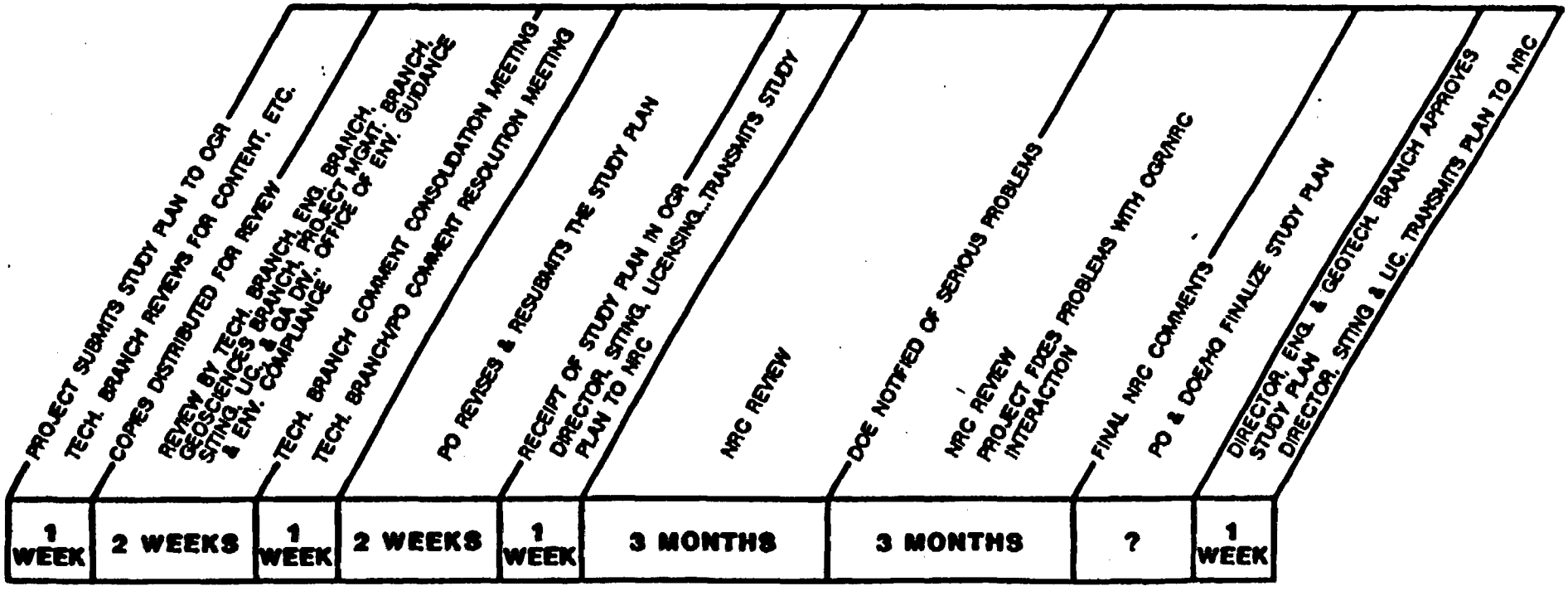
cc w/encl:
V. J. Cassella, HQ (RW-222), FORS
L. R. Hayes, USGS, Denver, CO
T. O. Hunter, SNL, 6310, Albuquerque, NM
D. T. Oakley, Los Alamos, NM
L. D. Ramspott, LLNL, Livermore, CA
M. D. Voegele, SAIC, Las Vegas, NV
D. B. Jorgenson, SAIC, Las Vegas, NV
J. L. Younker, SAIC, Las Vegas, NV
J. O. Neff, SRPO, CL
O. Lee Olsen, BWIP, RL
M. B. Blanchard, WMPO, NV
U. S. Clanton, WMPO, NV

U.S. DEPARTMENT OF ENERGY

OCRWM Nevada Nuclear Waste Storage Investigations PROJECT

OGR

OGR PROPOSED REVIEW CYCLE FOR STUDY PLANS



United States Government

Department of Energy

memorandum

DATE: APR 14 1987 (4/14/87 Please make copies for: C. Biddison, M. Pendleton, M. Voegele, M. Teubner, M. Glora, M. Gianpaoli, J. King, T. Grant, M. Jablonski, G. Fasano, L. Hoffman, J. Shaler, D. Jorgenson)

REPLY TO ATTN OF: RW-23.2

SUBJECT: Final Procedures for HQ Approval of Study Plans Supporting the Site Characterization Plans (SCP)

TO: J. Anttonen, BWIP
J. Neff, SRPO
D. Vieth, NNWSI

Attached is the final procedure for HQ approval of study plans prepared by the Project Offices to support the SCP (see Attachment A). This approval procedure was prepared in response to Project Office requests that HQ define its procedure for approving study plans before they were submitted to the Nuclear Regulatory Commission for review. A proposed procedure was forwarded to your offices for comment in December, 1986. [redacted] This procedure for approval of study plans is being implemented by HQ immediately.

In addition, guidance was developed on preparation and revision of study plans (see Attachment B). Upon receipt of this memo, your office should prepare a list of the study plans anticipated to be necessary to support the SCP during the site characterization process. As explained further in Attachment B, the study plans on this list should correspond exactly (in number, title, SCP section number, and any other identifier) with the "studies" that are now or eventually will be presented under the investigations in Section 8.3 of your SCP. This list should reflect the results of recent HQ-Project Office direction on development of issue resolution strategies and associated test strategies, and should include the following three parts: 1) the study plans for the several studies to be conducted in the exploratory shaft facility along with a brief description, approximately one paragraph in length, of the scope and content of each of these study plans; 2) the study plans in addition to exploratory shaft study plans necessary to support site characterization activities to be conducted in the first year; and 3) the study plans currently anticipated to be necessary to support site characterization activities conducted during the second and succeeding years of the program. The list should clearly differentiate between those study plans necessary to initiate new site characterization activities and those study plans required to restart activities that were delayed due to stop work orders imposed by the Project

c2
3

Offices. The list should be forwarded to HQ not later than April 24, 1987, along with the brief description of exploratory shaft study plans. It will be reviewed by HQ and discussed and approved by HQ in a telecon scheduled for 1:00 p.m. EDT on May 7, 1987.

We realize that aside from the discussion of exploratory shaft study plans, the remaining studies listed will be tentative and will be refined as the issue resolution strategies and test program presented in sections 8.2 and 8.3 of the SCP are finalized. Therefore, a revised list of study plans should be prepared after completion of the final HQ review of the assembled SCP for each Project Office and should be forwarded to HQ within three weeks of the completion of that review. Completion of these study plan lists will close out the open action item remaining from the SCP management meeting held August 27-28, 1986 in Denver, Colorado, when each of the Project Offices was requested to identify those study plans believed necessary to support the SCPs.

Finally, note that the exploratory shaft study plans should be forwarded to HQ for review sufficiently in advance of the date of SCP issuance to allow for the review and approval process set forth in Attachment A. For the NNWSI SCP, these study plans should be provided to HQ no later than July 3, 1987. For the BWIP SCP, these study plans should be provided to HQ by early August, 1987.

Your cooperation in this matter is appreciated. Should you have any questions, please contact Carol Hanlon on FTS 896-1224, or Steve Singal on FTS 896-2878.

Ralph Stein

R. Stein, Director
Engineering & Geotechnology
Division
Office of Geologic Repositories

attachments (3)

cc:
S. Kale
T. Isaacs
R. Stein
D. Alexander
C. Hanlon
S. Singal
S. Grodin
M. Frei
R. Nussler
S. Echols
C. Borgstrom
C. Bradley
M. Blanchard
M. Voegele
J. Mecca
J. Kovacs

A. Jelacic
J. Knight
C. Newton
J. Parker
J. Bresee
R. Blaney
V. Cassella
J. Daly
J. Morris
B. Gale

G. Appel
T. Baillieul
R. Jackson
J. Nelson
W. McClain
A. Van Luik
D. Edgar
C. Tsang

02/5

Attachment A

DOE/HQ Approval Procedure for SCP Study Plans

The study plan approval process will consist of a one-cycle review to be accomplished within approximately seven weeks of receipt of the study plan at DOE/HQ. Achieving this goal for the large number of study plans expected to be produced will require the Project Office and DOE/HQ staff to work in close cooperation throughout the approval process. The steps for DOE/HQ approval of the study plan are shown in the attached figure and described below:

1. During preparation of study plans, Project Office personnel will brief DOE/HQ staff at least bimonthly on their progress toward completing the study plans and any problems that may have arisen.

2. When the study plan is considered by the Project Office to be complete and ready for review, 10 copies of the study plan will be submitted to the Technology Branch for DOE/HQ approval.

3. Upon receipt of a study plan, the Technology Branch will review it for acceptability of content, level of detail, for compliance with the May 7-8, 1986 DOE/NRC agreement, and to identify the branch with lead responsibility for DOE/HQ review.

4. Upon determining that the study plan is acceptable for review and within one week of its receipt, the Technology Branch will provide copies to the Engineering Branch, Geosciences Branch, Project Management Branch, Siting, Licensing, and Quality Assurance Division, Office of Environment, Safety and Health, Office of General Counsel, Weston and technical reviewers at the National Laboratories for comment. Reviewers will have two weeks to review and comment on the study plan. All concerns and specific recommendations for resolution of the concerns will be documented on comment sheets, as has been done throughout the SCP review process.

5. On the last day of the two week comment period the lead branch will conduct a comment consolidation meeting to discuss all DOE-HQ comments on the study plan and develop a consolidated set of comments.

6. Within one week of the comment consolidation meeting, the lead branch will conduct a comment resolution workshop with the Project Office to resolve all DOE/HQ comments. The Director, Engineering and Geotechnology Division and the Project Manager, will be available, if necessary, to resolve any contentious issues.

7. Within two weeks after the comment resolution workshop, the Project Office will revise the study plan and resubmit it to the Technology Branch for the DOE/HQ approval.

8. Within one week of the receipt of the revised study plan, the Director, Engineering & Geotechnology Division will approve the study plan. After approval, the Director, Siting, Licensing, and Quality Assurance Division will provide the study plan to the NRC for its review and to the State and Tribes for their information.

9. The NRC will identify major concerns, if any, during the first three months of its six-month review period.

10. If major concerns are identified by the NRC in a study plan, the Project Office and DOE/HQ will jointly evaluate the concerns and meet with the NRC to discuss them, if necessary, and determine the appropriate resolution.

11. After receipt of the NRC comments following its six-month review, the Project Office will meet with DOE/HQ to determine how comments will be addressed. The Project Office will revise study plans, within three weeks.

12. Revised study plans will be forwarded to the NRC, and information copies will be provided to States and Tribes.

02
7

Attachment B

Preparation, Release, and Revision of Study Plans

In meetings held on October 29-30, 1985 and May 7-8, 1986, with the Nuclear Regulatory Commission on the level of detail to be presented in the Site Characterization Plan (SCP), the DOE defined the hierarchy of program activities to be conducted during site characterization as follows (in order of increasing detail): generic programs; specific programs; investigations; studies; and tests and analyses. At these meetings the DOE stated that in Section 8.3 the SCP itself would present details of site characterization activities to the investigation level and would identify with lists the studies, tests, and analyses that would support each investigation. Separate study plans supporting the SCP would be prepared to present specific details of each study, including the description of the tests and analyses to be performed as part of the study. Both the investigations presented in the SCP and the study plans presented separately would be prepared by the Project Offices to the specific level of detail agreed to between the DOE and the NRC at the May 7-8, 1986 meeting. For each of the studies identified in Section 8.3, an individual study plan will be prepared to describe the details of conducting that study. The specific topics and number of studies to be conducted and study plans to be prepared are expected to be site-specific and will be finalized after completion of issue resolution strategies and the associated testing programs presented in Section 8.2 and 8.3 of the SCP.

Individual study plans are to be linked directly to the SCP by using identical titles and numerical identifiers (e.g., Section 8.3.X.X.X.). Although each study will be described by an individual study plan, these study plans need not necessarily be separate, stand-alone documents. It is acceptable and in most cases, preferable to package any number of study plans together into a single document or "compilation of study plans," provided that they are related in some way and make a logical collection. This packaging can be done in ways to facilitate study plan preparation and review by reducing the total number of documents and providing common sections, such as introductions or background, where appropriate. Also, it is not necessary for all of the study plans ultimately making up a compilation of study plans to be prepared and reviewed simultaneously. In the case where activities are phased, study plans can be added to a compilation of study plans as site characterization progresses and supplemental detail, such as plans for out-year activities,

can be added to existing study plans. However, where either all details on a study plan are not presented or where all study plans in a compilation of study plans are not provided, the missing sections should be identified and a timetable for their preparation should be provided.

At this time, as the preparation of SCPs advances, the Project Offices are instructed to provide HQ with a list of those study plans anticipated to be necessary to support the SCP. This list will have four parts: 1) identification of the study plans for the several studies to be conducted in the exploratory shaft 2) identification of other study plans necessary to support site characterization activities within one year of SCP issuance 3) identification of study plans anticipated to be necessary to support site characterization activities to be conducted during the second and succeeding years following SCP issuance and 4) identification of the study plans to support site characterization activities that are initiated before SCP issuance. The list will also indicate how the individual study plans will be aggregated into compilations of study plans, as described above. The list will clearly differentiate between those study plans necessary to initiate new site characterization activities and those study plans required to restart activities delayed due to stop work orders imposed by the Project Office. The list of study plans should be forwarded to HQ by April 24, 1987, and the first bimonthly briefing on status of study plans should be presented to HQ by the Project Office by May 15, 1987.

Finally, the exploratory shaft study plans should be forwarded to HQ for review sufficiently in advance of the date of SCP issuance to allow for the review and approval process set forth in Attachment A. For the NNWSI SCP, these study plans should be provided to HQ no later than July 3, 1987. For the BWIP SCP, these study plans provided to HQ by early August, 1987.

Timing for release of SCP Study Plans and Start of Studies

The following provides instructions for the release of study plans for the four categories of study plans identified above (plans for ES studies, plans for first year studies, plans for subsequent studies, and plans for pre-SCP studies).

Category I: Exploratory Shaft Study Plans

The NRC will not begin review of the SCP until it has received the study plans for the studies to be conducted in or from exploratory shaft. (These do not include studies conducted in or from the underground facility at the bottom of the shaft.) Therefore, these study plans, expected to be between 5 and 10 in number, must be provided to the NRC along with the SCP. These study plans must be reviewed and approved by DOE/HQ before they are released to the NRC. Note that, in addition, the DOE will identify, at the time of SCP issuance, any additional studies

that have a significant adverse affect on shaft design and construction, or might be significantly adversely effected by shaft construction. Information needed to evaluate the effects of these additional studies will be included in the SCP, or provided in another more detailed form, depending on the extent of such information required.

Category II: First Year Study Plans

According to the agreements from the DOE-NRC May 7-8, 1986 meeting "study plans will be made available as soon as possible following SCP issuance and, in any case, will be available sufficiently in advance of start of the study to allow for review." Further, for all study plans "NRC will notify the DOE of major concerns in the study plans during the first three months of availability." Based on these agreements it is DOE's position that the first year study plans should be provided with the SCP to the maximum extent practicable. For studies where this is not practicable, the study plans will be provided as soon as possible after SCP issuance and these studies will be initiated no less than 3 months from study plan release, since this would allow sufficient time for the NRC to identify major concerns. Exceptions to the minimum 3-month NRC review time will be considered by DOE-HQ on a case-by-case basis.

Category III: Second Year and Beyond

For studies that are to be initiated more than one year after SCP issuance, the associated study plans will be provided to the NRC at least six months in advance of start of the study.

Category IV: Pre SCP Studies

Study plans for the surface investigations initiated before construction of the exploratory shaft facility must be prepared, approved by DOE/HQ, and forwarded to the NRC for review. These study plans should be provided to the NRC for review six months in advance of the study initiation, where practicable. For studies where this is not practicable, the study plans will be provided no less 3 months before study plan initiation, since this would allow sufficient time for the NRC to identify major concerns. Exceptions to the minimum 3-month NRC review time will be considered by DOE-HQ on a case-by-case basis.

Revision of Study Plans

Although the approved study plans will not be baselined through the formal HQ process for baselining program documents, all changes will be ~~controlled~~. As site characterization proceeds and specific information is acquired, it may be necessary to revise approved study plans. As the need for any revision is identified by either HQ or the Project Office it will be discussed in a meeting attended by the Chief, Technology Branch,

any other lead HQ branch and the Project Office SCP Manager. During that discussion, the advisability and ramifications of the change would be determined, alternatives will be evaluated, the impact to other Project Offices examined, and the appropriate manner for implementing the revision and the schedule for its completion will be agreed to. The authority for approving the implementation of any revision will rest wi[illegible] the chief of the HQ lead branch. Those changes that HQ and the Project Office agree are minor may be handled through controlled issuance of replacement pages to the plan. Those revisions agreed to be substantive will be handled through controlled issuance of supplements to the study plans, or, as needed, a revision to the complete plan. Substantive revisions, once completed by the Project Office, will be approved by HQ according to the process specified for new study plans. Copies of all revisions will be provided to the NRC for review, and to the States and Tribes for information. The semi-annual progress reports issued throughout the site characterization process will contain the current list of study plans to be prepared, will identify those study plans that have been completed, will indicate which study plans were revised during the 6 months preceding the progress report, and will indicate which study plans are anticipated to be revised during the next 6 month period.

United States Government | Department of Energy

memorandum

ACTION
CC Kunich
CC Blanchard
CC Dobson
CC Livingston
CC Canton
CC
REC'D IN WMP 8/3/87

DATE: JUL [illegible] 1987

REPLY TO ATTN OF: RW 23.2

SUBJECT: Clarification of, "Final Procedures for HQ Approval of Study Plans Supporting the Site Characterization Plans (SCP)", April 14, 1987

TO: R. Lahoti, SRPO
J. Mecca, BWIP
M. Blanchard, NNWSI

Based on recent discussions with staff from Nevada Nuclear Waste Storage Investigations (NNWSI) Project, the Basalt Waste Isolation Project (BWIP), and the Salt Repository Project Office (SRPO), it has become evident that clarification of several points in the "Final Procedures for HQ Approval of Study Plans Supporting the Site Characterization Plans (SCPs)" would be beneficial for all three project offices. This memorandum has been developed to provide such clarification.

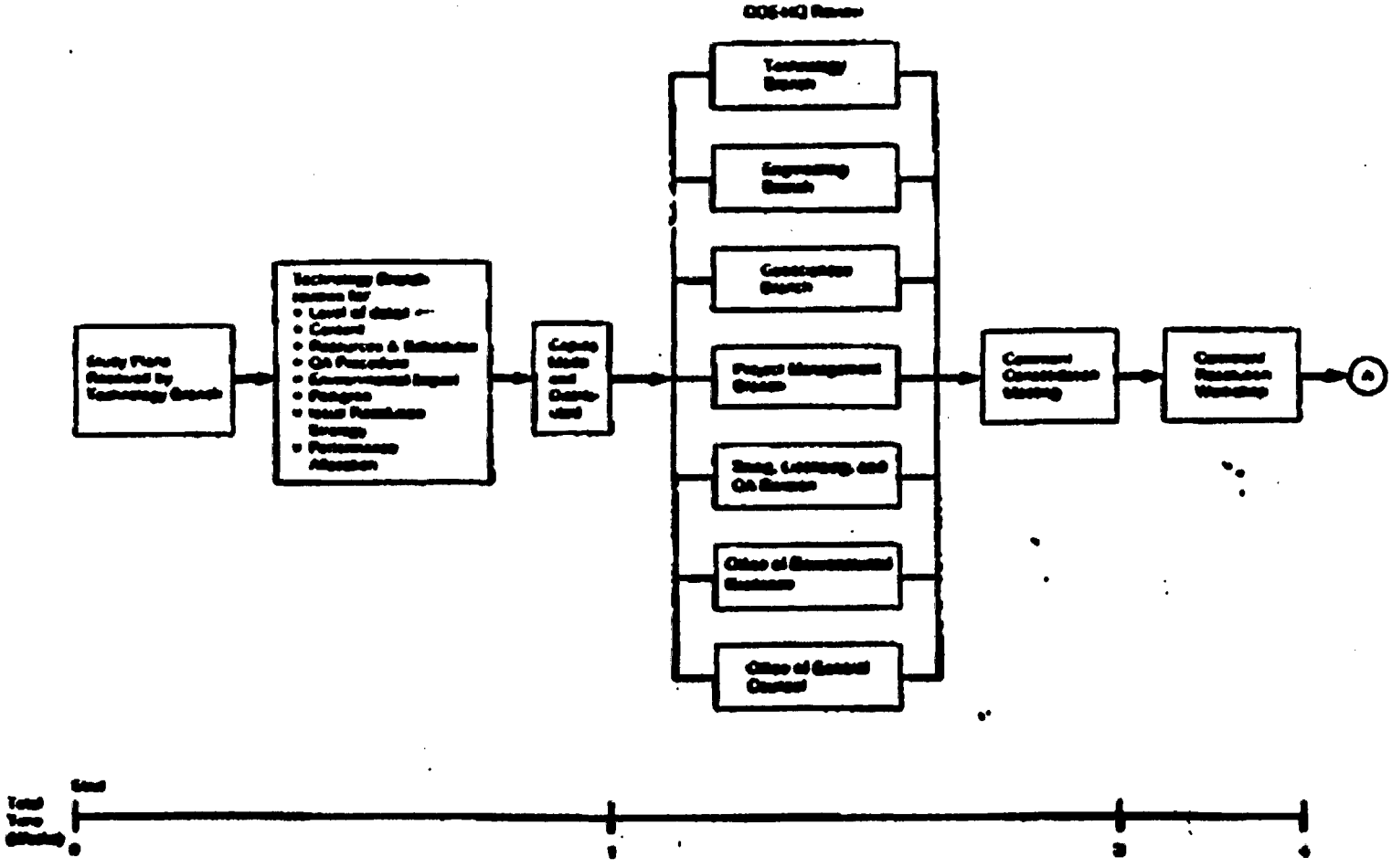
<u>Level of Review</u>

- Study plans are subject to Headquarters review and approval primarily because of Headquarters' responsibilities regarding NRC licensing interactions, the OCRWM budget, and provision of overview guidance to the Project Offices.
- A technical review, by Headquarters, of study plans is essential to ensuring adequacy and consistency of material forwarded to the Nuclear Regulatory Commission (NRC) for their review and comment and to the States and Indian Tribes for their information.
- The chart in the subject memo does <u>not</u> imply that all study plans will be reviewed by all of the DOE branches, divisions or offices indicated. Study plans will be sent only to those organizations with a direct interest in its review.

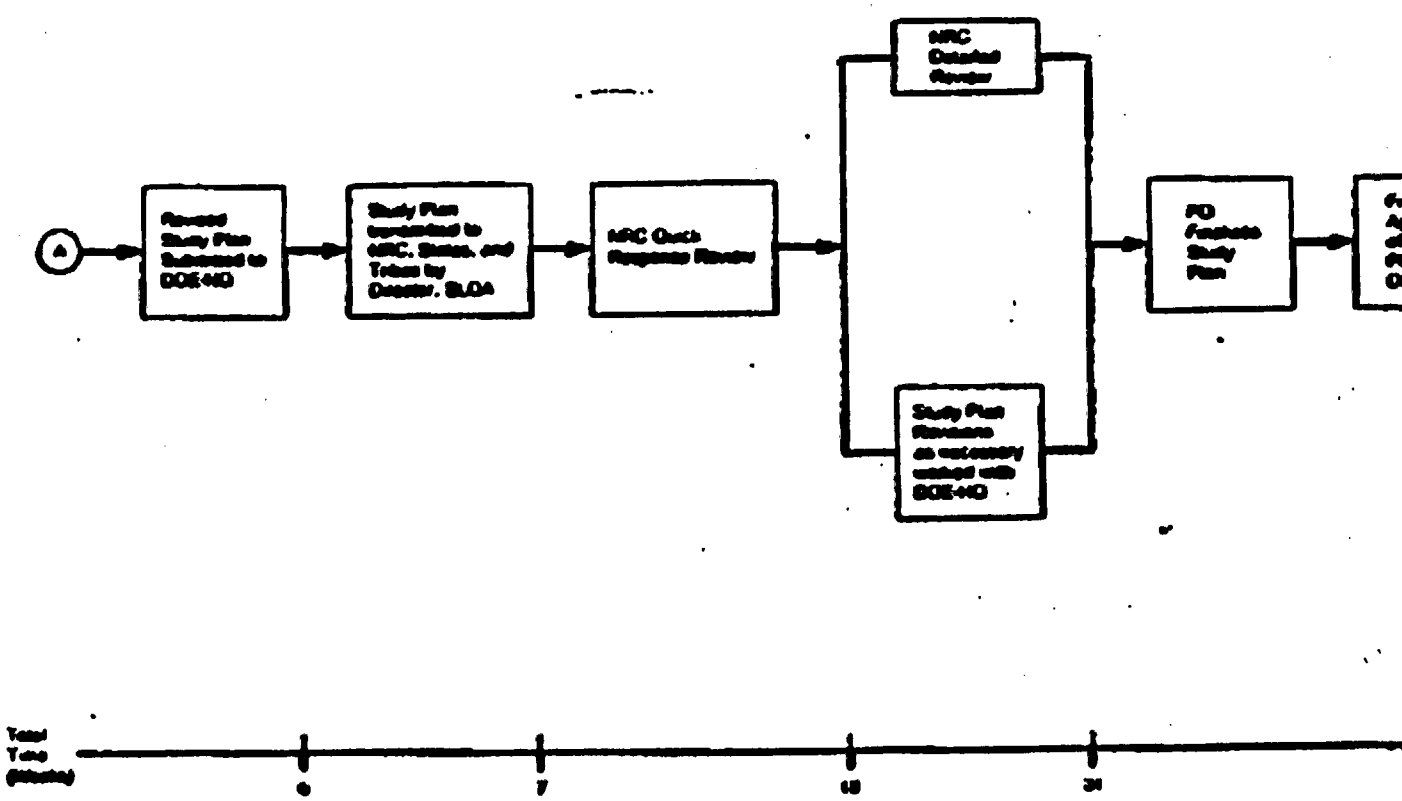
<u>Nature of HQ Review</u>

- The purpose of the HQ review is to ensure consistency of study plans with overall program policy and with the characterization program defined in the Site Characterization Plans.
- The objective of the Chief of the Technology Branch is to keep study plans on schedule and on the single-review cycle described in the subject memo.
- The two-week Headquarters review is primarily an "upper-level" technical review and a policy review. This review will focus on

Study Plan Approval Process



Study Plan Approval Process (Cont.)



the consistency between the issue resolution strategies (and accompanying performance allocations) given in the SCP and the technical approach and implementation described in the study plans, as well as the technical defensibility of the plans.

Timing-Initiation of Activities

- In general, studies and activities cannot be initiated prior to the 3-month NRC quick response review.
- Project Offices can take preliminary steps necessary to set-up tests, experiments, etc. prior to the 3-month preliminary NRC review, but should evaluate the risks in doing so.
- As stated in the study plan review procedures, exceptions to the minimum 3-month NRC review waiting period will be considered by DOE-HQ on a case-by-case basis for First Year Study Plans (Category II), and for Pre-SCP Studies (Category IV).

Ongoing Studies

- Ongoing studies, including those that have been halted due to stop work orders, are included in Category IV (Pre SCP Studies).
- Study plans for ongoing, as well as interrupted ongoing studies, will be reviewed by Headquarters and sent to the NRC for their information and comment.
- The continuation, or re-initiation, of these ongoing studies is not dependant on the receipt of NRC comments. The Project Offices should decide if these studies can proceed prior to receipt of the NRC comments. Major modifications to the study plans in response to NRC comments will be addressed according to the steps 10-12 given in the final procedures for study plan approval.

Study Plan Revisions

- Because approved study plans will be forwarded to NRC and will therefore have entered the licensing arena, revisions to them must be carefully controlled and approved by HQ in joint discussion with the Project Office.
- Project Offices are encouraged to construct study plans that are flexible. This could be accomplished, for example, by incorporating data review/analysis periods, related decision points (e.g. decision to drill boreholes or excavate trenches in alternate locations, perform additional or alternate tests or experiments, specifying approximate numbers of tests rather than committing to fixed numbers) and follow-on plans for more than

one possible decision. These options would then be part of the original study plan and would not require changes to study plans when these decisions are made. But would require additional review/approv

- Stop work should not be required on studies where minor changes are required for the activity descriptions in the study plans.

- DOE-HQ anticipates that requirements for revisions, including modification to activity descriptions, can be approved and details regarding their implementation can be agreed to in teleconferences. During these teleconferences, agreement should be reached between DOE-HQ and the Project Offices on the magnitude of revisions necessary in response to review comments, i.e, if revisions are major or minor. Results of these teleconferences will be documented by written summaries of the teleconferences. Meetings or workshops between Project Offices and Headquarters staff should most often be necessary only if an entire study is being revised (e.g. due to a major change in direction prior to NRC review.)

- The distribution of revisions to a study plan is to be handled by the Project Offices in a controlled manner. Minor revisions can be handled by the issuance of replacement pages, or addendum, to the original plan and sent to all parties concerned (DOE/HQ, NRC, project participants, etc.). Major revisions are to be approved by DOE/HQ according to the process specified for new study plans.

- Major or substantive changes are interpreted as those involving a completely new approach to a study (and, therefore, a substantial change to the existing study plan). Such changes in approach may result from a change in the licensing strategy to be followed to resolve the issue that the study supports, or changes in testing scale or duration, (for example lab scale tests show a need to do previously unplanned in situ room scale testing) that will result in significant schedule delays or budget impacts, or changes in testing that potentially could impact the performance of the site.

- Where major revisions to study plans are required, work stop should be necessary only on those activities undergoing revision. Work would be stopped on an entire study should be necessary only if most activities associated with the study required major changes.

- In most cases worked stopped on studies due to a totally new approach could resume after NRC's Quick Response Review.

Study Plan Priorities

- Project Offices should forward the approximately 5 to 10 exploratory shaft facility (ESF) study plans, which must be

provided to the NRC with the SCP, to Headquarters for review sufficiently in advance of the date set for SCP issuance to allow for review approval (no later than August 15, 1987 for NNWSI and early October for BWIP). MSP-related study plans are top priority.

- Both NNWSI and BWIP Project Offices should consider study plans for ongoing work as second priority and should strive to complete as many as possible for submission with the SCP.

- NRPO should forward those study plans required to initiate surface-based activities to be conducted in advance of SCP issuance, as well as those related to activities conducted in the exploratory shaft facility.

- Required bimonthly briefings on study plans status may be accomplished in a variety of ways, including briefings conducted by Project Office representatives at HQ; teleconferences accompanied by written fact sheets; or submittal of written reports. The specific vehicle for such briefing may be agreed to with HQ and Project Office on a case-by-case basis.

Public Release of Study Plans

- Each Project Office may develop a suggested distribution and transmittal letter for HQ consideration.

- The letter transmitting the study plan to the NRC and other interested parties will be signed by both HQ division directors as noted in Step 8 or Attachment A to the subject memo as well as by the Project Manager from the Project Office submitting the Study Plan.

States and Tribes

- The HQ Study Plan Approval Procedures described the minimum level of interaction to be conducted with affected States and Indian Tribes. These do not preclude the Project Offices from conducting additional interaction they believe appropriate. The Project Offices are encouraged to take the initiative on interactions with States and Tribes. Each Project Office should identify and appraise HQ of the additional action believed to be necessary for interaction with States and Tribes.

Should you have any questions, please contact Steve Singal on FTS 896-2878.

Donald Alexander, Chief
Technology Branch Office of
Geologic Repositories
Office of Civilian Radioactive
Waste Management

cc:

S. Pale	R. Museler	I. Altesman	J. Morris	C. Tsang
T. Isaacs	S. Echols	J. Knight	B. Gale	
R. Stein	C. Bergstrom	C. Newton	G. Appel	
D. Alexander	C. Bradley	J. Parker	T. Ballilieul	
C. Harlen	M. Blanchard	J. Bresee	J. Nelson	
S. Singal	M. Voegele	R. Blaney	W. McClain	
D. Johnson	J. Mecca	V. Cassella	A. Van Luik	
M. Frei	J. Kovacs	J. Daly	D. Edgar	

Enclosure 13: DOE/HQ memorandum initiating Study Plan reviews

United States Government | Department of Ene

memorandum

DATE: MAY 12 1987

REPLY TO ATTN OF: RW 23.2

SUBJECT: HQ Review of SCP Study Plan: Excavation Investigations

TO: Distribution shown on attached "Checklist"

The attached SCP Study Plan has been received and found acceptable for technical review. The responsible Lead Review Branch is indicated on the attached checklist as well as the HQ organizations requested to participate in the technical review. The technical reviews should focus on the content of the study plan and especially whether that content meets the requirements laid out in the May 7-8, 1986 DOE-NRC agreement. All review comments should be made on the standard (white) study plan review comment sheets.

A comment consolidation meeting under the chairmanship of the Lead Review Branch will be held:

Date: May 28, 1987

Time: 9:00 am

Location: GB003B

The comment resolution workshop on this study plan will be held with project office personnel:

Date: June 4, 1987

Time: 8:30 am

Location: GB003B

If you have any questions or problems related to this matter, please call me (586-1238) or Carol Hanlon (586-1224).

Donald Alexander, Chief
Technology Branch

cc: w/enclosures
J. Bresee J. Knight E. Taylor
T. Isaacs J. Nelson W. McCain
R. Stein D. Fenster

w/o enclosures
Submitting Project Office

DOE F 1325.8
(12-84)

United States Government

Department of Ene

memorandum

DATE: OCT 14 1987

REPLY TO ATTN OF: RW-23.2

SUBJECT: HQ Review of SCP Study Plan: Water Movement Tracer Test (S.P. No. 8.3.1.2.2.2)

TO: Distribution shown on attached "Checklist"

The attached SCP Study Plan has been received and found acceptable for technical review. The responsible Lead Review Branch is indicated on the attached checklist as well as the HQ organizations requested to participate in the technical review. The technical reviews should focus on the content of the study plan and especially whether that content meets the requirements laid out in the May 7-8, 1986 DOE-NRC agreement. All review comments should be made on the standard (white) study plan review comment sheets.

A comment consolidation meeting under the chairmanship of the Lead Review Branch will be held:

Date: October 23, 1987

Time: 9:00 am to 12:00 noon

Location: Room GE 069, Forrestal Bldg., Washington, D.C.

The comment resolution workshop on this study plan will be held with Project Office personnel:

Date: Tuesday, October 27, 1987

Time: 9:00 am to 5:00 pm

Location: Room 4E 081, Forrestal Bldg., Washington, D.C.

If you have any questions or problems related to this matter, please call Steve Singal (586-2878)

cel for Donald H. Alexander

Donald Alexander, Chief
Technology Branch
Office of Geologic Repositories
Office of Civilian Radioactive
Waste Management

cc: w/o enclosures:

J. Bresee, RW-22
T. Isaacs, RW-20
R. Stein, RW-233
S. Brocoum, RW-233
J. Knight, RW-24
D. Fenster, Weston
V. Cassella, RW-222
G. Faulkner, RW-233

w/enclosures:

S. Singal, RW-23.2
K. Czyscinski, Weston
M. Blanchard, DOE/NV
D. Dobson, DOE/NV
M. Pendleton, SAIC
B. Edgar, ANL
A. Van Luik, PNL
C. Tsang, LBL

United States Government

Department of Ene

memorandum

DATE: SEP 18 1987

REPLY TO ATTN OF: NW 23.2

SUBJECT: HQ Review of SCP Study Plan: Characterization of Yucca Mountain Unsaturated Zone Percolation Test ESF (S.P. No. 8.3.1.2.2.4)

TO: Distribution shown on attached "Checklist"

The attached SCP Study Plan has been received and found acceptable for technical review. The responsible Lead Review Branch is indicated on the attached checklist as well as the HQ organizations requested to participate in the technical review. The technical reviews should focus on the content of the study plan and especially whether that content meets the requirements laid out in the May 7-8, 1986 DOE-NRC agreement. All review comments should be made on the standard (white) study plan review comment sheets.

A comment consolidation meeting under the chairmanship of the Lead Review Branch will be held:

Date October 11, 1987

Time 8:30 am to 12:00 noon

Location RE069 (Forrestal)

The comment resolution workshop on this study plan will be held with project office personnel:

Date October 14, 1987 and October 15, 1987

Time 8:30pm to 5:00 pm and 8:30 am to 12:00 noon

Location RE069 (Forrestal)

If you have any questions or problems related to this matter, please call Steve Singal (586-2878).

cc: w/o enclosures
J. Breese
T. Isaacs
R. Stein
J. Knight
D. Forstar, Weston
V. Cassella

w/enclosures
K. Czyscinski, Weston
M. Blanchard, NMMSI
D. Dobson, NMMSI
B. Siegal
M. Tendleton, SAIC
D. Edgar, ANL
A. Van Luik, PNL
C. Tsang, LBL

DOE F 1325.8
(12-84)

United States Government | Department of Er

memorandum

DATE: SEP 18 1987

REPLY TO ATTN OF: RW 23.2

SUBJECT: HQ Review of SCP Study Plan: Characterization of Structual Features in the Site Area (S.P. No. 8.3.1.4.2.2)

TO: Distribution shown on attached "Checklist"

The attached SCP Study Plan has been received and found acceptable for technical review. The responsible Lead Review Branch is indicated on the attached checklist as well as the HQ organizations requested to participate in the technical review. The technical reviews should focus on the content of the study plan and especially whether that content meets the requirements laid out in the May 7-8, 1986 DOE-NRC agreement. All review comments should be made on the standard (white) study plan review comment sheets.

A comment consolidation meeting under the chairmanship of the Lead Review Branch will be held:

Date October 13, 1987

Time 1:00 pm to 5:00 pm

Location BE069 (Forrestal)

The comment resolution workshop on this study plan will be held with project office personnel:

Date October 15, 1987 and October 16, 1987

Time 1:00pm to 5:00 pm and 8:30 am to 5:00 pm

Location BE069 (Forrestal)

If you have any questions or problems related to this matter, please call Steve Singal (586-2878).

Donald Alexander, Chief
Technology Branch

DOE F 1320.6 (12-84)

United States Government

Department of En

memorandum

DATE: OCT 14 19[illegible]

REPLY TO ATTN OF: RW-23.2

SUBJECT: HQ Review of SCP Study Plan: Characterization of Site Ambient Stress Conditions (S.P. No. 8.3.1.15.2.1)

TO:

Distribution shown on attached "Checklist"

The attached SCP Study Plan has been received and found acceptable for technical review. The responsible Lead Review Branch is indicated on the attached checklist as well as the HQ organizations requested to participate in the technical review. The technical reviews should focus on the content of the study plan and especially whether that content meets the requirements laid out in the May 7-8, 1986 DOE-NRC agreement. All review comments should be made on the standard (white) study plan review comment sheets.

A comment consolidation meeting under the chairmanship of the Lead Review Branch will be held:

Date: October 23, 1987

Time: 1:00 pm to 5:00 pm

Location: Room 6E 069 (Forrestal)

The comment resolution workshop on this study plan will be held with Project Office personnel:

Date: Wednesday, October 28 and Thursday, October 29, 1987

Time: 9:00 am to 5:00 pm

Location: Room 4E 081, Forrestal Building, Washington, D.C.

If you have any questions or problems related to this matter, please call Steve Singal (586-2878).

clh for Donald H. Alexander

Donald Alexander, Chief
Technology Branch
Office of Geologic Repositories
Office of Civilian Radioactive
Waste Management

cc: w/n enclosures:

J. Bresee, RW-22
T. Isaacs, RW-20
R. Stein, RW-233
J. Knight, RW-24
D. Fenster, Weston
V. Cassella, RW-222

w/enclosures:

S. Singal, RW-23.2
K. Czyscinski, Weston
M. Blanchard, DOE/NV
D. Dobson, DOE/NV
M. Pendleton, SAIC
D. Edgar, ANL
A. Van Luik, PNL
C. Tsang, LBL

Enclosure 14: DOE/HQ Checklist for Study Plans

STUDY PLAN CHECKLIST

Project Office _____

Study Plan Number & Title _____

Other Identifiers, if any _____

Date of Study Plan _____

Acceptability Reviewer _____

Date of Review _____

Acceptable for Technical Review _____

_____

Lead Review Branch _____

Technical Reviews (distribution):

Technology Br.	Engineering Br.	GeoSciences Br.	Proj. Mgt. Br.
☐	☐	☐	☐
C. Hanlon S. Singal	M. Frei		R. Blaney

Siting, Licenses & QA Div.	Econ. & Int'l Analysis Br.	O. Environment Safety & Health	O. General Counsel
☐	☐	☐	☐
C. Head C. Newton G. Parker	B. Gale	C. Borgstrom C. Bradley	R. Mussler S. Echols

Approved _____ Date _____
(Chief, Technology Branch)

	YES	NO
1. Is the study identified in the SCP with the same title and numbers?	___	___
2. Is the study described in the study plan consistent with the study description presented in the SCP?	___	___
3. Is there an explicit link between the tests and analyses in the study and the relevant issue resolution strategies (including relevant performance goals or parameter goals) set forth in the SCP?	___	___
4. Is the overall schedule for the study in the study plan consistent with the schedule presented in the SCP Section 8.5?	___	___
5. Does the study plan contain the material called for in the May 7-8, 1986 DOE-NRC agreement on content requirements? Specifically, does it contain:	___	___
I. Purpose and Objective of Study	___	___
II. Rationale for Selected Study	___	___
III. Description of Tests and Analysis	___	___
IV. Application of Results	___	___
V. Schedule and Milestones	___	___

CHECKLIST FOR TECHNICAL REVIEW OF STUDY PLAN

Project Office _____

Study Plan Number & Title _____

Other Identifiers, if any _____

Date of Study Plan _____

Reviewer/Compiler _____

One of the primary purposes of the technical reviews of the study plans is to judge the adequacy and acceptability of the material against the requirements in the May 7-8, 1986 DOE-NRC agreement on content. This checklist is intended to focus and summarize that aspect of the review. The checklist therefore constitutes a general comment on the study plan. Because of that, any item checked "No" should also have a written-in comment. Supplemental comment sheets (white) can and should be filled out for any item the reviewer feels strongly about, whether or not it is indicated on the checklist.

The following checklist gives the responses to the question: Does the study plan provide adequate, appropriate and acceptable material meeting the requirements of the May 7-8 DOE-NRC agreement with regard to . . .

	YES	NO	N/A
I. Purpose and Objective of Study			
o Information to be obtained by the study and its use?	___	___	___
o Rationale/justification for information to be obtained?	___	___	___
II. Rationale for Selected Study			
o Rationale for selected tests and analyses?	___	___	___
o Rationale for selected number, location, duration, timing of tests, considering uncertainty and alternatives?	___	___	___
o Constraints for the study?	___	___	___

	YES	NO	N/A
III. Description of Tests and Analyses			
o For each type of test:			
- Approach, parameters, conditions, number, locations?	___	___	___
- Test methods, procedures, QA requirements?	___	___	___
- Tolerance, accuracy, precision?	___	___	___
- Expected results?	___	___	___
- Test Equipment?	___	___	___
- Data reduction and analysis?	___	___	___
- Representativeness of test, limitations, uncertainties?	___	___	___
- Locations, layout of test?	___	___	___
- Relationship of tests to performance/ parameter goals?	___	___	___
o For each type of analysis:			
- Purpose, including test or design activity being supported?	___	___	___
- Methods of analysis?	___	___	___
- Reference to procedures, QA requirements?	___	___	___
- Data input to analysis?	___	___	___
- Expected output of analysis and accuracy?	___	___	___
- Representativeness of analytical approach, limitations, and uncertainties?	___	___	___

	YES	NO	N/A
IV. Application of Results			
o Where results of study will be used?	___	___	___
o Reference to performance assessment analyses?	___	___	___
o Reference to design and development?	___	___	___
o Reference to planning other characterization activities?	___	___	___
V. Schedule and Milestones			
o Durations and interrelationships of activities in study?	___	___	___
o Timing of study relative to other studies?	___	___	___
o Dates for activities and milestones?	___	___	___