

# YUCCA MOUNTAIN PROJECT ADMINISTRATIVE PROCEDURE

N-AD-001A  
11/88

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.

Effective Date	Revision	Project Manager	Page	No.
12/14/88	0	<i>[Signature]</i> 11/23/88	1 of 20	AP 1.10Q
	Supersedes SCPP 5.6 Rev2	QA Manager <i>[Signature]</i> 11/23/88		

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**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

3.5.00

**AP-2.100 PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS**

**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/86-9), 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).

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	2 of 20	AP 2.100

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

**AP-1.100 PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS**

**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.

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	3 of 20	AP 1.100

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

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

**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.

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	4 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

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

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.

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	5 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

Title

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

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.

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	6 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

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

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

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	7 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

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

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 IRM (Exhibit 2) as a temporary method to identify these

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	8 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

Title

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

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.

**UNCONTROLLED**

**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.

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	9 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

**AP-1.10Q PREPARATION, REVIEW, AND APPROVAL OF SCP 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.**

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	10 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

Title

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

**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.

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	11 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

Title

**AP-1.100 PREPARATION, REVIEW, AND APPROVAL 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 2.4 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).**

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 2, Revision 2	12 of 20	AP 1.100

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

Title

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

- 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 uncertainty 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).**

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	13 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-0019  
11/88

**Title**

**AF-1.100 PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS**

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.

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

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	14 of 20	AP 1.100

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

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

**5. Schedules 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;
- o 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
- o 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).**

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	15 of 20	AP 1.10Q

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-0018  
11/88

TAC-6

**AF-1.100 PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS**

INTERIM REVISION NOTICE SCP AND SCP STUDY PLANS		T-AD-001 11/88
IRN NUMBER.	EFFECTIVE DATE.	PAGE of
<b>APPLIES TO</b>		
SCP Section Number _____		
Title _____		
or		
Study Plan Number _____ Revision _____		
Title _____		
<b>REQUIRED CHANGES.</b>		
<u>SECTION/PAGE NUMBER</u>	<u>CHANGE TO</u>	
<b>APPROVALS:</b>		
Technical Project Officer _____	Date _____	
Director, RMBED _____	Date _____	
Yucca Mountain Project Manager* _____	Date _____	
OCRWM: Chief, Soils and Geosciences* _____	Date _____	
<small>* if required</small>		

**Exhibit 2. Interim Revision Notice.**

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	16 of 20	AP 1.100

**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

FIG. 6

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

INTERIM REVISION NOTICE CONTINUATION SHEET SCP AND SCP STUDY PLANS		T-AD-004 11/88		
IIN NUMBER	EFFECTIVE DATE:	PAGE of		
<p>APPLIES TO:</p>				
<p>REQUIRED CHANGES:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><u>SECTION/PAGE NUMBER:</u></td> <td style="width: 50%; border: none;"><u>CHANGE TO:</u></td> </tr> </table>			<u>SECTION/PAGE NUMBER:</u>	<u>CHANGE TO:</u>
<u>SECTION/PAGE NUMBER:</u>	<u>CHANGE TO:</u>			

Exhibit 2. Interim Revision Notice (continued).

Effective Date	Revision	Supersedes	Page	No.
12/14/88	0	SCP Management Plan Section 6, Revision 2	17 of 20	AP 1.10C

# YUCCA MOUNTAIN PROJECT ADMINISTRATIVE PROCEDURE CONTINUATION PAGE

N-AD-001B  
11/88

**Title**

**AP-1.100 PREPARATION, REVIEW, AND APPROVAL OF SCP STUDY PLANS**

CHECKLIST FOR REVIEW OF STUDY PLANS		T-AD-087 11/88																											
Study Plan Title _____																													
Study Plan Number _____																													
Revision Number/Date _____																													
Principal Investigator/Organization _____																													
<p>Study Plan Coordinator or Designee shall sign and date when completed:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: left; font-weight: normal;">Action</th> <th style="width: 25%; text-align: center; font-weight: normal;">Signature</th> <th style="width: 25%; text-align: center; font-weight: normal;">Date</th> </tr> </thead> <tbody> <tr> <td>TPO Approved Study Plan received</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Screening Review completed</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Letter sent to reviewers to initiate review</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Reviewer questions received</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>All CRFs returned to the Project</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>CRFs sent to principal investigator</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Revised Study Plan/completed CRFs returned to the Project</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> <tr> <td>Resolution to all mandatory comments verified</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> </tr> </tbody> </table>			Action	Signature	Date	TPO Approved Study Plan received	_____	_____	Screening Review completed	_____	_____	Letter sent to reviewers to initiate review	_____	_____	Reviewer questions 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	_____	_____
Action	Signature	Date																											
TPO Approved Study Plan received	_____	_____																											
Screening Review completed	_____	_____																											
Letter sent to reviewers to initiate review	_____	_____																											
Reviewer questions 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	_____	_____																											
<p>The above review steps have been completed in accordance with Administrative Procedure, AP-1.100</p> <p>Director, R&amp;SED _____ Date _____</p>																													

**Exhibit 3. Checklist for Review of Study Plans.**

<b>Effective Date</b> 12/14/88	<b>Revision</b> 0	<b>Supersedes</b> SCP Management Plan Section 6, Revision 2	<b>Page</b> 19 of 20	<b>No.</b> AP 1.100
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**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

N-AD-001B  
11/88

Title

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

STUDY PLAN COMMENT RESOLUTION FORM		T-AD-089 11/88
Comment Number _____ of _____	Type of Review Management _____ Technical _____	Quality Assurance _____ Regulatory _____
1. Reviewer _____	6. Section _____	
2. Organization _____	7. Page _____	
3. Study Plan No. _____	8. Paragraph _____	
4. Title _____	9. Category _____	
5. Revision No./Date _____	(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.

Effective Date 12/14/88	Revision 0	Supersedes SCP Management Plan Section 6, Revision 2	Page 19 of 20	No. AP 1.10C
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**YUCCA MOUNTAIN PROJECT  
ADMINISTRATIVE PROCEDURE  
CONTINUATION PAGE**

**N-AD-001B  
11/88**

**Title**

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

**YUCCA MOUNTAIN PROJECT**

**T-AD-008  
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.**

<b>Effective Date</b>	<b>Revision</b>	<b>Supersedes</b>	<b>Page</b>	<b>No.</b>
12/14/88	0	SCP Management Plan Section 6, Revision 2	20 of 20	AP 1.10C