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6

YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT



(PRO	CEDURE				
Title: PREPARA' STUDY PL		IEW, APPROVA	L, AND REV	ISION OF SIT	E CHARA	CTERIZATIO	N PLAN	
Procedure No AP-1.10Q). :	Revision:	6	ICN:	0	Page 1	of	20
Approval: , J.R. Dyer	1,25	Da 4	Pate: /16/93	Approval: N/A			Date:	
Approval: N/A	0)	ate:	Concurrence: R.E. Spence	RC	loince	Date:	20 193
			REVIS	ION HISTORY		7	7	
Rev. No.	ICN No.	Effective Date	Description	of Revision/ICN				
0		12/14/88	Initial Is	sue				
1		01/22/90	Complet	e Revision				
2		10/09/90	(DOE)/I	ation to reflect leadquarters re ance with proc	organization	and to bring		in

Complete Revision to clarify process

Complete Revision to incorporate changes

Complete Revision to incorporate editorial changes

Complete Revision to reflect new study plan format

03/26/91

07/05/91

04/15/92

05/05/93

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1.0 PURPOSE

This procedure assigns responsibility and provides a process so that Site Characterization Plan (SCP), DOE/RW-0199 Study Plans (SPs) are prepared, reviewed, approved, and revised in a consistent manner. This procedure implements the 1993 DOE/Nuclear Regulatory Commission (NRC) Level of Detail Agreement and Review Process for SPs. Attachment 8.3 cannot be changed without negotiation with the NRC. This procedure also implements applicable requirements of the Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD), DOE/RW-0333P.

2.0 APPLICABILITY

This procedure applies to all Yucca Mountain Site Characterization Project (YMP) organizations and YMP personnel involved in the preparation, review, approval, and revision of SPs.

3.0 **DEFINITIONS**

Terms in this procedure are used as defined in the *Project Glossary*, YMP/89-15. The following additional definitions are specific to the workings of this procedure.

- 3.1 Comment Resolution Form (CRF) (Exhibit 9.1) A form used by a reviewer to document mandatory and nonmandatory comments resulting from a YMP technical review of a draft SP. The form is also used to document the proposed resolution and final disposition of the comments.
- 3.2 Document Action Request (DAR) A request submitted when the objectives, scope, or content of an SP differ from the YMP Requirements Document (RD). A DAR to request a change is prepared and submitted in accordance with (IAW) Administrative Procedure (AP) AP-6.1Q, Project Office Document Development, Review, Approval, and Revision Control.
- 3.3 Editorial Comments Comments that address grammatical or typographical errors and are resolved at the Principal Investigator's (PI's) discretion. Editorial comments are recorded directly on the text of the SP and do not become part of the permanent record.
- 3.4 Mandatory Comments Comments that a reviewer determines represent major technical concerns or inconsistencies with applicable DOE policies or regulatory requirements. Failure to resolve a mandatory comment could compromise the ability of the study or activity to achieve the objectives defined for the study or activity in the YMP RD. Reviewers shall cite the applicable requirement or technical rationale for changing the SP and shall provide a proposed resolution.
- 3.5 Nonmandatory Comments Comments that the reviewer designates for consideration by the PI about the organization or content of the document. Failure to resolve a nonmandatory comment would not compromise the ability of the study or activity to achieve the objectives defined for the study or activity in the YMP RD. Nonmandatory comments are incorporated at the discretion of the PI.

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- 3.6 Principal Investigator The PI is the individual who has the technical responsibility for a particular technical task. For the purposes of this procedure, the PI is the individual responsible for the preparation of an SP, the technical content of the SP, and the revision of the draft SP in response to comments.
- 3.7 Study Plan DOE documents that describe the studies, activities, tests, and analyses that constitute site characterization activities as defined by the Nuclear Waste Policy Act of 1982, as amended. SPs describe in more detail the studies presented in Chapter 8 of the SCP and are designed to meet the objectives given in the YMP RD. Guidance on the level of detail, format, and content of SPs is provided in Attachment 8.3.
- 3.8 Technical Review A documented, traceable review performed by qualified reviewers who are independent of the work described in the SP and who have demonstrated expertise in their area of review. Technical reviews are in-depth, critical analyses of the ability of the activities and tests described in the SP to meet the objectives of the study called for in the YMP RD.
- 3.9 Yucca Mountain Site Characterization Project Requirements Document (YMP RD) Project-level RD that contains the testing objectives for SCP studies. Currently this document is the Site Characterization Program Baseline, YMP/CM-0011, but in the future it may be the Site Design and Test Requirements Document.

4.0 RESPONSIBLE PARTIES

- 4.1 The Director, Regulatory and Site Evaluation Division (RSED), is responsible for the preparation and modification of this procedure.
- 4.2 This procedure and major modifications thereto are subject to review by the Yucca Mountain Site Characterization Project Office (YMPO) and those individuals and organizations identified on the Document Review Record.
- 4.3 The following YMP individuals and organizations or their designees are responsible for activities identified in Section 5.0 of this procedure:
 - a) Project Manager (PM)
 - b) Technical Project Officer (TPO)
 - c) PI
 - d) Branch Chief, Regulatory Interactions Branch (RIB)
 - e) Technical Reviewers
 - f) Director, RSED

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- g) Quality Assurance (QA) Organization
- h) Director, Yucca Mountain Quality Assurance Division (YMQAD)

5.0 PROCESS

A brief overview of this process is provided in the flowchart shown in Attachment 8.1. Acronyms used in this procedure are defined in Attachment 8.2 and/or in the flowchart legend.

5.1 STUDY PLAN PREPARATION AND REVIEW BY YUCCA MOUNTAIN SITE CHARACTERIZATION PARTICIPANT

5.1.1 The PM:

identifies YMP Participant Organizations responsible for preparing specific SPs.

5.1.2 The TPO:

assigns a qualified PI to write the SP for each SP assigned to his/her organization.

NOTE: Qualifications of the assigned PI(s) and reviewers are established and maintained IAW internal procedures of YMP Participating Organizations.

5.1.3 The PI:

prepares draft SP IAW the guidance as described in Subsection 6.1.

5.1.4 The TPO:

- a) ensures that a review of draft SP, including a QA review IAW criteria described in Paragraph 6.3.2, is performed and documented IAW internal review procedures of YMP Participating Organization; and
- b) forwards approved draft SP, along with a statement that QA and technical reviews are complete, copies of any references cited in the draft SP, and a copy of any required DARs to change the YMP RD, to the Director, RSED, for YMP review.

NOTE: Disputed mandatory QA review comments shall be elevated to higher-level QA management for resolution prior to draft approval.

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5.2 YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT REVIEW OF STUDY PLAN

5.2.1 The RIB Chief:

a) ensures that a screening review is conducted upon receipt of the SP to determine whether a QA review has been completed and whether the SP is adequate for technical review;

NOTE: The criterion for the screening review is that the SP appears, in general, to meet the guidance criteria specified in Subsection 6.1. The screening review also checks for unresolved commitments and DARs.

- b) determines the results of the screening review;
- c) prepares and sends a written request for the Director, RSED, to sign for the initiation of the YMP technical and QA review of the SP (See Subsection 6.2 for request information), if the SP is adequate for further review;
- d) returns the SP to TPO with review results for revision IAW YMP Participant procedures, if the SP is inadequate; and
- e) documents the results of this screening review in a letter, and submits it to the Director, RSED.

5.2.2 The Technical and QA Reviewers:

a) review the SP IAW the criteria as described in Subsection 6.3.

NOTE: Documentation of qualifications of reviewers is completed internally by the reviewing organization according to its own procedures prior to initiation of YMP technical reviews of the draft SP.

b) identify comments and determine whether they are editorial, mandatory, or nonmandatory in nature, as defined in Section 3.0 of this procedure;

NOTE: Editorial comments are recorded directly on the text and do not become part of the QA records.

- c) complete lines 1-10 of the CRF, if a comment is mandatory or nonmandatory;
- d) write a comment in Block 11 and suggest a proposed resolution for the comment in Block 12, preferably by providing and attaching text revisions;
- e) prepare and sign SP Review Checklist (Exhibit 9.2) by completing Blocks 1 and 2, if the review was initiated after the effective date of Rev. 2 of this procedure;

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- f) ensure SP review package consists of the following information:
 - 1) draft SP text, if there are editorial comments by reviewer
 - 2) CRFs
 - 3) SP Review Checklist
 - 4) DARs, if any, and reviewer's comments (on a CRF); and
- g) return SP review package to RIB Chief.

5.2.3 The RIB Chief:

forwards consolidated set of all draft SP CRFs and editorial comments to the TPO and the PI.

5.2.4 The PI:

prepares responses or draft revisions to the SP in response to comments.

NOTE: The PI may contact reviewers to clarify and resolve questions concerning comments.

5.2.5 The RIB Chief:

arranges for comment resolution meeting with reviewers to discuss and agree on proposed resolutions to mandatory comments, if required.

5.2.6 The PI:

compiles revised sections and markups that resolve all mandatory comments into a verification draft of the SP.

5.2.7 The TPO:

submits verification draft SP and CRFs to RIB Chief, or Designee.

5.2.8 The RIB Chief:

distributes verification draft SP, mandatory CRFs, and SP Review Checklist to reviewers.

5.2.9 The Technical and QA Reviewers:

a) review and verify resolutions of their mandatory comments in the verification draft SP;

NOTE: If the original reviewer is no longer available, a qualified alternate shall be designated by the reviewing organization.

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- b) sign SP Review Checklist in Block 3 and return CRFs to RIB Chief, or Designee and proceed to Paragraph 5.2.11, if mandatory comments have been adequately addressed in verification draft SP:
- c) attempt to resolve the problem with the PI, if mandatory comments have not been adequately addressed in revised draft SP; and
- d) complete the appropriate section of Block 3 of SP Review Checklist, including an explanation of the problem, and return CRFs and SP Review Checklist to Director, RSED, if resolution is not possible.

5.2.10 The Director, RSED:

- a) resolves disputed mandatory comments in consultation with the appropriate TPO and Division Director:
- b) prepares written instructions for final disposition of disputed mandatory comments; and
- c) signs the appropriate line in Block 3 of SP Review Checklist if one or more of the mandatory comments are disputed (Exhibit 9.2).

5.2.11 The PI:

prepares final camera ready SP.

5.2.12 The TPO:

sends final SP to Director, RSED for approval; include a current list of approved technical procedures for the activities described in the SP.

5.2.13 The Director, RSED:

- a) obtains YMQAD signature; and
- b) approves the final SP by signing SP Approval Form (Exhibit 9.3).

NOTE: Any required changes to the testing objectives in the YMP RD shall be approved before approval of the final SP.

5.2.14 The RIB Chief:

a) authorizes issuance of controlled copies of the SP under applicable procedures; and

NOTE: Comments on approved SPs are responded to IAW AP-1.14, Disposition of Comments on the Site Characterization Program.

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b) compiles a records package to document the completed review process IAW the requirements of Administrative Procedure AP-1.18Q, Records Management: Las Vegas Record Source Responsibilities.

5.3 REVISION OF APPROVED STUDY PLANS

5.3.1 The PI and TPO:

- a) identify the need for and nature of revision of the SP, and submit the proposed revised text, any required DARs, and a statement that QA and technical reviews are complete to the Director, RSED; and,
- b) use vertical change bars in the margins of affected pages, including the table of contents, of proposed revised text.

NOTE: Revisions that affect only a few pages may be submitted as specific page replacements.

5.3.2 The RIB Chief:

- a) checks whether unresolved commitments that affect the SP exist from responses to SCP or SP comments;
- b) reviews the request and determines the category of revision (see Subsection 6.4 for description of revision categories);
- c) documents results in a letter and submits to the Director, RSED.
- d) returns to Paragraphs 5.2.1c through 5.2.14b, substituting the term "revised SP" for "SP," if the proposed change is not a minor change or if the RSED requests a technical review; and
- e) returns to Paragraphs 5.2.13 through 5.2.14b, substituting the term "revised SP" for "SP," if the proposed revision is a minor change and Director, RSED does not request a technical review.

6.0 SUPPORTING DETAIL

6.1 STUDY PLAN PREPARATION GUIDANCE

- 1) SPs should conform to the level of detail, format, and content specified in Attachment 8.3 to the extent practical, unless written permission to deviate is obtained from the RIB Chief. SPs in YMPO review prior to approval of Revision 6 of this procedure may be written to conform to the present format (Attachment 8.3) or to the format guidance from previous revisions of this procedure.
- 2) SPs should include an abstract in front of the table of contents and a list of cited references in back of the text. Copies of the documents referenced in SPs should be provided to YMPO. These copies

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must be legible and reproducible; specific pages should be referenced where appropriate. Manuscripts in review or in preparation are not acceptable.

- 3) SPs shall be consistent with the contents of the YMP RD, unless a DAR to change the YMP RD is submitted IAW AP-6.1Q.
- 4) The SP or subsequent revisions will, if possible, be written to address unresolved commitments, such as Site Characterization Analysis open items, made in comment responses prepared under AP-1.14.

6.2 TECHNICAL REVIEW REQUEST INFORMATION

- 1) Identify the proposed reviewing organizations;
- 2) Establish a schedule for completion of the review; and
- Include a copy of the draft SP, relevant SCP and YMP RD text, any DARs, SP Review Checklist, and CRFs for completion.

6.3 STUDY PLAN REVIEW CRITERIA

6.3.1 TECHNICAL REVIEW CRITERIA

- 1) The technical descriptions in the SP are correct and adequate, within the reviewer's area of expertise.
- 2) Planned tests shall provide the information required by the YMP RD.
- 3) The review shall include a consideration of changes proposed by any DARs included in the review package.
- 4) The SP shall be consistent with applicable NRC agreements, as appropriate (See Attachment 8.3).

6.3.2 OUALITY ASSURANCE REVIEW CRITERIA

QA review criteria shall include applicable requirements of the QARD, Section 2 and Supplement III at a minimum.

6.4 REVISION CATEGORIES

- 1) Major Technical completion of activities omitted from previous revisions, changing parameters, or testing strategy listed in the YMP RD.
- 2) Restricted Technical changes to discussion of technical objectives, methods, or rationale. Responses to technical comments from outside reviewers.

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- 3) Programmatic changes to organization, titles, structure, and/or changes requiring review by Change Control Board.
- 4) Minor other changes that do not meet the criteria for other categories.

7.0 RECORDS

The following lifetime QA records are produced as a result of this procedure:

- 1) draft SCP SP or revised SP submitted by TPO to Director, RSED for review
- 2) results of screening review
- 3) SP Review Checklists or Comment Resolution Forms
- 4) approved or revised SP

NOTE: Handle these records IAW AP-1.18Q.

8.0 ATTACHMENTS

- 8.1 AP-1.10Q FLOWCHART
- 8.2 ACRONYM LIST
- 8.3 U.S. DEPARTMENT OF ENERGY CONTENT GUIDANCE FOR DESCRIPTIONS OF STUDIES IN STUDY PLANS

NOTE: Attachment 8.3 appears in this procedure verbatim, as issued by the DOE.

9.0 EXHIBITS

Exhibits are issued separately from this procedure in a format that may be copied for use when implementing this procedure. Exhibits referenced in this procedure and attached hereto in example format include:

Exhibit 9.1 - Study Plan Comment Resolution Form

Exhibit 9.2 - Study Plan Review Checklist

Exhibit 9.3 - Study Plan Approval Form

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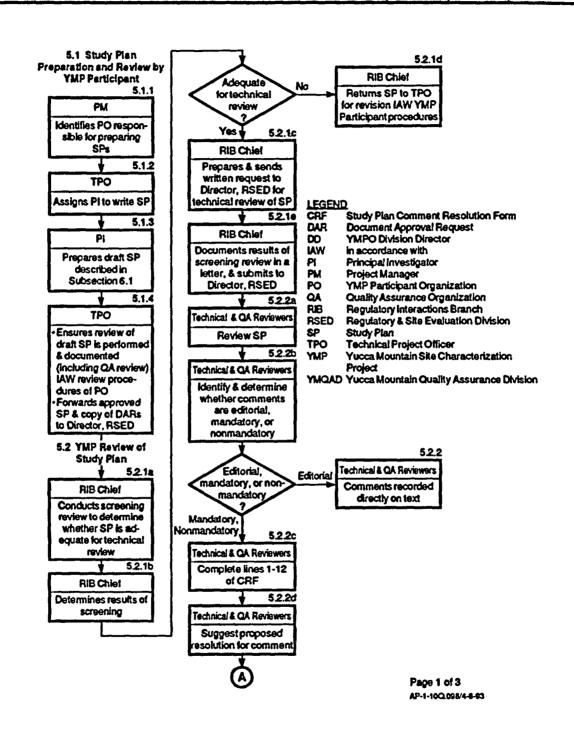
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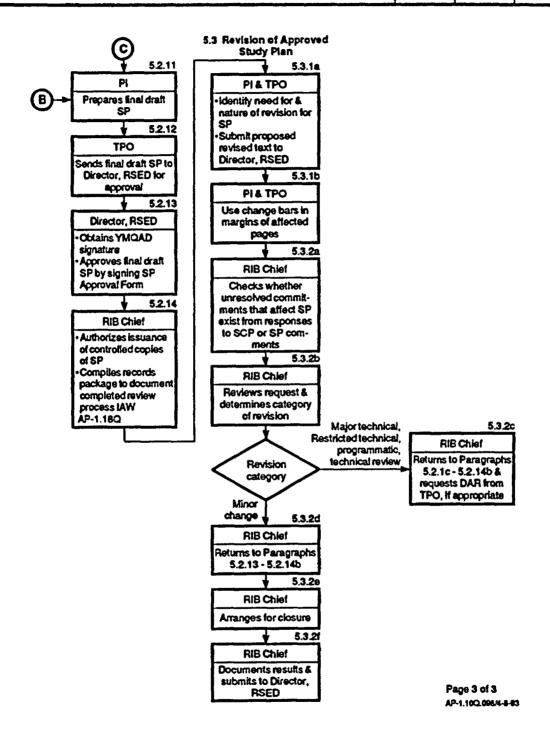
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AP Administrative Procedure Comment Resolution Form **CRF** Document Action Request DAR DOE U.S. Department of Energy **IAW** In accordance with Not Applicable N/A Nuclear Regulatory Commission **NRC** Principal Investigator PΙ PM Project Manager **OA** Quality Assurance **QARD** Quality Assurance Requirements and Description RD Requirements Document RIB Regulatory Interactions Branch **RSED** Regulatory and Site Evaluation Division **SCP** Site Characterization Plan SP Study Plan TPO Technical Project Officer Yucca Mountain Site Characterization Project YMP **YMPO** Yucca Mountain Site Characterization Project Office

Yucca Mountain Quality Assurance Division

YMQAD

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DOE CONTENT REQUIREMENTS FOR DESCRIPTIONS OF STUDIES IN SCP STUDY PLANS

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

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

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

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

I. PURPOSE AND OBJECTIVES

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

II. SCOPE OF WORK

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

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

- The area (and its approximate boundaries) to be studied.
- Aspects of the area that are known or are poorly known.

Attachment 8.3 - U.S. Department of Energy Content Guidance for Descriptions of Studies in Study Plans

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- Type of data to be collected.
- Approximate location and number of tests.
- Methodology or classification system to be used.
- Product, maps, cross sections, etc., to be produced.

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

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

If the study proposes analyses, provide discussion on:

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

Attachment 8.3 - U.S. Department of Energy Content Guidance for Descriptions of Studies in Study Plans (continued)

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

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

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

III. APPLICATION OF RESULTS

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

IV. SCHEDULE

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

Attachment 8.3 - U.S. Department of Energy Content Guidance for Descriptions of Studies in Study Plans (continued)

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All entries shall be legible and made in BLACK link. All spaces shall contain an entry or "NA". Corrections shall be made with a single line through the error and be initialed and dated. Insertions shall also be initialed and dated.					
Comment Number: of Type of Re		leview: creening Quality Assurance			
(Reviewer completes above and items 1	-12)				
1. Reviewer			ICN No /Date	- [
2. Reviewer Phone No.				- [
3. Organization				-	
4. Study Plan No.				- [
5. Title	10.	Category _	Mandatory / Non-mandatory (circle one)	-	
11. Comment					
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12. Proposed Resolution by Reviewer	······································				
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YMP-053-R1 7/1/92	YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT PROCEDURE				
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YMP-017-R2 YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT 5593 STUDY PLAN REVIEW CHECKLIST				
1. Title/Rev. No		All entries shall be legible and made in BLACK Ink. All spaces shall contain an entry or *N/A*. Corrections shall be made with a single line through the error and be initialed and dated. Insertions shall also be initialed and dated.		
Reviewer's Statement: I have reviewed the above referenced Study Plan in accordance with AP-1.10Q. I have completed the sections appropriate to my type of review (screening, technical, or QA). My conclusions with respect to the review criteria of AP-1.10Q are:				
Review Criteria	Yes: Adequ	ruate No: See Comment(s) Numbers		
A. The planned tests will provide the Information required by the YMP Requirements Document.				
B. The format and content of the Study Plan are consistent with the requirements of Section 6.1 of AP-1.10Q.				
C. The technical descriptions in the Study Plan are correct and adequate.				
D. Study Plan is consistent with requirements of the QARD.				
Comments 1 through are attached.				
Reviewer		Date		
3. Comment Resolution Record		:_: 		
The revised Study Plan adequately addresses the mandatory comments. Yes No The following mandatory comments have not been adequately addressed:				
Reviewer		Oate		
Mandatory comments not resolved between the reviewer and the author have been resolved by Yucca Mountain Project Management.				
Director, RSED		Date		

AP-1.10Q

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Study Plan Title _	
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	Prepared by:
	Date:
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Approved:	
	Director, Regulatory and Site Evaluation Division / Date
	Director, Quality Assurance Division / Date
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	Effective Date:

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