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SUMMARY OF NRC-DOE MEETING ON STUDY PLANS
December 15, 1988
Rockville, Maryland

Agenda: See Attachment 1

List of Attendees: See Attachment 2

Summary:

The objectives of the meeting were for NRC and DOE to come to a mutual understanding of: (1) the purpose and scope of study plans; (2) quality assurance (QA) concerns relating to study plans; (3) the DOE and NRC processes for review of study plans and related interactions; and (4) the schedule for study plan preparation and release.

After short opening statements by NRC, DOE, and the State of Nevada, DOE made a detailed presentation addressing the various steps conducted by DOE in preparing study plans under a controlled process (Attachment 3). DOE indicated that study plan reviews and revisions are performed according to approved QA procedures and are fully documented. Changes to study plans will incorporate NRC review comments as appropriate, and revised study plans will be transmitted to organizations and parties on the distribution list. In response to a question as to how seriously NRC review comments would be considered, DOE cited its Interim Procedure for the Review of Study Plans (Attachment 4, p. 5) wherein steps to resolve NRC concerns, including meetings with NRC if necessary, are described.

DOE next discussed the NRC staff draft Study Plan Review Plan (dSPRP). DOE recognized that NRC will segregate comments on study plans into categories and will notify the DOE of NRC objections, as defined in the NRC Review Plan, for a particular study plan within 3 months from time of receipt of the plan. DOE emphasized the importance of such early notification of major concerns by NRC in order to focus interactions on those concerns and hence enable site characterization work to proceed expeditiously.

DOE indicated that it does not believe that an NRC acceptance review of study plans as called for in the dSPRP is appropriate during the pre-licensing phase of the repository licensing program. NRC responded that it intends to do acceptance reviews on all documents submitted for review by DOE as an internal mechanism for deciding whether the documents are of sufficient quality that NRC staff resources should be allocated to review them.

With respect to references supporting study plans, DOE stated that references which support a specific study plan will be provided to NRC with that study plan if DOE has not previously provided them and if they are not readily available in the open literature.

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DOE questioned the validity of NRC's reviewing a study plan to verify the adequacy of the QA program under which the activities in that study would be conducted. NRC explained that DOE had apparently misunderstood the dSPRP in this respect. The NRC staff intends to evaluate the quality of a given study plan as one measure of the effectiveness of the QA program under which the study plan itself was prepared. NRC considers this to be an important component--along with audits, surveillances, and other reviews--of NRC's effort to assess the effectiveness of DOE's QA program.

DOE noted that, according to the dSPRP, although NRC will conduct "start work reviews" of all study plans, it will conduct detailed technical reviews of only selected study plans. DOE asked what criteria are to be applied by NRC in making those selections. NRC replied that study plans related to NRC's major site-specific concerns, as documented in materials such as the NRC comments on the final Environmental Assessment and on the Consultation Draft Site Characterization Plan (CDSCP), would be likely subjects of detailed technical reviews. However, NRC went on to say that the staff needs to evaluate each study plan on a case-by-case basis as it is received before deciding on the need for a detailed technical review. Also, inasmuch as NRC is taking an audit approach to review of DOE's program, i.e., the NRC staff will be doing detailed technical reviews of only a small percentage of study plans, DOE needs to have all of the study plans available for review in a timely manner.

A discussion occurred about the term "start work" in connection with NRC's "start work review" of study plans. To consider "start work" as the "beginning of collection of data" seemed too narrow to the State of Nevada given the potential for preparatory activities that could bear upon the ability to collect data at the site. Pending further discussion at some future time, the following definition of "start work" appears to take into account the concerns expressed by parties at this meeting:

"start work" on a study means the start of data collection or of activities in the field or laboratory preparatory to the start of data collection that may have significant and irreversible effects on characterization that could physically preclude the collection of data for this or any other planned study.

DOE's final comment on the NRC dSPRP was that if NRC solicits comments from the State of Nevada or other affected parties on a particular study plan, as is suggested in the dSPRP, those comments should be made available to DOE. NRC reaffirmed its position that any material received from any party is publicly available. Furthermore, NRC will request that comments transmitted by affected parties to the NRC be transmitted to DOE at the same time.

DOE next discussed standard and non-standard procedures, with an emphasis on (1) transmittal to NRC of non-standard procedures 60 days before implementation; and (2) notification of DOE by NRC of major concerns identified during their review within 30 days from time of receipt. NRC proposed that rather than the automatic submittal of non-standard procedures by DOE to NRC 60

days in advance of implementation, DOE should be prepared to submit them at that time upon verbal request by NRC. DOE agreed with this change. NRC also indicated a concern that the definitions of standard and non-standard procedures and the language used to describe them in this meeting may not be consistent with the language in the Yucca Mountain Project Quality Assurance Plan 88-9, Revision 2, that was recently accepted by NRC. DOE agreed to check that there is consistency with 88-9 in the concepts and descriptions of standard and non-standard procedures.

In concluding its discussion of topics related to study plan preparation and review, DOE indicated that flexibility in the agreement that study plans will be provided to NRC six months in advance of starting work would be beneficial to DOE. DOE intends to release study plans six months in advance of starting work whenever possible. DOE is willing to ensure that study plans will be released a minimum of three months in advance of initiating new work. DOE indicated it will proceed according to its integrated project schedules if no major concerns relating to a particular study plan are received from NRC during the three month period between release of the study plan and the planned start of work. NRC remained firm that the study plans should be furnished six months in advance of starting work, although NRC is willing to consider exceptions to this agreement on a case-by-case basis. The reason why the agreement for submittal of the study plans six months in advance of starting work was originally reached was to allow time for DOE to seriously consider NRC concerns, to have interactions with NRC if necessary, and to factor those concerns into possible revisions of study plans.

Relative to the NRC schedule for review of study plans, the State of Nevada asked if NRC has mechanisms for stopping the clock on review of a study plan if essential information is missing from the study plan and its supporting references. NRC replied that it is not bound by any clock if a need for further information exists to conduct an adequate review.

DOE's next major presentation provided information on quality level assignments for preparation of study plans and the treatment of quality assurance in study plans. The major points made included: (1) study plan preparation will be assigned quality assurance level 1 because study plan preparation is in direct line from SCP to the implementing technical procedures; and (2) each study plan will contain approved quality assurance level assignment sheets, a table listing NQA-1 criteria and the quality assurance and technical procedures to implement these criteria; and (3) DOE is in the process of developing and implementing QA procedures consistent with NNWSI QAP 88-9 Revision 2.

NRC welcomed the DOE commitment to prepare study plans under QA level 1 but noted that the five study plans related to exploratory shaft facility (ESF) construction-phase testing, due to be submitted with the SCP, will not have been done under QA level 1. In addition, DOE QA audits have indicated significant deficiencies exist in connection with the QA programs at the organizations responsible for preparation of those study plans. Hence, while the SCP will not be rejected on the basis that the five study plans were not

prepared and reviewed under an accepted QA program, and while those study plans will be accepted as information, NRC will not start its review of those study plans until DOE provides an evaluation supporting that the five study plans are of the same technical quality as if they had been prepared under a QA level 1 program. DOE agreed to review the five study plans again for that purpose and will document the results of that review.

The statement appearing on one of DOE's viewgraphs that "study plans are the authorizing document for initiating site characterization work" prompted the State of Nevada and NRC to point out that it could be interpreted to mean DOE would initiate site characterization work after issuance of a study plan but without consideration of NRC comments. DOE agreed that the sentence may need clarification and indicated that the term "authority" was used in the sense that it authorizes the scope of work and not the initiation of work. DOE reaffirmed its commitment to seriously consider NRC comments prior to initiation of site characterization work.

NRC expressed a concern that at least some of the prototype tests being done in preparation for development of certain study plans is not being conducted as QA level I activities. NRC explained that prototype testing needs to be considered as potentially QA level I because in the licensing hearing DOE will need to demonstrate not only that the data were collected by a particular method but also that that method is appropriate for collecting the data. Prototype testing may be the primary basis for demonstrating that latter point. After asking some clarifying questions about the types of testing that the NRC staff was considering in raising this concern, DOE indicated that it understood the concern. DOE agreed to provide NRC with its position relative to QA for prototype testing. NRC indicated that this topic may need to be addressed in a future interaction.

The third topic presented by DOE was on the interpretation of the Level-of-Detail Agreement (LODA) reached in the May 7-8, 1986 NRC-DOE Level of Detail for Site Characterization Plans and Study Plans Meeting. DOE described the content of each study plan as consistent with the content requirements of the LODA as appropriate to the type of activities described in the specific study plan. Study plans are not stand alone documents; therefore, reviewers need to be knowledgeable of the related content within the Site Characterization Plan (SCP). Points emphasized in the presentation included that study plans 1) implement the requirements specified by the testing strategies developed in the SCP, 2) address test interference and testing impacts on waste isolation relative to selection of test methods, 3) describe performance and design requirements; provide details regarding activities, tests, analyses, and relationships of activities; and provide dates, duration, constraints, and sequencing of tests and analyses. The content of a study plan was then compared to the content and purpose for the SCP and for technical procedures (refer to Attachment 3, pp. 24-28). DOE stated that the SCP is the appropriate document (sections 8.3 and 8.4) to discuss considerations of waste isolation, interference, and ability to characterize the site. DOE concluded this presentation by providing a description of the revisions incorporated in

the study plans entitled (1) Water Movement Test and (2) Excavation Investigations in response to NRC concerns resulting from review of those two study plans and provided in an NRC letter to DOE dated August 5, 1988. DOE indicated that it agreed on balance with the NRC staff review comments on those study plans and had attempted to revise them accordingly.

The final presentation made by DOE covered the schedule for release of study plans. Five study plans related to ESF construction-phase testing are due to be released with the SCP. DOE provided a schedule for near-term (within the next six months) submittal to the NRC of 12 more study plans and a list of 13 other study plans in preparation and/or review. DOE emphasized that finalizing the 12 study plans scheduled for near-term release as well as those study plans covering ongoing activities was a high priority effort for DOE.

In closing remarks primarily related to DOE's final presentation, NRC pointed out that the agreement in the May, 1986 NRC-DOE Level of Detail Meeting was that study plans for ongoing activities would accompany the SCP. NRC considers that these study plans need to receive highest priority and that, based upon the DOE's lists of study plans currently in preparation/review and of those scheduled for near-term issuance, indications are that study plans for ongoing activities are not being given the appropriate level of priority. NRC requested that, within a month of issuance of the SCP, DOE provide to NRC a list of (1) all ongoing activities; (2) which study plan covers each ongoing activity; and (3) date on which each of those study plans is scheduled for release.

In its closing remarks, DOE restated the point that finalizing ongoing study plans was a high priority effort. DOE stated that ongoing activities are not resulting in significant adverse effects to the site. DOE agreed to complete an evaluation of the quality of the five study plans related to ESF construction-phase testing that will accompany the SCP. In addition, DOE agreed to provide to the NRC a list of the activities to be covered by study plans, participants preparing plans, and which activities from the list are ongoing.

In its closing remarks the State of Nevada stated that it shares NRC's concern over the continuing unavailability of study plans covering ongoing activities and that this problem has dragged on far too long. The State also indicated that inasmuch as the SCP is being issued accompanied by only five study plans--and those are themselves of uncertain quality--the State considers that the SCP, like the CDSCP, is incomplete. In particular, the State needs the study plans to evaluate environmental impacts of site characterization. The State intends to correspond with DOE on this matter. In addition, the State expressed concern that the overall program schedule will be further compressed than it already is, with the submittal of study plans to NRC three months prior to start of work rather than six months likely to become the general rule.

Clark County encouraged dialogue of the sort that took place at this meeting to continue as a means of working toward resolution of issues.

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Agenda

DOE/NRC Technical Meeting
on Study Plans

December 15-16, 1988
Rockville, MD

OBJECTIVES

The objectives of this meeting are to come to a mutual understanding with the NRC on 1) the scope and purpose of study plans ; 2) quality assurance (QA) concerns relating to study plans; 3) the DOE and NRC processes of study plan review and interactions; and 4) the schedule for study plan preparation and release.

December 15, 1988 (Thursday)

8:30 - 8:45

Opening Remarks

DOE

S. Brocoum

NRC

TBD

State of Nevada

TBD

Other Affected Parties

TBD

8:45 - 9:00

Scope of Meeting

Summarize Topics of Discussion:

- o Study plan preparation and review and DOE/NRC interactions
- o Quality assurance issues related to study plans
- o Interpretation of the Level-of Detail Agreement (LODA)
- o Schedule for release of study plans

9:00 - 10:30

DOE Study Plan Preparation and Review Process:

- o Summary of internal DOE process (participant/Project Office/HQ levels) for study plan preparation and review
- o DOE position on DOE/NRC commitments/interactions for release and review of study plans, and references
- o Standard and non-standard procedures
- o Relation of NRC review to timing of DOE starting work

10:30 - 12:00

Quality Assurance Issues Related to Study Plans:

- a) QA Level for Study Plan Preparation/Review
- b) Treatment of QA in Study Plans

12:00 - 1:00

LUNCH

1:00 - 3:00

Interpretation of the Level-of-Detail Agreement (LODA):

- a) Relationship of study plans to the SCP
- b) Contents of study plans relative to LODA format
- c) DOE revision of 2 ESF plans reviewed by NRC (included in ESF construction phase study plans)

3:00 - 4:00

Schedule for Release of Study Plans

4:00 - 5:00

Meeting Summary and Agreements

December 16, 1988 (Friday)

Meeting Summary and Agreements (if needed)

Attendance List for NRC-DOE Technical Meeting ^{Attachment 2}
on Study Plans, December 15, 1988

<u>Name</u>	<u>Organization</u>	<u>Phone</u>
Steve Frishman	State of NV	702/885-3744
CHED BRADLEY	DOE/EH-25	586-4600
RAY WALLACE	USGS-HQ/DOE-HQ	586-1244
Charlotte Abrams	USNRC/HLGP	492-0572
Fred Ross	USNRC/HLGP	492-0527
MYSORE (RAJ) NATARAJA	USNRC/HLEN	492-3459
DINESH GUPTA	NRC/HLEN	492-0547
ROBERT BROWNING	NRC/HLWM	492-3456
Karen Unnerstall	Newman & Holtzinger	(202) 955-6600
Ralph Stein	DOE/HQ	(202) 586-6046
Phyllis Sobel	WESTON	202-646-6614
MARTHA PENNINGTON	SAIC	FTS 544-7635
Thomas Blejwas	Sandia Nat. Labs	FTS 846-0541
William Langer	USGS	303 236 1421 FTS 776 1421
Jim Kennedy	USNRC	FTS 492-3402 301-492-3402
KEN CZYSEWSKI	WESTON	646-6642
Gordon Appel	DOE/HQ	(FTS) 896-1462
DICK BAKER	DOE/HA	FTS 896-1330
STEPHAN BROCEUM	DOE/HA	FTS 896-5355
David C Dobson	DOE/YMP	FTS 544-7940
Joe Holonick	NRC/HLWM	FTS 492-3465
Robert L. Johnson	NRC/HLWM	FTS 492-0409
JOHN LINEHAN	NRC	FTS 492-3387
King Stablein	NRC	FTS 492-0446
DENNIS BECHTEL	CLARKE CO, NV	(702) 455-4181

DOE/NRC MEETING ON STUDY PLANS

DECEMBER 15-16, 1988

SUMMARY OF DISCUSSION TOPICS

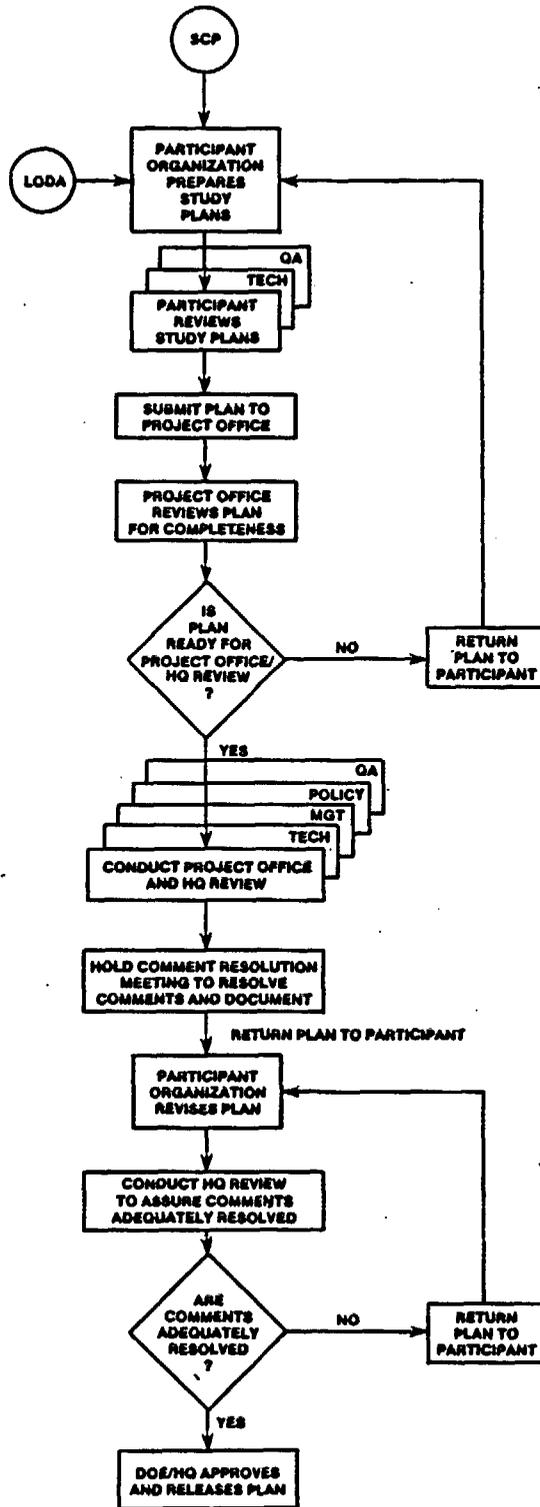
- **STUDY PLAN PREPARATION AND REVIEW AND DOE/NRC INTERACTIONS**
- **QUALITY ASSURANCE TOPICS RELATED TO STUDY PLANS**
- **INTERPRETATION OF LEVEL-OF-DETAIL AGREEMENT**
- **SCHEDULE FOR RELEASE OF STUDY PLANS**

STUDY PLAN PREPARATION AND REVIEW AND DOE/NRC INTERACTIONS

INTERNAL DOE STUDY PLAN PREPARATION/REVIEW PROCESS

- **STUDY PLANS ARE REVIEWED BY THE PREPARING ORGANIZATION , OTHER PARTICIPANT ORGANIZATIONS AND THE DEPARTMENT OF ENERGY**
- **THE REVIEWS AND REVISIONS ARE CONTROLLED PROCESSES PERFORMED ACCORDING TO APPROVED QA PROCEDURES AND ARE FULLY DOCUMENTED**
- **ONCE THE STUDY PLANS ARE ISSUED, CHANGES TO STUDY PLANS WILL BE CONTROLLED AND DOCUMENTED**
- **QUALITY ASSURANCE PROCEDURES WILL BE DISCUSSED LATER IN THE PRESENTATION**

FLOW DIAGRAM FOR DOE PREPARATION AND REVIEW OF STUDY PLANS



DOE PLANS FOR RESPONDING TO NRC REVIEW COMMENTS ON STUDY PLANS

- 1) DOE WILL REVIEW AND CONSIDER NRC REVIEW COMMENTS
AND REVISE THE STUDY PLANS AS APPROPRIATE**
- 2) NRC WILL BE ON CONTROLLED DISTRIBUTION FOR ALL STUDY
PLAN REVISIONS**

DOE COMMENTS ON NRC REVIEW PLAN FOR STUDY PLANS AND PROCEDURES

BACKGROUND

- 1) THE NRC REVIEW PLAN REQUIRES THE SEGREGATION OF NRC COMMENTS INTO CATEGORIES**

- 2) WITHIN THE 3 MONTH PERIOD, THE DOE UNDERSTANDS THAT THE NRC WILL NOTIFY DOE OF ANY COMMENTS CATEGORIZED BY NRC AS OBJECTIONS. OBJECTIONS ARE UNDERSTOOD TO BE RELATED TO THE FOLLOWING:**
 - (A) TESTING THAT WOULD COMPROMISE THE ABILITY OF THE SITE TO ISOLATE WASTE**

 - (B) TESTING THAT WOULD COMPROMISE THE DOE'S ABILITY TO FULLY CHARACTERIZE THE SITE**

 - (C) DEFICIENCIES THAT WOULD CAUSE THE DATA TO BE UNACCEPTABLE FOR LICENSING**

DOE COMMENTS ON NRC REVIEW PLAN FOR STUDY PLANS AND PROCEDURES

DOE COMMENTS

- **DOE DOES NOT BELIEVE AN ACCEPTANCE REVIEW IS APPROPRIATE DURING THE PRELICENSING PHASE. DOE REQUESTS THAT THE NRC THREE MONTH START-WORK REVIEW BE INITIATED AS SOON AS THE PLANS ARE RECEIVED AT NRC**
- **ADEQUACY OF THE QA PROGRAM IS VERIFIED FOR THE STUDY AT THE PROGRAM LEVEL BY REVIEWS, AUDITS AND SURVEILLANCES. STUDY PLANS WILL DESCRIBE QA LEVEL ASSIGNMENTS AND LIST APPLICABLE QA PROCEDURES**
- **NRC CRITERIA FOR SELECTING PLANS FOR DETAILED TECHNICAL REVIEW SHOULD BE GIVEN TO DOE SO THAT DOE CAN EXPEDITE THE PREPARATION OF THESE PLANS**

DOE COMMENTS ON NRC REVIEW PLAN FOR STUDY PLANS AND PROCEDURES

DOE COMMENTS (CONTINUED)

- **ACKNOWLEDGE THE TERM ACTIVITIES, i.e., THE SUB COMPONENTS OF A STUDY CONSISTING OF ANY COMBINATION OF TESTS OR ANALYSES**
- **REFERENCES WILL BE SUPPLIED IF THEY ARE NOT AVAILABLE IN THE OPEN LITERATURE, PROJECT REPORT STANDARD DISTRIBUTIONS , OR SCP REFERENCES ALREADY SUPPLIED BY THE DOE**
- **IF NRC SOLICITS COMMENTS FROM THE STATE, ANY INDIAN TRIBES OR OTHER AFFECTED PARTIES, THESE COMMENTS SHOULD BE MADE AVAILABLE TO THE DOE**

TECHNICAL PROCEDURES

DEFINITIONS

TWO MAJOR CATEGORIES OF TECHNICAL PROCEDURES ARE RECOGNIZED IN THE LODA:

- (1) STANDARD PROCEDURES; AND**
- (2) NON-STANDARD PROCEDURES**

STANDARD PROCEDURES

USED BY WORKERS IN MANY FIELDS, DOCUMENTED IN SOURCES SUCH AS ASTM, ASME REFERENCES, STANDARD METHODS TEXTS, ETC. THEY HAVE BEEN EXTENSIVELY TESTED FOR RELIABILITY AND HAVE A SIGNIFICANT RECORD OF USE

EXAMPLES - STANDARD METHODS FOR GROUND WATER ANALYSIS, X-RAY DIFFRACTION ANALYSIS OF MINERALS, ETC.

USED WIDELY WITHIN A SPECIALIZED AREA OF APPLICATION. THEY HAVE BEEN TESTED FOR PRECISION AND ACCURACY AND HAVE A HISTORY OF SUCCESSFUL APPLICATION

EXAMPLE - LABORATORY SORPTION TESTING, SPECIALIZED GEOPHYSICAL LOGGING TECHNIQUES

NON-STANDARD PROCEDURES

PROCEDURES DEVELOPED FOR UNIQUE TESTING APPLICATIONS. THEY MAY BE USED FOR FIRST-OF-A-KIND TESTING AND OFTEN INVOLVE PROTOTYPE TESTING TO DEVELOP THE PROCEDURE. THEY MAY INVOLVE THE MODIFICATION OF WELL ESTABLISHED TECHNIQUES TO NEW APPLICATIONS WHERE PREVIOUS EXPERIENCE IS LACKING. LIMITS OF REPEATABILITY AND RELIABILITY ARE NOT WELL ESTABLISHED

EXAMPLES - UNSATURATED MEDIUM LABORATORY SORPTION TESTS, HYDROLOGIC TESTING OF ROCKS IN THE UNSATURATED ZONE USING METHODS MODIFIED FROM SOIL TESTING

NON-STANDARD PROCEDURES

LEVEL-OF-DETAIL AGREEMENT STATES:

- **DOE WILL RELEASE NON-STANDARD PROCEDURES FOR INFORMATION AT LEAST 60 DAYS BEFORE IMPLEMENTATION**
- **NRC SHOULD NOTIFY DOE OF SPECIFIC PROCEDURES THEY WANT TO REVIEW PRIOR TO THE 60 DAY RELEASE COMMITMENT**
- **NRC WILL NOTIFY DOE OF MAJOR CONCERNS WITHIN FIRST 30 DAYS**

DOE ISSUANCE AND TRACKING OF PROCEDURES

- 1) PROCEDURES ARE LISTED IN SCP SECTIONS FOR THE STUDIES THEY SUPPORT**
- 2) DOE WILL IDENTIFY STANDARD AND NON-STANDARD PROCEDURES IN THE STUDY PLANS**
- 3) ALL NON-STANDARD PROCEDURES WILL BE APPROVED AND AVAILABLE 60 DAYS PRIOR TO IMPLEMENTATION**
- 4) STANDARD PROCEDURES WILL BE APPROVED PRIOR TO DATA COLLECTION AND WILL BE SENT TO NRC UPON REQUEST**
- 5) PROCEDURES ARE CONTROLLED DOCUMENTS**

DOE PLAN FOR STUDY PLAN RELEASE

- 1) DOE INTENDS TO RELEASE STUDY PLANS SIX MONTHS IN ADVANCE OF STARTING WORK WHEN EVER POSSIBLE. STUDY PLANS WILL BE RELEASED A MINIMUM OF 3 MONTHS IN ADVANCE OF INITIATING NEW WORK. NRC WILL BE ON CONTROLLED DISTRIBUTION FOR ALL STUDY PLANS AND WILL RECEIVE ALL REVISIONS.**
- 2) DOE WILL SUPPLY REFERENCES THAT ARE NOT AVAILABLE TO THE NRC FROM THE OPEN LITERATURE, SCP REFERENCES, OR PROJECT REPORT STANDARD DISTRIBUTION**

SUMMARY-RELATIONSHIP OF STUDY PLAN REVIEW TO START OF WORK

FOR NEW WORK TO BE INITIATED

- 1) STUDY PLANS MUST BE REVIEWED AND APPROVED THROUGH DOE (PROJECT OFFICE AND HQ)**
- 2) STUDY PLANS WILL BE SENT TO NRC FOR REVIEW AT LEAST THREE MONTHS BEFORE SCHEDULED START OF WORK**
- 3) NRC "START WORK REVIEW" PERIOD BEGINS WHEN THE PLAN IS SUBMITTED TO NRC**
- 4) IF NO MAJOR CONCERNS ARE RECEIVED FROM NRC DURING THE THREE MONTH PERIOD, DOE WILL PROCEED ACCORDING TO PROJECT SCHEDULES**

QUALITY ASSURANCE TOPICS RELATED TO STUDY PLANS

QUALITY LEVEL ASSIGNMENT FOR PREPARATION OF STUDY PLANS

**STUDY PLAN PREPARATION WILL BE ASSIGNED QUALITY
ASSURANCE LEVEL 1**

RATIONALE

- **FOR CONTROL OF SCIENTIFIC INVESTIGATIONS, STUDY PLAN PREPARATION IS IN DIRECT LINE FROM THE SCP TO THE IMPLEMENTING TECHNICAL PROCEDURES**
- **STUDY PLANS ARE THE AUTHORIZING DOCUMENT FOR INITIATING SITE CHARACTERIZATION WORK**

TREATMENT OF QA IN STUDY PLANS

DOE/NRC LEVEL OF DETAIL AGREEMENTS REQUIREMENTS:

"INDICATE THE LEVEL OF QUALITY ASSURANCE AND PROVIDE A RATIONALE FOR ANY TESTS WHICH ARE NOT JUDGED TO BE QA LEVEL I. REFERENCE THE APPLICABLE SPECIFIC QA REQUIREMENTS THAT WILL BE APPLIED TO THE TEST"

TREATMENT OF QUALITY ASSURANCE (QA) IN STUDY PLANS

EACH STUDY PLAN WILL INCLUDE A QUALITY ASSURANCE APPENDIX WITH:

- **APPROVED QUALITY ASSURANCE LEVEL ASSIGNMENT SHEETS (QALAS)**
- **A TABLE LISTING THE NQA-1 CRITERIA AND THE QUALITY ASSURANCE AND TECHNICAL PROCEDURES THAT IMPLEMENT THESE CRITERIA**
- **BRIEF TEXT TO INTRODUCE AND EXPLAIN THE QALAS AND THE TABLE**

TREATMENT OF QA IN STUDY PLANS (CONTINUED)

- **DOE IS IN THE PROCESS OF DEVELOPING AND IMPLEMENTING QA PROCEDURES THAT ARE CONSISTENT WITH NNWSI QAP 88-9. REV. 2**
- **FOLLOWING IMPLEMENTATION OF THESE PROCEDURES, DOE WILL RE-EVALUATE EXISTING QALAS THAT ARE NOT LEVEL-1, AND REVISE AS NEEDED**

INTERPRETATION OF THE LEVEL-OF- DETAIL AGREEMENT

LEVEL OF DETAIL IN STUDY PLANS

THE LEVEL OF DETAIL IN STUDY PLANS IS BASED ON THE FOLLOWING

- THE FORMAT OF STUDY PLANS IS GUIDED BY THE LODA AGREEMENT. THE SPECIFIC CONTENT OF EACH PLAN IS APPROPRIATE TO THE TYPE OF ACTIVITIES DESCRIBED.
- STUDY PLANS ARE DESIGNED FOR REVIEW BY TECHNICAL PEERS
- THE REVIEWER IS FAMILIAR WITH THE SCP, AND THEREFORE STUDY PLANS ARE NOT STAND ALONE DOCUMENTS
- STUDY PLANS REFERENCE TECHNICAL PROCEDURES BUT DO NOT DESCRIBE THEM IN DETAIL
- STUDY PLANS MUST IMPLEMENT THE REQUIREMENTS SPECIFIED BY THE TESTING STRATEGIES DEVELOPED IN THE SCP
- STUDY PLANS ADDRESS TEST INTERFERENCE AND TESTING IMPACTS ON WASTE ISOLATION RELATIVE TO SELECTION OF TEST METHODS

SUMMARY OF THE CONTENT OF THE SCP

- **PRESENTS THE GENERAL PLAN FOR SITE CHARACTERIZATION ACTIVITIES (NWPA)**
- **PRESENTS THE OVERALL RATIONALE FOR THE SITE CHARACTERIZATION PROGRAM AND DERIVES TESTING STRATEGY FROM PERFORMANCE ALLOCATION**
- **DISCUSSES "PROGRAMS" AND "INVESTIGATIONS" TO BE CONDUCTED, AND IDENTIFIES INFORMATION NEEDS**
- **IDENTIFIES AND DESCRIBES IN GENERAL THE STUDIES, ACTIVITIES, TESTS, METHODS, AND PROCEDURES DESIGNED TO PROVIDE THE NEEDED INFORMATION**
- **PRESENTS AN INTEGRATED SITE CHARACTERIZATION SCHEDULE**
- **EVALUATES TEST INTERFERENCES AND IMPACTS ON WASTE ISOLATION**

SUMMARY OF THE CONTENT OF STUDY PLANS

- **SUMMARIZES PURPOSE/OBJECTIVE OF STUDY, INCLUDING PERFORMANCE AND DESIGN REQUIREMENTS AND REGULATORY RATIONALE, AND PROVIDES ADDITIONAL DETAIL TO SCP DESCRIPTIONS OF TESTS**
- **SUMMARIZES AND DESCRIBES THE RATIONALE FOR THE TESTING STRATEGY DERIVED IN THE SCP AND PROVIDES ADDITIONAL DETAIL ON THE RATIONALES FOR THE SELECTION OF THE PREFERRED TESTS AND ANALYSES**
- **DISCUSSES SELECTION OF TEST METHODS RELATIVE TO VARIOUS CRITERIA INCLUDING TEST INTERFERENCE AND IMPACTS ON WASTE ISOLATION**
- **DESCRIBES IN DETAIL PLANNED STUDIES, ACTIVITIES, TESTS, AND ANALYSES AND RELATIONSHIP OF ACTIVITIES**
- **REFERENCES PROCEDURES AND IDENTIFIES NON-STANDARD PROCEDURES**
- **DESCRIBES DATES, DURATION, AND SEQUENCING OF TESTS AND ANALYSES AND CONSTRAINTS ON OTHER ACTIVITIES**

SUMMARY OF THE CONTENT OF TECHNICAL PROCEDURES

- **SUMMARIZES REQUIREMENTS, OBJECTIVES, METHODS AND CHARACTERISTICS TO BE TESTED (i.e. PARAMETERS TO BE MEASURED)**
- **ESTABLISHES ACCEPTANCE LIMITS, IF APPLICABLE**
- **ESTABLISHES PREREQUISITES SUCH AS CALIBRATED INSTRUMENTATION, EQUIPMENT, ENVIRONMENTAL CONDITIONS, etc.**
- **ESTABLISHES ACCEPT/REJECT CRITERIA, IF APPROPRIATE**
- **REPORTS METHODS OF DATA DOCUMENTATION AND REDUCTION**
- **ESTABLISHES TRAINING REQUIREMENTS AND PERSONNEL RESPONSIBILITIES**
- **IDENTIFIES SOURCES OF UNCERTAINTY AND ERROR AND MEASURES FOR CONTROL**
- **WHERE APPROPRIATE, IDENTIFIES PROVISIONS TO MINIMIZE RISK OF UNDETECTED FAILURE OR MALFUNCTIONS**

SCP VS STUDY PLAN CONTENT REQUIREMENTS WITH RESPECT TO THE NRC CONCERNS ON 1) WASTE ISOLATION, 2) INTERFERENCE, AND 3) ABILITY TO CHARACTERIZE THE SITE

- THE DOE RECOGNIZES THAT THE ABOVE CONCERNS REQUIRE AN INTEGRATED APPROACH/ANALYSIS. THE DOE BELIEVES THAT THE APPROPRIATE PLACE TO DESCRIBE THE CONCERNS IS IN THE INTEGRATED PLANNING DOCUMENT, THE SITE CHARACTERIZATION PLAN. SECTIONS 8.3 AND 8.4 OF THE SCP ADDRESSES THESE ISSUES**
- THE DOE ALSO RECOGNIZES THAT MANY OF THE ACTIVITIES WHICH REQUIRE THE MOST STRINGENT ANALYSIS ARE BEYOND THE SCOPE OF THE STUDY PLAN**

STUDY PLAN CONTENT REQUIREMENTS (CONTINUED)

- TO BE CONSISTENT WITH THE REQUIREMENTS OF THE MAY 7 AND 8 AGREEMENT, STUDY PLANS DISCUSS THESE THREE CONCERNS IN TERMS OF HOW THEY AFFECT THE CHOICE OF TESTS TO BE CONDUCTED**
- THE SCP DISCUSSION OF WASTE ISOLATION/INTERFERENCE RELATED TOPICS IS REFERENCED IN STUDY PLANS**

**DOE RESPONSE TO NRC GENERAL COMMENTS ON STUDY
PLANS FOR
STUDY 8.3.1.15.1.5 EXCAVATION INVESTIGATIONS
STUDY 8.3.1.2.2.2 WATER MOVEMENT TESTS**

NRC CONCERNS

**QA LEVEL OF STUDY PLAN
PREPARATION**

REFERENCE AVAILABILITY

DOE RESPONSE

**QA LEVEL-I AS DISCUSSED IN THIS
MEETING**

**DOE WILL PROVIDE ALL REFERENCES
WHICH ARE NOT AVAILABLE TO NRC,
INCLUDING UNPUBLISHED REFERENCES
WITH THE STUDY PLAN**

DOE RESPONSE TO NRC CONCERNS ABOUT STUDY 8.3.1.15.1.5 EXCAVATION INVESTIGATIONS

NRC CONCERN

- NO DISCUSSION OF POTENTIAL FOR INTERFERENCE AMONG (a) TESTS AND (b) BETWEEN THE SHAFT AND TESTS

- LOCATION OF SEQUENTIAL DRIFT MINING EXPERIMENT NOT PROVIDED

DOE RESPONSE

TEXT MODIFIED TO REFERENCE INTEGRATED SCP DISCUSSION OF INTERFERENCE IN SECTION 8.4 AND TO CLARIFY INTERFERENCE RELATED CONSTRAINTS THAT EXIST FOR THIS STUDY

TEXT MODIFIED TO CLARIFY THAT INTERFERENCE RELATED CONCERNS WILL BE CONSIDERED WHEN SELECTING FINAL LOCATION OF EXPERIMENT

DOE ACTIONS IN RESPONSE TO NRC CONCERNS ON STUDY 8.3.1.2.2.2 WATER MOVEMENT TEST

NRC CONCERN

DOE RESPONSE

— NO DISCUSSION OF APPLICABILITY OF TEST RESULTS TO (1) PERFORMANCE ANALYSES (2) OTHER STUDIES (3) CONSTRUCTION EQUIPMENT AND ENGINEERING DESIGN (4) PLANNING OTHER SITE ACTIVITIES

TEXT MODIFIED TO CLARIFY APPLICABILITY OF RESULTS TO 1,2 AND 4
3 IS NOT APPLICABLE TO THIS STUDY

— LACK OF INFORMATION ABOUT TECHNICAL PROCEDURES

NEW TABLE AND TEXT INCLUDED TO IDENTIFY NON-STANDARD PROCEDURES AND DATES OF AVAILABILITY

— OPTIONAL TESTING OUTSIDE ESF

NONE IN STUDY PLANS IF DOE AUTHORIZES EXPANSION OF SCOPE OF STUDY TO INCLUDE DRILL HOLE SAMPLES, NRC WILL BE NOTIFIED

SCHEDULE FOR RELEASE OF STUDY PLANS

STUDY PLANS TO BE AVAILABLE WITH THE SCP

5 CONSTRUCTION PHASE ESF PLANS

- 8.3.1.2.2.2 WATER MOVEMENT TEST**
- 8.3.1.2.2.4 UZ PERCOLATION TESTS**
- 8.3.1.4.2.2 STRUCTURAL FEATURES (SHAFT MAPPING)**
- 8.3.1.15.1.5 EXCAVATION INVESTIGATIONS**
- 8.3.1.15.2.1 AMBIENT STRESS CONDITIONS**

SCHEDULE FOR STUDY PLAN SUBMITTAL
TO THE NRC

<u>NUMBER</u>	<u>TITLE</u>	<u>STATUS</u>	<u>ESTIMATED DATE TO THE NRC</u>
8.3.1.2.1.3	CHARACTERIZATION OF THE GROUND-WATER FLOW SYSTEM	IN PREP	6/89
8.3.1.2.2.1	CHARACTERIZATION OF THE UNSATURATED ZONE INFILTRATION	IN PREP	6/89
8.3.1.2.2.2	WATER MOVEMENT TEST	IN REVISION	12/88
8.3.1.2.2.3	CHARACTERIZATION OF PERCOLATION IN THE UNSATURATED ZONE- SURFACE-BASED STUDY	IN REVIEW	4/89
8.3.1.2.2.4	CHARACTERIZATION OF YUCCA MOUNTAIN PERCOLATION IN THE UNSATURATED ZONE-ESF INVESTIGATIONS	IN REVISION	12/88
8.3.1.2.2.8	HYDROCHEMICAL CHARACTERIZATION OF THE UNSATURATED ZONE	IN REVIEW	5/89
8.3.1.2.3.1	CHARACTERIZATION OF THE SITE SATURATED-ZONE GROUND-WATER FLOW SYSTEM	IN PREP	6/89
8.3.1.3.2.1	MINERALOGY, PETROLOGY, AND CHEMISTRY ALONG TRANSPORT PATHWAYS	IN REVISION	3/89
8.3.1.3.2.2	HISTORY OF MINERALOGIC AND GEOCHEMICAL ALTERATION OF YUCCA MOUNTAIN	IN REVIEW	5/89
8.3.1.3.4.1	BATCH SORPTION STUDIES	IN PREP	6/89
8.3.1.4.2.2	CHARACTERIZATION OF THE STRUCTURAL FEATURES WITHIN THE SITE AREA	IN REVISION	12/88
8.3.1.5.2.1	CHARACTERIZATION OF THE QUARternary REGIONAL HYDROLOGY	IN REVIEW	4/89
8.3.1.15.1.3	LABORATORY DETERMINATION OF THE MECHANICAL PROPERTIES OF INTACT ROCK	REVISED	3/89

SCHEDULE FOR STUDY PLAN SUBMITTAL
TO THE NRC (Cont'd)

<u>NUMBER</u>	<u>TITLE</u>	<u>STATUS</u>	<u>ESTIMATED DATE TO THE NRC</u>
8.3.1.15.1.5	EXCAVATION INVESTIGATIONS	IN REVISION	12/88
8.3.1.2.15.2.1	CHARACTERIZATION OF THE SITE AMBIENT STRESS	IN REVISION	12/88
8.3.1.17.4.1	HISTORIC AND CURRENT SEISMICITY	IN PREP	TBD
8.3.1.17.4.2	LOCATION AND RECENCY OF FAULTING POTENTIAL NEAR PROSPECTIVE SURFACE FACILITIES	IN REVIEW	5/89
8.3.1.17.4.6	QUARTERNARY FAULTING WITHIN THE SITE AREA	IN REVIEW	5/89

ADDITIONAL STUDY PLANS IN PREPARATION
AND REVIEW

<u>NUMBER</u>	<u>TITLE</u>
8.3.1.15.1.2	LABORATORY THERMAL EXPANSION TESTING
8.3.1.15.1.8	IN SITU DESIGN VERIFICATION
8.3.1.16.1.1	CHARACTERIZATION OF FLOOD POTENTIAL OF THE YUCCA MOUNTAIN SITE
8.3.1.17.3.6	PROBABILISTIC SEISMIC HAZARD
8.3.1.17.4.4	QUARTEINARY FAULTING PROXIMAL TO THE SITE WITHIN NORTH-EAST TRENDING ZONES
8.3.4.2.4.1	CHARACTERIZE CHEMICAL AND MINERALOGIC PROPERTIES IN THE POSTEMPLACEMENT ENVIRONMENT
8.3.4.2.4.2	HYDROLOGIC PROPERTIES OF THE WASTE PACKAGE ENVIRONMENT
8.3.1.2.2.5	DIFFUSION TEST IN THE EXPLORATORY SHAFT
8.3.1.3.6.1	DYNAMIC TRANSPORT COLUMN EXPERIMENTS
8.3.1.3.6.2	DIFFUSION
8.3.1.4.2.1	CHARACTERIZATION OF THE VERTICAL AND LATERAL DISTRIBUTION OF STRATIGRAPHIC UNITS WITHIN THE SITE AREA
8.3.1.5.1.3	CLIMATIC IMPLICATIONS OF TERRESTRIAL PALEOECOLOGY
8.3.1.15.1.1	LABORATORY THERMAL PROPERTIES

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. 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 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 at 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 within an agreed-upon time limit for an audit review. 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

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 plan.
- 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 emphasize headings I, II, III, and IV.

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 justification.
- 3) The description of purpose and objectives is inadequate.

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.

- 2) There is insufficient detail in the description of numbers, types, and locations of tests and the rationales for these, as well as the uncertainties involved.

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.
- 2) Discussion of application of the data is absent or lacking sufficient detail.

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 man 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-SOP-3.0, RO

Reviewers

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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.

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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).

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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.

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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.

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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.

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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.

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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

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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

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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.

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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.

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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.

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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.

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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 3.4 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
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- 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
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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).

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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).

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

INTERIM REVISION NOTICE		T-AD-086
SCP AND SCP STUDY PLANS		11/88
IRN NUMBER:	EFFECTIVE DATE:	PAGE of
APPLIES TO:		
SCP Section Number _____		
Title _____		
or:		
Study Plan Number _____ Revision _____		
Title _____		
REQUIRED CHANGES:		
<u>SECTION/PAGE NUMBER:</u>	<u>CHANGE TO:</u>	
APPROVALS:		
Technical Project Officer _____	Date: _____	
Director, R&SED _____	Date: _____	
Yucca Mountain Project Manager* _____	Date: _____	
OCRWM: Chief, Soing and Geoscience* _____	Date: _____	
<small>*if required</small>		

Exhibit 2. Interim Revision Notice.

Effective Date	Revision	Supersedes	Page	No.
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Title

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

INTERIM REVISION NOTICE CONTINUATION SHEET		T-AD-086		
SCP AND SCP STUDY PLANS		11/88		
IRN 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).

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Title

AP-1.10Q 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 _____				
Study Plan Coordinator or Designee shall sign and date when completed:				
<u>Action</u>	<u>Signature</u>	<u>Date</u>		
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, RASED _____ Date _____				

Exhibit 3. Checklist for Review of Study Plans.

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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 _____ Quality Assurance _____ Technical _____ 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.

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

YUCCA MOUNTAIN PROJECT

T-AD-088
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

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Exhibit 5. Approval Form for Study Plan.

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