



Department of Energy  
Washington, DC 20585

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Mr. Joseph J. Holonich, Director  
Repository Licensing & Quality Assurance  
Project Directorate  
Division of High-Level Waste Management  
Office of Nuclear Material Safety  
and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Dear Mr. Holonich:

In preparation for the July 23, 1992 DOE/NRC management meeting on the level of detail agreement for Study Plans, the DOE has prepared a revised draft DOE/NRC agreement for review by the NRC (enclosure 1). The rationale for the proposed changes is summarized in the following paragraphs. This revised agreement would replace the May 7 & 8, 1986 and the December 15, 1988 agreements. These agreements predated the acceptance of the Site Characterization Plan (SCP) and the DOE's quality assurance (QA) program by the NRC. Since these documents were signed, the Yucca Mountain Site Characterization Project (YMP) has developed a detailed plan for the management of site characterization. SCP Study Plans are an integral part of this process. However, the current format and procedures that relate to Study Plans are not producing the optimum product for the project. Experience gained in the site characterization program during the last six years has led the DOE to propose a revision to the DOE/NRC level of detail agreement on Study Plans. The DOE believes that the following major points should be addressed.

1. How the format of SCP Study Plans can be revised to optimize their role in the plan for management of the Yucca Mountain Site Characterization Project?
2. How NRC concerns about adverse effects on the site can be addressed in an efficient and timely manner, i.e., without delaying the initiation of work any more than necessary?

The revised agreement that is being proposed by DOE involves new "content requirements for descriptions of studies in study plans" (attachment 1 to enclosure 1) and procedural agreements identified as points 2 through 4 of the agreement. The purpose of a new agreement is to more accurately reflect the present YMP site characterization program and to streamline and improve the process of study plan preparation, review, approval and revision.

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The proposed agreement includes changes that the DOE believes are needed in the format of study plan documents. This includes changes to the requirement for referencing technical procedures and recognition of YMP procedures that should eliminate the requirement for 3 to 6 month hold on the beginning of work while the NRC conducts a "Phase I review".

The proposed format for study plans represents an improvement designed to streamline and clarify the preparation and review of the documents. At present, the format contains unnecessary material, as discussed above, and is unsuited to much of the work involved in site characterization. The present format refers to "tests and analyses". DOE believes that the broader term "activities" would be more appropriate and consistent with the hierarchy and nomenclature in the SCP. We believe that this change in terminology should be accompanied by a change in the organization and requirements of the study plan outline. The present organization is structured by the idea that the work being described will involve data collection in a laboratory setting or from instrumentation in a borehole or a similar situation. However, many site characterization activities do not fit such a format. For instance, geologic mapping involves activities such as observing and interpreting geometric and spatial relations in the field. This revision aims to improve and broaden the format for the description and evaluation of these activities.

The proposed format distinguishes four types of activities: (1) observation and description of field relations, (2) laboratory or field-based testing, (3) data analyses, and (4) synthesis and modeling. The information required for each type of activity is provided in the Study Plan annotated outline (attachment 1 to enclosure 1). We believe that our improved format will facilitate reviews by emphasizing important material and removing duplicative material from the study plan. For a comparison to the old agreement see enclosure 2. DOE believes that this will significantly shorten the time involved in the preparation, review and approval of study plans.

Certain material should not be required in study plans written in the future. All discussion of regulatory rationale is unnecessary, because this information is provided in the SCP and has, subsequently, been baselined and controlled by the DOE. All reference to QA controls on the work to be performed is unnecessary, because QA requirements are now specified in documentation that is maintained outside of Study Plans.

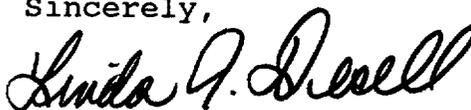
All technical procedures that have been written and approved are available to the NRC for information purposes. There is now a requirement for each Study Plan to contain a list of technical procedures to be used in that study. It has proven difficult to keep these lists current with the advent of new procedures and revisions. It leads to unnecessary paperwork with no improvement in quality, because of the potential to continually revise study

plans as procedures are developed and/or modified. We recommend that a list be maintained by each participant that identifies all technical procedures that are being used for each study plan that falls within the participants' area of responsibility. These lists would be available to the NRC on-site representative who could request copies of any procedure for review, either directly from the participant organization or from the YMPO. DOE does not maintain schedules for the preparation and approval of participant procedures. Job Packages are prepared prior to starting work and include verification that required technical procedures are approved and available.

DOE suggests that the completion of reviews by the NRC, to identify major concerns and objections, should no longer be required to start work on studies that have met YMP requirements. We believe that there is good justification for making this change. The NRC Phase I Review addresses major concerns with study activities, "that, if started, could cause significant and irreparable adverse effects on the site, and the site characterization program, or the eventual usability of the data for licensing". The YMP has developed internal procedures that address these concerns in a systematic way. All of these procedures are subject to quality assurance (QA) surveillance and audit. Test planning packages for each study activity include a waste isolation analysis and a test interference evaluation. These analyses are available for audit by the NRC. In addition, the NRC Phase I review was initiated before DOE and participant quality assurance programs were accepted by the NRC. All project participants, as well as DOE's, quality assurance programs have since been accepted by the NRC and all work is done under approved procedures that are traceable to the requirements in each participant's quality assurance program description.

Should you have any questions or require more information, please contact Chris Einberg at (202) 586-8869.

Sincerely,



for

John P. Roberts  
Acting Associate Director for  
Systems and Compliance  
Office of Civilian Radioactive  
Waste Management

Enclosures:

1. Draft 1992 DOE/NRC Agreement on Study Plans
2. DOE Content Requirements for Descriptions of Studies in Study Plans

cc: w\enclosures  
Alice Cortinas, CNWRA, San Antonio, TX

cc: w\enclosures  
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F. Mariani, White Pine County, NV  
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B. Mettam, Inyo County, CA  
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**Predecisional Draft**  
**Preliminary Draft**

Preliminary Predecisional Draft

ENCLOSURE 1  
DRAFT 1992 DOE/NRC  
AGREEMENT ON STUDY PLANS

1. Study Plans are documents that present details of the studies and activities from Chapter 8.3.1 of the YMP Site Characterization Plan (SCP). Study Plans are developed by the YMP participant organizations and are approved by the YMPO. The content requirements for study plans are presented in attachment 1. These requirements are not retroactive to Study Plans that have already been submitted to the YMPO. The DOE will determine if any Study Plans now approved or in review would benefit from conversion to the revised format.
2. Technical procedures for the site characterization activities described in the study plans are developed and approved by the YMP participant organizations. A current list of approved technical procedures for each approved study plan will be maintained by the participants and will be available to the NRC. The listed procedures will be provided to the NRC staff or on-site representative upon request. Technical procedures are not required to be referenced in Study Plans.
3. Some references cited in Study Plans may not be readily available to the NRC. Examples of not-readily-available references are listed in attachment 2. Not-readily-available references for approved Study Plans may be requested by the NRC staff or on-site representative and will be provided by DOE.
4. The NRC may conduct an initial acceptance review or a more detailed technical review of any approved Study Plan at its discretion. The completion of such NRC reviews is not required for DOE to start work on activities described in approved Study Plans that have met all YMP prerequisites.

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Licensing and QA  
Project Directorate

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John P. Roberts  
Acting Associate  
Director for Systems  
and Compliance

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Carl P. Gertz  
Project Manager  
YMPO

Attachments:

1. DOE Content Requirements for Descriptions of Studies in SCP Study Plans.
2. Examples of not-readily-available references.

Predecisional Preliminary Draft

ATTACHMENT 1  
DOE CONTENT REQUIREMENTS FOR DESCRIPTIONS  
OF STUDIES IN SCP STUDY PLANS

The test program presented in Chapter 8.3.1 of the SCP will be subdivided into a hierarchy of increasing detail. The SCP test program hierarchy will include (in increasing detail): generic program, investigation, study, activity and test procedures. Details for the studies, listed in Chapter 8.3.1 of the SCP, will be presented in the study plans. Study plans will be separate from the SCP proper and will be issued as required for site characterization. Individual test methods will be discussed in study plans.

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

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

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

I. Purpose and Objectives

Describe the objectives of this study. What technical issues, of importance to the project, will be addressed by this study? What aspect of site characterization will be accomplished through this study?

## II. Scope of Work

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

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

- The area to be studied.
- Aspects of the area that are unknown or poorly known.
- Type of data to be collected.
- Methodology or classification system to be used.
- Product, maps, cross-sections, etc., to be produced.

If the study proposes laboratory or field testing, provide:

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

If the study proposes analyses, provide discussion on:

- The purpose of the analysis. Indicate any sensitivity or uncertainty analyses that will be performed.

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- The methods of analysis, including any analytical expressions or statistical methods that will be employed.
- The data input requirements of the analysis.
- The representativeness of the analytical approach (e.g. with respect to spatial and temporal variability of existing conditions and future conditions) and indicate limitations and uncertainties that will apply to the results.

If the study proposes synthesis and modeling, provide discussion on:

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

### III. Application of Results

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

### IV. Schedule

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

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## ATTACHMENT 2

### Examples of Not-Readily-Available References

1. Contractor and participant reports that will not be captured in the national data base for government-sponsored information (National Technical Information Service).

Such items as USGS Open-File Reports, SAND Reports, etc. are captured in the National Technical Information Service.

2. Foreign national journals and books that would not be expected to be found in a good research library (i.e. Library of Congress).
3. State publications.
4. Symposium, meeting, and workshop abstracts and papers that are not published.
5. Commercial and trade contract reports (e.g. EPRI).
6. Academic M.S. theses (dissertations are not included because they can be obtained from University Microfilms Inc., of Ann Arbor, Michigan).
7. Participant mangement plans, QA plans, etc.
8. Computer code manuals.
9. Draft, unpublished, or "letter" reports and documents.
10. Personal communications (written only) (oral or personal communications are not included).
11. Manuscripts of "in press," "in review," or "in preparation" works are to be provided only if the publication outlet is a medium defined in this list.
12. Monograph reports and handbooks from Federal agencies (e.g., local USDA soil reports).

## ENCLOSURE 2

DOE CONTENT REQUIREMENTS FOR DESCRIPTIONS OF STUDIES  
IN STUDY PLANS

The test program presented in Chapter 8.3.1 of the SCP will be subdivided into a hierarchy of increasing detail. The SCP test program hierarchy will include (in increasing detail): generic program; investigation; study; activities; ~~tests, and analyses~~; and test procedures. Details for studies and ~~activities test and analyses~~, listed in Chapter 8.3.1 of the SCP, will be presented in study plans. Study plans will be separate from the SCP proper and will be issued periodically throughout site characterization. Individual test methods will be discussed in study plans.

The following outline describes the information on studies ~~and tests and analyses~~ that will be presented in SCP study plans. A study plan may involve a single activity or a set of activities ~~a single test or a set of tests and analyses~~, as appropriate. ~~The tests include those measurements of physical parameters, or observations of physical phenomena, that are performed in the field or in the laboratory.~~ Testing ~~activities~~ includes preparation of procedures, test set-up, conduct of the test, data acquisition, and data reduction. The analyses include those calculations or other evaluations needed to assess site characteristics and support design activities. All site characterization studies will be completed under DOE's quality assurance program, that has been accepted by the NRC.

The items listed in the outline will be addresses for studies and ~~activities tests and analyses~~ to the extent that each item applies. Not all items will be applicable to all studies.

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

I. Purpose and Objectives of studies:

- Describe the objectives information that will be obtained in of this study. ~~Briefly discuss how this information will be used, and~~ What technical issues, of importance to the project, will be addressed by this study? What aspect of site characterization will be accomplished through this study?

~~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 the results that will be described elsewhere in the SCP); 2) a design goal and a confidence level in that goal (a design~~

~~goal beyond those related to performance issues); 2) a direct Federal, State, and other regulatory requirements for specific studies. Where relevant performance or design goals actually apply at a higher level than the study (e.g., where the goals apply to a group of studies), describe the relationship between this study and that higher level goal~~

### ~~II. Rationale for Selected Study:~~

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

~~Provide the rationale for the selected number, location, duration, and timing of tests with consideration to various sources of uncertainty (e.g., test method, interference with other tests, and estimated parameter variability). This rationale should also identify reasonable alternatives, summarize reasons for not selecting these alternatives and reference, if available, reports which evaluate alternatives considered (refer to NRC Observation 8).~~

~~Describe the constraints. (see Section II)~~

### II. Scope of Work

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

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

- The area to be studied.
- Aspects of the area that are unknown or poorly known.
- Type of data to be collected.
- Methodology or classification system to be used.
- Product, maps, cross-sections, etc., to be produced.

~~Since studies are comprised of tests and analyses, provide If the study proposes laboratory or field testing, provide for each type of test provide discussion on:~~

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

- ~~Summarize the test methods to be used. Reference any standard procedures (e.g. ASTM, API) procedures 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 to test, how it will be modified, and reference the technical procedures that will be followed during the test. If the 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 for 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 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 in terms of spatial and temporal variability of the parameters that will be measured existing conditions. Also indicate limitations and uncertainties that will apply to the use of the results, and~~

~~Provide illustrations such as maps, cross sections, and facility design drawings to show the locations of tests and schematic layouts of tests.~~

~~Relationship of the test to the set of performance goals and confidence levels.~~

Describe The specific constraints on testing described in the study 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 test study needs to simulate repository conditions;

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

- ~~— Limits of analytical methods that will be used to use the information from the tests.~~
- ~~— Capability of analytical methods to support the study and~~
- ~~— Time required versus time available to complete the study.~~
- ~~— The scale of the phenomena, especially the limitations of the equipment relative to the scale of the phenomena to be measured and the~~
- Applicability of tests 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.~~
- Generic and site specific test to test interference.
- ~~— Interrelationships involving significant interference among tests and exploratory shaft facility design and construction (as appropriate, refer to Section 8.4 of the SGP or its reference for specific exploratory shaft facility design information such as design drawings or specifications) (refer to NRC observation 4).~~
- Significant interference among tests and design and construction of the Exploratory Studies Facility.
- If appropriate, describe alternative test methods and provide a rationale for selecting a specific method, if appropriate.
- For If the study proposes each type of analyses provide discussion on:
  - 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 of performance goals and confidence levels.
  - Describe the methods of analysis, including any analytical expressions and numerical models that may well be employed;
  - ~~— Reference the technical procedures document that will be followed during the analysis. If procedures are not yet available, indicate when they will be available. Indicate the level of quality assurance that will be applied to the analysis and provide a~~

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

If the study proposes synthesis and modeling provide discussion on:

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

III. Application of results

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

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

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

~~For design uses, refer to, or describe, where the information from the study described above will be used in~~

~~construction equipment design and development and engineering system design design and development (e.g., waste package, repository engineered barriers, and shafts and borehole seals); and~~

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

#### IV. Schedule and milestones

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

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

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

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