Department of Energy
Washington, DC 20585

February 17, 1993

Mr. Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Bernero:

This is to respond to the U.S. Nuclear Regulatory Commission's (NRC) review of the U.S. Department of Energy's (DOE) fifth "Progress Report on Site Characterization: Yucca Mountain, Nevada" in the NRC letter of October 27, 1992. This letter identified 12 items, including 11 observations and recommendations concerning the importance of the progress report and the ability of this document to provide a clear picture of the status and results of site characterization activities.

DOE agrees that the progress report is an important means by which the NRC is apprised of significant changes and progress in the Yucca Mountain site characterization program as noted in Item 12 of the NRC letter. The purpose of this response is to indicate how several of the recommendations have already been incorporated into progress report 7 (hand-carried to you on December 31, 1992) or how they will be incorporated into subsequent progress reports. A brief response to each of the 11 observations and recommendations is provided below.

1) The NRC staff is concerned that the progress report does not provide enough information to assess DOE's progress toward closing open items from NRC's Site Characterization Analysis (SCA) and study plan reviews. DOE is compiling a spreadsheet for internal management and tracking of actions or information still needed before documentation can be prepared by DOE to address open items. In addition to Table 2.1 of the progress report, which identifies the remaining 138 open items from the SCA, the spreadsheet will be used to identify specific studies and/or activities that resolve or partially resolve SCA or study plan open items. In progress report section 2.2, study plan status is discussed and in the future will include references to how specific study plans are relevant to open items. In addition, study plan transmittal letters from DOE to NRC in the future will include information about how the study plan addresses any open items.

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2) The NRC review identified a concern with work that is proceeding in the absence of approved study plans and cited Study 8.3.1.9.2.1 as an example. In progress report 5, work summarized under this study included work that is not analytical or empirical. Two reports were referenced in progress report 5. One includes only compilations of new and existing mineral claims and status of mineral exploration activity in general. The other includes discussion of geophysical work specific for the intended study, which is essentially an amplification of the Geophysics White Paper published in July 1990. DOE believes these compilations of existing data and routine statusing of activity are well within the bounds of background preparation necessary for the development of a study.

3) DOE has recently initiated an effort to integrate geophysical activities, including the formation of a Geophysical Integration Team (GIT). The GIT will provide a forum for the consideration, integration, coordination, planning, and execution of all site characterization activities requiring application of geophysical techniques for the Yucca Mountain Site Characterization Project (YMP) surface-based testing program. Beginning with progress report 7, the status of the GIT's efforts was reported under Activity 8.3.1.4.1.2 in Section 2.2. In addition, DOE has scheduled a technical exchange on the topic of DOE's approach to the integration of geophysical activities with other site characterization activities on June 8, 1993.

4) DOE provided a brief summary of investigations in addition to the summaries of studies and activities in progress report 5. The inclusion of summaries at this level is currently being evaluated, and DOE has not yet determined if summaries at the investigation and/or Site Characterization Plan (SCP) section level will be included in subsequent progress reports. The objectives for all investigations, studies, and activities is provided in the SCP. Many of the participants already include brief descriptions of objectives where appropriate, and DOE will encourage this practice. Inclusion of a "percent complete" estimate for each study would not be an accurate indicator of progress and would lead to false expectations that YMP would continually need to explain.

5) Beginning with progress report 7, a new section was added after each study called the "Forecast." This one to two paragraph section summarizes anticipated activities over the next 6-12 month time period.

6) With respect to the NRC staff concern with cross-references between studies, it should be noted that the progress report is an informational reference that is in addition to, and

not a substitute for, other programmatic documents. The SCP established relationships between studies and illustrated how studies fit together, what studies require data from other studies, and what studies feed data to other studies.

7) DOE agrees that the issue of data qualification is important. However, it is premature at this point to apply valuable resources toward a systematic data qualification effort. It is DOE's intention to address the need for data qualification as our understanding of how particular site processes mature and as part of our issue resolution initiative. A letter (enclosed) transmitted to NRC from DOE on September 9, 1992, explains DOE's data qualification position in more detail. Decisions involving data qualification and issue resolution will be reported in the progress reports as they are made by DOE.

8) This observation concerning the inadequacy of information provided in progress report 5 pertaining to how individual studies address NRC SCA issues has been discussed in item (1) above.

9) The references cited by NRC that were not located in the references section of progress report 5 are documents that were not yet officially published but which represented progress by virtue of significant preparation time on behalf of the affected participant. DOE's policy is to include in the progress report references section only documents that were officially published during the applicable progress report reporting period. In this particular example, it was not clearly indicated that the documents were in draft form. A scan of progress reports 6 and 7 will show how this distinction has been more clearly indicated.

10) This observation concerning the inadequacy of information on changes to study plans has been partially addressed in item (1) above. DOE's effort to include in the progress report pertinent information relative to open items also extends to including information regarding changes to study plans as well as the Site Characterization Program Baseline.

11) DOE agrees that conflicting statements appeared in progress report 5 concerning iterative Total Systems Performance Assessments (TSPA). DOE fully intends to produce iterative TSPAs as is evident in progress reports 6 and 7.

If you have any further questions, please contact Mr. Dwight E. Shelor of my staff at 202-586-6046.

Sincerely,

Lake H. Barrett
Acting Director
Office of Civilian Radioactive
Waste Management

Enclosure:
DOE letter from John Roberts to Joseph Holonich dated September 3, 1992

cc:w/encl.
C. Gertz, YMPO
K. Hooks, NRC
R. Loux, State of Nevada
T. J. Hickey, Nevada Legislative Commission
M. Baughman, Lincoln County, NV
J. Bingham, Clark County, NV
B. Raper, Nye County, NV
P. Niedzielski-Eichner, Nye County, NV
G. Derby, Lander County, NV
P. Goicoechea, Eureka, NV
C. Schank, Churchill County, NV
F. Mariani, White Pine County, NV
V. Poe, Mineral County, NV
E. Wright, Lincoln County, NV
J. Pitts, Lincoln County, NV
R. Williams, Lander County, NV
J. Hayes, Esmeralda County, NV
B. Mettam, Inyo County, CA

Department of Energy
Washington, DC 20585

SEP 03 1992

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

Dear Mr. Holonich:

This letter is in response to recent oral requests from the U.S. Nuclear Regulatory Commission (NRC) for clarification regarding the U.S. Department of Energy (DOE) position on qualification of existing data, in general, and on the need for qualification of specific existing data at this time. DOE also wishes to clarify statements appearing in the minutes of the April 30, 1992, DOE/NRC Quality Assurance (QA) Bimonthly Meeting that pertain to this subject.

The NRC published NUREG-1298 (Generic Technical Position on Qualification of Existing Data for High-Level Waste Repositories) to provide guidance to the DOE regarding the use of information not collected under a QA program that conformed to the requirements of 10 Code of Federal Regulations (CFR) Part 60, Subpart G. The position taken by the staff in the NUREG (Section IV, 1) states, "Data related to systems, structures and components important to safety, to design and characterization of barriers important to waste isolation, and to activities related thereto which are used in support of a license application should be qualified to meet the requirements of 10 CFR 60, Subpart G."

The need for "qualified" data applies to that data required to support a license application. The NRC regulation, 10 CFR 60.17, indicates that plans for characterizing a site should be based on available (not "qualified") information. Therefore, the systematic identification of all existing data which might need to undergo a qualification process like that outlined in NUREG-1298, as implemented by the Yucca Mountain Site Characterization Project Office (YMPO) Administrative Procedure 5.9Q (Qualification of Data or Data Analyses Not Developed Under the Yucca Mountain Project Quality Assurance Plan), would be premature at present.

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It would not only be premature, but an inappropriate application of resources for YMPO to undertake a general review of the totality of data that might need to be qualified at this time. Rather, DOE prefers to focus on collecting the additional data, and performing the analyses that have already been identified as necessary in the Site Characterization Plan (SCP). The DOE December 14, 1991, response to the NRC Site Characterization Analysis (SCA) Comment 125 (enclosure 1) articulates this position. The NRC indicated that it accepts this approach and has closed this SCA comment in its July 31, 1991, evaluation of the DOE responses to the SCA (enclosure 2).

With respect to when decisions would be made about qualifying data, DOE can state at this time that such decisions would be made as our understanding of particular site processes mature. It is DOE's intention to address the need for data qualification as part of our issue resolution initiative. When DOE determines that sufficient information has been developed to approach resolution of an issue, the need for qualification of data to support the technical basis of a DOE position would be addressed at that time. For example, the DOE is preparing a topical report on the subject of erosion that will implement a methodology for qualifying data used to derive the conclusions contained in the report. The NRC may wish to provide comments on this methodology when NRC reviews the topical report.

It would be an erroneous conclusion to infer that the DOE believes that the quality of data required for preliminary design and performance assessment calculations is unimportant, or that documentation and traceability of that data is not required. To the contrary, the data management systems developed by YMPO (specifically, the Reference Information Base [RIB]) are intended to provide for the documentation of the quality and sources of needed data. Further, the testing strategies described in the SCP were developed to ensure that the data available to support a license application will have been supplemented or corroborated by, or collected entirely under, a 10 CFR 60, Subpart G, program. The evolution of available data, from the current preliminary information to the "qualified" data anticipated at the completion of site characterization, will be documented in the records system and traceable through annotations in the RIB, supporting information in the Project Technical Data Base, and entries in the Automated Technical Data Tracking System.

DOE also wishes to clarify some statements made on page 2 of the minutes to the DOE/NRC QA Bimonthly Meeting of April 30, 1992 (enclosure 3), about data qualification. With respect to qualifying past core samples, there are no plans to undertake qualification of any core taken before the current QA program was accepted by NRC. In general, where traceability of the core is an issue, it is DOE's intention to rely on analyses of core,

acquired from drilling activities performed under the accepted QA program. New core may corroborate old core in specific circumstances, but conduct of such an evaluation is purely hypothetical at this time.

Sentence 2 of paragraph 2 of the April 30, 1992, meeting minutes is not correct. The DOE general approach to data qualification is stated above. Lastly, the last two sentences of paragraph 2, page 2, of the meeting minutes refer to the data qualification exercise for the erosion topical report mentioned above.

This summarizes the current DOE position and status on qualification of existing data. Further dialogue may be needed after DOE presents data to the NRC that has been qualified under YMPO procedures.

If you have any questions, please contact Sharon Skuchko of my office at (202) 586-4590.

Sincerely,

Linda J. Desell

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

3 Enclosures:

1. DOE Response to SCA Comment 125

2. NRC Evaluation of DOE Response

3. Page 2 of Minutes for DOE/NRC QA Bimonthly Meeting, April 30, 1992

cc w/Enclosures:
C. Gertz, YMPO
K. Hooks, NRC
T. J. Hickey, Nevada Legislative Committee
R. Loux, State of Nevada
M. Baughman, Lincoln County, NV
J. Bingham, Clark County, NV
B. Raper, Nye County, NV
P. Niedzielski-Eichner, Nye County, NV
G. Derby, Lander County, NV
P. Goicoechea, Eureka, NV
C. Schank, Churchill County, NV
F. Mariani, White Pine County, NV
V. Poe, Mineral County, NV
E. Wright, Lincoln County, NV
J. Pitts, Lincoln County, NV
R. Williams, Lander County, NV
J. Hayes, Esmeralda County, NV
M. Hayes, Esmeralda County, NV
B. Mettam, Inyo County, CA

Section 8.6.4.1 Quality Assurance before Site Characterization

COMMENT 125

This section states that data was gathered during site exploration from 1977 to 1986 which may be used for characterization and to support a license application. It further states that if any data is identified as primary information in support of items and activities important to safety or waste isolation, the data will be qualified against the current QA program on a case-by-case basis in accordance with approved administrative procedures incorporating the guidance provided in the U.S. Nuclear Regulatory Commission's "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298. 1987.

DOE has not identified the existing data that will be used in the licensing process and needs to be qualified, nor have they submitted the procedures which will be used to qualify existing data.

BASIS

o 10 CFR Part 60, Subpart G requires that a QA program be implemented for all systems, structures and components important to safety; design and characterization of barriers important to waste isolation; and activities related thereto. These activities include the development of site characterization data which will be used in support of the license application. Data used in support of the license application and not originally collected under the QA requirements of 10 CFR Part 60, Subpart G should be qualified to meet these requirements.

In the response to CDSCP comment 108, DOE committed to meeting the staff's guidance on qualifying existing data in NUREG-1298 and to submit a procedure for doing so.

o Section 8.3.1.4.2.1.5 of the SCP states that samples have been collected prior to the implementation of an acceptable QA program, and the data will subsequently be used in the licensing process.

It is not clear what data DOE plans to use in licensing or if, based on existing data, DOE has determined that it is not necessary to collect certain types of data during site characterization.

o For the NRC to be able to completely evaluate the sufficiency and viability of the proposed program, the NRC needs to understand what pre-existing information the DOE is planning on qualifying.

RECOMMENDATIONS

As soon as practicable, DOE should:

o Submit the procedures which will be used by the Yucca Mountain Project (YMP) Office and the major participants on the YMP to qualify data which has not been gathered under a QA program which meets the requirements of Subpart G to 10 CFR Part 60.

ENCLOSURE 1

o Provide a general listing by activity of existing data that will be qualified for use in licensing and areas where DOE has determined, based on existing data, it is not necessary to collect certain types of data.

REFERENCES

U.S. Nuclear Regulatory Commission, "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298, 1987.

RESPONSE

Project Office Administrative Procedure (AP)-5.9Q revision 0, "Qualification of Data or Data Analyses Not Developed Under the Yucca Mountain Project Quality Assurance Plan," was furnished to the U.S. Nuclear Regulatory Commission (NRC) for comment in February 1990. Comments were received from the NRC in March, and these which were incorporated into a revision of this procedure, AP-5.9Q revision 1, approved on July 7, 1990.

The implementation of the recommendation calling for a listing, by Site Characterization Plan activity, of existing data that will be qualified for use in licensing is premature. Identification of which existing data would undergo the process defined in AP-5.9Q has not, and will not, be made before beginning site characterization data gathering and analysis. During site characterization, when data is identified that requires "qualification" by the process descripted in AP-5.9Q, the NRC will be informed.

REFERENCES:

U.S. Nuclear Regulatory Commission (NRC), 1987. Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories, NUREG-1298, Prepared by W.D. Altman, J.P. Donnelly, and J.E. Kennedy.

U.S. Department of Energy (DOE), 1990. Qualification, Data or Data Analyses Not Developed under the Yucca Mountain Quality Assurance Plan, AP-5.9Q, Rev 1, DOE, Las Vegas, Nevada.

Section 8.6.4.1 Quality Assurance before Site Characterization

SCA COMMENT 125

This section states that data was gathered during site exploration from 1977 to 1986 which may be used for characterization and to support a license application. It further states that if any data is identified as primary information in support of items and activities important to safety or waste isolation, the data will be qualified against the current QA program on a case-by-case basis in accordance with approved administrative procedures incorporating the guidance provided in the U.S. Nuclear Regulatory Commission's "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," NUREG-1298, 1987.

DOE has not identified the existing data that will be used in the licensing process and needs to be qualified, nor have they submitted the procedures which will be used to qualify existing data.

EVALUATION OF DOE RESPONSE

- In October 1990, DOE submitted Yucca Mountain Project Administrative Procedure (AP) 5.9Q "Qualification of Data or Data Analyses Not Developed Under the Yucca Mountain Project Quality Assurance Plan," Revision 1 dated July 5, 1990, to answer the staff's questions concerning the qualification of existing data. The staff has reviewed AP-5.9Q for conformance with the NRC Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories, NUREG 1298 and finds it acceptable.

- DOE has indicated that identification of existing data that requires "qualification" by the process described in AP-5.9Q will only be made during site characterization data gathering and analysis. The NRC will be informed at that time, and the staff will evaluate the actual compliance with AP-5.9Q.

- The NRC staff considers this comment closed.

Next, DOE presented information on efforts to qualify past core samples. DOE stated that it currently has no plans to qualify past core samples, but instead the samples will be used only as corroborating data.

The third presentation by DOE was about the status of its efforts to define, evaluate, or qualify data that were not produced under an accepted QA program. At present, DOE has no plans to qualify any data produced before QA programs were accepted. An internal DOE letter of September 12, 1991, so states. Data being generated now will be collected in accordance with a qualified program. NRC asked DOE whether the basis for determining when data is qualified is the date of DOE program approval or the date of NRC program acceptance. DOE agreed to state the basis for determining when data is qualified. The State asked whether Administrative Procedure AP 5.9Q precludes the possibility of bad data being accepted because it was collected under an approved QA program. DOE responded that bad data would be recorded as deficient and would have to go through a QA corrective action program. Later in the meeting, USGS stated that the M&O is preparing a package on qualifying past data on soil samples by peer review. This topic will be discussed at the May 27, 1992, technical exchange on erosion.

Next on the agenda was DOE's presentation on the Quality Concerns Program (see Attachment 3). In response to an NRC question, DOE said that neither employee quality concerns or their resolution would be put into the PDR. The NRC asked DOE to provide a breakdown of the origin of the concerns raised to date, if it does not violate the confidentiality of the contributors. In response to a question from Edison Electric Institute, DOE stated that no concerns have been raised that would cause them to take major action, and that a number of concerns had been identified earlier and were being corrected. Nye County asked about the process for closure of concerns. DOE explained the process of investigation and closure of concerns and indicated that there had been some appeals, but generally closure was satisfactory.

DOE, NRC and the State then discussed the mini-audit (limited-scope audit) process. The NRC stated that preparation for mini-audits was more difficult for the technical staff when technical checklists and technical procedures are not available before the entrance meeting. The State added that early receipt of programmatic checklists would also be helpful. DOE stated that the purpose of the audits is not to satisfy the NRC or the State but to determine the effectiveness of the QA programs. However, DOE will try to assist the NRC and the State at the same time. DOE stated that it is not satisfied with either the mini-audit process or the annual programmatic audits with respect to the information being provided to DOE managers. DOE is considering treating the participants as vendors and doing a programmatic (compliance) audit triennially with annual evaluations and technical performance (vertical slice) audits whenever work dictates. A decision has not yet been made. The NRC stated its likely preference for at least an annual evaluation of any program doing significan amounts of work. The State asked that "annual evaluation" be defined. DOE stated that it may be any approach available, such as a desk