Department of Energy
Washington, DC 20585

FEB 24 1993

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

Reference: Ltr, Roberts to Holonich, dtd 7/20/92

Dear Mr. Holonich:

Enclosed (enclosure 1) is the Yucca Mountain Site Characterization Project Office (YMPO) technical assessment (TA) performed to qualify existing data used as the basis for conclusions in the U.S. Department of Energy's (DOE) topical report, "Evaluation of the Potentially Adverse Condition of Extreme Erosion During the Quaternary Period at Yucca Mountain, Nevada." The data forming the basis for this assessment was collected prior to DOE approval of the U.S. Geological Survey (USGS) and Los Alamos National Laboratory (Los Alamos) quality assurance (QA) programs (reference).

The U.S. Nuclear Regulatory Commission (NRC) published NUREG-1298, "Generic Technical Position on Qualification of Existing Data for High-Level Waste Repositories," to provide guidance to DOE regarding the process by which existing data should be qualified to meet the requirements of Title 10 Code of Federal Regulations Part 60, Subpart G. DOE implemented Administrative Procedure 5.9Q, Revision 2, "Qualification of Existing Data," (enclosure 2), to allow a qualification process for project data gathered prior to DOE approval of a QA program that meets Title 10 Code of Federal Regulations Part 60, Subpart G. The qualification process itself was carried out by means of a TA in accordance with YMPO Quality Management Procedure 02-08, Revision 1, "Technical Assessment," (enclosure 3).

This TA empaneled a team of five qualified geoscientists who examined: (1) all directly related technical and QA procedures; (2) relevant correspondence; (3) a sampling of scientific notebooks; and (4) Los Alamos' Independent Peer Panel review. The TA Notice, Revision 0 and Revision 1, together with items 1-4 above, are part of the TA documentation package (enclosure 1). Enclosure 4 contains the USGS and Los Alamos procedures that were examined.

100019 ADD: Charlotte Abrams Ltr. Encl. 1 Original Encl. 1 02.8 WM-11 NH02

Original enclosure

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The TA was conducted in two phases. In Phase I, the TA team members compared technical and QA procedures in place for USGS and Los Alamos that guided sample collecting, laboratory analyses, and field measurements to the technical and QA procedures that control these processes today. Phase II of the TA verified that scientific notebooks used to document the sampling, analyses, and field work conformed to and followed the procedures in place during the time the notebooks were prepared.

The TA team determined that: (1) data gathering and evaluation activities were conducted under controls of an equivalent QA program, and (2) corroborative data exists to substantiate the data examined. The TA team also factored into their assessment a Los Alamos Independent Peer Review by leading geomorphologists who examined the varnish cation-ratio age dating process used by the principal investigators. The TA team concurred that this technique was the best analytical technique currently available.

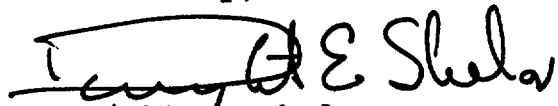
All five TA team members unanimously agreed that the age dating process used and the application of that process to interpretation of erosion rates completed prior to DOE approval of Los Alamos and USGS QA programs can be qualified under current Office of Civilian Radioactive Waste Management Quality Assurance Requirements Document, Revision 4, requirements.

On September 8, 1992 (enclosure 5), the DOE accepted the recommendations of the TA team members. The conduct and documentation of this TA was included within the scope of YMPO QA audit 92-24 held on September 28-October 2, 1992. No concerns were identified by the QA organization.

Consistent with DOE's letter of September 3, 1992 (enclosure 6), we request that NRC review the TA documentation and report any concerns with the process that DOE has developed for data qualification. Otherwise, future qualification efforts for existing data sets will be undertaken in a similar manner.

If you have any questions, please contact Mr. Chris Einberg of my office at 202-586-8869.

Sincerely,



Dwight E. Shelor
Associate Director for
Systems and Compliance
Office of Civilian Radioactive
Waste Management

Enclosures
1. TA Documentation
2. AP 5.9Q, Revision 2
   (Not Record Material)
3. QMP 02-08, Revision 1
   (Not Record Material)
4. Procedures Examined as Part
   of the TA
5. Ltr, 9/8/92, Gertz to Distribution
6. Ltr, 9/3/92, Roberts to Holonich,
   w/encls

on the shelf in binder

cc: w\ enclosures
C. Gertz, YMPO (w\o enclosures)
T. J. Hickey, Nevada Legislative Committee
R. Loux, State of Nevada
C. Abrams, NRC
D. Bechtel, Las Vegas, NV
Eureka County, NV
Lander County, Battle Mountain, NV
P. Niedzielski-Eichner, Nye County, NV
W. Offutt, Nye County, NV
C. Schank, Churchill County, NV
F. Mariani, White Pine County, NV
V. Poe, Mineral County, NV
J. Pitts, Lincoln County, NV
J. Hayes, Esmeralda County, NV
B. Mettam, Inyo County, CA

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Yucca Mountain Site Characterization
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P. O. Box 98608
Las Vegas, NV 89193-8608

WBS 1.2.5.2.2
QA: N/A

SEP 08 1992

Larry R. Hayes, USGS, Las Vegas, NV
Julie A. Canepa, LANL, Los Alamos, NM

TECHNICAL ASSESSMENT (TA) FOR DATA QUALIFICATION AND SCIENTIFIC NOTEBOOK DOCUMENTATION SUPPORTING U.S. DEPARTMENT OF ENERGY (DOE) TOPICAL REPORT ON EROSION

The TA to qualify data and analyses performed prior to approval of DOE's Quality Assurance Requirements Document has been completed.

Based on a review of the Technical Assessment Team's (TAT) assessment, the Yucca Mountain Site Characterization Project Office (YMPO) is accepting the recommendations of the TAT members and finds that the data and analyses, upon which the conclusions in the topical report rest, are qualified in accordance with YMPO Administrative Procedure 5.9Q, Revision 2, and consistent with the guidance, U.S. Nuclear Regulatory Commission NUREG-1298, "Qualification of Existing Data." The results of this TA will be included as an appendix to the final topical report.

Before the topical report can be approved, we ask that your organization arrange to enter the data contained in the scientific notebooks evaluated by the TAT into YMPO's technical data management (TDM) system. The contact identified below for the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) will negotiate a schedule with your staff and the technical data manager for entry of this data into the TDM system.

Let me add on behalf of YMPO that we are very pleased to see how smoothly this process has worked, and that feedback from your staff indicates that the process is simple enough to satisfy many Yucca Mountain Site Characterization Project scientists' concerns that a data qualification process not be unduly burdensome.

If you have any questions, please contact either B. William Distel of the CRWMS M&O at (702) 794-1827 or Thomas W. Bjerstedt at (702) 794-7590.

Carl P. Gertz
Project Manager

RSED:TWB-5165

SEP 08 1992

cc:
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C. E. Einberg, HQ (RW-331) FORS
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C. D. Harrington, LANL, Los Alamos, NM

Department of Energy
Washington, DC 20585

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Dyer
Bjerstedt / Spence
Barton / Brocoum-Swan
w/o Blanchard / Crawley
Cooper / Gil / Gertz
Jones, S / Sinuela
Voegele-Sau / Weaver-Tess
Kelley / Lugo, M
Geer / Williamson
Leonard
Gowert
9/25/92

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 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)-5.3Q 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-5.3Q 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-5.3Q 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 described in AP-5.3Q, 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-5.3Q, 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.

ENCLOSURE 2

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 signif amounts of work. The State asked that "annual evaluation" be defined. DOE stated that it may be any approach available, such as a desk