



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 26, 1995

Mr. Ronald A. Milner, Director
for Program Management and Integration
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW 30
1000 Independence Avenue, SW
Washington, D.C. 20585

SUBJECT: MINUTES OF THE SEPTEMBER 27, 1995, TECHNICAL EXCHANGE ON DATA
QUALIFICATION

Dear Mr. Milner:

Enclosed are the minutes of the September 27, 1995, technical exchange between the staff of the U.S. Nuclear Regulatory Commission and the U.S. Department of Energy (DOE) on data qualification. This meeting was held by videoconference at DOE Headquarters in Washington, DC and DOE offices in Las Vegas, Nevada.

During the meeting, the NRC highlighted several points regarding data qualification that are discussed in the meeting summary. Several points, in particular, bear reiteration. First, NRC would have difficulty accepting data as qualified without knowing the intended use of the data. Second, NRC does not review data solely for the purpose of determining if it is "qualified." The purpose of the NRC review is to determine if a safety requirement or objective has been achieved. Therefore, DOE should expect comments from NRC in any instance that it questions the technical accuracy or suitability of the data for its intended function. Third, when DOE questions whether or not a proposed method of qualification would be acceptable, the NRC would be willing to provide comments on any written method submitted regarding data qualification.

If you have any questions regarding this letter, or the meeting summary, please contact Ms. Sandra L. Wastler of my staff. Ms. Wastler can be reached at (301) 415-6724.

Sincerely,

A handwritten signature in cursive script, appearing to read "D. Gillen".

Daniel M. Gillen, Acting Chief
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: See attached list

9803190382 980218
PDR WASTE
WM-11 PDR

Enclosure 4

CC List for letter to R. Milner dated 12/26/95 :

cc: R. Loux, State of Nevada
J. Meder, Nevada Legislative Counsel Bureau
W. Barnes, YMPO
C. Einberg, DOE/Wash, DC
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
D. Weigel, GAO
P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
V. Poe, Mineral County, NV
W. Cameron, White Pine County, NV
R. Williams, Lander County, NV
L. Fiorenzi, Eureka County, NV
J. Hoffman, Esmeralda County, NV
C. Schank, Churchill County, NV
L. Bradshaw, Nye County, NV
W. Barnard, NWTRB
R. Holden, NCAI
E. Lowery, NIEC
R. Arnold, Pahrump, NV
N. Stellavato, Nye County, NV
J. Lyznicki, AMA

SUMMARY OF THE SEPTEMBER 27, 1995
U.S. NUCLEAR REGULATORY COMMISSION/U.S. DEPARTMENT OF ENERGY
TECHNICAL EXCHANGE ON DATA QUALIFICATION

On September 27, 1995, staff from the U.S. Nuclear Regulatory Commission (NRC) met with U.S. Department of Energy (DOE) staff to exchange information about data qualification. The meeting was held by videoconference between DOE facilities in Washington, D.C. and Las Vegas, Nevada at 12:30 PM EDT. Other attendees of this meeting represented the State of Nevada; Nye County, Nevada; the United States Geological Survey; the Nuclear Waste Technical Review Board; DOE's Civilian Radioactive Waste Management System Management and Operating Contractor (M&O); Weston; Idaho National Energy Laboratory; and NRC's Center for Nuclear Waste Regulatory Analysis. Attachment 1 provides the attendance lists at the two videoconference locations. Attachment 2 is the meeting agenda.

The objectives of the technical exchange as stated by DOE were to discuss the following topics:

1. "A formal process intended to provide a desired level of confidence that data are suitable for their intended use."
2. NUREG-1298 qualification options emphasize different aspects of Quality Assurance (QA) program equivalency and technical correctness,
3. Qualification of data without taking a position on its technical correctness,
4. QA program equivalency and procedural equivalency, and
5. Acceptance of data.

The first DOE presentation began with a comparison of data requirements for site suitability and repository licensing, both of which are end points in a regulatory compliance assessment and both of which are based on a single site characterization program. However, there are important differences. For repository disposal of high-level radioactive waste, 10 CFR Part 60 requires that data and analyses be gathered or qualified under a Subpart G QA program; but 10 CFR Part 960 for site suitability requires only that data be used which can be cited, referenced or

attributed. However, quality assurance for activities and items important to safety and waste isolation must also meet the requirements of a Subpart G QA program in order to be used in a repository licensing program. Any data and analyses collected outside the controls of a Subpart G QA program are to be accepted and validated for specific applications and qualified under Quality Assurance Requirements Document (QARD) Supplement III.2.4.D. The challenge for DOE is how to articulate data collection and handling for the two compliance demonstrations under a single site characterization program. The QARD Supplement contains the five options for the qualification on existing data from NUREG-1298 entitled "Qualification of Existing Data for High-Level Nuclear Waste Repositories." Additional information on DOE's presentation can be found in Attachment 3.

DOE then presented examples of three data qualification exercises that had been performed from 1992-1995. DOE discussed the rationale each exercise followed and related it to NUREG-1298. In 1992 DOE undertook a data qualification exercise in support of the Extreme Erosion Topical Report. Based on the experience from this data qualification effort, DOE has stated that data can be qualified without taking a position on its technical correctness, that data qualification is not the process by which to resolve technical correctness issues, and that NUREG-1298 was not intended to govern the resolution of differing technical opinions. Further details on DOE's presentation on data qualification for the Extreme Erosion Topical Report are in Attachment 4.

In 1995 DOE undertook a data qualification exercise for about 1000 existing borehole geophysical logs. DOE concluded that, when using the QA program equivalency option in NUREG-1298, that equivalency for a particular data gathering activity is demonstrated when procedures are determined equivalent for those parts of the QARD relevant to the data set being qualified. A conclusion was that data could be found qualified without a specific use identified at that time. Further details on DOE's presentation regarding borehole data qualification is provided in Attachment 5.

DOE next explained an acceptance process for qualification of radionuclide thermochemistry data. Because the radionuclide thermochemistry data will be used in process-level models to constrain solubility limits. DOE presented additional material and discussion about their approach for compliance with the

guidance in NUREG-1298. One aspect of this presentation is that data is made available and that is used by the technical community, such as meteorological data from National Oceanographic and Atmospheric Administration or seismic monitoring data from the U.S. Geological Survey national network, is factual and acceptable for use in licensing. Further information on DOE's presentation is provided in Attachment 6.

DOE's final presentation was on the implementation of the QARD requirements for "Software". This particular presentation presented information on the successful implementation of data qualification program by the M&O. Additional details on this presentation is provided in Attachment 7.

NRC acknowledged that the presentations and associated discussions were extremely beneficial in attempt to achieve an understanding of DOE's data qualification process. As a result, the NRC highlighted seven points regarding data qualification:

1. NRC has difficulty, from a licensing perspective, in declaring data qualified without knowing the intended use of the data. NRC understands that DOE needs to determine if existing borehole geophysical data was collected in a defensible process, but from the NRC perspective that is only half of the answer. For data to be qualified from the NRC perspective, the intended use of the data must be known and documented.
2. If DOE has doubt about an approach to qualifying existing data, DOE should document its rationale for the approach it intends to use and send it to the NRC for a written response. This is in keeping with NUREG-1298, which allows for an acceptability review by the NRC on a case-by-case basis.
3. If DOE were to attempt to qualify data using more than one option stated in NUREG-1298 and then chose to abandon an option, NRC would want DOE's rationale for abandoning one of the options. This does not mean that if DOE staff were to discuss all the options available and then pick one option to pursue in detail that the NRC would need justification for why the other options were not pursued. However, if DOE were to invest significant resources in researching several viable options and then chose to abandon one option, the NRC would like to know the reason the option was abandoned. The

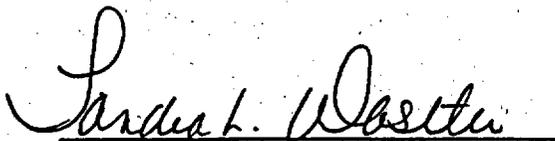
justification could be as simple as one method was considered more cost effective than another.

4. DOE's License Application Annotated Outline (LAAO) would be confusing if unqualified data were referenced. Some NRC staff suggested that only qualified data should be used to support any successive iterations of the LAAO. However, other staff noted that the use of unqualified data may be acceptable depending on the intended use of the unqualified data, such as supporting or strengthening a point.
5. The hearing process should be kept in mind throughout the data-gathering process. It was suggested that as part of planning the handling of data, DOE should talk to its General Counsel on the rules of evidence and keep these in mind during the data gathering process, because quality of data will become part of the hearing.
6. The declaration of new data as scientific fact because it is accepted by the international community will be difficult from a legal perspective. But if DOE documents the process of getting the data accepted by the international community, that should satisfy the alternative requirements in NUREG-1298 for qualifying data for its intended use. *what?*
7. Part of the DOE presentation focused on a desire for NRC to accept data as qualified even if NRC does not agree that the data is technically accurate or correct. NRC does not review data solely for the purpose of determining if it is "qualified." The purpose of the NRC review is to determine if a safety requirement or objective has been achieved. Therefore, DOE should expect comments from NRC in any instance that it questions the technical accuracy or suitability of the data for its intended use. If NRC does not agree that data is technically accurate or suitable for its intended function, it does not matter from a licensing perspective to declare the data "qualified" for another function.

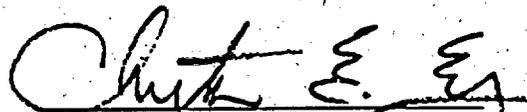
M&O Technical Database Management staff assured the NRC that DOE had no intentions to attempt to qualify technically incorrect data. The DOE's intent is to determine the technical correctness of data during the qualification process.

Nye County, although not having any closing remarks, questioned DOE on why they were pushing to qualify old well logs. In response DOE indicated that it was trying to provide confidence in the data.

The meeting was adjourned after the State of Nevada and Nye County indicated they had no closing remarks.



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