

JULY 6 AND JULY 7 MEETINGS

- 1 -

NOV 29 1989

Mr. Ralph Stein, Associate Director
 for Systems Integration and Regulations
 Office of Civilian Radioactive Waste Management
 U. S. Department of Energy, RW 30
 Washington, D.C. 20545

Dear Mr. Stein:

SUBJECT: MINUTES FROM JULY 6, 1989 QUALITY ASSURANCE MEETING AND JULY 7, 1989
 DESIGN CONTROL MEETING

By letter dated August 7, 1989, the State of Nevada's Agency for Nuclear Projects, Nuclear Waste Project Office provided a copy of an August 4, 1989 letter discussing its views on the July 6, 1989 quality assurance meeting and the July 7, 1989 design control meeting and requested that the August 4, 1989 letter be placed in the minutes for those meetings. Unfortunately, the minutes were transmitted to you in my letter dated August 4, 1989, and the State of Nevada's request was received too late to allow the inclusion of its letter in the minutes. Therefore, the purpose of this letter is to append the July 6 and 7, 1989 meeting minutes with the addition of the State of Nevada's August 4, 1989 letter, a copy of which is contained in Enclosure 1. In addition, a copy of the U.S. Nuclear Regulatory Commission staff's September 28, 1989 response to the State's letter is being provided for your information. The staff's response is contained in Enclosure 2.

If you have any questions, please feel free to contact the staff representative for this meeting, Mr. Joe Holonich. Mr. Holonich can be reached at (301) 492-3403 or FTS 492-3403.

Sincerely,

ORIGINAL SIGNED BY

John J. Linehan, Director
 Repository Licensing and Quality
 Assurance Project Directorate
 Division of High-Level Waste Management

Enclosures: As stated

cc: R. Loux, State of Nevada
 C. Gertz, DOE/NV
 S. Bradhurst, Nye County
 M. Baughman, Lincoln County
 D. Bechtel, Clark County
 K. Turner, GAO

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Enclosure 1
State of Nevada
August 4, 1989 Letter



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

SEP 28 1989

Mr. Robert Loux, Executive Director
Agency for Nuclear Projects
Nuclear Waste Project Office
State of Nevada
Carson City, Nevada 89710

Dear Mr. Loux:

I am responding to your August 4, 1989 letter to me identifying two concerns you have with positions recently taken by the U.S. Nuclear Regulatory Commission (NRC) staff. One is with the staff's review of the U.S. Department of Energy's (DOE) quality assurance (QA) programs and the other is with the staff's consultations with DOE in technical areas. In particular, you are concerned that the staff's approach to reviewing DOE's QA programs is being relaxed, and that the staff's approach to reviewing the exploratory shaft facility (ESF) design process is inconsistent with the NRC staff's role.

The staff has not held the position that the entire QA program must be in place prior to beginning work in any area. Rather, the staff position has been that site characterization activities in any specific program area could be conducted if they were done in accordance with acceptable QA controls that fully covered the activities to be undertaken if those activities were to be important for the licensing review. However, the entire QA program for a particular DOE organization or contractor's organization does not have to be in place, nor do all of the DOE and DOE contractors' programs have to be in place, before work can start at any one organization.

This position was first taken in August 1987 in connection with the hydrologic drilling at the Basalt Waste Isolation Project Site and is the position currently embodied in the Yucca Mountain Site Characterization Analysis (SCA) objection on QA. To quote the Director of the Office of Nuclear Material Safety and Safeguards in his July 31, 1989 letter transmitting the SCA:

"Once the agreed upon steps have been satisfactorily accomplished, for each of the participants involved in a given area, the NRC has no QA related concern with DOE proceeding with that area of its site characterization program while it continues to complete the steps needed for other areas of the site characterization program."

Such an approach will achieve the objective of ensuring that data are qualified for licensing while at the same time allowing DOE to develop and implement its program in a practical and realistic manner.

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You also noted that the staff is utilizing observations of DOE audits for accepting QA programs, rather than independent NRC audits. We believe this is an appropriate position, which is consistent with the findings of the "Ford Study" (NUREG-1055) of reactor QA problems, that puts the responsibility for finding and correcting deficiencies on DOE, rather than on the NRC staff. The staff will be conducting its own audits once baselined programs are in place and found to be acceptable.

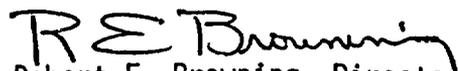
With respect to your concern on early consultations, the staff's actions are consistent with the Nuclear Waste Policy Act (NWPA). The NRC is obligated to review and to comment on DOE's Site Characterization Plan. On several occasions, the Commission has taken the position that the staff must be involved early in understanding the DOE technical work to ensure that regulatory concerns are appropriately considered. The most recent position was taken in the Commission's comments on the DOE Mission Plan Amendment. In his September 16, 1988 letter transmitting the comments, then NRC Chairman Lando W. Zech stated:

"The NRC staff is prepared to meet as early and as often as needed in order to ensure DOE understands and is resolving NRC's concerns that need to be addressed during the pre-licensing application phase so that a complete and high-quality license application can be submitted."

It is my understanding that your concern regarding early consultations between the staff and DOE resulted from the staff position taken at the July 6 and 7, 1989 meeting. Your concern is that the DOE/NRC consultations would be limited to just the two agencies and not involve other participants in the program. As stated at the meeting, and recorded in the minutes, the staff intended that the consultations would follow our standard practice for all meetings on technical subjects and would be open to the participation of the State and affected units of local and tribal governments. In summary, the NRC's approach for conducting early consultations is consistent with its role under the NWPA and with the Commission's regulations allowing prospective applicants to informally confer with the staff prior to filing an application.

I trust that this letter helps to clarify any misunderstandings you may have on the staff's positions on QA and consultations with DOE.

Sincerely,


Robert E. Browning, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety and
Safeguards

Enclosure 2

U. S. Nuclear Regulatory Commission Staff
September 28, 1989 Response to August 4, 1989 Letter



AGENCY FOR NUCLEAR PROJECTS
NUCLEAR WASTE PROJECT OFFICE

Capitol Complex
Carson City, Nevada 89710
(702) 885-3744

August 4, 1989

Mr. Robert E. Browning, Director
Waste Management Division
Office of Nuclear Material
and Safety and Safeguard
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Browning:

At the July 6-7 NRC/DOE meeting on Quality Assurance and the Exploratory Shaft Facility (ESF) Design Control Process, the State of Nevada expressed concern with the new approach taken by the NRC staff relative to its review of the Department of Energy's program. Specifically the concerns centered on; 1) what appears to be a relaxation of the staff's review of the DOE's quality assurance program prior to the start of the site characterization, and 2) emergence of a new category of interactions, called consultations, with the Department on quality assurance and ESF Title II design process matters. This letter is intended to clarify and amplify our remarks made at the July 6-8 meeting, and is being forwarded under separate cover to your staff as our attachment to the meeting minutes.

It is clear from both correspondence and public statements that the NRC position is to require that DOE have a qualified quality assurance program in-place prior to the start of site characterization. DOE, on numerous occasions, has committed to having such a fully qualified program in-place. It appears now that this NRC position has been eroded. As early as 1985, NRC (Miller to Vieth letter, June 25, 1985) stated that a complete and fully implemented QA program should be in place prior to start of site characterization. Later correspondence (Kennedy to Linehan letter, December 18, 1986, Linehan to Knight letter, March 8, 1987) addressed the need for a "fully qualified" QA program prior to site characterization. In July 1988 NRC defined a "qualified" QA program as having plans and procedures in place which satisfy 10 CFR 50 Appendix B, 10 CFR 60 Subpart G, and Staff Guidance Documents, and satisfactory completion of audits to verify

effective implementation of the QA program. It was further indicated that two observation audits would be needed by the NRC to accept a QA program, assuming no major problems. However, we note that deterioration of this position and definition began in early 1989 when NRC staff announced that it would review "selected" technical products during a qualification audit before NRC acceptance of the program. It is obvious that NRC no longer intends to review the complete DOE QA program, but only "selected" parts, and would no longer require its own audits prior to acceptance, but rather would observe and accept DOE internal audits as demonstration of full program implementation. The State supported the original NRC position requiring the Department to have a fully qualified QA program in-place and the definition of what constituted a fully qualified program. We cannot now support this relaxation of that position and definition, as it no longer provides assurance that DOE will have a qualified program in-place and fully implemented prior to the start of site characterization. The NRC cannot allow the DOE to continue its practice of the last nine years of gathering data of questionable quality and then contaminating the literature set for Yucca Mountain with analyses and interpretations based upon data of suspect validity.

At the July 6-7 meeting, the staff also indicated that the "NRC and DOE must have ongoing consultations in the ESF, Title II design process. These must be timely so that DOE has an opportunity to consider NRC's comments, if necessary, before it completes subsequent steps". Separately, the staff stated that the "NRC would entertain consultations on qualifying DOE's quality assurance programs." 10 CFR Part 60, Subpart B Licenses indicates that during the preapplication period the NRC's responsibility is limited to review and comment, not consultation as now being contemplated by the staff. It is clearly not NRC's responsibility to guide the Department's program. It is the Department's responsibility to develop its characterization program, including quality assurance and ESF design, and ensure that the program meets NRC requirements. NRC's requirement is to review the program to determine if it meets relevant applicable regulation. Guidance and assistance in program development and execution is clearly not a regulator's responsibility. The State opposes the concept of NRC consultations with the Department of Energy for the purpose of assisting and guiding the specifics of DOE's development of a repository program which meets the regulations. We have stated this position in numerous past discussions with you and your staff. Furthermore, we believe that our position is not only fully consistent with the intent of 10 CFR Part 60, but also is consistent with the guiding principles of the so-called Morgan-Davis Agreement (FR, Vol. 48, No. 166, Aug. 25, 1983, p. 39701).

An example of the consequences of the NRC staff's apparently eroding commitment to its prior positions in regard to its dealing with the DOE as a potential license applicant is contained in the June 28, 1989 letter from Samuel Rouso, Acting Director of the DOE

OCRWM, to Hugh Thompson, of the NRC staff. This letter makes it clear that Mr. Rousso believes the NRC staff should do more to assist and guide the DOE in implementing its site characterization responsibilities. Also included is the clear implication that for NRC to continue under current (albeit eroded) review practices, or for NRC to reinstate a greater arm's-length relationship with DOE only frustrates the DOE's progress, and reduces interested parties' confidence in DOE's capability to plan and implement its site characterization program. The underlying assumptions of this DOE position are not consistent with NRC's established regulatory role, yet are somewhat reflective of the continuing trend of NRC staff interaction with the DOE discussed earlier in this letter.

The matters discussed in this letter are of great concern to the State of Nevada as they are at the core of the intent of the Nuclear Waste Policy Act's separation of roles of the major parties (DOE, NRC, and the affected state) involved in geologic repository site selection. The Act recognizes this clear separation of roles and duties as an indispensable element of promoting confidence in the safety of a geologic repository. By any logical interpretation, the independent, objective role of the regulator must be preserved throughout the regulatory process.

I would be pleased to discuss further the views presented in this letter at your convenience, should you so desire.

Sincerely,



Robert Loux
Executive Director

RRL:CAJ:ane

cc: Nevada Congressional Delegation