



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

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October 13, 1994

Dr. Daniel A. Dreyfus, Director  
Office of Civilian Radioactive  
Waste Management  
U.S. Department of Energy  
1000 Independence Ave., S.W.  
Washington, DC 20585

SUBJECT: CONCERNS WITH QUALITY ASSURANCE PROGRAM

Dear Dr. Dreyfus:

I wish to advise you that the U.S. Nuclear Regulatory Commission staff continues to have concerns with the Civilian Radioactive Waste Management System Management and Operation contractor's (M&O's) lack of an effective Quality Assurance (QA) program. The staff also is concerned about the U.S. Department of Energy's (DOE's) oversight of the M&O's program. The NRC staff, in its letter of August 20, 1993, raised a number of concerns with the acceptability of the design activities being conducted by the M&O under its QA program. These concerns were based on deficiencies identified by DOE during QA audits and surveillances of the M&O design process, and on independent design reviews of Design Packages 2A and 2B performed by DOE and its contractors. Subsequently, DOE provided a Design Control Improvement Plan (DCIP), Revision 1, dated September 28, 1993. This DCIP was intended to correct the identified concerns. Also, by letter dated November 18, 1993, DOE provided its responses to the concerns raised by the NRC staff in its August 20, 1993, letter.

Having reviewed the information provided in the DCIP, the November 18, 1993, DOE letter, and at several DOE/NRC interactions, the NRC staff concluded that DOE appeared to be making progress towards resolution of the staff's concerns. However, the staff noted [in a March 30, 1994, letter from B. J. Youngblood (NRC) to Dwight Shelor (DOE)], that it would not be able to verify this progress until the actions proposed by DOE had been properly implemented and verified through surveillances, audits, and design reviews. As a result of its review of the implementation to date, the staff does not find that the M&O's QA program and corrective actions contained in the DCIP are being effectively implemented by the M&O. This conclusion is based on: 1) the observation of several DOE audits conducted in June and July 1994; 2) the 90 percent design review of Design Package 2C; and 3) a failure to demonstrate resolution of the issues identified in the August 20, 1993, letter. In addition, because DOE is responsible for ensuring acceptable implementation of the M&O's QA program, the staff is concerned that DOE is not effectively exercising its oversight role. In particular, the staff believes that DOE and the M&O need to detect QA problems at an early stage, and initiate timely corrective actions consistent with Title 10 of the Code of Federal Regulations (10 CFR), Part 60, Subpart G (which references 10 CFR Part 50, Appendix B).

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cc w/encl - Letter to D. Dreyfus dated / /94

SUBJECT: CONCERNS WITH QUALITY ASSURANCE PROGRAM

R. Loux, State of Nevada  
T. J. Hickey, NV Legislative Committee  
J. Meder, NV Leg. Counsel Bureau  
R. Nelson, YMPO  
M. Murphy, Nye County, NV  
M. Baughman, Lincoln County, NV  
D. Bechtel, Clark County, NV  
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C. Schank, Churchill County, NV  
L. Bradshaw, Nye County, NV  
W. Barnard, NWTRB  
E. Lowry, Nevada Indian Environmental Coalition  
R. Holden, National Congress of American Indians  
S. Brocoum, YMPO

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At an NRC-DOE August 31, 1994, meeting, DOE discussed the above NRC staff concerns. Also discussed was the "Management Plan for Resolving QA Issues Resulting from M&O and DOE Audits/Surveillances" that DOE and the M&O believe will correct the problems identified. However, the staff does not have confidence that this new "get well" plan will work. The basis for this concern is that DOE and the M&O failed to effectively implement corrective actions intended by the DCIP. Therefore, the NRC staff is issuing the comment contained in Enclosure 1. This comment documents the staff's concerns with the lack of an effective QA program for the M&O as well as the failure of DOE to effectively oversee the M&O program by promptly identifying and correcting deficiencies at an early stage. In addition, the staff has several questions which request more details on various aspects of the QA concerns as well as the Exploratory Studies Facility (ESF) design. These are contained in Enclosure 2.

The staff believes that there is an opportunity for DOE to resolve the problems and staff concerns identified before any major impact on site characterization or the waste isolation capability of the site occurs. In doing this, DOE and the M&O should resolve the enclosed comment and questions together with the NRC staff concerns documented in the August 20, 1993, and August 19, 1994, letters. It is the NRC staff's position that this should be done prior to beginning any construction work that might cause any irreparable, adverse effects on waste isolation or site characterization. Examples of where site characterization could be impacted include recent concerns on pneumatic pathways. If the staff finds that DOE and the M&O plan to proceed with work that could adversely impact site characterization or the waste isolation capability of the site without acceptably addressing the staff's concern, NRC will issue an objection to any further ESF work. Please provide a written response to the comment and questions within 30 days of the date of this letter.

If you have any questions on this letter, please feel free to contact me or Mr. Joseph Holonich, of my staff. I can be reached at (301) 415-7800, and Mr. Holonich can be reached at (301) 415-6643.

Sincerely,

Robert M. Bernero, Director  
Office of Nuclear Material Safety  
and Safeguards

- Enclosures: 1. U.S. NRC Staff Comment on the QA Program for a High-Level Waste Repository  
2. U.S. NRC Staff Questions on Issues Related to QA and the Design of the Exploratory Studies Facilities

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DATE	10/ /94		10/ /94	H	10/11 /94		10/ /94		10 /13 /94

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OFC	HLUR*	E	ENGB*	E	DWM		NMSS		NMSS	
NAME	JHolonich/km		MBell				GArlotto		RBernero	
DATE	9/26/94		9/26/94	H	/ /94		/ /94		/ /94	

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**U.S. Nuclear Regulatory Commission Staff Comment  
on the Quality Assurance Program  
for a High-Level Waste Repository**

**COMMENT**

Based on the findings from recent U.S. Department of Energy (DOE) quality assurance (QA) audits of the Civilian Radioactive Waste Management and Operations (M&O) contractor, the U.S. Nuclear Regulatory Commission staff is concerned that the M&O QA program is not being effectively implemented in a manner that will assure acceptability of the Exploratory Studies Facility (ESF). In addition, at this time, the NRC staff questions DOE and the M&O's ability to implement a program to correct the problems identified. Finally, although the concerns are based on findings from DOE audits, surveillances, and design reviews, the recurrence of problems and the inability to correct them erodes the NRC's confidence in DOE's oversight of the M&O's QA program.

**Basis**

- o The basic philosophy of the NRC is that the safety of any nuclear facility is the responsibility of the operator. As such, DOE is the primary party responsible for ensuring that a high-level waste repository meets the requirements of 10 CFR Part 60. In order to gain confidence that DOE is fulfilling its responsibilities in an acceptable manner, the NRC requires DOE and its contractors to establish and execute a QA program for those structures, systems, and components important to safety and waste isolation. This QA program should provide measures to assure structured and systematic methods exist for: 1) obtaining data; 2) performing analyses; 3) preparing designs; and 4) providing supporting documentation for the NRC licensing decisions. Effective implementation of a QA program is intended to show that work was done properly, and the design will acceptably perform its function. As part of the NRC licensing process, the NRC staff needs to acquire the necessary confidence that the ESF is being acceptably designed, and will be built consistent with an approved design.
- o Construction being performed by DOE at the ESF could cause irreparable adverse effects on DOE's ability to perform site characterization or maintain the waste isolation capability of the site. Without an effectively implemented QA program, the staff does not have confidence that DOE will include all necessary considerations in the ESF design, or identify and correct problems. Examples include: 1) drifting that will be part of the geologic repository operations area too close to a fault; 2) ramp constructed at an improper angle; or 3) an incorrect seismic acceleration used in the structural analysis.
- o The August 20, 1993, letter from the staff to DOE expressed concern with findings from DOE audits of the M&O QA program. The findings demonstrated a lack of effective implementation of the M&O's QA program. Because of this, the staff requested that DOE provide a rationale for continuing ESF

Enclosure 1

- PPA design work being conducted by the M&O. The letter also requested that DOE submit a detailed plan for corrective actions for the M&O design deficiencies that were identified during audits and surveillances.
- o Although the staff found the Design Control Improvement Plan (DCIP) submitted in response to the August 20, 1993, letter acceptable, the NRC staff noted in its March 30, 1994, letter that acceptable and effective implementation of the DCIP still needed to be demonstrated. Subsequently, findings identified by DOE QA audits and design reviews since development of the DCIP demonstrated a recurrence of earlier problems. Therefore, at this time, the NRC staff does not have confidence that DOE and the M&O can effectively implement the "Management Plan for Resolving QA Issues Resulting from M&O and DOE Audits/Surveillances" developed in response to the latest findings on the M&O QA program.
  - o DOE and the M&O have not effectively trended and integrated findings from different review activities such as QA audits and design reviews in determining trends, root causes, and recurrence of problems. At the August 30, 1994, QA meeting, DOE reported that it did not see a recurrence of problems based on its analysis of Corrective Action Reports (CARs) from QA audits. It did not, however, consider similar findings from design reviews conducted on Design Packages 2A, 2B, and 2C. For example, as part of its observation of the design reviews for packages 2A and 2B, the NRC staff raised a concern about the lack of conservatism in both the packages. A similar finding was reported in CAR-072 by the DOE audit team. The staff understood that DOE did not include the comments on conservatism from the design reviews in determining whether similar concerns existed on the M&O's QA program.
  - o The M&O continued to conduct design work on Design Package 2C, even though DOE and M&O QA audits and surveillances had found recurring deficiencies in the M&O's QA program. Only after DOE indicated that it would issue a stop work order as a result of the findings on Design Package 2C did the M&O withdraw the design package. In addition, although minor in effort, the M&O continues to conduct design work on other ESF Design Packages.
  - o DOE continued to allow work to proceed on Design Package 2C, and it still does allow design work to be done on other ESF design packages. This has been done despite numerous significant and repetitive findings on the M&O's QA program. In addition, DOE has not ensured that the M&O corrective action program required under Criterion 16 of its QA plan is being effectively implemented, or that root cause and trending analyses are identifying the reason for the problems. During the June 1994 DOE Audit of the M&O, DOE mentioned the M&O Trend Program as being ineffective in obtaining corrective action of identified trends.
  - o Problems continue to be found with tracing the flowdown of design requirements from 10 CFR Part 60 to design specifications. This concern was raised: 1) in 1989 as part of the basis for Objection 1 of the Site Characterization Analysis; 2) by the NRC on-site representative in May 1993; and 3) most recently, by the DOE audit team in CAR-074. It also serves as another example of DOE's lack of effective integration in evaluating all findings from various reviews.

## **Recommendation**

In order to build the staff's confidence that DOE and the M&O can develop and implement a QA program, it will be necessary for DOE to demonstrate that the work which has been or will be done is acceptable. Because DOE and the M&O have not demonstrated that they can effectively implement a "get well" program, the staff recommends that DOE allow the NRC an opportunity to determine the acceptability of DOE work prior to the start of any ESF construction that could impact site characterization or the waste isolation capability of the site. The acceptability of the get-well program will be determined based on observations of DOE reviews and audits as well as independent evaluations. In addition, the staff will gain confidence that the get-well program is effective if DOE demonstrates that the process under which the ESF is designed and constructed is identifying and correcting problems.

In addition, DOE should demonstrate that the work on Design Package 2C is acceptable. This should be done by conducting any necessary QA audits, design reviews, or readiness reviews that are needed to demonstrate the acceptability of the work. The number and significance of findings from these reviews can serve as a basis for demonstrating the acceptability of the process and design. DOE also should demonstrate that design work on other design packages is acceptable given the problems identified.

**Staff Questions on Issues Related to Quality Assurance  
and the Design of the Exploratory Studies Facilities**

**QUESTION 1**

**What are the differences between the various phases of design and construction proposed under the different phases of Design Package 2C?**

**Basis**

- o In telephone calls and meetings with the U.S. Department of Energy (DOE), the staff understood that DOE would implement the design and construction of Design Package 2C in phases. Within each phase, certain design and construction work would be completed. Because some of the terminology and activities for the phases have been unclear and evolving, DOE needs to provide the staff with written documentation that will allow the staff to fully understand the work that will be conducted in the various phases of Design Package 2C. This information is needed so the staff can review DOE's response to Question 2 regarding potential adverse impacts on site characterization or the waste isolation capability of the site.**

**Recommendation**

**DOE should provide a description of the work, including design and construction, that will be completed in each phase of Design Package 2C. This information should relate the completion of construction to significant site features such as the Bow Ridge Fault, or issues raised on ESF construction such as pneumatic pathways.**

## QUESTION 2

What are the impacts to site characterization and the waste isolation capability of the site that are associated with the completion of work under Design Package 2C? At what point in the construction of the ESF north ramp is there the potential to impact site characterization and the waste isolation capability of the site?

### Basis

- o The staff needs to fully understand the construction work that will be completed by the operation of the TBM, and its potential to impact site characterization or the waste isolation capability of the site. Without this information, the staff is unable to determine the point beyond which construction should not proceed without DOE and the M&O having demonstrated effective implementation of a quality assurance program. Examples of where site characterization could be impacted include recent concerns raised on pneumatic pathways.

### Recommendation

DOE should provide the requested information along with its rationale for where site characterization or the waste isolation capability of the site could be impacted. If DOE determines that there is no impact from work being completed for Design Package 2C, it should provide justification.

### QUESTION 3

- a) What is the current reference conceptual design for the geologic repository operations area (GROA)?
- b) What is the current ESF design and testing strategy?
- c) What is the current control mechanism to ensure compatibility and integration among the GROA conceptual design and the ESF, including design, construction, operation and the proposed testing strategy?

#### Basis

- o In order to ensure that ongoing ESF design and construction do not impact the ability to meet 10 CFR Part 60 requirements for future repository, DOE needs to have considered at least a conceptual design of the GROA in designing the ESF. The staff has requested in its letters dated March 24, 1993, and August 20, 1993, a description of DOE's conceptual GROA design so it can confirm that DOE is incorporating repository design considerations into the ESF. To date, DOE has not provided the requested information.
- o If Yucca Mountain becomes the site for the repository, construction of the ESF north ramp will determine the horizon for the main drift of the underground facility. Because DOE is beginning construction of the ESF north ramp, and it is the staff's understanding that over a third of it will be completed prior to Spring 1995, the staff needs to have an understanding of how the ESF relates to the various GROA options under consideration.
- o DOE is completing the Title II design of the ESF in individual packages rather than as a complete facility. Because of this, DOE needs to ensure tight control of interfaces among the individual design packages as well as integration with the conceptual design of the GROA options. DOE has not shown the staff that it is fully considering the interfaces among individual packages or their relationship to the GROA.
- o The location of in situ tests is continuing to change even as the TBM has started excavating the rock. The acceptability of the ESF design cannot be judged in isolation, without a reference test plan.

#### Recommendations

- (1) DOE should provide a description of the conceptual design of the GROA that shows how the individual design packages being prepared for the ESF relate to the repository design.
- (2) DOE should provide the latest thinking on its testing strategy and in situ test locations.