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

March 9, 1995

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

Dear Mr. Milner:

SUBJECT: RESULTS OF INITIAL STAFF REVIEW OF U.S. DEPARTMENT OF ENERGY NOVEMBER 14, 1994, QUALITY ASSURANCE LETTER AND PLAN FOR VERIFICATION

By letter dated October 13, 1994, the U.S. Nuclear Regulatory Commission documented its concerns regarding the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management's Management and Operating Contractor's (M&O's) quality assurance (QA) program and DOE's oversight of the M&O's QA program. DOE responded to the NRC concerns by letter dated November 14, 1994 (Dreyfus to Bernero). NRC staff has reviewed the DOE November 14, 1994, correspondence to determine the acceptability of the information provided, and plans to determine whether acceptable corrective actions have been effectively implemented. The NRC staff's effort consists of the three phases described below. The purpose of this letter is to describe the total NRC staff QA effort and document the results of Phase 1.

Phase 1 was a review of DOE's November 14, 1994, response to determine if it acceptably addresses the NRC concerns. The detailed NRC staff evaluations for Phase 1 are contained in Enclosure 1. Basically, the NRC staff concludes that the DOE response appears acceptable. However, final approval cannot be determined until implementation of the corrective actions is verified. These activities will be completed by the staff in Phases 2 and 3.

Phase 2 will verify the design and corrective actions being completed by DOE and the M&O. It will be sufficiently detailed to allow the NRC staff to further assess the acceptability of the DOE response, and evaluate the implementation of the DOE/M&O program. Phase 2 will include an independent, limited-scope, in-field verification conducted by a team of QA and technical staff from the NRC and the Center for Nuclear Waste Regulatory Analyses. Although this letter provides slightly less than 30 days prior notification, the in-field verification, described in Enclosure 2, will take place during April 3-6, 1995 as approved by Robert Clark by phone conversation with John Buckley on March 9, 1995. The verification team will use an internal checklist developed in advance of the in-field verification in accordance with standard auditing practices.

The in-field verification team will hold a pre-verification meeting with members of your staff on Monday, April 3, 1995, beginning at 9:00 a.m. in the Las Vegas, Nevada, DOE offices. At this meeting, DOE/M&O should be prepared

to briefly discuss the status and progress-to-date in resolving the open items and to identify the principal contacts for the audit team. A post-verification meeting is tentatively scheduled for 2:30 p.m. on Thursday, April 6, 1995. Please arrange for the appropriate DOE and M&O personnel to attend these meetings and the relevant documents to be available. Also, please arrange for a location where the pre-verification and post-verification meetings will be held and a meeting/working room for the team during the in-field verification.

In addition to the team in-field verification during Phase 2, NRC staff assigned to observe operation of the tunnel boring machine have also be conducting verification activities. The NRC has observed DOE Audits YM-ARP-95-02 and HQ-ARC-95-04 of the M&O's corrective action and other program elements. These activities by the staff will be used as further independent verification of the acceptability of DOE and M&O processes.

Phase 3 will involve: 1) the review of DOE's report regarding impacts on waste isolation and site characterization, which DOE stated it would submit 120 days after November 14, 1994, (March 14, 1995); 2) the review of DOE's response to the October 6, 1994, NRC letter (Federline to Milner) regarding pneumatic pathways; and 3) a limited-scope, in-field verification to verify the acceptability and effectiveness of DOE/M&O activities related to these documents. A plan and schedule for this in-field verification will be issued later. The completion of Phase 3 should permit the NRC staff to determine whether the remaining open items can be resolved.

If you have any questions, please contact Jack Spraul at (301) 415-6715.

Sincerely,

Joseph J. Holonich, Chief
High-Level Waste and Uranium
Recovery Projects Branch
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards

Enclosures:
1. NRC Evaluation of DOE Response to Comments and Questions of October 13, 1994
2. In-field Verification Plan

cc: See attached list

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DATE		H	03/01/95		03/03/95		03/03/95		03/9 /95	

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cc: List for R. Milner letter dated March 6, 1995

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ENCLOSURE 1

NRC Evaluation of DOE Response to Comment and Questions of October 13, 1994

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.

NRC EVALUATION OF DOE RESPONSE

The NRC staff reviewed DOE's response of November 14, 1994, to the comment in NRC's letter of October 13, 1994. This resulted in the following evaluation.

DOE's response provided preliminary information regarding changes to the M&O organization designed to strengthen the design and design assurance functions. The staff believes that the M&O organizational changes outlined in the DOE response should improve the process of identifying and correcting problems associated with ESF design and construction. Therefore, this approach is acceptable. However, the NRC staff needs to review the new organization and assess the acceptability/effectiveness of its operation.

DOE's response states that a team of senior personnel, external to the M&O, will evaluate M&O engineering and QA activities to determine whether there are any programmatic and/or organizational weaknesses. The NRC staff believes that the development of such an oversight team will improve the M&O's corrective action process. Therefore, the approach presented is acceptable. However, the NRC staff needs to review the results of this work.

DOE's approach for verifying effective corrective action to prevent recurrence of problems and determining the effectiveness of procedure implementation is acceptable. However, the NRC staff needs to review the results of this work.

DOE has committed to establish an Office of Civilian Radioactive Waste Management- (OCRWM) wide quality trend program to be in place by July 1995. Although this action should contribute toward more timely corrective actions for adverse trends and evaluation of the effectiveness of these corrective actions, it is not clear in DOE's response whether or not design nonconformances found during design reviews will be included in this program and, if not, how the design process and products will be evaluated. The NRC staff will follow-up, during its in-field verification, to clarify DOE's intent in this area and to evaluate progress toward the July 1995 trend program commitment.

The NRC staff also reviewed the M&O's "Management Plan for Resolving QA Issues Resulting from M&O and DOE Audits/Surveillances" (August 25, 1994 - Attachment 1 to DOE's November 14, 1994, response). Under this plan, the M&O is committed to perform the following activities for Design Package 2C:

1. Implement corrective action on all open corrective action requests related to Design Package 2C.

2. Analyze items corrected during recent audits/surveillances for similar products and implement corrective action as appropriate.

3. Review the design process, revise the process and procedures that implement the process as required, and train the affected personnel.

4. Review the quality classification process, revise the process and procedures that implement the process as required, and train the affected personnel.

5. Review design products by both an internal and an external team, consolidate results, and implement the resultant corrective action recommendations.

6. Close the Management Plan with a report that summarizes the objective evidence of the above activities and an appropriate statement of acceptability.

Under this plan the M&O is committed also to evaluate the root causes and recommend actions to correct mistakes made by personnel involved in the design process. These personnel are to be briefed/trained regarding their involvement in the quality/QA aspects of their work.

The actions proposed in the plan are acceptable. However, the schedule for these actions (beyond Design Package 2C), included in DOE's response, was generally not specified. The NRC staff needs to review the current schedule and assess implementation.

As described above, DOE actions and plans in response to the comment are generally acceptable. However, because of the NRC staff's overall concern with the earlier lack of effective implementation, the staff's in-field verification and observations of DOE audits of the M&O will be conducted to evaluate implementation and determine whether the comment can be resolved. At this time, NRC considers this comment open.

QUESTION 1

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

NRC EVALUATION OF DOE RESPONSE

The NRC staff reviewed DOE's response of November 14, 1994, to Question 1 in NRC's letter of October 13, 1994. This resulted in the following evaluation.

DOE provided a detailed description of the phased design and construction approach that would allow construction activities before completion of ESF design. The ESF design products, designated as Design Packages, were two for surface construction activities and eight for subsurface construction activities. A description of these 10 design packages is given in DOE's response.

To optimize the design effort, considering various factors and funding restrictions, DOE has further divided these design packages into smaller work-scope groupings that retain the initial logic and sequencing schemes. DOE has explained the subdivision of Design Packages 1 and 2. For example, Design Packages 2A, 2B, and 2C comprise the entire design package for the North Ramp portion of the ESF. Overall, Design Package 2 is the basis for all future subsurface design packages. Design Package 2C is being released as smaller products (2C-1 through 2C-4), as and when drawings and specifications are reviewed, verified, and accepted for construction.

DOE has explained the rationale behind the enhanced layout of the ESF. Since the ESF layout is expected to be optimized as more site information becomes available, the NRC staff expects this to be an ongoing activity and will follow the changes to the ESF layout and design.

There is no correlation between the Design Package 2C products being released and the phased Tunnel Boring Machine (TBM) operations. TBM operations are labeled as TBM Phase 1 - "Testing," TBM Phase 2- "Shakedown," TBM Phase 3 - "Limited Operations," and "TBM Phase 4 - "Sustained Operations." These phases are part of the TBM start-up and regular operations. DOE has explained the details and the difference among these phases.

The NRC staff considers that the DOE response to Question 1 is satisfactory. The staff expects to provide comments on any future changes to the ESF. The staff will review the issues of the timing of releases of design drawings and specifications during in-field verifications.

NRC considers this question resolved.

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?

NRC EVALUATION OF DOE RESPONSE

The NRC staff reviewed DOE's response of November 14, 1994, to Question 2 in NRC's letter of October 13, 1994. This resulted in the following evaluation.

DOE stated that it has placed a hold on TBM operation beyond the upper Paint Brush Nonwelded (PTn) Unit contact until data have been collected for several pressure fronts. DOE stated further that it has installed one pressure monitoring system as of early November and planned to install another system as of mid-November. DOE plans to reach the hold point of excavation in about 8 months (from November 14, 1994) and considers this time to be sufficient for adequate data collection.

DOE has also stated that it considers its processes adequate to provide confidence that other waste isolation and test interference aspects have been identified and controlled sufficiently to meet the requirements of 10 CFR 60.15(c)(1). As a rationale for this statement, DOE provided an explanation of its Determination of Importance Evaluation (DIE) process, as the process pertains to the requirements of 10 CFR 60.15(c)(1).

DOE responded to the two major aspects of Question 2: (1) identification of impacts to site characterization and waste isolation and (2) identification of a point in the construction of the ESF north ramp where there is potential to impact site characterization and the waste isolation capability of the site.

In regard to identification of impacts, we consider the explanation of the DIE process as it pertains to 10 CFR 60.15(c)(1) to be sufficient. The basis for this conclusion is that the examples of evaluated impacts provided in the response are appropriate for the operation being evaluated. The NRC in-field verification will assess the effectiveness of the DIE process in selected areas.

In addition, DOE committed to discuss, in a forthcoming letter to NRC, the rationale for its conclusion that it has adequately considered the pneumatic pathways issue in terms of potential site characterization impacts. This forthcoming letter is expected to be a further response to technical questions raised in the October 6, 1994, NRC letter to DOE (Federline to Milner).

In regard to a point in the construction where there is a potential for impact, the DOE identified the penetration of the PTn Unit. We agree that this is an appropriate point in regard to the pneumatic pathways issue. We have also considered DOE's position that its performance assessment models have not found the PTn layer to be a significant barrier to radionuclide release. However, this does not address the State of Nevada's concern

regarding the effect of a barrier on the redistribution of moisture (NRC letter of June 21, 1994, to DOE - Holonich to Shelor). Hence we do not consider DOE's contention that the PTn layer is unimportant to repository performance to be justified from the explanations submitted. The staff will continue to review this issue in coordination with DOE and the State of Nevada as part of its efforts in Phases 2 and 3.

In conclusion, we consider the responses submitted to be adequate, because DOE has explained its process with respect to Design Package 2C and because DOE has identified a hold point in the construction of the ESF north ramp. However, pending completion of 1) the review of DOE's 120-day report on impacts to waste isolation and site characterization; 2) the review of DOE's response to the October 6, 1994, NRC letter (Federline to Milner) regarding pneumatic pathways; and 3) a limited-scope, in-field verification to verify the acceptability and effectiveness of DOE/M&O activities related to these documents, the NRC considers this question open.

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?

NRC EVALUATION OF DOE RESPONSE

The NRC staff reviewed DOE's response of November 14, 1994, to Question 3 in NRC's letter of October 13, 1994. This resulted in the following evaluation.

DOE has provided a set of six drawings showing the compatibility and integration of ESF and Repository layout. DOE has identified the portions of the ESF that will become part of the potential repository. The NRC staff is in the process of reviewing the GROA design described in a recent DOE interim document, "Initial Summary Report for Repository/Waste Package Advanced Conceptual Design," August 1994. DOE states that the repository design is 1) in process and evolving and 2) likely to be finalized in FY 95. Therefore, the GROA/ESF layout drawings are also expected to be updated in FY 95. The staff will continue to review the updated information as it becomes available.

The DOE has indicated that the ESF, GROA, and Surface Based Testing (SBT) interfaces are evolving and are presented in several documents. DOE is planning to replace the current Site Characterization Program Baseline (SCPB) document with a new document that will: 1) contain summary descriptions of ESF, GROA, and SBT concepts and interfaces; and 2) describe how the SBT and ESF programs will be incorporated into the GROA. The staff expects that DOE will provide this information in the next Site Characterization Plan Progress Report (SCPPR), which should reference the supporting documentation. The NRC staff plans to review this new information when it becomes available. DOE has also identified some of the differences between the GROA design concepts presented in the Site Characterization Plan and the current concepts of GROA design presented in the next SCPPR. The staff notes that DOE has not defined a thermal loading in the current conceptual design of the GROA; instead, both low and high thermal loading options are being carried forward and evaluated. The staff notes that this approach could have an enormous impact on the site characterization testing strategy. The staff will continue to evaluate DOE's testing strategy.

DOE states that the control mechanism for compatibility and integration between GROA and ESF design is the inclusion of interface drawings in Appendix A.2 of the ESF Design Requirements document. DOE also states that the control mechanism for the construction and operational aspects is the DIE process in which the construction and operation activities will be evaluated for their impact on compliance with the performance objectives. Any requirements resulting from the DIEs will be included in the specifications for the affected item. The NRC staff notes that in the past, the DIE was not

completed for all items of Design Package 2B at the time of 90 percent design review. Although the control mechanism for coordination between testing and design appears to be in place, the layouts and concepts of repository and ESF are evolving and this has resulted in DOE not finalizing the test locations. The staff appreciates the need for some flexibility in specifying exact locations to accommodate the in-situ conditions and the changing testing and design concepts. In addition, DOE's new Program Approach and the draft Five-Year Plan also impact the scope and schedule of the proposed testing. The staff will examine the effectiveness of the control mechanism and its implementation during the final two phases of the review. Further, the staff expects that DOE will document changes in testing and their impacts on the site characterization program in the next SCPPR, which should reference the revised Test Planning Package. The staff may review the detailed information in the Test Planning Package through future field activities.

The concern on demonstrating the flowdown of 10 CFR Part 60 Design Requirements in the ESF design has resulted in an NRC Open Item (Site Characterization Analysis Comment 130) and, recently, DOE CAR YM-94-100. The NRC staff will selectively examine how DOE has translated the appropriate regulatory requirements into design bases and specifications during the final two phases of the review.

The NRC staff will review changes to the design presented in the next SCPPR and will conduct detailed evaluations of DOE's Thermal Load Strategy, Test Planning Package (as revised to reflect the new Program Approach), Advanced Conceptual Design, revised SCPB, and the revisions made to Design Package 2C as a result of QA audit findings to ensure that adequate control processes are in place and are being effectively implemented before final acceptance of DOE's response to Question 3. Therefore, NRC considers this question open pending the completion of the above reviews.

ENCLOSURE 2

In-Field Verification Plan