MAR 30 1994

Mr. Dwight E. Shelor, Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, D.C. 20585

Dear Mr. Shelor:

SUBJECT: EXPLORATORY STUDIES FACILITY DESIGN AND DESIGN CONTROL PROCESS

In its letter of August 20, 1993, (B. J. Youngblood to D. Shelor), the U.S. Nuclear Regulatory Commission staff raised a number of concerns with the U.S. Department of Energy's (DOE) exploratory studies facility (ESF) design and design control process. The NRC concerns generally related to the design activities of the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O) and included concerns arising from deficiencies identified by DOE during quality assurance audits and surveillances of the M&O design process and from independent design reviews of several design packages, which were observed by the NRC staff. These concerns were further discussed in detail at the September 17, 1993, meeting on ESF concerns held in Bethesda, MD (see Attachment 3 to the October 15, 1993, letter from J. Holonich to D. Shelor).

Additionally, the August 20, 1993, letter noted that the NRC staff had no clear understanding of DOE schedules for many proposed surface-based tests or DOE plans for integrating the resulting data into its ESF Title II design. As a consequence, the NRC staff stated it could not determine the adequacy of certain aspects of the ESF design.

In DOE's November 18, 1993, letter response (D. Shelor to B. J. Youngblood), DOE provided information relating to the NRC staff requests noted above and to another related concern, namely, the manner in which DOE resolves NRC staff concerns identified during independent design reviews.

Based on its review of the DOE November 18, 1993, letter and the information provided at the NRC/DOE interactions held on September 17, 1993, October 4-5, 1993, December 8, 1993, and January 5-7, 1994, the NRC staff considers that DOE has made progress towards resolution of NRC staff concerns. However, the NRC staff is unable to verify that the actions taken by DOE have been properly implemented and, until this verification is accomplished through audits, surveillances, and design reviews, the NRC staff concerns remain unresolved. The basis for the NRC staff's determination is noted below and detailed in the enclosure to this letter.

The NRC staff notes that DOE is making progress towards resolution of NRC staff concerns through its commitment to conduct bi-monthly meetings to keep the NRC staff informed of activities related to the ESF design and design control process, its plans to provide the NRC staff with predecisional design

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packages in advance of any design reviews, and DOE's plans to conduct a follow-up audit of the M&O which the NRC staff plans to observe. However, the NRC staff participated in the DOE 90 percent review of Package 2B, "North Ramp Studies, Analyses and Specifications," for the Exploratory Studies Facility, held in Las Vegas, Nevada, January 5-7, 1994 where questions were raised regarding the effectiveness and adequacy of the design interface among the design disciplines and the DOE/M&O contractors during development of the design and prior to the 90 percent design review of Package 2B. The NRC staff comments on this design review are documented separately in a design observation report (letter from J. Holonich to D. Shelor dated February 18, 1994). These comments in part, form the basis for the NRC staff determinations that there is need for verification of the successful implementation of DOE actions regarding the design control process.

The status of specific NRC staff concerns expressed in the August 20, 1993, letter are addressed in the enclosure. If you have any questions or concerns related to this letter, please contact William Belke of my staff at (301) 504-2445.

Sincerely,

/s/

B. J. Youngblood, Director
Division of High-Level Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc: R. Loux, State of Nevada
T. J. Hickey, Nevada Legislative Committee
J. Meder, Nevada Legislative Counsel Bureau
R. Nelson, YMPO
M. Murphy, Nye County, NV
M. Baughman, Lincoln County, NV
D. Bechtel, Clark County, NV
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P. Niedzielski-Eichner, Nye County, NV
B. Mettam, Inyo County, CA
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C. Schank, Churchill County, NV
L. Bradshaw, Nye County, NV

| OFC | HLPD | E | HLPD | E | HLGE | | HLWM | | HLWM | N |
|---|---|---|---|---|---|---|---|---|---|---|
| NAME | WBelke | | JHolonich | | RBallard | | JLinehan | | BJYoungblood | |
| DATE | 03/30/94 | | 03/30/94 | | 03/30/94 | | 03/ /94 | | 03/ /94 | |

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SUBJECT EXPLORATORY STUDIES FACILITY DESIGN AND DESIGN CONTROL PROCESS

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U.S. NUCLEAR REGULATORY COMMISSION STAFF EVALUATION OF U.S. DEPARTMENT OF ENERGY NOVEMBER 18, 1993, RESPONSES TO NRC's AUGUST 18, 1993 LETTER ON DESIGN CONCERNS

1. • The NRC August 20, 1993, letter requested DOE to:

Provide rationale for proceeding with the Civilian Radioactive Waste Management System Management and Operating Contractor (M&O) design activities and Exploratory Studies Facility (ESF) construction while the design control process deficiencies are being investigated and corrected.

• The NRC October 15, 1993, letter for the September 17, 1993, meeting stated for this request:

The U.S. Department of Energy (DOE) should have in place a design control process under which the design, rationale for the design, information needed for the design, etc. are integrated. Construction includes drilling boreholes to be used for design.

• A summary of the November 18, 1993, DOE response to this concern is:

Each deficiency in the design process which had been identified by DOE or the M&O was evaluated to determine if a stop work order was appropriate. This evaluation determined that there were no stop work conditions.

NRC EVALUATION OF DOE RESPONSE

The NRC staff performed an overview of the deficiencies and corrective actions in process (Enclosure 2 to the November 18, 1993, DOE response) associated with the DOE response to the above NRC staff concern. The corrective actions and design plan improvements were also discussed in detail by DOE and the M&O at the October 4-5, 1993, NRC/DOE Technical Exchange in Las Vegas, Nevada, and at the December 8, 1993, Technical Meeting in Washington, D.C. The NRC staff recognized and documented in the summaries for these two meetings (November 3, 1993 letter from J. Holonich to D. Shelor and January 6, 1994, letter from C. W. Reamer to D. Shelor for the October 4-5, 1993, and December 8, 1993, meetings respectively), that an aggressive corrective action program was underway to correct previously identified conditions adverse to quality in the ESF design/construction phases. The NRC staff indicated that the DOE corrective action program looked positive, but the NRC staff will still need to observe implementation of this program through participation as observers to DOE audits/surveillances to acquire sufficient confidence that deficiencies in the design process are being satisfactorily investigated and corrected. If appropriate, the NRC staff will perform its own audit(s) to verify the effectiveness of corrective actions.

Based on the above NRC staff evaluation and experience with the DOE process of identifying, evaluating and correcting deficiencies as documented by NRC Audit Observation Reports, the NRC staff finds this response generally acceptable subject to future verification of implementation of proposed corrective actions.

2. • The NRC August 20, 1993, letter requested DOE to:

Provide a detailed action plan providing for corrective actions for the M&O design deficiencies, including root cause analysis and verification of the effectiveness of corrective actions.

- The NRC October 15, 1993, letter for the September 17, 1993, meeting on ESF concerns stated for this request:

The NRC staff would expect to see a discussion of deficiencies identified during recent audits, a discussion of the root cause determined for each, a description of the corrective actions taken to rectify the deficiencies, and the steps DOE will establish to help ensure the problems do not reoccur.

- A summary of the November 18, 1993, DOE response to this concern is:

A M&O Design Improvement Plan was developed and sent to NRC by a letter from D. Shelor to J. Holonich dated September 28, 1993. This plan was a self-evaluation by the M&O to improve the design process, to review the CARs, and 1993 M&O Management Assessment Report. In addition, the November 18, 1993, response provides a summary of the DOE and M&O Corrective Action Requests (CARs) that were written. This summary identifies the CAR number, open or closed status, significance, a description of the adverse conditions, root cause, and a synopsis of corrective/remedial actions.

NRC EVALUATION OF DOE RESPONSE

A formal review of the M&O Design Improvement Plan furnished to the NRC staff was not requested by DOE and therefore, no external comments were generated by the NRC staff. However, an internal cursory overview of the M&O Design Improvement Plan was performed by the NRC staff with the results indicating that we agreed proper implementation of the plan would improve the M&O's design process. The NRC staff also performed an overview of the deficiencies and corrective actions in process to resolve the concerns with the M&O design process. This overview included evaluating the finding, its significance, proposed corrective action, root cause determination, and corrective action to preclude recurrence. The results of the NRC staff overview indicate that the documented actions also appear to be generally acceptable.

The NRC staff finds the response to the above concern to be generally acceptable based upon its experience with the DOE Quality Assurance (QA) program, review of the M&O Design Control Improvement Plan, and corrective actions program in process. However, complete closure of the NRC staff

concerns for this item cannot occur until the NRC staff determines that the corrective actions are effective and adequately implemented.

3. • The NRC August 20, 1993, letter requested DOE to:

Provide the date when a controlled baseline ESF design, integrated with a conceptual geologic repository operations area (GROA) design, will be formally submitted to the NRC for review and comment. On May 19, 1993, the DOE transmitted to the NRC, an uncontrolled copy of the ESF Technical Baseline Document (YMP/CM-0016) which contains discussion and drawings depicting the approved ESF design as of the transmittal date. The letter of transmittal of the baseline document states that Progress Report Number 8 will contain information related to the approved design. Although the incorporation, by reference, of an up-to-date baseline document and a description of the significance of that document in a Progress Report would be the first step toward meeting this request, DOE needs to describe how the ESF is incorporated into the GROA. Also, it needs to provide in its progress report a complete summary of all design documents that have been, or need to be, formally submitted to the NRC for review, and a discussion of how those documents relate to one another to present a complete picture of the ESF and conceptual GROA design.

- The NRC October 15, 1993, letter for the September 17, 1993, meeting on ESF concerns stated for this request:

DOE would need to answer the questions: 1) What are the documents that are needed to conduct a review and understand the complete ESF? 2) How are these documents integrated? 3) What is the control mechanism in place to assure that design documents are integrated with study plans? 4) How are the ESF design documents integrated with study plans, etc. that discuss plans to gather information needed as input to design? 5) How are ESF construction sequences and schedules integrated with other schedules for gathering of information needed for ESF design and testing?

- The November 18, 1993, DOE response in summary to this concern is:

1) DOE cited nine reference documents (enclosure 1 to DOE's letter) that would provide an understanding of ESF design and integration with GROA conceptual design. Those documents are:

- The Site Characterization Program Baseline, Revision 9 (SCPB, transmitted to NRC on March 5, 1993), a primary descriptive baseline document containing a relatively high-level description of the ESF Test Program, the ESF, and the relationship of the ESF to the potential repository.

- The Site Characterization Progress Reports which are used to summarize the descriptions of changes to SCPB as well as in-process plans for modification to the SCPB.

- The ESF Design Requirements (ESFDR, YMP/CM-0019, transmitted to NRC on October 27, 1993), a technical baseline document presenting technical requirements for the ESF.

- More detailed technical information is documented in the ESF Technical Baseline (ESFTB, transmitted to NRC on May 19, 1993) and its referenced documents, which are:

  a. ESF Title I Design Summary Report (transmitted to NRC in 1991).

  b. Exploratory Studies Facility Alternate Studies (transmitted to NRC on March 3, 1992).

  c. Site Design and Test Requirements Document (SDTRD, not transmitted to NRC).

  d. Plan for Phased Approach to ESF design, Development and Implementation (Transmitted to NRC on December 19, 1991).

  e. The ESF PLAN - includes the plan for integration of the Title II Design packages (not transmitted to NRC).

2) DOE presented a table in its response letter to show the relationship among SCPB, other Baseline documents and technical reports listed under above item #1. DOE also presented a document hierarchy chart in October and December, 1993, DOE/NRC ESF meetings.

3) DOE presented a Generic Scientific Investigation Control Process (GSICP) package in the December 1993, DOE/NRC ESF technical meeting to show the process for integration of ESF design with study plans.

4) DOE tabulated the relationship among study plans, ESF design, SCPB, ESFDR, and SDTRD in its response letter. The GSICP also showed the integration of ESF design with the study plans during the test planning stage, test implementation stage, and test evaluation stage to resolve the Performance Assessment (PA) and design issues, as well as determine site suitability.

5) DOE stated that schedule of specific study plans and test activities with respect to specific ESF design and construction activities is closely related to annual funding, and long-range plans do not reflect information useful for interaction between NRC and DOE staff. DOE recommended that fiscal year plans for these related activities be a topic of discussion at the bimonthly meetings. DOE provided a table (enclosure 3 to DOE's letter) showing the study plans associated with the underground test program. The ESF testing prioritization and study plan status are also included in this table.

   DOE has also presented information on the integration among the ESF, GROA, and Waste package design process in the October, 1993 DOE/NRC ESF Technical Exchange Meeting and December 1993 DOE/NRC Technical

Meeting on the ESF. Most recently, DOE described its document hierarchy during the February 3, 1994, DOE/NRC ESF bimonthly meeting.

NRC EVALUATION OF DOE RESPONSE

1) Documents needed to review and understand ESF design:

DOE has identified the documents required to conduct a review and to understand the complete ESF design.

2) Integration of ESF/GROA design documents:

The DOE presented a table showing the relationship among the above mentioned technical documents. However, no detailed information is provided on how the integration has been done. For example, DOE has indicated in its response that the Yucca Mountain SCPB is a critical document in the identification of interrelationships between the ESF and the potential repository. However, its status can not be determined in the M&O document hierarchy. Because of this and the fact that two of the documents (SDTRD and ESF plan) were not transmitted to the NRC, a detailed verification of this integration process could not be performed. A cursory verification was performed and numerous discrepancies were found during a spot check of the SCPB. Those discrepancies are discussed below at the end of this section (Cursory review of the SCPB). Furthermore, the document hierarchy should clearly demonstrate how the SCPB or its replacement is integrated with other documents in the hierarchy.

3) ESF design document and study plan integration control mechanism:

DOE's GSICP package discussed the change control and QA process for test planning, test implementation, and test evaluation. The flow chart explains how the regulatory and performance assessment requirements and baseline requirements fit into study plan preparation. Study plan preparation, study plan review, field and laboratory test planning, field and laboratory testing, test results verification, and data evaluation steps are identified in this chart. However, DOE's GSICP does not show how the control process ensures that the existing study plans are modified to account for the changes in the ESF configuration and design requirements.

For example, Study Plan (SP) 8.3.1.15.1.5 - Excavation Investigations, Revision 0 (this is the current copy in NRC's file), includes shaft convergence, demonstration breakout rooms, and sequential drift mining experiments. The Study Plan states that "all three experiments will be conducted in, or adjacent to, Exploratory Shaft 1 (ES-1) or at the main test level inside the underground facility." However, in the current approved ESF baseline design, the Exploratory Shaft has been replaced by a ramp. Apparently, the SP has not been revised to accommodate the ESF design changes. It is not clear to the staff what mechanism is in place to address the control of such changes to SPs.

On September 16, 1993, a related question was raised, during the NRC observation of DOE's Sandia National Laboratory QA audit. The question related to a QA controlled proceduralized system that provides details of design changes and their effects on the testing program(s) to participant PIs on a real-time basis so that such effects on SPs and data-collection could be evaluated. DOE provided the answer that QA Procedure 6.2, Administrative Procedure (AP) 3.3Q, and AP3.5Q will be applied to integrate the ESF design change and SP revisions. DOE may need to revise the GSICP to reflect this stated control process. DOE also needs to demonstrate by example how the control process has been implemented.

This might be accomplished during an audit if done in such a way that the NRC staff can understand the scientific investigation control process.

4) How are ESF design documents integrated with study plans and plans for gathering information needed as input to design:

The GSICP chart shows the relationship of the ESF requirements and baseline requirements that are input into the study plan preparation. The GSICP chart also shows the test data verification and test data evaluation process that tie with the baseline requirements. The chart shows the use of test results to resolve performance assessment and design issues. However, the NRC staff believes that evaluation of the ESF design integration with SPs and test information cannot be performed with the information presented by DOE in its response letter and expects that further evaluation will be necessary through audits and design package reviews.

5) How are ESF construction sequences and schedules integrated with other schedules for gathering of information needed for ESF design and testing:

DOE states that the topic of schedule and integration of ESF related design, test, and construction activities will be discussed at DOE/NRC bimonthly meetings. DOE's response states that the schedule of specific activities is closely related to funding, and therefore, long-range plans do not reflect useful information. DOE provided information on the SPs associated with the underground testing program in the ESF and SP status in a table (enclosure 3 to DOE's letter). According to the table, the ESF tests will be conducted in four phases during the ESF construction. DOE has not directly answered how the ESF construction sequences and schedules integrate with other schedules for gathering of information needed for ESF design and testing. Since this is a complicated issue and a number of DOE contractors will be involved, the staff will continue to monitor DOE's integration of testing schedules with that of ESF construction.

Considering all the information presented by DOE in its November 18, 1993 response, and the recent NRC/DOE interactions on the related topics, the staff believes that more information and more interaction

are needed before the NRC staff can understand DOE's process for integrating ESF and GROA issues. We intend to follow up on the issue of DOE's implementation of the design control process during design reviews and audits. The NRC staff also expects to review a corrected version of the SCPB in the near future. The NRC staff concludes that DOE has provided generally satisfactory response to parts of the issues raised under concern 3.

CURSORY REVIEW OF THE SCPB

The first paragraph of the DOE response to NRC Item 3 states that the Yucca Mountain Site Characterization Program Baseline (SCPB), YMP/CM-0011, Revision 9., Shelor to Holonich dated March 5, 1993, is the primary document used by the project to provide the information requested by the NRC. The NRC staff conducted a limited review of sections 8.4.2.3.3 through 8.4.2.3.6 of the SCPB and found numerous technical and editorial inconsistencies and errors. It appears that the SCPB version given to the NRC staff may not have undergone a thorough review. Examples of discrepancies in the SCPB include:

- References to wrong figures.

  For example, Figures 8.4.2-15 and 8.4.2-16 are referenced in the text as ramp portals (last paragraph of page 8.4.2-78), but the Figures 8.4.2-15 and 8.4.2-16 presented in the SCPB, Revision 9, are "An analysis of demonstration breakout room -- percentage change from in situ vertical stress" and "Zones of influence from main test level experiments on dedicated test area layout" respectively. Similar problem occurred for Figures 8.4.2-14 and 8.4.2-14d. Figures 8.4.2-15 and 8.4.2-18 are identical except numbers are different.

- Reference to wrong table.

  The text states that "The MTL dedicated testing area will contain space for different tests identified in Table 8.4.2-12" (Second paragraph of page 8.4.2-77). But there is no Table 8.4.2-12 in this document.

- References to non-existing sections.

  The text (fourth paragraph of page 8.4.2-67) references Section 8.4, but there is no Section 8.4 in the SCPB document. The text (first paragraph of page 8.4.2-78) references Section 8.4.1.1, but there is no Section 8.4.1.1 in this document either.

- References of this document are not provided.

  There are many references cited in pages 8.4.2-88 through 8.4.2-93. But there are no references provided in this document.

Since DOE states that the SCPB is the primary document used by the project to provide information to the NRC, DOE should provide the NRC staff with a corrected version for review..

4. • The NRC August 20, 1993, letter requested DOE to:

Provide a detailed plan for the process DOE will use to keep the NRC staff informed in a timely manner of design changes which have the potential to impact ongoing testing activities, the ability to conduct proposed testing activities, or the ability of the site to isolate waste. In addition, DOE should discuss how proposed changes will be responsive to the staff's Site Characterization Analysis concerns related to the site characterization and the ability to gather representative technical data in the ESF.

• The NRC October 15, 1993, letter for the September 17, 1993, meeting stated for this request:

DOE has not provided timely information such that the NRC staff is able to evaluate changes in the ESF design as they occur. Supportive documentation such as study plans, etc., should be revised and submitted 90 days prior to the initiation of major site disruptive work. Unless DOE has submitted a description of the design changes to the ESF, the NRC staff would not be able to conduct its review of that study plan. DOE should provide this information in a timely manner such that the NRC staff will have sufficient time to review that change by the time the study plan is submitted.

• The November 18, 1993, DOE response to this concern is:

- The DOE will continue to publish Progress Reports (PRs) to report the progress and to update the changes made in ESF/GROA.

- The DOE will provide the NRC with subsequent versions to the SCPB in a timely manner.

- The DOE has initiated a weekly teleconference between the DOE Chief, ESF Branch and the NRC Geotechnical Section Leader to discuss items of interest that occur each week.

- The DOE has also initiated bimonthly ESF/GROA update meetings to discuss issues and selected topics.

- The DOE will continue to invite the NRC to participate in the 50% and 90% design reviews.

- The DOE has the Determination of Importance Evaluation program for evaluating items and activities in the MGDS for a specific item's potential impact on safety, waste isolation, and QA controls.

- The DOE uses NRC Site Characterization Analysis (SCA) comments as input to evaluate design changes and to revise the study plans. When

the DOE sends study plans to the NRC, the DOE also sends a separate letter to NRC documenting the open items and DOE's rationale to resolve the SCA open items.

NRC EVALUATION OF DOE RESPONSE

Based on the above information, the NRC staff is satisfied with DOE's plan and expects to evaluate DOE's implementation of this plan.

5. • In addition to the NRC concerns described above, the NRC August 20, 1993, letter indicated that the NRC staff is concerned with how DOE resolves NRC staff concerns that are identified during independent design reviews.

   • The November 18, 1993, DOE response to this NRC concern is:

   - The DOE will assign qualified reviewers to review the entire design package and provide comments in their areas of expertise.

   - The recorded review comments are then distributed to appropriate personnel for comment resolution.

   - After comments have been successfully resolved and appropriate changes have been made to the design, the reviewers have to verify that their comments are satisfactorily resolved.

   - The NRC and affected parties are invited to participate as observers in the design review.

   - The DOE and NRC discuss NRC observer's comments, along with the comments of the affected party observers.

   - The DOE ensures that M&O regulatory reviewer submits NRC observations for resolution.

   - These resolutions may be discussed during DOE-NRC bimonthly ESF/GROA technical meeting, if desired.

NRC EVALUATION OF DOE RESPONSE

Based on the above information, the NRC staff is satisfied with DOE's response on the NRC staff's concerns identified during independent reviews. NRC staff concerns addressed in this letter not only include ESF design process but also QA audit and surveillance topics. The NRC has limited resources to review the DOE's design packages. Therefore, NRC staff will review only certain portions of design packages. The NRC staff will focus mainly on issues affecting safety and waste isolation. NRC staff review will not constitute approval or disapproval of the design packages. Its review will only pass on comments/observations on the portions reviewed.