

**AUGUST 20, 1993
LETTER ON THE
EXPLORATORY STUDIES FACILITY**

**Joseph J. Holonich, Director
Repository Licensing and Quality
Assurance Project Directorate
Division of High-Level Waste Management
Office of Nuclear Material Safety and Safeguards**

**Presentation to the U. S. Nuclear
Waste Technical Review Board
October 19, 1993**

AGENDA

- o NRC's Independent Regulatory Role
- o NRC Position on Pre-Licensing
- o DOE's Quality Assurance (QA) Program
- o Importance of DOE QA
- o Findings From DOE's QA Audits
- o Observation of the Design Review for Package 2A
- o Background on Letter
- o Summary of August 20, 1993 Letter
- o Subsequent Interactions
- o Conclusion

NRC'S INDEPENDENT REGULATORY ROLE

- o Develops Regulations and Guidance
 - 10 CFR Part 60
 - License Application Format and Content Regulatory Guide
 - License Application Review Plan
- o Pre-application Review
 - Early Identification and Resolution of Issues at the Staff Level
 - Pre-licensing Consultation to help Enable the U. S Department of Energy (DOE) to Provide a Complete and High Quality License Application
 - Prepare Preliminary Site Characterization Sufficiency Comments to be Included in DOE's Recommendation to the President
- o Review of License Application
 - Burden of Proof on DOE to Provide Complete and High Quality License Application that Demonstrates Compliance with 10 CFR Part 60
 - NRC Reviews License Application and Determines Acceptability of DOE Demonstration of Compliance

NRC POSITION ON PRE-LICENSING

- o As the Commission noted in its development of 10 CFR Part 60, during site characterization there would be no facility for storage of HLW, and therefore, no basis for the exercise of the Commission's Licensing Authority. (46 Federal Register 13971, 13975, February 25, 1981).
- o Furthermore, the Commission stated that "The Commission cannot direct the Department to comply with the provisions for involving it during site characterization activities." (44 Federal Register 70408, 70409, December 6, 1979).
- o However, the Commission also noted that "[A]lthough the Commission cannot direct the Department to comply with the provisions for involving it during the site characterization activities, any failure to do so is likely to result in imprudent expenditures and subsequent delays, and ultimately could result in the denial of the application for the proposed site."

DOE'S QUALITY ASSURANCE (QA) PROGRAM

- o QA Program Requirements
 - 10 CFR Part 60, Subpart G
 - 10 CFR Part 50, Appendix B as Applicable and Appropriately Supplemented by Additional Criteria
- o QA Program Application
 - Structures, Systems, and Components Important to Safety
 - Design and Characterization of Barriers Important to Waste Isolation
 - Activities Related Thereto
- o QA Program Coverage
 - Site Characterization
 - Facility and Equipment Construction
 - Facility Operations
 - Performance Confirmation
 - Permanent Closure
 - Decontamination Dismantling of Surface Facilities

IMPORTANCE OF DOE QA

- o NRC Cannot Review or Inspect Everything
- o DOE QA
 - Provides the Framework for a Structured and Systematic Method of Obtaining Facts and Data and Performing Analyses, and Documenting These Activities
 - Provides Assurance That Work is Done Properly
- o DOE Records
 - Supporting Documentation for NRC Licensing Decision
 - Provide Traceability of Work
- o Lack of Complete Records Could Raise Issues in Licensing

FINDINGS FROM DOE'S QA AUDITS

- o October 1992 Audit
 - Control of As-Built Drawings
 - Objective Evidence
- o March 1-8, 1993 Audit
 - Preparation of procedures
 - Methodology to Fully Accomplish Quality Affecting Activity
 - Quality Assurance Program Description
 - Processing of Field Change Requests
- o March 22-24, 1993 Follow-up Surveillance
 - Implementing Line Procedures
 - Selection and Review of Design Methods per NQA-1
 - Control of Design Information
 - Documentation of Reviews
- o NRC Efforts in Early May
 - On-site Representative Review
 - Traceability of Flowdown Design Requirements
 - Lack of Objective Evidence
 - Lack of Complete Design

Observation of the Design Review for Package 2A

- o Use of Judgement Instead of Data and Analyses
 - Determination of Importance Evaluation (DIE)
 - Amount of Water that can be Added During Construction
 - Effects of Drill and Blast on Permeability
- o Models May Not Be Sufficient for Recognized Phenomena
 - Continuum Codes for Rock Falls
 - Continuum Codes for Fracture Flow
 - Static Analyses for Dynamic Loads
- o Level of Conservatism is not Explained
 - Tunnel Support is Based on Mines and Highway Tunnels
 - Lack of Dynamic Analyses are Based on Mines and Tunnels
- o Specifications of the DIE may be Tough to Meet
 - Water use may not be Metered Correctly
 - Pressure Grouting is not Defined
- o Some Calculations may not Meet the Criteria of the Procedure

BACKGROUND ON LETTER

- o July 27, 1993 Technical Exchange
 - DOE Requested Postponement
 - Understand why DOE did it

- o Needed Additional Information from DOE
 - July 20, 1993 Quality Assurance Meeting

 - Address Issues
 1. What are the Problems?
 2. How Serious?
 3. What will DOE do to Correct it?

 - Told DOE about the Letter

SUMMARY OF AUGUST 20, 1993 LETTER

- o Concern with Design and Surface Based Testing Integration
- o Need for July 27, 1993 Technical Exchange
 - Understand how DOE is Factoring the Staff's Concerns into Decisions Related to the ESF
 - Discuss ESF Design Changes
 - Make DOE Aware of any Potential Concerns the Staff may have Related to Ongoing ESF Design Work
- o Request for Information from DOE
 - Rationale to Continue Work
 - Corrective Actions
 - Completeness of Design Information
 - Timeliness of Design Information and Response to NRC Concerns
- o Provide Response in 90 Days

SUBSEQUENT INTERACTIONS

- o **September 17, 1993 ESF Concerns Meetings**
 - Amplification of August 20, 1993 Letter
 - NRC Position on What Should be Covered by Design Control Process
 - Provided Additional Information on Four Major Items in the Letter
 - Nevada Suggested NRC Reinstate Objection 1 and Conduct its own Audit

- o **October 4 and 5, 1993 Technical Exchange**
 - Opportunity to Understand Processes Better
 - Recognize the Need for Continuing Dialogue
 - Identified Approach to Observing DOE Technical Review Activities
 - Provided Feedback on Package 2A Concerns that Appears Acceptable

CONCLUSIONS

- o Concerns
 - Findings from DOE Audits and Surveillances
 - Lack of Objective Evidence
- o Opportunity for Discussion Postponed
- o Burden on DOE to Provide Needed Information
- o Letter Identifies Areas of Concern
- o Subsequent Interactions Provided Opportunity for Clarification
- o Awaiting DOE Response to Letter
- o Both DOE and NRC Agree to Continuing Dialogue
- o DOE Recognizes Need for Timely Submittals to NRC