

**SUMMARY OF THE
U.S. NUCLEAR REGULATORY COMMISSION / U.S. DEPARTMENT OF ENERGY
QUARTERLY MANAGEMENT MEETING
ROCKVILLE, MARYLAND
September 12, 2006**

Introduction

The U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Energy (DOE) held a public Quarterly Management Meeting on September 12, 2006. The meeting was held at NRC Headquarters in Rockville, Maryland, with video connections at the Center for Nuclear Waste Regulatory Analyses (CNWRA) in San Antonio, Texas, and the Office of Civilian Radioactive Waste Management (OCRWM) in Las Vegas, Nevada. Teleconference connections were also made available to interested stakeholders. The agenda for this meeting can be found in Enclosure 1. Enclosure 2 contains the list of attendees present at the above noted locations.

The purpose of this meeting was to discuss the overall progress of the Yucca Mountain Project (Project) at the proposed geologic repository site at Yucca Mountain, Nevada. The discussions focused on an update of the NRC high-level waste program, the DOE high-level waste program, and the Project activities.

Opening Remarks

Mr. Jack Strosnider (NRC) welcomed members of the public, and all other stakeholders in attendance, with a special welcome to Mr. Edward Sproat, who has recently been confirmed as the Director for the OCRWM.

NRC Program Update

Mr. Strosnider provided the following comments on NRC's high-level waste program. The Environmental Protection Agency's (EPA's) acting Assistant Administrator indicated it was EPA's goal to complete a final revised standard for Yucca Mountain by the end of the calendar year. NRC staff will recommend final regulations to the Commission for adoption shortly after EPA finalizes its revised Yucca Mountain standards.

Regarding DOE's design activities, DOE has completed its Critical Decision (CD)-1 process and has shared the results of that process with the NRC at the August 29, 2006, technical exchange. DOE has now laid out a schedule leading to submittal of a license application (LA) in June 2008. It is very important for DOE to actively engage NRC staff to address technical and regulatory issues relevant to DOE's developing a high-quality LA. NRC continues to urge DOE to take the time necessary to ensure a high quality license application.

Last winter DOE chartered the Integrated Requirements Product Team (IRPT) to identify and complete the design control/requirements flow down actions to correct problems and prevent recurrence. DOE is asked to describe how it is ensuring the completion and success of this effort and which specific DOE organization has been assigned responsibility to verify that the actions to correct and prevent recurrence are completed.

DOE had committed to address the design control/requirements flow down issue to ensure acceptable design control as it begins design activities stemming from the CD process. A recent DOE audit of OCWRM suggests that the DOE procedures are inadequate and do not address

all of the DOE functions described in the DOE Quality Assurance Requirements Description (QARD), including some for design control. NRC would like to hear during the meeting how DOE understands its responsibilities for design and design control in regards to the QARD.

NRC understands that DOE has identified Sandia National Laboratories (SNL) as DOE's Lead Laboratory for conducting scientific activities for the Project. NRC hopes to hear DOE's plans, process, and schedule for making this transition, what are the roles, responsibilities, and relationships of BSC, SNL, USGS, and the others. Also important are the actions DOE will take to ensure that SNL develops and implements an effective Quality Assurance (QA) program that meets all applicable requirements. It is not evident to NRC staff that DOE's Office of Quality Assurance (OQA) staffing, technical support, and leadership will be able to provide the oversight of SNL to ensure acceptable QARD implementation.

NRC would like to hear about the status of DOE's activities regarding the USGS-developed Infiltration Model and SNL's work being done in that same area, what steps have been taken to resolve the outstanding issues regarding infiltration, and DOE's plans and schedule to complete the necessary actions. In addition, NRC would also appreciate an update on DOE actions to follow up on the USGS e-mail issues, including the extent of condition analysis of the USGS e-mail issues, DOE's follow up to the recommendations in the Government Accounting Office (GAO) report, and what DOE is doing to address the overall issue of adherence to QA requirements uncovered by the review of the USGS e-mails.

Regarding DOE's Corrective Action Program (CAP), NRC staff have been observing many of DOE's CAP activities and note that the CAP processes appear to be cumbersome, slow, inefficient, and duplicative; however, these are management issues not regulatory issues. However, complete and timely action identification, initiation, and completion remain a major challenge.

It is vital to have good communication between NRC and DOE in all areas. To this end, NRC and DOE have recently held several technical exchanges and plan to hold numerous others in the coming months. These technical exchanges are very important and should continue to identify issues that DOE should address in a high quality and technically sound LA.

The Project is very important to the NRC. DOE and its contractors, subcontractors, USGS, and the national labs have a great deal of important work to do. It is critical that adequate and qualified resources be applied to these work activities, and that these work activities be controlled in order to ensure that DOE submits a high-quality LA to NRC.

Mr. Bill Reamer (NRC) provided the following comments on NRC's high-level waste program. A key regulatory principle during pre-licensing activities is independence in NRC's observation activities and any follow-up activities. However, independence does not mean isolation from DOE's processes and activities. Rather, to fulfill its regulatory review responsibility, the NRC staff will continue to engage the DOE on methods and bases for its planned license application, through technical exchanges, staff meetings, review of documents, and correspondence. NRC's central purpose is to understand the DOE methods and approaches in order to be prepared for an efficient and timely license application review. NRC's presence as observers of DOE activities has been, and will continue to be, at arms length. If NRC believes there is a need to provide views on the direction or acceptability of any DOE pre-license application activities, NRC staff will communicate them in a public setting. DOE, and its contractors, should not interpret NRC's silence as tacit approval or endorsement. NRC staff will continue to be actively engaged in their observation role until NRC receives an LA.

NRC and DOE had several technical exchanges this past spring, and have a significant number scheduled for this fall and winter. NRC staff is encouraged by DOE's commitment to openly discuss complex technical issues, and welcome the opportunity to clarify the regulatory requirements, as needed. NRC is very supportive of these meetings in the hope that potential licensing issues can be identified, discussed, and be resolved at the staff level during the pre-licensing period. NRC feels that the communication between NRC and DOE in these technical exchanges is vital to the DOE's addressing NRC's information needs in the development of a high quality and technically sound LA. NRC would like to stress the importance of DOE's taking the time it needs to address the technical and regulatory issues necessary to consider in developing a high-quality LA.

This past spring, NRC had a technical exchange with DOE on methods for analyzing seismically initiated event sequences and demonstrating performance of structures, systems, and components important to safety in the Project. In support of this meeting, NRC developed a draft Interim Staff Guidance (ISG) document entitled "Review Methodology for Seismically Initiated Event Sequences." NRC staff solicited and received public comments on this ISG and will be meeting with the Nuclear Energy Institute (NEI) later this week in a public meeting at NRC Headquarters to discuss their concerns. The ISG provides a methodology to demonstrate compliance with 10 CFR Part 63 risk-informed, performance-based regulations, considering the site-specific hazard and performance reliability of structures, systems, and components, important to safety. It is consistent with the NRC's philosophy of using risk-informed, performance-based, technology-neutral criteria for licensing of new nuclear power plants, and takes advantage of improvements in probabilistic seismic hazard analyses and performance-based safety assessments.

In May 2006, NRC and DOE held a technical exchange on the Pre-Closure Safety Analysis for the Project. The meeting included discussions on the level of design information required for NRC to independently review the pre-closure safety analysis, and different approaches to quantifying the reliability of structures, systems, and components to enable categorization of event sequences in the pre-closure safety analysis. This public meeting provided valuable communication between the NRC and DOE on the level of detail on the pre-closure engineering design that needs to be included in a LA. As a follow-up to this technical exchange, NRC staff is working on a draft ISG entitled "Pre-Closure Safety Analysis - Level of Information and Reliability Estimation." This ISG will enhance what is already contained in the NUREG 1804, Yucca Mountain Review Plan, on reviewing the pre-closure safety analysis.

This past month, NRC issued a letter to DOE outlining the regulatory requirements pertaining to the proposed TAD canisters for packaging the waste. Since the TAD canisters perform a variety of functions, they must satisfy the requirements in several different regulations, including 10 CFR Parts 72, 71, and 63. This letter was followed up with a technical exchange between NRC and DOE in which the applicability of these requirements were discussed. This technical exchange also provided an opportunity for DOE to present many of the new design concepts for incorporation of the TAD canisters in the surface and subsurface facilities developed in support of the CD-1 process.

NRC has recently received letters from the State of Nevada and from the Nevada Nuclear Waste Task Force questioning certain aspects of its letter to DOE on TAD-related regulatory requirements, with particular focus on a possible aging facility at the proposed repository. NRC staff is currently preparing responses to those letters and expects to issue those responses soon.

In May 2006, members of the NRC staff observed the field trip, meetings, and discussions associated with the DOE's Probabilistic Volcanic Hazard Analysis (PVHA). In a July 2006 letter, NRC communicated comments to DOE regarding the conduct of the PVHA in three areas: making the information available to the PVHA panel members available to NRC and the public; the need for DOE to follow all applicable DOE QA procedures in the creation, analysis, and reporting of the data; and the proper use of proponents in the PVHA process. NRC staff looks forward to observing the next PVHA meeting in September 2006.

During August and September 2006, NRC staff observed a DOE OQA audit of OCRWM and a BSC QA audit of seismic consequence abstraction. Regarding the OQA audit of OCRWM, the OQA audit team examined the recent OCRWM reorganization, its readiness to review design products for the Project facilities, and the adequacy of procedures for DOE QA program implementation. This audit was well planned and conducted. Regarding the QA audit of seismic consequence abstraction, BSC conducted an audit to determine whether inputs provided to the seismic consequence abstraction model had been developed and calculated using technically sound and defensible methods with adequate transparency and traceability. During the audit, the NRC observers questioned the audit team's limited review of certain analysis and model inputs, which would not meet the planned scope or objectives of the audit. BSC management and the audit team made the necessary adjustments in that audit process, extended the audit time and resources, and completed the audit scope and objectives. NRC notes that adequate audit planning and audit resources are needed, particularly for performance-based audits.

The State of Nevada has recently sent a letter calling NRC's attention to certain DOE approaches to qualifying previously unqualified data that the State finds objectionable. NRC expects to provide a response to this letter in the near future.

DOE Program Update

Mr. Sproat, the newly appointed Director of the OCRWM, introduced himself and summarized his four strategic objectives for the OCRWM¹.

- 1) Submit the LA by June 30, 2008. Mr. Sproat noted that he will sign the LA and will be very intimately involved in the strategy and approval process. The design will meet licensing requirements and accurately reflected in the LA, with supporting data in compliance with QA requirements, that addresses Yucca Mountain Review Plan issues, and LA authors will attest to the accuracy and completeness of the LA.
- 2) Develop the OCRWM staff into a design and licensing organization with the right culture and skill mix.
- 3) Address the government standard contracts and settle the utility lawsuits.
- 4) Develop a transportation plan.

Requests for proposals were issued yesterday for three external independent assessments of the QA program, engineering processes (including configuration management and design control) and a gap analysis of preliminary LA text to help prepare for the LA submittal. In addition to DOE's own assessments, these assessments are expected to result in changes in processes, organization, and personnel.

¹ Mr. Sproat noted that his presentation would focus on the first two of his strategic objectives.

Mr. Sproat stated that he intends to fill all acting positions by the end of the calendar year. The OQA Director should be in place before the next DOE/NRC management meeting in December 2006. The positions for Chief Engineer and Infrastructure Manager are Senior Executive level positions and will have to be competed both internally and externally.

The extent of condition for the USGS e-mail issue should be released in the next two to three weeks. The USGS is conducting an internal investigation on the extent of condition which is to be complete by the end of the year.

Regarding the CAP, there is a history of ineffective corrective action in the Program. Mr. Sproat will be personally involved in improvements to the CAP; the DOE and BSC management team fully understand the importance of QA and the importance of an effective CAP. In the future, quality will not be inspected into the work.

In explaining the design control, Mr. Sproat noted that BSC is currently the Design Authority and design control processes and procedures are in place. However, when LA is submitted, DOE will transition from role of design oversight to Design Authority and will be directly involved in the design process.

Licensing

Mr. Mark Williams (DOE) discussed several topics including a summary of DOE and NRC interactions and proposed technical exchanges, a discussion of LA project scope and implementation status, potential impacts of programmatic changes to key technical issue (KTI) agreements, and response to NRC's audit observation report OAR-05-05 (Enclosure 3).

In response to NRC questions related to performance technical specification for TAD canister and availability for review by the NRC prior to a technical exchange, DOE stated that a technical exchange will be scheduled after the TAD performance specifications are released in November 2006. NRC noted that they have put together a team to review the DOE response to NRC observation report on the BSC QA audit of Lawrence Livermore National Laboratories that was submitted in August 2006 and will plan a technical exchange on that topic. Also, NRC noted the importance of integrating preclosure and postclosure issues (e.g., for TAD). NRC would like to include the mapping of the Yucca Mountain Review Plan to the LA as a topic in the technical exchange on programmatic issues and that a technical exchange on Additional Information Needs (AINs) may be desirable given the time available until LA submittal.

In response to an NRC question on the value of NRC Interim Staff Guidance (ISG), Mr. Williams stated that ISGs provide a valuable opportunity to exchange views and for NRC to provide clear, written guidance to their staff, but that the guidance will not be treated as a requirement for LA. Mr. Williams noted that NRC written responses have been valuable for understanding the issues. NRC stated that a process may be needed for revisiting the KTIs. Ultimately, these issues would be addressed in the LA. Also, Dr. April Gil (DOE) noted that it is very helpful that NRC provides their expectations in correspondence ("key messages") prior to technical exchanges.

Corrective Action Program

Mr. John Arthur (DOE) provided the status of the CAP (see Enclosure 3). This included a summary of various recommendations for improvements to the CAP from the GAO, the

Inspector General (IG), and a DOE/BSC self assessment, and improvements underway for the CAP (improving clarity and detail, with substantiating evidence).

To continue the improvements, a CP performance improvement plan is underway that will engage OCRWM employees in the new CAP expectations. In summary, the CAP is not where DOE would want it to be, however, improvements are continuing. Mr. Arthur responded to a question related to definition of effectiveness to prevent recurrence and how the new definition for significance applies to current Condition Reports (CRs) and its impact on trending. Effectiveness measures are being improved to help DOE determine if it is being effective at identifying, resolving, and taking action to prevent recurrence. Several questions from NRC dealt with various existing databases that track corrective actions, their differences, and how they feed into CAP trending system. DOE explained that these are not trending systems but are used for business processes. However, DOE will ensure that, any corrective actions identified by these systems will be included in the CAP program and trended accordingly. Mr. Reamer asked if DOE anticipates any CAP related problems due to the transition to SNL as the lead lab. DOE responded that SNL will use the same CAP system and trending processes as DOE and BSC and there will be only one CAP/Trending Program.

In closing, the NRC asked questions related to QA oversight of the process and effectiveness. DOE responded by explaining that QA will play a significant role in independent review of effectiveness of closures and the review of the overall effectiveness of the CAP process.

Science

Dr. Russ Dyer (DOE) presented an update on Lead Laboratory transition and Science and Technology (S&T) program activities. As discussed at the June 2006 Management Meeting, the transition of post-closure work for the Project to SNL is underway and expected to be complete by September 30, 2006. Transition activities began in April of 2006. A joint DOE/BSC/SNL Transition Plan and a tri-party procedure governing transition activities were approved in May 2006. Shortly after approval of the plan and procedure, transition teams were mobilized for postclosure and supporting work scopes (e.g., QA program development, procedure development, and license application preparation and support) to identify transition issues, develop transition resolution plans, and resolve transition issues. DOE is the ultimate approval authority for the transition.

As of August 31, 2006, 149 transition issues have been identified; approximately 80 percent of the transition issues resolution plans are approved and 50 percent of the transition issues have been verified closed and complete. About 10 issues will remain open after September 30. DOE has evaluated these issues and determined that closure after September 30, 2006, has no impact on the Lead Lab's ability to proceed with the transition of the post-closure work scope.

The readiness review to verify that the Lead Lab is prepared to proceed with the postclosure work scope and supporting activities for the Project included the following activities: Software Integration System for the Project; Environment, Safety & Health and Integrated Safety Management; Project Management, Organizational and Project Controls; Configuration Management, Controls and Interfaces; Scientific Product Development and Controls, such as Data, Models, Analysis and Model Reports, etc.; Requirements Management; Procurement and Controls; and Procedure Review, Qualification of Personnel, Training, Audit Reports, Open Deficiencies, Surveillance. The review also encompassed other areas that interface with the scientific processes such as Document Control, Records Management, Lessons Learned, Safety-Conscious Work Environment, Employee Concerns, and the Licensing Support Network.

Results of the readiness review indicate the Lead Lab has management and infrastructure processes in place to perform the postclosure work scope and supporting activities. There were no deficiencies identified during the readiness review; however, several observations were noted. Observations primarily focused on ensuring clear Lead Lab roles, responsibilities, and organizational interfaces, which are the same areas addressed in the outstanding transition issues previously discussed. Remaining observations propose future enhancements to Lead Lab processes and would not preclude transition of the postclosure work scope to the Lead Laboratory. The final draft of the readiness review report is expected to be completed by November 2006.

The transition effort is on track for the Lead Lab to successfully assume the management and integration responsibilities for the post-closure technical basis and related licensing preparation by October 1, 2006.

Design Overview

Mr. Paul Harrington (DOE) presented an overview of Design and Engineering activities including: CD-1 change to canister-based waste disposal system; status of TAD performance specification development; design control and requirements management; status of Preclosure Safety Analysis (PCSA) reliability methodology. Mr. Harrington's presentation is provided in Enclosure 3.

In response to a question related to roles and responsibilities, Mr. Harrington noted that at this stage of the design BSC is the design authority and DOE's role is that of oversight. Eventually, DOE will become the design authority to implement and maintain the design. At this time, DOE is developing procedures that will define DOE's role with respect to design activities. While there is no regulatory distinction between passive and active components, DOE will perform the PCSA generally using fragility analysis for passive components and fault trees for active components. More information about the PCSA analysis will be provided to NRC in future exchanges. NRC stated that their interest was in reliability, however it was determined. Mr. Harrington noted that processes and products need to meet both NRC regulatory requirements and DOE QA requirements for the LA. DOE is expanding its technical capabilities and increasing federal staff to be able to meet these requirements.

Quality Assurance

Mr. Michael Ulshafer (DOE) provided an overview of the QA activities. An audit of site activities indicated that the management and operating contractor is effectively implementing the QA requirements at the site. Six conditions adverse to quality were identified during the audit. An audit of the Total Systems Performance Assessment (TSPA) concluded that TSPA-LA, Revision E, process is effective. One condition adverse to quality was identified. Also, an audit of DOE implementation of the QA Program was completed and sixteen conditions adverse to quality were identified. Based on the significance of the issues identified in the QARD, implementation of the QA Program was determined to be unsatisfactory. The issues were related to QARD Section 1.0, Organization (less than adequate management planning to address changes in the OCRWM organization as a result of the May 2006 reorganization, and lack of procedures to address OCRWM responsibilities identified in the QARD); 2.0, QA Program; and 3.0, Design Control.

Scheduled audits include an audit of the infiltration model upon completion of the model with an interim surveillance; OQA audit of Hanford Spent Nuclear Fuel Program; BSC QA Program

audit (week of September 11-18, 2006); SNL Qualification Audit (November/December, 2006); and BSC QA qualification audit (November/December, 2006). Also, at OQA's request, NEI will perform an evaluation of OQA in December, 2006.

With respect to OQA staffing, OQA has completed the interview process for hiring several federal employees; eight to ten federal positions will be filled in the near term, including lead auditors and quality engineers, and six intermediate level positions will be posted shortly. OQA is in the process of obtaining a new, limited support contractor starting October 26, 2006. OQA will continue to maintain the staffing necessary to perform all of its responsibilities in the QARD.

QARD, Revision 18 has been issued and approved with an effective date of October 2, 2006. This revision is baselined to 10CFR63.142, and will be provided to the NRC. Lead Lab elected to implement QARD/AQAP with matrices as their QA program and OQA reviewed the matrices to verify the applicable QARD/AQAP requirements have been addressed. OQA has completed the review and accepted Lead Lab QA Program Documents (*Quality Assurance Program Description; Preparing and Approving Programmatic Procedures; and Preparing and Approving Technical Procedures*). OQA is in the process of reviewing the procedures as part of the Readiness Review and will schedule a qualification audit in November/December 2006.

Mr. Thomas Matula (NRC) asked how performance-based audits at SNL will be applied to other labs and how DOE will establish confidence in effectiveness of SNL audits of other labs. Mr. Ulshafer responded that the scope of audits of other labs is to be determined but that DOE will observe the audits and that development of audit schedule will be coordinated with both BSC and SNL.

Action Item Status

DOE and NRC agreed to keep open five previous action items and close one action item. No new action items were identified. The status of action items is summarized in the attached table.

Public Comments

Mr. Marty Malsch (Egan and Associates) asked four questions that were responded by DOE as follows:

Since the LA data will be qualified, will DOE abandon qualification of previously unqualified data? Mr. Sproat replied in the negative.

Does DOE need legislation to meet the June 2006 LA submittal date? Mr. Sproat replied in the negative.

Is the current infiltration work being used to support EPA's rule on peak dose? Dr. Dyer replied in the negative.

Will the level of design detail be similar to a preliminary safety analysis report (PSAR) or a final safety analysis report (FSAR) for reactors? Mr. Williams replied that the level of design detail will be more than a PSAR and less than an FSAR with component-specific fault trees.

In response to a question from Ms. Susan Lynch (State of Nevada), Mr. Ushafer noted that, per the NRC/DOE Prelicensing Agreement (1998), the State of Nevada may observe any NRC observed SNL audits and that the full complement to OQA staffing will include 29 federal staff and an additional 10 support staff.

Mr. Steve Frishman (State of Nevada) asked if DOE has made a decision on State of Nevada's request that DOE release the Conceptual Design Report and Preliminary Hazards Report supporting CD-1. Mr. Sproat noted that the decision is being developed in cooperation with General Counsel.

Closing Remarks

Mr. Lawrence Kokajko (NRC) stated that NRC appreciated hearing Mr. Sprout's strategy and action plan, as expressed in his opening remarks, and that what he says seems promising. However, others before Mr. Sprout have had similar program changes, and NRC will be looking forward to seeing results.

Mr. Kokajko mentioned that technical exchanges are needed with an eye toward integration in a variety of areas such as KTI Agreements, Additional Information Needs, and engineering design topics. Also, NRC staff will be monitoring the transition to SNL as the Lead Laboratory for the program, particularly its impact on post-closure models and performance assessment. It is difficult to overstate the importance of this transition, and NRC has some concerns about the planning and execution of this transition. NRC will take a hard look at QA implementation at the labs.

Mr. Kokajko stressed the importance of effective design controls and that NRC staff will be tracking DOE's responses regarding DOE and BSC staff's roles and responsibilities issues in the area of design control.

Lastly, Mr. Kokajko stated that NRC staff is encouraged by the CAP changes, and would continue to closely monitor progress in this area. Much effort has been devoted to improving this process but it is critical that management emphasis in increasing the effectiveness of the DOE's CAP be maintained.

Mr. Williams noted that OCRWM staff has high confidence in Mr. Sproat's initiatives. DOE understands the importance of interactions during prelicensing and will consider interactions with NRC staff on ITIs and Additional Information Needs as information becomes available. DOE is tracking issues with the Lead Lab transition and is aware of and working the design control issues. The NRC ISGs are useful, especially because they allow DOE and NRC to develop a common understanding by discussing positions and putting them in writing.



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