

**SUMMARY OF THE
U.S. NUCLEAR REGULATORY COMMISSION / U.S. DEPARTMENT OF ENERGY
QUALITY ASSURANCE TECHNICAL EXCHANGE
LAS VEGAS, NEVADA
JUNE 26, 2007**

Introduction

The U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Energy (DOE) held a Technical Exchange on June 26, 2007. The goal of this meeting was for NRC staff to understand the actions that DOE, Bechtel SAIC, LLC (BSC), and Sandia National Laboratory (Lead Lab) are taking, and plan to take, to ensure that DOE's potential license application (LA) for the high-level waste repository at Yucca Mountain, Nevada, meets the requirements of 10 CFR Part 63 and is traceable, transparent, and technically sound. The meeting was held at NRC's Atomic Safety and Licensing Board Panel hearing facility in Las Vegas, Nevada, with video conferencing to the NRC Headquarters in Rockville, Maryland, and the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas. Teleconferencing was also made available to interested stakeholders.

Opening Remarks and Program Updates

In their opening remarks, NRC noted the importance of public interactions to facilitate communication and timely review of the LA. In a letter dated June 12, 2007, NRC requested more information on those actions planned or being taken by DOE to ensure that the LA and supporting documents are transparent, traceable, and technically sound.

Mr. Larry Newman (DOE) confirmed that DOE is ensuring that quality is built into the LA and that the discussion would focus on accountability taken by line management who are responsible for LA development. DOE has taken a number of significant actions and improved processes to ensure that the LA is transparent, traceable, and technically sound.

In an overview of the quality assurance (QA) program, Mr. Thomas McKinney (BSC) noted that a task force sponsored by Mr. Paul Golan, Office of Civilian Radioactive Waste Management (OCRWM) Principal Deputy Director was formed in May 2007 to continue and expand management attention to ensure quality in the LA and supporting products. The task force is comprised of senior managers from OCRWM line management including the Office of the Quality Assurance (OQA), BSC, and Lead Laboratory; the task force is focusing on improving processes, behaviors, and instilling a quality culture in Project management and staff.

Presentations

Several presentations were made by senior DOE line management to address topics requested in the NRC June 12, 2007, letter. A copy of all presentations is provided as an Attachment.

License Application Oversight: Mr. Robert Warther's presentation summarized management of preparation of the LA. Mr. Warther stated that LA quality will be assured by addressing all applicable regulatory requirements and the acceptance criteria specified in the NRC's *Yucca Mountain Review Plan* (YMRP – NUREG-1804). The primary challenges in LA production are

related to integration and parallel development of the LA sections and underlying design and science products. The sections and products are managed through an integrated team approach with affected organizations participating. LA development follows processes and procedures, as described in the LA Management Plan, to ensure transparency, traceability, and technical accuracy of the LA. Also, LA quality is further assured through clear organizational roles and responsibility, direct oversight by the OCRWM senior management, as well as initiatives that include self-assessments, independent reviews, assessment of condition reports for impact on LA, and integrated oversight of the LA project.

Following a discussion of the use of the terms "high quality LA" and "quality LA", it was agreed that quality is assured when the LA addresses and meets all the applicable regulatory requirements and when the information in the LA is transparent, traceable, and is technically accurate.

Quality Improvement Plan: Mr. Jerome McMahon (DOE) presented a discussion of the QA oversight for the LA and described the management plan to ensure compliance with NRC regulations and conformance with guidance documents. Mr. McMahon noted that a team of nine assessors are conducting surveillances and audits. These inspections verify that effective processes that produce quality results are in place and functioning as the products are developed. As each of the areas is assessed, issues are tracked and trended in the corrective action program (CAP). In addition, independent assessments are conducted by non-Project experts and the results are reported to senior management to correct any issues identified. The goal is to protect the health and safety of the public, and to provide NRC with a quality product.

Root Cause Evaluation: Mr. Richard Craun covered a summary of a recent assessment by the Nuclear Energy Institute (NEI) of the effectiveness of the OCRWM QA program, their findings and recommendations, progress in implementing corrective actions, and OCRWM strategic objective for organizational development.

Quality Improvement Plan: Mr. Michael Ulshafer's presentation focused on a description of the Quality Improvement Plan that was developed based on results from the NEI assessment of OCRWM's QA program. The Quality Improvement Plan was developed using the excellence criteria developed by the nuclear industry and is designed to take advantage of the industry experience, the CAP, and other data in support of continuous improvement.

Line Ownership of Quality – Science: Dr. Russ Dyer discussed roles, responsibilities, and an overview of the work performed by the Office of Chief Scientist. This includes review and acceptance of postclosure work plans and Analysis and Model Reports, participating in and providing oversight of condition reports, support and participation in audits and surveillances, and review of LA chapters for transparency, traceability, and technical accuracy. In response to a question regarding the quality of humidity data collected above 70 deg C (NRC letter to DOE dated March 15, 2007), Dr. Dyer indicated that DOE does not intend to use such data in a potential License Application.

Line Ownership of Quality - Engineering: Similarly, Mr. Kirk Lachman discussed the roles and responsibilities and work performed by the Office of Chief Engineer. The Engineering organization is responsible to ensure the technical and regulatory adequacy of design and preclosure safety analysis (PCSA). The Office of Chief Engineer and staff are responsible for performing reviews and acceptance of the design and PCSA products, and development and

maintenance of project-level requirements. They also participate in and provide oversight of condition reports, support and participate in audits and surveillances, and review of LA chapters with emphasis on line ownership of transparency, traceability, and technical accuracy.

Corrective Action Program: Mr. Scott Wade provided a discussion of the CAP improvements currently underway and planned for future implementation. Mr. Wade provided background information from internal and external assessments indicating that the CAP was neither fully effective nor implemented effectively. A root cause analysis concluded that management failed to consistently exercise leadership by establishing expectations and standards for CAP performance and enforcing them as a core business activity for all Project personnel. Mr. Wade described corrective actions addressing the CAP issues with a focus on quality of the condition reports, organizational ownership of the CAP, improvements in CAP procedures to promote quality, timeliness, and accountability for actions, trending, and progressive levels of CAP oversight and management. The CAP improvement initiative is sponsored by Messrs. Ward Sproat and Paul Golan, the OCRWM Director and Principal Deputy Director, respectively.

Independent Review of Quality Assurance: Mr. Bruce Hinkley provided information on the scope and overall process for an independent review of OCRWM, BSC, and Lead Lab QA Plans and audit of their implementation. Mr. Hinkley described the composition of the review team as industry experts with an average of 25 years of QA experience. The focus of the review is to assess effectiveness of the implementation of the QA Plans and associated products developed from these plans. Corrective actions will be developed as issues are identified. The results of this review will be included in reports expected to be complete by September 2007.

Action Item Status

Two action items proposed during the meeting are identified below:

1. DOE and NRC to schedule future Appendix 7 meetings to discuss QA program activities;
2. DOE to provide to NRC additional information on performance indicators as they are developed.

Public Comments

Ms. Susan Lynch (State of Nevada) commented that it would be nice to see what NRC and DOE think are the top QA issues. Thomas Matula (NRC) stated that the top QA issues had been identified and discussed during the course of the meeting.

Mr. Rod McCullum (NEI) commented that DOE has been very responsive to the NEI assessment of the effectiveness of OCRWM's QA program; in fact, DOE is going beyond standard industry practices to address and respond to the results of NEI's independent assessment.

Closing Remarks

In closing, Mr. Mohseni (NRC) thanked DOE for well-prepared presentations that were responsive to NRC's June 12, 2007, letter. It is important that quality is built into LA and DOE needs to follow through on planned actions. The NRC goal is to understand DOE's processes and actions taken to ensure quality in LA; however, NRC would like to see more substance and substantial improvements. The DOE's emphasis on cultural and management issues is well-

placed. Transparency, traceability, and technical soundness are critical to the LA and DOE addressed them well. The NRC has seen some improvements in DOE's QA program; for example, the recent audit of the infiltration model at Lead Lab was well planned, integrated, and conducted. Regarding the CAP, Mr. Mohseni noted that although timeliness in addressing corrective actions is important, the NRC is concerned about the program's effectiveness, which cannot yet be determined. Mr. Mohseni encouraged DOE to follow through with the plans discussed during the meeting and to maintain management's emphasis and focus on the CAP.

Mr. Newman concluded that what is different today relative to the past is important: the people on the management team and their commitment to succeed. QA oversight is provided through alignment of DOE's, BSC, and Lead Lab Quality organizations to ensure overall effectiveness and integration of the QA program. In particular, the importance placed on the role of QA oversight and line ownership helps ensure that quality is built into the LA. Mr. Newman recognized several industry experts in attendance at the meeting having substantial management and QA experience who are currently making significant contributions to the OQA organization. Mr. Newman added that success is assured by a learning organization that is self-critical, continuously improving, and is focused on behaviors. For example, the condition reports identified in a self-assessment of the design control and requirements flowdown process are not an indictment of the design but, from a QA and cultural perspective, are considered a success and the sign of the cultural behavior leading toward a healthy organization.

Aby Mohseni Date: 8/8/07

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