

October 6, 2006

Mr. Mark H. Williams, Director
Regulatory Authority Office
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1551 Hillshire Drive
North Las Vegas, NV 89134-6321

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT
REPORT OAR-06-05, OBSERVATION AUDIT OF THE OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE
AUDIT OQA-OCRWM-06-15 OF THE IMPLEMENTATION OF THE QUALITY
ASSURANCE PROGRAM

Dear Mr. Williams:

Enclosed is the U.S. Nuclear Regulatory Commission Observation Audit Report OAR-06-05 regarding the U.S. Department of Energy's (DOE's) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit OQA-OCRWM-06-15, conducted on August 07-15, 2006, at OCRWM offices in Las Vegas, Nevada, and Washington, DC. The audit evaluated the adequacy of implementation of the quality assurance program. The U.S. Nuclear Regulatory Commission (NRC) observers assessed the effectiveness of the Audit Team and the audit process.

The DOE Audit Team determined that, overall, the Quality Assurance program and associated procedures had been developed; however, procedures and processes used to manage organizational change and to address its impacts on quality-affecting activities needed improvement. The DOE Audit Team did identify significant quality-affecting issues related to work processes, procedure implementation, training, timely corrective action to condition reports, and the inadequate review of vendor proposals and vendor packages. The NRC observers agreed with the DOE Audit Team's findings, recommendations, and conclusions. The NRC Observer Team determined that if the aforementioned quality-affecting issues were not addressed and corrected, the programmatic importance and regulatory significance of the identified adverse conditions could have a direct impact on the quality of the license application.

The NRC observers noted that the DOE Audit Team was well-prepared and effective in evaluating previous audit issues, and associated reports that described completed corrective actions. The NRC observers expressed concern over whether the recent organizational change was analyzed for potential interface gaps within the new organization, and whether adequate resources have been applied to completely ensure the full application of QA program requirements to technical activities. Therefore, the NRC Observer Team concludes that the relative importance of the issues identified suggests that improvement is needed in addressing: (1) the lack of Quality Assurance Requirement Description implementing procedures and work

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process instructions; (2) organizational change management; (3) timely corrective action, particularly in planning and (4) review of Condition Reports.

A written response to this letter and the enclosed report is not required. The staff will continue to interface with the U.S. Department of Energy and follow the actions OCRWM is taking to address the issues identified during this audit. If you have any questions, please contact Paul Bell at (301) 415-8093.

Sincerely,

/RA/

Frank Akstulewicz, Deputy Director
Licensing and Inspection Directorate
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure:
U.S. Nuclear Regulatory Commission
Observation Audit Report OAR-06-05,
Observation Audit of the Office of Civilian
Radioactive Waste Management, Office of
Quality Assurance Audit,
OQA-OCRWM-06-15 on the Implementation
of the Quality Assurance Program at
Las Vegas, NV and Washington, DC

cc: See attached list

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cc: See attached list

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Letter to M. Williams from L. E. Kokajko dated: October 6, 2006

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D. Feehan, GAO

E. Hiruo, Platts Nuclear Publications

G. Hernandez, Las Vegas Paiute Tribe

K. Finrock, NV Congressional Delegation

P. Johnson, Citizen Alert

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Lisa Mascaro, Washington Correspondent
Las Vegas Sun, Washington, DC