

May 17, 2000

MEMORANDUM TO: C. William Reamer, Chief
High-Level Waste and Performance
Assessment Branch, DWM/NMSS

FROM: Robert M. Latta, Senior On-Site Representative */RA/*
Projects and Engineering Section
High Level Waste and Performance
Assessment Branch, DWM/NMSS

SUBJECT: HIGH-LEVEL WASTE QUALITY ASSURANCE
OBSERVATION ACTIVITIES

Attached for your information is the summary of the assessment performed by the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, High-Level Waste and Performance Assessment Branch (HLWB), Quality Assurance (QA) observers concerning the U.S. Department of Energy's (DOE's) surveillance of the data qualification/verification process for the Yucca Mountain High-Level Waste Program. The surveillance of DOE's data qualification/verification process, witnessed by the HLWB QA observers, was performed by the DOE's Office of Quality Assurance (OQA) using an independent team of experienced personnel.

The HLWB QA observers witnessed all aspects of DOE's surveillance activities performed during the week of March 20-24, 2000, at DOE's Office of Civilian Radioactive Waste Management, Yucca Mountain Site Characterization Office, located in Las Vegas, Nevada. The purpose of the surveillance was to confirm the adequacy of the corrective actions associated with data traceability and procurement deficiencies initially documented in Corrective Action Request (CAR) LVMO-98-C-002, Data Listed as Qualified in the Technical Database is Suspect Due to Vendor Qualification Inadequacies. Specifically, the scope of the surveillance included the evaluation of CAR LVMO-98-C-002 commitments related to the to-be-verified (TBV) and to-be-determined (TBD) process, completion of the checklists/roadmaps, resolution of issues identified during completion of checklists, and the qualification of unqualified data.

As a result of this surveillance activity, it was generally concluded that the Analysis Model Reports (AMRs) and Process Model Reports (PMRs) data verification processes are being effectively performed and that DOE's sampling plan for data re-verification was being appropriately implemented. No deficiencies were identified, and based on the results of the previous PMR audits and the successful outcome of this surveillance, OQA has recommended that CAR LVMO-98-C-002 be closed. The two recommendations identified during this surveillance concerning the justification of Qualified-Verification Level 2 determinations were closely related to the issues documented in CAR LVMO-99-C-001, Lack of Data Traceability from Technical Report to the Technical Data Management System, and will therefore be tracked to resolution during the future closure of CAR LVMO-99-C-001.

Contact: Robert Latta, NMSS/DWM/HLWB
(301) 415-5228
Attachment: As stated

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HIGH-LEVEL WASTE AND PERFORMANCE ASSESSMENT BRANCH
QUALITY ASSURANCE OBSERVATION
SUMMARY OF ACTIVITIES MARCH 20-24, 2000
U.S. DEPARTMENT OF ENERGY SURVEILLANCE OF THE
VERIFICATION OF CORRECTIVE ACTIONS FOR CAR LVMO-98-C-002

During the week of March 20-24, 2000, members of the Division of Waste Management (DWM), High-Level Waste and Performance Assessment Branch (HLWB), observed all aspects of the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), conduct of Surveillance LVMO-SR-00-006, concerning the data qualification/verification process for the Yucca Mountain Site Characterization Office (YMSCO). Specifically, this surveillance was performed by DOE's Office of Quality Assurance (OQA) in order to evaluate the adequacy of data confirmation checklists and roadmaps, the qualification of unqualified data, and the resolution of to-be-verified (TBV) and to-be-determined (TBD) data in the Technical Data Management System (TDMS). The OQA surveillance team also examined commitments related to Corrective Action Request (CAR) LVMO-98-C-002, Data Listed as Qualified in the Technical Database is Suspect Due to Vendor Qualification Inadequacies, to determine if appropriate corrective actions had been implemented.

The DOE Surveillance team was comprised of the following personnel:

Robert Hasson	Team Leader	OQA/Quality Assurance Technical Support Services (QATSS)
Kristi Hodges	Team Member	OQA/QATSS
Victor Barish	Team Member	OQA/QATSS
Harvey Dove	Team Member	OQA/QATSS

The NRC observers were:

William Belke	NMSS/HLWB	NMSS/DWM/HLWB, Onsite Representative
Robert Latta	NMSS/HLWB	NMSS/DWM/HLWB, QA Specialist

BACKGROUND

As documented in CAR LVMO-98-C-002, the use of unqualified vendors and suppliers rendered the qualification status of technical products in the database indeterminate. Because the technical product inputs affected a wide range of data sets (DTNs), the associated corrective actions specified that all data furnished by unqualified suppliers be classified as potentially "unqualified." In order to address these issues, Procedure AP-3.15Q, Managing Technical Product Inputs, was revised to establish the responsibilities and processes necessary to identify DTNs, track incomplete reference checks, and provide the status of technical product inputs that were used or referenced in Analysis Model Reports (AMRs) and Process Model Reports (PMRs). Procedure AP-3.15Q was also revised to address the actions necessary to resolve TBV data, which is identified as preliminary information that needs to be re-evaluated or requires confirmation, and TBD data, which is identified as information that is not currently defined. The TBV and TBD resolution packages are developed for specified DTNs in order to uniquely identify and link the objective evidence that demonstrates the qualification of the data. The TBV/TBD resolution packages are also used to document that there are no outstanding

issues affecting data qualification from other ongoing corrective actions including procurement, software or modeling concerns.

SURVEILLANCE RESULTS

In order to evaluate the adequacy of the AP-3.15Q data confirmation checklists and roadmaps, the qualification of unqualified data, and the resolution of TBV and TBD data in the TDMS, the surveillance team selected a representative sample of 27 data confirmation checklist packages associated with the Principal Factors. These checklist packages included samples from the CRWMS M&O, National Laboratories, U.S. Geological Survey, and the PMRs, as appropriate.

In particular, the surveillance team reviewed the AP-3.15Q TBV process including the assignment of TBV tracking numbers, the results from the final checking of technical products, completion of reference control activities, and the resolution of TBV data. The surveillance team also reviewed the status of 34 DTNs in the TDMS related to the clearing, canceling or rejection of DTNs and the qualification of unqualified data in accordance with the requirements of Procedure AP-SIII.2Q, Submittal and Incorporation of Data to the Technical Data Management System. As a result of these reviews, the surveillance team determined that there was a well documented interface control process, that the notification and tracking of TBV/TBD status in the TDMS was appropriate, and that the resolution of TBV data is being effectively managed by Data/Software Qualification Department.

An evaluation was also performed on the qualification of three unqualified data packages that were prepared in accordance with Procedure AP-SIII.2Q. These record packages contained a total of 62 unqualified DTNs that were qualified using either a technical assessment or a corroborating data process. Two of these data packages (MOY-000307-05-02 and MOY-991221-09-02) were associated with the Biosphere PMR and the third data set (MO9609RIB00038.00) concerned the Saturated Zone Flow and Transport PMR. Based on the evaluation of these data packages, the surveillance team determined that the data qualification process used for each data package was well documented and that they appropriately implemented the requirements of Procedure AP-SIII.2Q.

Additionally, the surveillance team reviewed the data classification and grading process related to the identification of DTNs which have Quality Verification Level 2 (QV-L2) determinations in the AMR inputs. As a result of these reviews, it was ascertained that the requirements for the classification and grading of data, as specified in the current revision of Procedure AP-3.15Q, have been properly established and that future AMRs will include appropriate justification for the QV-L2 determinations in the AMR inputs. However, two recommendations were identified by the surveillance team related to the current AMRs, which do not explicitly include a technical basis to justify the QV-L2 determinations in the AMR inputs. As stated by CRWMS M&O, this condition resulted from the recent revision of Procedure AP-3.15Q (ICN 1, dated February 25, 2000), which added the requirement to provide the rationale for the QV-L2 determination. Because these two recommendations were closely related to the issues previously documented

in CAR LVMO-99-C-001, Lack of Data Traceability from Technical Report to the TDMS, they will be tracked to resolution during the future closure of CAR LVMO-99-C-001.

SURVEILLANCE TEAM'S CONCLUSIONS

Based on the results of the surveillance team's review of completed AP-3.15Q data confirmation packages, it was determined that the responses to the checklist questions were well documented and that the associated roadmaps were detailed and provided appropriate justification for the TBV/TBD determinations. The surveillance team concluded that the necessary procurement and software checklists were properly completed and that appropriate technical justifications had been developed. Accordingly, the surveillance team concluded that the AP-3.15Q process controls for completing the data confirmation checklists and roadmaps were being effectively implemented. Additionally, the surveillance team noted that the CRWMS M&O has taken positive steps to manage and coordinate the AP-SIII.2Q process related to the qualification of unqualified data and the processing of accepted data.

No deficiencies were identified during the surveillance and based on the cumulative results of previous OQA Phase I and II Verification Reports, the PMR audits and the successful outcome of this surveillance, OQA has recommended that CAR LVMO-98-C-002 be closed. Because the two recommendations identified during this surveillance, concerning the justification of QV-L2 determinations, were closely related to the issues previously documented in CAR LVMO-99-C-001, Lack of Data Traceability from Technical Report to TDMS, they will be tracked to resolution during the future closure of CAR LVMO-99-C-001.

NRC OBSERVER CONCLUSIONS

The NRC staff observers determined that the OQA surveillance team performed a thorough evaluation of the AP-3.15Q data confirmation process and that the conclusions reached by the surveillance team, regarding the acceptability of the AMRs/PMRs data verification activities, were appropriately supported by objective evidence. Furthermore, as a result of the NRC observers' evaluation of the completed CAR Management Plan Phase I and II Verification Reports, documentation reviews, and personnel interviews, it was concluded that the OQA surveillance team's basis for recommending the closure of CAR LVMO-98-C-002 was acceptable. The NRC observers also confirmed that the Data/Software Qualification Department was appropriately staffed with technically competent and experienced personnel, that they were effectively completing the data confirmation checklists and roadmaps for the TBV resolution process, and that the associated sampling plan for data re-verification was being appropriately implemented.