JUN 25 1993

Mr. Dwight E. Shelor, Associate Director
for Systems and Compliance
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Mr. Shelor:

SUBJECT: OBSERVATION OF THE U.S. DEPARTMENT OF ENERGY AUDIT OF THE SAVANNAH RIVER SITE DEFENSE WASTE PROCESSING FACILITY

This letter transmits the Nuclear Regulatory Commission staff comments resulting from its observations of the May 3-7 and May 24-28, 1993, U.S. Department of Energy (DOE) Office of Environmental Restoration and Waste Management Vitrification Projects Division (EM-343) quality assurance (QA) audit (No. 93EA-SR-AU-01) of the Savannah River Site Defense Waste Processing Facility (DWPF). Two observers (one programmatic and one technical) represented the DOE Office of Civilian Radioactive Waste Management (OCRWM). The State of Nevada elected not to send a representative to this audit.

The audit evaluated the adequacy and effectiveness of implementation of the DOE Savannah River Operations Office Defense Waste Processing Division (DWPD) and the Westinghouse Savannah River Company (WSRC) QA Program Descriptions as applied to the waste acceptance activities associated with high-level waste form production at the DWPF.

The EM-343 audit team consisted of 16 DOE and DOE contractor personnel, namely, 11 programmatic auditors, 4 auditor/technical specialists, and the Audit Team Leader. Audit checklists addressed the 19 programmatic elements of the DWPD and WSRC QA programs and some technical items, and were used throughout the audit. The audit objective was to verify procedural compliance as opposed to being a performance based audit (which focuses on results), or a qualification audit (which essentially qualifies the QA programs for continued activities).

In general, the NRC staff observers determined that the audit appeared to be effective from a programmatic aspect. The technical activities audited were waste container canister design and procurement and waste acceptance; however, these were not identified in the audit plan. Since the NRC observer staff did not include any technical specialists, no NRC technical evaluation was made of the technical adequacy of work products.

As a result of the audit, seven preliminary Deviation Corrective Action Requests (DCARs) were issued and 32 Observations were noted by the EM-343 audit team. Overall, the NRC staff generally agrees with the audit team's

conclusion that the implementation of the DWPD and WSRC programs is adequate with the exception of three criteria the audit team considered to be marginally effective (Criterion 5, "Instructions, Procedures, and Drawings"; Criterion 15, "Nonconformances"; and Criterion 18, "Audits"). The adverse conditions identified in the DCARs during the audit do not appear to be significant in terms of the overall QA program as implemented by DWPD and WSRC.

The audit commenced with DWPD and WSRC presenting comprehensive overviews of their organizational structures and of the completed and ongoing activities. The information presented was beneficial to the NRC staff observers and appeared to contribute to better organizing the logistics of the audit. DWPD/WSRC explained that qualification runs for the vitrification process may be delayed two or more months due to a flooding incident in the melter during cold chemical runs and the associated corrective action implementation to resolve this and other issues. The audit team indicated that it would not review the melter incident, since a separate investigation team was presently looking into this matter.

The audit books which contained the audit plan, team selection, checklists, open items from the previous audit, EM-343 audit and corrective action procedures, and audit team and observer forms, were received on the opening day of the audit. The NRC staff needs to have the audit plan and the technical checklists at least one week prior to commencement of an audit, to make a determination whether NRC staff technical observers should observe the audit. This matter has been discussed several times with DOE and documented in a previous NRC Observation Audit Report (see Section 5.9.2 of NRC Observation Audit Report, J. Holonich to J. Roberts dated February 17, 1993, for Audit HQ-93-02 of EM-343 January 11-15, 1993). The NRC staff requests for all future audits, that it receive at least one week in advance, as a minimum, copies of the audit plan and technical portion of the checklists (even if in draft form).

As a result of the audit conducted of DWPF by EM-343 during September 14-18, 1992, 5 DCARS were issued and 14 Observations were noted. All of the findings from the September 14-18, 1992, audit were still open and were scheduled to be verified and closed during this audit. Several of the findings were relatively minor in nature (e.g., procedural deficiencies requiring a revision to a procedure) and could have been closed out in "timely manner" as required by Section 16.1.(8) of the EM-343 Quality Assurance Program Description and Section 16.4 of the DOE Quality Assurance Requirements Document DOE/RW-0214. The NRC staff inquired why corrective action took so long (about eight months), especially for the items relatively minor in nature. The EM-343 QA Manager explained that its policy is to verify the corrective action taken to resolve the discrepancy at the point of origin of the finding. The EM-343 QA Manager indicated that EM-343 will consider revising its corrective action procedure to allow minor deficiencies, such as procedure revisions, to be verified and closed in a more timely manner when the documented evidence is received.

During the auditing of the equipment storage areas and canister design and testing, the auditee indicated that there had been 13 internal and external audits and surveillances of the equipment storage area from August 1992 to February 1993, and over 20 internal and external audits and surveillances of the canister design and testing area in the past 12 months. Based on its experience and "lessons learned" in audits for nuclear reactors, the NRC staff recommends that DOE consider combining audits where possible, to avoid the adverse impacts of excessive audits.

The NRC staff noticed that the DWPD/WSRC QA implementing procedure structure may be redundant or excessive. A similar type of comment was noted during the NRC staff observation of the EM-343 July 27-31, 1992, audit of the West Valley Demonstration Project (WVDP) (see letter from J. Holonich to J. Roberts dated September 24, 1992). The auditors noted two examples where audited personnel were unaware that a particular procedure or specific requirement existed. Due to the multiplicity of implementing procedures, certain implementing requirements may be unintentionally overlooked or bypassed. The NRC staff recommends that consolidation of implementing procedures be considered where feasible. This may contribute to more accurate implementation of the DWPD and WSRC QA programs.

The daily status sheets and status boards of the concerns noted by the audit team were beneficial to the audit team members, auditee, and observers in keeping them informed. They provided a brief description of the potential finding, the open or closed status, and whether the finding was being considered as an Observation or DCAR.

Auditors and observers experienced some difficulties in integrating their respective roles compared to recent OCRWM audits. The NRC staff recommends that EM-343 auditors attempt to more positively include observers in the audit process by (1) identifying the activities the auditor may wish to observe; (2) keeping the observer appraised of the auditor's approach to the audit, for example, by identifying the checklist items being covered, what objective evidence is to be reviewed, the roles of the auditees being interviewed, and (3) eliciting comments and questions from the observer at appropriate points.

The OCRWM and NRC observers noted an apparent inconsistency in the way deviations were being documented as Observations and not as DCARs. Standard Practice Procedure (SPP) 4.02, Revision 3, "Administration and Conduct of QA Audits," requires adverse findings to be recorded on a DCAR in accordance with SPP 5.01, "Deviations and Corrective Actions." A Deviation as defined in paragraph 3.b.(3) of SPP 5.01, is, " A condition adverse to quality that is a departure from specified requirements." The OCRWM and NRC observers noted that deviations are being documented as Observations and not as DCARs as required to meet the intent of SPPs 4.01 and 5.01. Additionally, it appeared that several of the deviations appeared to be subjective opinions as opposed to basing the findings on specified requirements. The DOE observers cited four examples in the area of software validation and existing data where this procedure was knowingly not being followed or being interpreted differently than OCRWM does. OCRWM requires that existing data used for waste acceptance

be qualified. WSRC has used some existing data for designing the vitrification process, and has developed plans for qualification of the data during waste qualification runs. An audit observation was presented that the Waste Form Qualification Report did not identify data requiring qualification, although it was identified in a subsequent "Plan for Qualification of Existing Data for Waste Acceptance." The OCRWM Observers felt that a DCAR was warranted because the data had not been qualified before use. The NRC staff is concerned with this inconsistency in that conditions adverse to quality documented as Observations, do not require a response and do not require a tracking system. This matter was previously discussed and documented in the Observation Report of EM-343 Audit No. 93-WV-AU-01 (Letter from D. Horton to R. Erickson dated March 9, 1993). A written response concerning this practice is requested and it will be carried on the NRC/DOE Open Items list.

Product Composition Control System software predicts waste form acceptability based on melter feed composition. This software is classified as essential; the process cannot operate without it functioning. The software specification includes requirements for an on-line, back-up computer (hardware) system. The audit team identified that this system design requirement was not included in the test plan, nor had it been tested. During the course of the audit, the auditors strongly considered this for a DCAR, however, no specific requirement to test the hardware configuration of this system was found. The preliminary conclusions of the auditors appeared to be based on their judgement that the hardware should be tested, rather than on QA requirements.

An Audit Observer Inquiry was submitted to request a copy of the procedure(s) used to determine those items under the DWPF QA program and a copy of the actual listing of the items. The reply to this inquiry was received just prior to the Post Audit meeting and there was insufficient time for the NRC staff observer to fully understand the detail of the response. However, the response appeared to indicate there was not a standardized list available. This is also of concern to the audit team since two observations were listed which questioned the waste items/activities and the requirements for determining the actual items and activities. The subject matter of the listing of items and activities which fall under the purview of the QA program has surfaced during the audits of West Valley Demonstration Project (see NRC comments for EM-343 Qualification Audit No. 92EA-WV-AU-001, from J. Holonich to J. Roberts dated September 24, 1992), and EM-343 (see Sections 5.3.1 and 5.9.2 of NRC Observation Audit Report 93-04 for the OCRWM performance based QA Audit No. HQ-93-02 of EM-343, from J. Holonich to J. Roberts dated February 17, 1993). This matter was briefly discussed with the EM-343 QA Manager during the audit, and it was indicated that a meeting may be held between EM-343, DWPF, and WVDP to mutually resolve this issue. The NRC staff will continue to carry this item on the NRC/DOE Open Items list and a written response is requested.

The DWPD and DWPF procedures appear to address the QA program elements applicable to their activities, and their staffs appear to be generally familiar with QA program requirements. The DWPF technical staff members observed seemed particularly comfortable with their QA program as a routine part of their work practices. Implementation of the DWPF QA program for scientific investigations and design control appear effective.

A written response to the two items noted above is requested. Should you have any questions regarding this letter, please contact W. Belke on (301) 504-2445.

Sincerely,

/s/

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

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