



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

ENTERED

OFFICE OF
AIR AND RADIATION

June 24, 2003

Dr. Inés Triay, Manager
U.S. Department of Energy
Carlsbad Field Office
P.O. Box 3090
Carlsbad, NM 88220



Dear Dr. Triay:

On June 17-19, 2003, the U.S. Environmental Protection Agency (EPA) conducted an inspection of a Carlsbad Field Office (CBFO) audit of the Hanford Site's quality assurance (QA) program for the WIPP. The EPA inspection team concurs with a CBFO concern that identified a breakdown in the Hanford QA program. (See attached letter from Ava Holland to Mike Eagle dated June 19, 2003.)

40 CFR Part 194.22 requires DOE to execute a QA program for items and activities that are important to the containment of transuranic waste within the WIPP, including the transuranic waste characterization activities at the Hanford Site. Hanford's QA program must be in accordance with the Nuclear Quality Assurance (NQA) standards developed by The American Society of Mechanical Engineers. The *Organization* element of the NQA standards requires that "...organizations responsible for...verifying that activities affecting quality have been correctly performed...shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations." However, personnel interviews during the audit indicated that Hanford's QA Organization did not have sufficient independence from cost and schedule considerations. In addition, resources for the QA Organization appeared insufficient for a growing rate of waste characterization activities. An EPA inspection report will follow this letter to further document this issue.

With EPA participation, the DOE QA Manager reviewed documentation of QA activities related to the shipment scheduled for June 19, 2003. The EPA inspectors concurred that the concerns did not have an adverse effect on the QA activities performed in preparation for the shipment. Therefore, the EPA approved that the shipment could continue.

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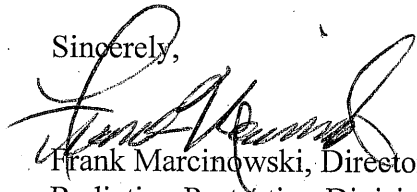


Until corrective actions from the inspection can be completed and verified, all shipments of waste from Hanford to WIPP must be reviewed by CBFO QA, as described in Ms. Holland's letter, to confirm that QA has been adequately applied. The EPA must be notified of the results of CBFO's review for each shipment prior to its departure from Hanford. Drums shall not be approved for shipment until verification of satisfactory completion of corrective actions related to those drums. The EPA will conduct follow-up inspections to verify implementation of corrective actions at the Hanford site.

The EPA concurs with the CBFO QA Manager's assessment that the breakdown occurred on or around the time of January 1, 2003, and that it may have had an adverse effect on the QA of drums processed after January 2003. The EPA requires that CBFO QA identify drums characterized after January 1, 2003, and already emplaced in the WIPP. CBFO QA must conduct reviews—equivalent to those being conducted for current shipments from Hanford—to determine if the QA was adequate for those shipments, and provide the results of such reviews to EPA. DOE should provide EPA, within one week of receipt of this letter, a summary of the shipments that were sent and a schedule for completing these reviews.

This letter will be placed in EPA Air Docket No. A-98-49. Please contact Betsy Forinash at (202) 564-9233 if you have questions.

Sincerely,



Frank Marcinowski, Director
Radiation Protection Division

Enclosure

cc: Matthew Silva (EEG)
Ava Holland (CBFO)
Steve Zappe (NMED)
Mark French (DOE)
Lynn Smith (DOE)



Department of Energy
Carlsbad Field Office
P. O. Box 3090
Carlsbad, New Mexico 88221

June 19, 2003

Mr. Mike Eagle
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Mr. Eagle:

I have reviewed the documentation of Quality Assurance (QA) activities related to the payload scheduled for shipment from Hanford Site to WIPP on June 19, 2003. I have verified to my satisfaction that the condition identified during CBFO Audit 03-14 as concern number one has not had an adverse effect on the QA activities performed in preparation for the shipment.

This concern number one identifies a break down in the Hanford TRU Waste QA program in the NQA-1 elements of organization and assessments. The breakdown occurred on or around the time of January 1, 2003. The evidence I have evaluated clearly shows that this breakdown in administrative functions of the QA program did not affect these particular drums. In the evidence I reviewed there were documents indicating that deficiencies associated with these drums had been identified, documented and corrected.

At the same time as my review of these particular drums, my Audit Team also verified the adequacy, implementation and effectiveness of the characterization processes performed on these drums. Based on this review I have concluded that except for the above identified QA elements, the remainder of the QA program was implemented and effective. I do not have a similar satisfaction that the breakdown in these administrative elements did not have an adverse affect on the QA of drums processed after January 2003. Therefore, an accelerated significant corrective action report will be issued to document and track necessary corrective actions until satisfactory closure of the identified condition adverse to quality.

In the interim period that is necessary for corrective action to be performed and verified, I will perform the same review on upcoming shipments. Drums characterized during or after January 2003 will not be approved for shipment until verification of satisfactory completion of corrective actions. This review and approval process will be performed in addition to the normal shipment review and approval process required by the site's certification authority.

Sincerely,

A handwritten signature in black ink, appearing to read "Ava L. Holland".

Ava L. Holland
Quality Assurance Manager

Mr. Mike Eagle

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cc:

I. Triay, CBFO
K. Watson, CBFO
B. Forinash, EPA
M. French, RL
R. Dunn, RL