Dear Dr. Triay and Mr. Lee:

On February 12, 2001, NMED received the initial Final Audit Report of the Idaho National Engineering and Environmental Laboratory (INEEL), Audit Number A-01-02 (Audit Report), from the Department of Energy’s Carlsbad Field Office (CBFO). CBFO and Westinghouse (the Permittees) were required to submit this Audit Report under the Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit as specified in Permit Condition II.C.2.c. The scope of this audit was to evaluate the adequacy, implementation, and effectiveness of the INEEL waste characterization processes for retrievably stored contact-handled homogeneous solid waste relative to the requirements of the WIPP Permit. NMED delayed extensive review of the Audit Report until the Permittees submitted a revised version of the Audit Report on February 23, 2001, which contained the six-part B6 checklist.

The Audit Report documentation submitted to NMED consisted of the following items:

- a narrative report
- completed copies of relevant Permit Attachment B6 checklists
- final INEEL implementing procedures on CD-ROM

RE: NMED COMMENTS ON INEEL FINAL AUDIT REPORT, AUDIT A-01-02
WASTE ISOLATION PILOT PLANT
EPA I.D. NUMBER NM4890139088

Dr. Inés Triay, Manager
Carlsbad Field Office
Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Mr. John Lee, General Manager
Westinghouse TRU Solutions LLC
P.O. Box 2078
Carlsbad, New Mexico 88221-5608

April 17, 2001

010434
items corrected during the audit (CDAs)

objective evidence examined during the audit
- general information
- solids and soils/gravel sampling
- acceptable knowledge
- visual examination

NMED has examined the Audit Report for evidence of compliance with the requirements of Permit Conditions II.C.2 (Audit and Surveillance Program) and II.C.1 (Waste Analysis Plan). NMED representatives observed the INEEL audit on December 5 - 7, 2000, and specifically evaluated the Audit Report for compliance with the following permit requirements:

- Permit Condition II.C.2.a (Requirement to Audit) - the Permittees shall demonstrate to the Secretary that the generator/storage sites have implemented and comply with applicable requirements of the WAP by conducting an audit of the generator/storage sites as specified in Permit Attachment B, Section B-4b(1)(iii), and Permit Attachment B6 (Waste Isolation Pilot Plant Permittees’ Audit and Surveillance Program), and as required by 20 NMAC 4.1.500 (incorporating 40 CFR §264.13).

- Permit Condition II.C.2.c (Final audit report) - the Permittees shall provide the Secretary a final audit report as specified in Permit Attachment B6. The final audit report shall include all information specified in Permit Attachment B6, Section B6-4, and: (i) A detailed description of all corrective actions and the resolution of any corrective action applicable to WAP requirements, including re-audits if required; (ii) documentation necessary for the Secretary to determine if the corrective action was resolved.

Attached are NMED’s comments based upon observation of the INEEL audit and review of the submitted information. NMED concludes that the Audit Report is incomplete in that it does not adequately address all elements examined during the audit. Because of this incompleteness, NMED is withholding approval of the Permittees’ Final Audit Report for INEEL Audit A-01-02 until the Permittees submit the additional information identified in the attached comments that demonstrate full implementation of WAP requirements. Please indicate revisions to any text in the Audit Report and checklists with redline/strikeout annotation.
If you have any questions regarding this matter, please contact me at (505) 827-1758.

Sincerely,

[Signature]

Gregory J. Davis
Director
Water and Waste Management Division

GJL:soz

Attachment

cc: James Bearzi, NMED HWB
    John Kieling, NMED HWB
    Steve Zappe, NMED HWB
    Susan McMichael, NMED OGC
    C. Steven Allred, ID DEQ
    Kathleen Trever, INEEL Oversight
    David Neleigh, EPA Region 6
    Mary Kruger, EPA ORIA
    Connie Walker, TechLaw
    Matthew Silva, EEG
    Don Hancock, SRIC
    Joni Arends, CCNS
    File: Red WIPP '01
GENERAL REPORT COMMENTS

GR-1. In general, past audit reports have tended to under-describe the supplemental information examined during the course of the audit. Reliance upon general summary documents to support audit reports alone is not sufficient; general summary reports should be evaluated relative to supplemental supporting reference, documents, and other "background" information.

GR-2. The INEEL Audit included discussion pertaining to PCB sampling and segregation of PCB wastes, but this information was not presented in the INEEL Audit Report (Audit Report). Audit Reports should address all technical elements, in the appropriate sections, which are observed.

GR-3. The Audit Report does not re-address many elements that were covered under previous audits and were presumed unchanged with respect to Solids Sampling. However, it is recommended that NMED and DOE develop decision criteria for determining when a checklist element need not be reevaluated during a subsequent audit, so that these requirements are consistently applied throughout the DOE complex.

SPECIFIC REPORT COMMENTS BY REPORT SECTION

1.0 EXECUTIVE SUMMARY

SR-1. The Executive Summary states that the audit assessed "solid waste." Please include the specific summary waste category group for which approval is sought; NMED was under the impression that approval was being sought for the S3000 summary category group retrievably stored waste. Other sections of the report (i.e., Section 2.2) do specify the certification/approval scope, but this should also be included in the Executive Summary.

2.1 Scope

SR-2. The Scope presents each technical and QA element examined, but does not correlate these with B6 checklist elements. B6 checklist correlation should be identified on this listing to facilitate review.

2.2 Purpose

SR-3. The Audit Report should indicate why the audit was accomplished in two phases; i.e., because the AK documentation initially reviewed for the solids sampling did not include any confirmation information.
5.2.1 Table B6-1

SR-4. The B6-1 checklists should cross reference elements on other checklists, as applicable, to simplify the review process.

SR-5. The Audit Report concludes that WSPF generation was sufficient. However, when examining checklist elements dealing with generation of new waste stream profile forms, it was discovered that when discrepancies are noted between AK and analysis, a unique AK Summary (Waste Stream Summary Sheet, WSSS) was not generated for the new waste stream. Instead, the existing WSSS was updated to include information for the new waste stream, with the intent being that the updated WSSS would apply to both the previous and new waste streams. Unique AK summaries are required for each WSPF; an AK summary cannot extend to several waste streams. This observation was captured on the AK Checklist and was apparently resolved (CDA 3), but CBFO must ensure that sites recognize the importance of the AK confirmation process and subsequent segregation of waste streams based on confirmation results.

5.2.2 Table B6-2 Solids and Soils/Gravel Sampling Checklist

See General Checklist Comments.

5.2.3 Table B6-3 Acceptable Knowledge Checklist

SR-6. The AK portion of the audit had to be addressed in two phases; revise the Audit Report to include why this was necessary and what information was obtained during each phase.

SR-7. The site should revise the AK Record to include Shipping Records identified by NDA personnel who assembled EDF 1242. EDF 1242 is an important AK document, and relevant supporting information should be included in the AK Record. The absence of this document is included in Checklist Element 135, but this should have been brought forward to the body of the text and included as an observation because an incomplete AK record is of major concern and should be mitigated as soon as possible.

7.1 Observations

SR-8. The Audit Report stated that AK confirmation should be completed “before a determination of implementation and effectiveness can be made on the AK process.” However, previous sections of the report indicate that the complete AK process is sufficient and, hence, approval is warranted. Clarify whether this sentence is still applicable given results of the January 18 portion of the audit.
7.2 Recommendations

SR-9. Document RWMC-803 has been updated to include new information, and a section is added to the document describing new information is included. However, the revised text includes no sidebars and no references to the sources of the revision.

GENERAL CHECKLIST COMMENTS

GC-1. Include all revision numbers on the checklists, including applicable sections and pages reviewed.

GC-2. The B6 checklists are consistently filled out after the fact using information gathered by filling out the CBFO audit checklist. This practice should be discontinued and the B6 checklist should be filled out during the audit, or the B6 checklist should be integrated into the site-specific checklists to ensure B6 elements are addressed.

GC-3. Several incorrect procedure references were in the B6 checklists. For example, Cited references were often found in sections of the procedure other than those indicated in the checklists. Other references cited did not address the checklist element, and other, relevant, procedures were not cited. The Checklist citations should be reconfirmed to provide the correct reference and section for each checklist question, particularly those dealing with Solids Sampling.

GC-4. Several of the Solids Sampling references (TABs and Procedures) did not sufficiently demonstrate or describe how the reference supported the checklist element it was referenced with. While the TAB might allude to a practice or requirement, TABs sometimes did not provide enough information to support the procedure; similarly, cited procedures sometimes did not provide specific enough information to ensure that the WAP requirement would be met if the procedure were followed. Checklist responses should indicate if a requirement is only partially met or if the procedure cited is incomplete or does not contain sufficient detail. Solids Sampling Checklist references should be reexamined to determine if additional references should be cited and if the available procedures are sufficient.

GC-5. Solids Sampling checklist elements that are implemented in multiple procedures were not clearly documented to show the WAP requirement addressed by each procedure cited. The procedures provided by INEEL divide relevant tasks among multiple procedures and often it is not clear what procedure or portion of the procedure applies to which checklist element (or portion of a checklist element). Also, the different procedures cited would describe a specific activity, such as independent technical review, from different perspectives. For example, PNL-600 includes specific data validation procedures and checklists while MCP-2008 includes data review and reporting requirements that are relevant to the ITR process. It is often unclear what procedure was used by the Auditor to evaluate acceptance for a particular requirement. Revise the Solids Sampling checklist to clarify these points.
GC-6. Examples of objective evidence for Solids Sampling activities that cannot be readily documented through batch data reports (sampling or analytical) or other documentation should be more clearly described in the checklist response. For example, responses to checklist questions pertaining to solid sample collection were typically answered by stating that a specific sampling event was “observed.” However, the response did not provide information pertaining to other relevant activities that may have been observed, such as the order of sample collection to ensure that VOC samples were collected first, whether field QC samples were collected in an appropriate manner, or whether samples were handled in a manner to avoid VOC loss. Solids Sampling checklist element responses to activities or requirements that are not included in objective evidence documents should be answered in a more descriptive manner in the checklist “comments” section. This would also apply to miscertification rate calculations that may have been observed.

GC-7. Several of the references cited in the Solids Sampling checklist appear to be incomplete. For example, the SVOC and VOC batch reports did not contain data generation or project level validation or verification checklists and the Audit Report therefore includes no direct evidence that these tasks were performed, or that the QAOs for the data package were evaluated or met. Similarly, the Metals batch report only contained the data generation level checklists for ITR, TSR, and QAO reviews found in PLN-600. There were no other data generation level or project level checklists in the batch data report. Also, the sampling batch reports did not include the TSR sampling/batch review checklist or the QADR sampling batch checklist as specified in procedure NT-AP-03. Therefore, the evidence was incomplete with respect to showing that all data generation review activities were performed in accordance with site procedures (and, hence, the WAP).

Additionally, the referenced procedure revisions sometimes contained different forms (or versions of forms) than those provided in references. For example, the TSR analytical validation checklist that was found in the metals batch data report was a revision 0 form. However, procedure PLN-600 references a revision 1 form that contains additional information.

Additionally, the data generation level QAO review checklist found in PLN-600 contained information not included on the QAO checklist in the batch report (neither the form in the procedure or the form batch data report contained a revision number, but the date on both of these checklists was 11/2/00). Because the effective date of the data package was 11/2/00 for revision 0 and the effective date of PLN-600 was 11/01/00, it is unclear whether the appropriate forms were used. Revise the checklists and references to ensure that the appropriate forms were used, or to explain when the appropriate form was not used.

**SPECIFIC CHECKLIST COMMENTS BY CHECKLIST ELEMENT**

1. While the Waste Stream Profile form and associated documentation are helpful, other AK documents better support the initial waste stream designation (i.e., TAB AK1).

5. While NMED has approved the lot designation for HSG, the Auditor should have re-examined this element with respect to solids sampling.
6. TAB AK7 would have been a better reference to cite that addresses assignment of hazardous waste codes.

9. Waste incompatibilities are assessed through TRUCON code comparison, and it is unclear how the referenced TAB or procedures address this requirement.

11, 12, 18, 24. NMED observers were under the assumption that INEEL was not going to be certified to perform PCB analysis, yet this checklist element comment indicates that this is not the case. Please clarify.

12. The response to the checklist question regarding how absence of prohibited items is verified inadvertently indicated that the absence of compressed gas is evaluated through PCB analyses and that PCB analyses has previously been audited and approved (see checklist element 11, above). In addition, the referenced procedures for evaluation of the hazardous waste codes only included the analytical methods and did not include data validation or acceptable knowledge procedures that are also relevant to the process of verifying hazardous waste codes.

21. The referenced procedures did not indicate how the samples would be selected randomly, but the objective evidence to answer this was provided in EDF-909.

22. The procedures do not indicate when TIC evaluation is performed nor how frequently TIC evaluation is performed to determine if additional target compounds must be added to method target lists.

30. Procedure MCP-2527 specifically deals with the calculation of UCL values and evaluation of the hazardous constituents of the waste stream. However, this procedure was not referenced.

31. The procedures for calculating completeness and comparability were not found in the procedures cited for this question. In addition, none of the batch data reports for VOC, SVOC, and metals analysis included objective evidence that the QAOS were evaluated for the referenced report.

40. The response to the checklist question indicates that the site project officer reviews were acceptable for totals analyses. However, there was no evidence of the site project officer reviews in the totals analyses batch data reports for metals, SVOCs, and VOCs included in the Audit Report.

41. The response to the checklist question indicates that the site project quality assurance officer reviews were acceptable for totals analyses. However, there was no evidence
of the site project quality assurance officer reviews in the totals analyses batch data reports for metals, SVOCs, and VOCs included in the Audit Report.

42. This element was not evaluated because it was previously audited. However, the mechanism for preparing the quarterly revalidation could extend to the totals data generation level, which was not previously audited. Therefore, the Auditor should have evaluated the quarterly revalidation for the totals analyses.

43. The response to the checklist question indicates that the site project officer reviews were acceptable for totals analyses. However, there was no evidence of the site project officer reviews in the totals analyses batch data reports for metals, SVOCs, and VOCs included in the Audit Report.

45. This element was not evaluated because it was previously audited. However, the mechanism for ensuring nonconformance feedback and corrective action implementation also applies to core sampling and totals analytical data generation level, and the implementation of nonconformances in these specific areas was not previously audited. Therefore, the Auditor should have evaluated the nonconformance process for solid sampling and totals analyses.

46. Procedures for preparing Chain of Custody records and sample labels included examples of the forms to be used. However, the procedures did not contain instruction on how to properly complete the Chain of Custody records or sample labels. The custody and sample labeling procedures should include directions for completion of all custody documents.

54. The checklist response indicated that project level reviews were adequate for solid sampling and analysis. However, there was no evidence of the site project officer or site quality assurance officer reviews in the totals analyses batch data reports for metals, SVOCs, and VOCs.

57. Clarify where, in the cited references, nonconformances or noteworthy observations are presented.

58. This checklist item should have been checked with respect to solids sampling results.

68,69. Preparation of a WSPF does not address the checklist element, which asks whether procedures are in place to require maintenance of Lifetime Records. Additionally, the Auditor should have spot checked the Non-Permanent Records to be sure that those related to solids sampling were included.

70. The referenced sections of procedure MCP-2008 did not contain information related to checklist element 70. The Auditor should verify and document the correct section.
of the procedure to serve as evidence that the checklist requirement was documented in a procedure.

86. The WAP indicates that solid samples may be collected by taking a representative subsection of the sample core. However, if the waste is such that a single subsection cannot be representative of the waste, then three separate subsections of the core that do represent the waste are to be collected and composited to form the sample. Site procedures do not require assessment of the waste to determine if a single subsection of the core is representative of the drum contents. Also, no procedures were referenced for collecting composite core samples in the event that a single subsection of the core is not representative of the waste.

87, 88, 89, 100, 104, 106, 107 The referenced sections of procedure HFEF-OI-6910 did not contain information related to the checklist elements 87, 88, 89, 100, 104, 106, and 107. The Auditor should verify and document the correct section of the procedure to serve as evidence that the checklist requirement was documented in a procedure.

92. The procedures do not include any discussion of the permit requirement to use the F-Test to evaluate the precision of co-located core sampling prior to establishing site sampling precision limits. The response to the checklist question did not indicate whether this requirement was addressed.

100. The procedure did not indicate that the acceptance criteria for equipment blanks states that all compounds must be less than 3 times the MDL for a particular compound or analyte. The procedure only indicates that the laboratory will notify the appropriate representatives if the equipment batch is bad. The procedure should indicate the acceptance criteria and sampling personnel should be familiar with the equipment blank acceptance criteria. The procedure should be modified to indicate the equipment blank acceptance criteria.

104. The provided reference did not include disposition of malfunctioning sampling equipment. The response to the checklist question indicated that the referenced procedure was adequate, but the procedure did not appear to address this WAP requirement.

105. The referenced section in Procedure HFEF-OI-6921 did not contain information regarding storage of sampling equipment. The correct reference should be provided.

106. The provided reference did not include any discussion regarding spare part inventories for equipment. The response to the checklist question indicated that the
referenced procedure was adequate. However, the procedure did not appear to address this requirement.

107. The provided reference did not include development of a maintenance logbook for maintenance and repair of sampling equipment. The response to the checklist question indicated that the referenced procedure was adequate, but the procedure did not appear to address this WAP requirement.

110, 112, 114, 115, and 117 The referenced sections of procedure HFEF-O1-6862 did not contain information related to checklist elements 110, 112, 114, 115, and 117. The Auditor should verify and document the correct section of the procedure to serve as evidence that the checklist requirement was documented in a procedure.

113. The procedures did indicate how the QC designation would be denoted on the sample labels, and the sample label did not have a place in which QC designation is documented. The response to the checklist question did not mention this or otherwise indicate how the WAP requirement was met.

121. The procedures did not include detection of VOC cross-contamination. The Auditor indicates that the facility uses a clean sand matrix as a trip blank, but the referenced procedure did not address this requirement.

128, 129. The referenced sections of procedure NT-AP-03 did not contain information related to checklist elements 128 and 129. Revise the checklist to reference the correct procedure or location in cited procedures where the requirements are addressed.

134. Also reference AK1, AK3, AK9, and AK10.

136. List the seven drums that had been completed by the Jan. 18 audit, and the type of information available for said drums. Clarify whether the cited references include or link to drum-specific data.

137 Include reference AK1.

138. It is unclear what is meant by the statement “the requisite information is available”; i.e., did the Auditor mean that the requisite AK information is available so waste (thus far) need not be characterized in the same manner as newly generated waste, or did the Auditor mean that the requisite information committing to said characterization is available?
140, 141. Include all supplemental information examined to check the mandatory information presented in AK2.

142. Examples of AK-AK document discrepancies should have been included wherein different AK hazardous waste determinations were recognized (i.e., AK12). Also reference AK6.

145. List supplemental information examined to support the mandatory information assembled. As noted in the checklist element, supplemental (better described as background) information must be acquired to support mandatory data. Additionally, all supplemental information must be clearly applicable to the document in which it is referenced; at INEEL, NMED observers did note that some references had little “connection” to the mandatory documentation in which it was referenced (Pl27, for example). Include reference AK13 and associated supporting (supplemental) documentation.

152. Include reference AK4; this reference summarizes the statistical analysis performed to confirm AK. While inclusion of batch reports is helpful, this section must also directly reference statistics and other analysis performed in support of AK confirmation.

159, 160. The reference should cite the specific batch reports examined; also, HSG was determined via sample compositing, but it is difficult if not impossible to discern this from information examined. Revision of the WSPF or other documentation to identify sample compositing activities is suggested.

164, 165, 166, 167. The Audit Report should include any statistical analysis reports that present the results of data evaluation with respect to AK confirmation (i.e., F test, etc.).

286-295. While it is agreed that the mechanisms associated with miscertification rate calculation were assessed under previous audits, the Auditors should have examined ongoing information pertaining to recalculated miscertification rates (i.e., 6 months after SWCG undergoes characterization) to check the current site-specific miscertification rate, and associated calculations. That is, miscertification rate determination is an ongoing process, and probably should be examined at each audit to assess miscertification rate calculations at that particular time.