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PETER MAGGIORE
SECRETARY

December 3, 1999

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

Dear Dr. Triay:

RE: NMED Review of Interim Final Audit Report for Rocky Flats Environmental Technology Site, Audit Number A-99-21

The New Mexico Environment Department (NMED) has completed its review of the above referenced document received on October 8, 1999. As specified in Section II.C of the Memorandum of Agreement (MOA) signed June 17, 1999, the Department of Energy (DOE) and NMED agreed "to work toward a mutually-acceptable Interim Audit Report." NMED further clarified in a letter dated September 1, 1999 that the submittal of an audit report prior to issuance of a final Hazardous Waste Facility Permit would be viewed primarily "as an opportunity to assist DOE in improving the quality and content of these reports." It is from this perspective that NMED provides the attached comments for your consideration.

NMED recommends that DOE provide greater detail in the audit checklist to identify the specific items reviewed under the column heading "Examples of Implementation." Alternately, or in conjunction with the first recommendation, DOE may submit copies of relevant portions of these significant documents reviewed to verify implementation of the requirements. In making these recommendations, NMED believes that DOE must exercise a certain degree of judgment to determine the proper balance of additional information necessary for an independent reviewer to reach the same conclusion as the audit report. If too little information is provided, DOE risks delay as NMED reviewers will be obliged to request additional documentation to substantiate the audit report conclusions. If too much information is provided, delay is also a likely result as NMED reviewers attempt to locate relevant information in a potentially unmanageable mountain of paper.

NMED notes that the WIPP hazardous waste facility permit became effective on November 26, 1999, on which date the MOA terminated as specified in Section III.G of the MOA. At a later

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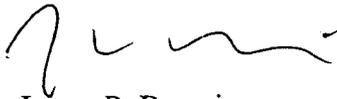


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date, NMED will submit an invoice to DOE for reimbursement of costs associated with Section III.E of the MOA, in which DOE agreed to provide NMED with sufficient funding for review of waste documentation submitted pursuant to the MOA. NMED also wishes to initiate discussions with DOE to develop a mechanism for funding costs associated with NMED's participation in future audits and review of audit reports under the permit.

If you have any questions, please contact me at (505) 827-1567, or Mr. Steve Zappe of my staff at 827-1560, x1013.

Sincerely,



James P. Bearzi
Chief
Hazardous and Radioactive Materials Bureau

Attachment

cc: Paul Ritzma, NMED
Greg Lewis, NMED
Steve Zappe, HRMB
Susan McMichael, NMED OGC
David Neleigh, EPA Region 6
Mary Kruger, EPA ORIA
Connie Walker, TechLaw
WIPP File - Red '99

Attachment

NMED's Evaluation of the Interim Final Audit Report for the Audit Process and Activities Conducted at the Rocky Flats Environmental Technology Site June 16-18, 1999.

1. The audit report does not provide any information to "back-up" the checklist and report claims that objective evidence of examples of implementation were obtained, and that checklist/ permit requirements were adequately met. The intent of the audits conducted by the Permittees is to ensure that: 1) the operators of each generator/storage site who plan to transport transuranic (TRU) mixed waste to the WIPP facility conduct sampling and analysis of waste in accordance with the current WIPP Waste Analysis Plan (WAP), and 2) the information supplied by each site to satisfy the waste screening and acceptability requirements of Section B-4 of the WAP is being managed properly. The initial audit reports submitted by the Permittees to NMED will undergo significant public scrutiny and, as such, the audit reports must be as near to stand alone documents as possible to allow reviewers to verify that the audit was conducted properly. As a result, the initial audit reports should include either more detailed presentation of audit results citing specific items observed, etc., or copies of *relevant* portions and pages of all documents reviewed to obtain objective evidence of implementation of a checklist/permit requirement. Note that it is not NMED's intent that the Permittees submit the entire contents of every document reviewed during the audit, only those pages that were actually checked to provide the objective evidence. The Audit Report should include enough information for reviewers to quickly assess whether DOE has ensured site compliance with the WAP (i.e., through more detailed implementation example data), but it should not be burdened with unnecessary information that would delay the review process.
2. The final audit report and checklists must be based on the Final Permit and associated B6 checklist. If any discrepancies between the Final Permit and its checklist are noted, the Final Permit takes precedence. These types of discrepancies can be noted on the checklist and don't necessarily require clarification by NMED.

1.0 Executive Summary

3. The Executive Summary states that the audit team "concluded that the adequacy of the RFETS technical and Quality Assurance (QA) programs...was satisfactory in meeting CAO WIPP Program requirements contained in ...Attachment B6, except for the deficiencies identified in the corrective action report (CAR) discussed below". Section 2.1 also indicates this process was followed. However, the purpose of the audit is not to determine compliance with CAO WIPP requirements as embodied in the WIPP WAP, but to instead assess site compliance with the WAP *independent* of CAO requirements. Further, and as identified in the report cover letter, the CARs identified in the text of the report do not identify the majority of elements NMED would expect to see identified as CARs. Specifically, NMED would expect to see WAP non-compliances such as inconsistent requirement of headspace gas analysis, lack of total VOC analysis, etc.,

identified as CARs that should be resolved prior to waste management and disposal at WIPP.

4. The audit report should specify, in more detail, the criteria by which CARs are identified. As indicated above, CARs should include WAP non-compliances, and the criteria by which CARs are identified, evaluated and resolved should be specified in the audit report.
5. The report and executive summary should specifically identify the scope of the audit with respect to the waste summary categories and waste streams assessed during the audit. The scope should be clearly specified so that those waste summary categories and waste streams not included in the audit are identified and therefore would not be approved by CAO or NMED. For example, it appears that this report approves procedures with respect to AK, RTR, VE, and HSG of retrievably stored debris waste, but implies that only newly generated LECO crucibles were included in the AK audit (thereby limiting the newly generated debris AK audit scope to LECO crucibles). It is also unclear whether the scope of the audit with respect to newly generated homogeneous solid waste is intended to be limited only to salt residues, and then whether this limitation only applies to the AK portion of the newly generated waste characterization process. Because coring was not reviewed, the report also implies that retrievably stored solids/soil/gravel are not included in the audit with respect to the sampling/analysis procedure examined (although AK, RTR, VE, and HSG could apply to retrievably stored solids/soils). The report should clearly identify the scope of the audits performed, specify the summary waste category groups to which the audit applied, and identify limitations of the audit (if any) with respect to the Summary Waste Category Group and waste streams that were covered by the audit.

2.1 Scope

6. All reports for audits previously performed that are used as part of the audit process should be included as attachments to the audit report. See comment 5, above, regarding audit scope requirements.

2.2 Purpose

7. The Interim Audit Report states that the audit was performed to verify compliance. More accurately, audits are performed to assess compliance. Ensure that the audit report includes a complete list of procedures examined, audit participants, and any other information NMED may need to examine to determine whether referenced portions of these audits satisfy the audit requirements.

4.0 Audit Participants

8. The list of Audit Participants should include the technical checklist area(s) for which participants were interviewed. Audit personnel interviewed should also be indicated, as appropriate, on the checklists. In addition, specific personnel interviewed should be presented in Sections 5.2.1 - 5.2.6.

5.1 Program Adequacy and Implementation

9. Revise the statement “the audit team concluded that the applicable RFETS TRU waste characterization activities.....satisfactorily meet the CAO WIPP Program Requirements...” to more accurately reflect the purpose of the audits. Audits are performed to assess site compliance with the WAP, irrespective of CAO requirements. In addition, future checklists may clarify WAP/checklist interpretations, but should not be used (as this report was) to specify permit modifications. The checklists must ensure that RFETS requirements reflect WAP requirements; deviations from WAP requirements, unless a minor interpretive clarification issue, would constitute a deviation from the WAP which must be identified and rectified prior to waste management and disposal at WIPP.
10. In the case of the permit modifications that have been submitted which could rectify outstanding CARS, the audit report must identify those permit modification submissions including the date submitted and exact language of the submission. NMED will then assess approval of the report with outstanding CARS in light of forthcoming permit modifications that would be in place prior to waste shipment. However, NMED cannot consider approving such a report until the relevant modifications are incorporated into the permit.

5.2 Technical Activities

11. The audit report should specify those elements corrected during the audit on the checklists (as possible and applicable), as well as within the body of the report. The audit report should also detail how examples of implementation were identified and examined. In addition, audit reports should not include an “issues” section that deals with permit modification requests, and it is not necessary to identify permit requirements that CAO has not required because the audit does not deal with CAO requirements. The audit report could identify clear interpretive questions that are not permit modification requests, but it would be more desirable to identify these issues and resolve them in another forum so that the audit report is as clear, decisive, and definitive as possible. As such, the third paragraph in Section 5.2 will require removal or extensive modification in forthcoming audit reports.
12. Subsections of Section 5.2 should discuss how the checklist and permit elements were assessed, major issues identified, and resolution of those issues. Site-specific data should be provided (i.e., drum numbers examined), and each section should include a list of all procedures observed, documents observed, and personnel interviewed. The B6-1 discussion as well as Section 5.2.2 - 5.2.6 discussions are very general, and should include a more detailed discussion of the assessment process, including examples of data examined, significant procedures examined (and procedure content), items corrected during the audit, personnel interviewed, CARs, and other conclusions.

5.2.1 Table B6-1 WAP Checklist

13. The audit report includes a discussion of pyrochemical salt sampling to justify deviations from the WAP with respect to sampling procedures and analytical suite. However, this justification cannot be addressed in an audit report; instead, permit modification requests should be submitted for NMED consideration and proposed incorporation. It is expected that permit modification request "clarification" issues will not be included in forthcoming audit reports.

14. Issue Response; Table B6-1 checklist:

Clarification

Response to Issue, Item 2: Agreed. Issue of semantics.

Response to Issue, Items 18, 19: Agreed.

Response to Issue, Item 20: So long as the PDP requirement is retained, the document that presents this requirement can be the QAPjP.

Response to Issue, Item 22: Agreed.

Response to Issue, Item 26: It is unclear why these requirements would not be presented in procedures, but the requirements must, at a minimum, be included in the QAPjP to ensure site compliance.

Response to Issue, Item 35: Agreed.

Response to Issue, Item 45: Agreed.

Response to Issue, Item 48: Agreed.

Response to Issue, Item 51: Agreed.

Response to Issue, Item 56: The text was not removed; it was moved to Section B-4a(6) of the final permit.

Response to Issue, Item 57: Waste Stream Summary and Data Summary Reports are required for submission to the Permittees; more detailed information (i.e. detailed, drum-specific data) is not required to be submitted to the Permittees, but the Permittees must have immediate access to this information, if requested. The specific data format is included in permit attachment B3; the sites should be audited to ensure that procedures are in place to follow B3 requirements. Infrequency of submission is no reason that required procedure should not be in place.

Response to Issue, Item 59: The text was not removed; it was moved to Section B-4a(6) of the final permit.

Response to Issue, Item 75: See response to Item 57.

Permit Modification

Response to Issue, Item 29: This issue addresses a violation of WAP requirements at the site, and attempts to justify this variation. The audit report is not the correct forum for such a request; a permit modification should be submitted to address the issue.

Checklist Discrepancy

Response to Issue, Item 38: The checklist does not appear to adequately reflect the permit; the checklist could be modified to clarify permit requirements.

Response to Issue, Item 58: WAP requirements, not CAO requirements, are the subject of these audits. If a requirements is included in the WAP but is not addressed by a site, this should be identified in the audit report and remedied, regardless of whether the issue complies with CAO requirements.

Section 5.2.2 Table B6-2 Solids and Soil/Gravel Sampling Checklist

15. The Interim Audit Report states that actual waste generation activities were observed, but does not provide detail regarding these activities. Activities performed, personnel observed, and detailed observations should be included in the body of the audit report. Alternatively, attach the sampling observation report. Also clarify the specific waste summary category group addressed by this audit; it is assumed that since the retrievably stored sampling method (coring) was not observed, that audit scope does not include retrievably stored waste. If the sampling method is intended to include retrievably stored waste, then a permit modification request would be required to allow use of the audited sampling method on retrievably stored waste. Refer to comment no. 18.
16. The Interim Audit Report implies that statistical methods were employed to determine sample number, but provides no information regarding the procedure used or whether it was appropriately applied to the correct waste grouping (i.e., retrievably stored vs. newly generated). The audit report text should not only provide a more thorough discussion of sampling procedures observed and any method deviations, but should also discuss sample number determination and whether associated methods were correctly applied. Further, the audit report should not cite justification for permit deviations; a permit modification request would be required (i.e., deviation from statistical sample number selection methods).
17. No discussion of analytical parameters or analytical procedures is included in the body of the Interim Audit Report. Also, there are no provisions in the permit that allow for an exemption from VOC or SVOC analysis. The permit requires that VOC and SVOC sampling is to be performed for all samples collected. Any proposed modifications to the permit must clearly demonstrate how specific treatment processes eliminate all VOCs and SVOCs of concern in a waste stream.

18. The Interim Audit Report states that the sample collection method (dipper) was deemed equivalent to coring, citing correspondence supporting this conclusion. However, the permit does not include provisions for equivalency demonstrations, requiring instead that the methods specified in the permit be used. A permit modification would be required to allow this approach, and it is expected that the Final Audit Report will not include methods or allowances for procedures or activities in conflict with the WAP.
19. Issue Response; Table B6-2 Checklist

Clarification

Response to Issue, Item 3: The checklist item should have more appropriately indicated samples were collected to assess concentration with respect to the regulatory threshold.
Response to Issue, Item 40: NMED agrees that the reference to waste containers should refer to sample containers.

Response to Issue, Item 49: Trip blanks are required by permit, regardless of CAO requirements; the checklist and audit report should reflect this. Trip blanks would provide evidence of cross contamination of sample containers.

Response to Issue, Item 52: The generator/storage site must be able to demonstrate a mechanism to ensure that the participating laboratories are currently in the PDP program and have demonstrated proficiency; the QAPjP could be where this requirement is fully stated.

Permit Modification

Response to Issue, Item 19: The preservation requirements for the metals samples were not followed because the site apparently did not analyze for mercury. There are no provisions in the permit that allow for an exemption from the sample preservation requirements found in Table B1-4 of the Permit, regardless of CAO allowances. In addition, there are no provisions in the permit to allow exemption of analytes for analysis; therefore, the generator/storage site was required by permit to analyze for mercury. Any modification of sample preservation methods or analytical suite should first be addressed through permit modification.

Response to Issue, Items 56, 58: TIC identification is required for solids analysis of both VOC and SVOC. Section B3-1 clearly identifies the TIC identification requirements for SVOC and VOC solid sampling. The checklist could be clarified through permit modification to instead reference B-3d.

Response to Issue, Item 65: The classification of the molten salt waste as retrievably stored waste would preclude sampling by means other than coring. Use of any methods different than those specified in the permit would be a permit violation, regardless of whether this change was allowed by CAO. Changes of this nature require permit modification.

Checklist Discrepancy

Response to Issue, Item 41: The checklist does not appear to adequately reflect the permit; the checklist could be modified to clarify permit requirements.

Section 5.2.3 Acceptable Knowledge Checklist

20. The WIPP Proposed Final and Final permits require auditing of select waste stream(s) from each of the Summary Waste Category Groups being covered under a given audit. The Interim Audit Report should specify here, and in each section, the exact scope of the audit in terms of Summary Waste Category Groups and waste streams (if the audit is limited to specific waste streams).
21. The AK discussion should detail the specific waste streams/containers examined, and should better discuss the evaluation and traceability analysis performed. The audit report should also address, in more detail, how the AK confirmation process (e.g. confirmation via sampling/analysis results) was evaluated.
22. Issue Response; Table B6-3 Checklist:

Clarification

Response to Issue, Item 10: Agreed.

Response to Issue, Item 19: Agreed.

Response to Issue, Item 20: Agreed.

Response to Issue, Item 37: The item is appropriate and *necessary* for this report, whether it be on the checklist or in the text of the report. If the scope of audit elements varies between characterization processes, then this should be specified, and it would be very helpful to have these scope changes/limitations presented on individual checklists.

Permit Modification

Response to Issue, Item 11: The Final Permit states that “if the required information is not available for a particular waste, supplemental information shall be obtained and the waste will not be accepted for management, storage, or disposal at the WIPP facility as a retrievably stored waste,” i.e., the waste must be considered newly generated and must be characterized accordingly. If the Permittees disagree with this requirement, a permit modification request should be suggested. Is it agreed that this requirement could be presented in the QAPjP, so long as the site is required to follow it.

Section 5.2.4 Headspace Gas Sampling Checklist

23. The headspace gas sampling equipment discussion did not provide adequate detail regarding the overall headspace gas sampling configuration, including but not limited to the number of sampling ports, location of gauges and sensors, and drum intrusion mechanism. More detailed information and description of the HSG system should be provided to allow NMED to evaluate the system with respect to the WAP requirements. Consider including explanatory figures and tables, particularly if NMED is not present at the audit.
24. The scope of the headspace gas sampling program discussion did not adequately address audit activities. This section should include drum numbers/ IDCs for which sampling or documentation was observed, a list of all procedures that were observed (including title, number, and function), a list of all documents observed, and a list of all personnel interviewed (name, position, function).
25. There are no provisions in the permit to allow an exemption from VOC headspace gas sampling or analysis. The permit requires that VOC headspace gas sampling is to be performed for all waste containers. Deviations from permit requirements, such as this, is an issue that should be resolved prior to waste management and disposal at WIPP. Changes to permit requirements should be addressed in permit modification requests.
26. Issue Response; Table B6-4 Checklist:

Clarification

Response to Issue, Item 1: The QAPjP is an appropriate venue to define the requirement for headspace gas sampling of all waste containers. However, the generator/storage site must also have an administrative mechanism to ensure that the headspace sampling is performed. The checklists or audit report should indicate whether the required 100% headspace sampling is taking place.

Response to Issue, Item 5: Radiation controls were addressed in the permit and NMED believes that it does not mandate specific radiation containment requirements.

Response to Issues, Items 9, 10: The audit report did not contain an adequate description of the system and system specifications or procedures needed to assess WAP compliance. In general, NMED recognizes that there may be minor differences between sampling systems at the different generator/storage sites, and has written the permit to allow for these differences. However, the permit does not include an equivalency demonstration process.

Response to Issue, Item 38: Trip blanks would provide evidence of cross contamination of sample containers. Because leaks developing during shipping and handling of canisters are possible, there is still a need for trip blank collection. There does not appear to be sufficient reason to modify the trip blank requirement for headspace gas sampling episodes.

Permit Modification

Response to Issue, Item 2: The permit currently does not allow modification of the equilibration time. The allowable time frames for transit should be clearly identified in any proposed permit modification.

Response to Issue, Item 14: The permit currently does not allow sampling under the poly liner for a drum in which the poly liner was not vented. A permit modification should be submitted to demonstrate how this alternate sampling method is equivalent and that all collection requirements and provisions of the permit will be met. These provisions include but may not be limited to: sample volume requirements, prevention of sample equipment contamination, and collection of equipment blanks.

Response to Issue, Item 19: NMED concurs that gas cylinders do not generally specify a shelf life. The permit could be modified to clarify the distinction between gas standards and solid standards.

Response to Issue, Item 22: The permit currently allows the use of nitrogen as an impurity free gas. A permit modification may be proposed if the Permittees require clarification of the use of nitrogen gas.

Response to Issue, Item 23: The permit currently does not allow alternate forms of manifold cleaning. However, NMED does agree that alternate methods of cleaning as demonstrated by appropriate blank collection and analysis may be proposed as a permit modification. The modification must demonstrate that the level of decontamination will be equivalent to manifold heating.

Response to Issue, Item 36: NMED agrees that cold packs for headspace gas samples are not necessary. A permit modification lifting the preservation requirement for headspace gas samples could be submitted.

Response to Issue, Item 39: The nanogram limits in Table B3-2 are expressed assuming a volume of 10 milliliters, which is equivalent to units of ppmv. However, NMED agrees that the MDL values for headspace gas constituents could be more clearly defined through a permit modification.

Section 5.2.5 Radiography Checklist

27. The audit report includes a number of conclusions regarding the adequacy of the radiography operations at RFETS, but does not include adequate back-up documentation to support these conclusions. The audit report could include attachments which contain copies of all relevant portions and pages of all documents reviewed to obtain objective evidence of compliance with the WIPP WAP.
28. Issue Response; Table B6-5 Checklist

Clarification

Response to Issue, Item 3: DOE believes that the statement that “every” waste container will undergo radiography or VE is incorrect since newly generated waste will not undergo RTR and VE. DOE is also concerned that the acronym VE implies only the RTR QC check. Since the Table B6-5 checklist applies only to Radiography, and the permit specifies that radiography will only be used on retrievably stored waste, a potential resolution to this issue is to add the words “retrievably stored” after the word “every.” Note that this change would not be required to clarify the specific statement in Permit Attachment B-3c (first paragraph) from which the checklist requirement was derived since the sentence is used in a much broader context in the permit.

Permit Modification

Response to Issue, Item 3: Permit Attachment B, Sections B-3d and B-3d(1), clearly states that for newly generated waste, physical form and prohibited items will be verified during packaging (using the VE technique). Any clarification or modification of the visual examination and visual inspection process should be done through permit modification, as NMED has interpreted visual examination and visual inspection to be the same activity.

Response to Issue, Items 47, 48 and 52: DOE is concerned that the checklist requires a project-level review of RTR videotapes. DOE’s concern is that the Site Project Office (SPO) personnel are not qualified to interpret RTR videotapes, they can only ensure that the required tape review has been performed by an independent, qualified reviewer.

With respect to Item 47, the checklist requirement was taken from the Data Generation Level subsection of Attachment B3, Section B3-10. Thus, the issue could be easily clarified by adding the words “at the data generation-level” after the word “reviewed,” as NMED agrees with the tenant of the issue resolution posed by the Permittees.

With respect to Item 48 and Item 52, and based on an evaluation of the project level data validation and verification requirements specified in Attachment B3, Section B3-10 (pages B3-25 to B3-26) of the Final permit, it appears that the intent of the permit language was for the Site Project QA Officer to ensure that the data generation-level review of the radiography tapes had been successfully accomplished. It does not appear that the intent of the permit language was to require the Site Project QA Officer to personally review the radiography videotapes. NMED agrees with the tenant of the issue resolutions posed by the Permittees. Clarification of this issue could be accomplished by revising the language of Item 48 of the June 25, 1999 Attachment B6, Table B6-5. At a minimum, the word “project-” within the parentheses could be replaced with the words “data generation-.” Additional clarification might be provided by adding the words “ensure that the” at the beginning of the example within the parentheses and the words “have occurred” at the end of the example within the parentheses. Likewise, clarification of Item 52 could be accomplished by adding the words “results of the data generation-level” before the word “videotape.”

Section 5.2.6 Visual Examination

29. The audit report provides brief statements regarding how the RFETS visual examination activities were evaluated during the audit, but does not provide any conclusions regarding whether the visual examination activities were found to be in compliance with the WIPP WAP. The audit report should clearly state whether or not the visual examination activities at the RFETS were found to be in compliance with the WIPP WAP. The audit report should also include attachments which contain copies of all relevant portions and pages of all documents reviewed to obtain objective evidence of compliance with the WIPP WAP.
30. Issue Response; Table B6-6 Checklist

Clarification

Response to Issue, Item 6: DOE apparently believes that the ranges shown in Table B2-1 are not required numbers and that to construe the table as required ranges would mean that population sizes are limited and miscertification rates are prescribed. In response to public comment, NMED updated Table B2-1 in the June 25, 1999 Proposed Final Permit to include additional miscertification rates and additional selections for the annual number of containers undergoing characterization. The Attachment B2, Table B2-1 updates from the Proposed Final Permit have been carried through to the Final Permit. The "numbers" on the table are required by Permit. The use of any other numbers (such as might be calculated for intermediate population sizes) would have to be justified in the auditable record.

Permit Modification

Response to Issue, Items 3, 4 and 5: DOE believes that the miscertification rate is calculated as a site overall rate, not on a waste stream basis, and that calculating the rate on a waste stream basis will not be statistically meaningful because of the sample size. Permit Attachment B2, Section B2-1 of the June 25, 1999 Proposed Final Permit provides clear directions for calculating an initial site-specific miscertification rate, and a waste stream-specific miscertification rate. The Attachment B2, Section B2-1 language from the Proposed Final Permit has been carried through to the Final Permit. If the Permittees desire to delete the Final Permit requirement for calculating a waste stream-specific miscertification rate, the Permittees will need to submit a permit modification request to change the requirements of Permit Attachment B2, Section B2-1.

Response to Issue, Item 26: DOE believes that the inclusion of Item 26 on the Table B6-6 checklist is the result of a typographical error within the original RCRA Part B permit application that was carried through to Permit Attachment B1, Section B1-4 (Chain of Custody) and then to the checklist. The typographical error appears to be in the fifth bullet of Section B1-4 (page B1-26), which states "Description of final waste container disposition, along with signature of individual removing the waste container from custody." DOE indicates that the statement should actually refer to "waste sample"

disposition and custody. Considering that the subject matter for the remainder of Section B1-4 is all related to samples and sample containers, it appears that DOE's argument is valid and the Table B6-6 checklist Item 26 can be modified to refer to sample containers without compromising compliance with the WIPP WAC. However, since the language for checklist Item 26 is based directly on a requirement that is currently in the permit, any change in the permit language and the checklist will require a permit modification.

6.0 Corrective Actions, Observations, and Recommendations

31. The Interim Audit Report does not include a summary section which provides overall conclusions. In addition, while the CARs in the report appear to be satisfactorily discussed, CARs in future reports should include WAP non-compliance issues (i.e. lack of headspace gas sampling requirement for all waste streams, etc.). Deficiencies corrected during the audit (CDAs) should also reference the WAP section that the report(s) or procedures were corrected to address, and CDAs/CARs should be included in appropriate checklist sections.

General Comments Regarding the Audit Checklists

1. The intent of the example of implementation requirement was to ensure that the DOE examined documents, activities, processes, or other elements which demonstrated that the requirement posed in the question were being met (hence the modification of the checklist language to state "objective evidence"). In nearly all instances, the examples of implementation cited must be more specific, citing exact page numbers and section numbers that address the issue at hand. In addition, the comments column or Example of Implementation column should include a more detailed presentation of the item examined, including, for example, specific waste stream examined, drum(s) data examined, etc. Data summaries/conclusions should also be included. Alternatively, the cover page for each document examined as part of the example of implementation, along with the specific page(s) that address the issue, should be attached to the report so that NMED can quickly confirm the example of implementation. Copies of entire documents are not acceptable except in instances where almost all of the document is cited, in various locations, as evidence of implementation.
2. Copies of procedures examined must be provided in their entirety, and must be of the same revision number examined and approved in the audit. References to procedures should be specific and include detailed section number references and (if possible) page numbers so that the exact location of the element in question can be located easily within the procedure.

Checklist B6-1

Checklist B6-1, Items 1-4: It is unclear whether RMRS-98-100, R3 includes specific waste stream information to assess whether a given waste stream is appropriately defined, including sufficient background information regarding waste stream definition. Cite the specific section(s)/page numbers of the referenced report examined. In all instances, the Example of Implementation

section should specify an example waste stream or report section which, upon examination, would demonstrate that the checklist question has been appropriately addressed. For example, Item 3 should cite an example, if possible, of a waste stream that had to be redefined as newly generated because the acceptable knowledge information did not meet the requirements of Attachment B-4.

Checklist B6-1, Items 4-8: While the Examples of Implementation sometimes reference batch reports or WSPFs, the checklist should specify sections within reports examined and the specific results of that examination (i.e. examined WSPF XXX, Section YYY, and determined that waste stream ZZZ was identified as AAA). Alternatively, this information could be attached to the report so that quick examination of the evidence can be made. With respect to Item 8, cite the specific waste stream(s) examined and codes identified.

Checklist B6-1, Item 9: The Example of Implementation should include sufficient background information to allow determination of whether the summary waste category groups had been appropriately identified. It is unclear whether the cited documents would include sufficient information to make this demonstration.

Checklist B6-1, Item 11: The Example of Implementation should include information examined which show that the incompatible materials are segregated, including report(s) that identify the incompatibility and records which demonstrate that this segregation has taken place.

Checklist B6-1, Item 12: Indicate, on the checklist, the type of ventilation filters observed; it is also advisable to examine more than one drum for evidence of implementation. (Also applies to Item 15).

Checklist B6-1, Item 14: Provide the page numbers for each batch report which serve as evidence that the batches are appropriately grouped; also provide additional information regarding batch samples.

Checklist B6-1, Item 15: For ease of review, drums could correspond to waste stream profile forms, etc., examined for different checklist items or checklist elements (i.e. carry a drum through each checklist to examine headspace gas information for that drum, RTR data, etc.). In this fashion, NMED could examine drums from a given waste stream to understand the entire characterization process and could more easily assess whether the waste characterization process had been completely followed.

Checklist B6-1, Items 16 and 25: When specific procedures performed are in conflict with the permit requirements or specific procedures were not performed on all wastes, the checklists should not indicate that the example of implementation was adequate. Instead the checklist should specify the differences/deficiencies and why the elements weren't performed. The checklist must compare the permit WAP with the procedures and activities performed at generator sites, and identify deviations from permit requirements; if permit modifications have been submitted and decisions are pending, this could be cited/detailed within the checklist to clarify apparent permit violation instances, but the violations should not be overlooked.

Checklist B6-1, Item 20: The specific results of the PDP program cycles should be stated in the Example of Implementation, or a summary page/ summary information pertaining to PDP qualification for each cycle should be attached.

Checklist B6-1, Item 21: It is unclear whether the referenced batch reports were examined to assess whether analytical QAOs were met, or to determine whether the reports were examined to determine if laboratory -documented SOPs were referenced. Be sure that the specific elements examined in referenced examples are clearly distinguished. Again, include applicable page numbers/sections examined.

Checklist B6-1, Item 22: Cite the results of the WEMS review; does the worksheet show the types/concentrations of VOCs in headspace gas and does it include an AK comparison and reassignment? If the worksheet does not cover all elements, examination of additional information could have been warranted.

Checklist B6-1, Item 26: Specify the solid analysis data evaluation reports examined, including page numbers, and summarize report information (i.e. what was found which demonstrates compliance).

Checklist B6-1, Items 27- 29: When citing the results of other audits, ensure that these audit reports are provided as reference. These reports should provide adequate information for the NMED to determine whether the previously performed audits were of sufficient scope and detail to demonstrate that the checklist condition was adequately assessed. All acronyms should be clarified, and all reports, letters, or memos should be adequately referenced in detail (i.e. dates of memos, references/page numbers/section numbers for the reports). The comment that HSG sampling/VOC/SVOC solid sampling are not required for salt residues is not consistent with the permit and should not be included in the checklist as worded; there is, to date, no permit modification request submitted otherwise, and this type of permit non-compliance cannot be overlooked.

Checklist B6-1, Items 30, 31, 39, 44, 45: The referenced material should include evidence that, for a given waste stream, the DQO reconciliation process was examined to ensure that all of the bulleted items presented in Item 30, 31, and (as applicable) 44 were addressed. Also, checklist items should forward reference or cross reference other checklist elements that could include or address general checklist elements (e.g. Checklist B6-1, Item 44 for Items 30/31). With regard to DQO/QAO review, the checklist should include sufficient reference to material which demonstrates, for an example waste/waste stream, that the appropriate reviews and examinations were performed to ensure that DQOs/QAOs were met. This does not mean that "perfect" examples of implementation must be submitted because implementation of appropriate procedures could also catch instances of potential DQO/QAO problems; rather, it is important to demonstrate, through audit, that the process is fully implemented and "works." If the process (i.e. level of review) requires explanation, then the appropriate documentation should be reviewed at that level to ensure that permit objectives were met, and this review should be appropriately referenced.

Checklist B6-1, Items 32, 33, 34, 35, 36, 37, 38, 46: Space restrictions should not limit provision of necessary information. Attach the required information, and/or include copies of *applicable portions* of Level 1 and Level 2 data packages/information which demonstrate that the example containers have undergone complete and thorough Level 1 and Level 2 data validation and the appropriate releases, etc. In the case of Data Validation and confirming appropriate signatory review/release, copies of *applicable portions* of examined material would greatly enhance the demonstration that the site was thoroughly assessed with regard to its Level 1 and Level 2 data validation, reported, and other related requirements. Items 34-37 indicate that several containers were examined; the report should either provide detailed discussion of a few representative report contents which show that the appropriate raw data collection/management occurred as cited in the checklist item, or selected, representative copies of pertinent information should be attached to the audit report.

Checklist B6-1, Items 40, 41, 42: Provide a more detailed reference (i.e. section/page or other appropriate designator) which demonstrates that the one container/quarter repeat data review process is performed. Attachment of a copy of *appropriate sections* of such evidence would be helpful.

Checklist B6-1, Items 48, 49, 50: Examples of the pre-approved format would be helpful. Additionally, items reviewed should be more thoroughly referenced, with statements as to why the example of implementation was sufficient in terms of the elements examined; alternatively, attach *appropriate examples* of report pages, etc., which show that site reports have, for example, the appropriate table of contents with respect to contents required in the QAPjP, etc.

Checklist B6-1, Item 51, 52: This would be an ideal place to test whether the sites can respond to requests for information. The auditor should have tested the site's data transmission abilities, be it hard or electronic copy, for a representative data request. Subsequent references in the checklist to Section B-4a(5) are incorrect; these should refer to Section B-4a(6).

Checklist B6-1, Item 53, 54: Examples of manual entry tables, tests, supervisory reviews (e.g. the WIPP Characterization and Certification Report, Waste Container Data Report and Waste Container Data Report--Approved by WIPP), and other pertinent WWIS documentation should have been referenced, including the specific containers observed during transmission.

Checklist B6-1, Items 55, 56: Waste stream summary reports must be submitted to the Permittees. Transmission of information more detailed than that included within the waste stream summary report will be done as requested by the Permittees. Additionally, although some elements were deleted from section B-4a(5), the same elements are actually included in B-4a(6); the final checklist, which will be used for the site audits, should have reconciled this problem.

Checklist B6-1, Item 57: Refer to response to comments.

Checklist B6-1, Item 58: The purpose of this checklist is to assess WAP compliance, not CAO-requirement compliance. The WAP *clearly* requires reconciliation and reporting of non-conformances, and this element should have been identified as a CAR, as the site does not appear to comply with WAP requirements.

Checklist B6-1, Item 59, 60: Refer to section B-4a(6) and revise accordingly. The text was not removed, it was moved.

Checklist B6-1, Item 61: The permit requires an analysis of the sufficiency of waste stream profile form preparation with respect to waste stream summary information; review of the WSPF alone will not demonstrate that this comparison has been performed. Reference any other portions of the checklists that may help satisfy this requirement, but be sure that the checklist includes an examination of summary data and comparison of this data with the WSPF to ensure accurate compilation of the WSPF.

Checklist B6-1, Item 62: The audit of this requirement should have checked to determine whether data was adequately submitted to the Permittees together with accompanying waste characterization documentation, not that the WSPFs were filled out.

Checklist B6-1, Items 63, 64, 67, 69, 70: Specify all records reviewed, including sections/page numbers; cross reference other checklist sections, as appropriate, which may have addressed elements of this requirement.

Checklist B6-1, Item 71: The checklist should specify whether the appropriate document legibility was observed in the documents reviewed, and specific pages/sections of observed evidence should be specified.

Checklist B6-1, Item 75: Refer to response to comments.

Checklist B6-1, Item 76: Hazardous waste manifests should be available when the audit using the WIPP permit checklist is performed.

Checklist B6-1, Item 78: Specify the data observed, including specific containers examined to determine whether the require information is documented by the generator site.

Checklist B6-2

General: The audit report or checklist did not clearly indicate which waste stream IDCs were subject to review during the audit. Checklist responses 3, 5, 9, 38, 39, 59, and 60 in which the auditor observed actual sampling events did not reference the waste container or IDC that was sampled. Also, actual examples of objective evidence, such as copies of reviewed data packages and log sheets, were not included in the audit report.

Checklist B6-2, Item 1: The permit does not exempt solid or soil/gravel VOC and SVOC sample analysis. Appropriate portions of the document TRG-016-99 should be provided as an attachment to the audit report. Based on the auditor response, it is unclear how the referenced document adequately addresses the requirement of Item 1.

Checklist B6-2, Item 3: The audit report should include a copy of the sample calculation memo. In addition, the auditor did not adequately verify or identify adequacy of program or results.

Checklist B6-2, Items 12-18, 20-29, 31-32, and 66-68: Although coring sampling is not yet performed at RFETS, the auditor did not indicate if written procedures are in place to ensure that required elements of the coring sampling procedures are performed and that adequate procedural mechanisms are in place to ensure that core sample collection is performed at the appropriate frequency and manner. Inclusion of this information would facilitate review of future audit reports that would address coring.

Checklist B6-2, Item 19: Exemption of metals from preservation requirements are not contained in the permit. In addition, based on the auditor comment, it appears that mercury was not analyzed for the observed data package. The permit requires analysis for mercury, and this should be identified on the checklist and in the audit report.

Checklist B6-2, Item 34: Inventory control of disposable sampling equipment prevents a scenario in which a sampling crew could potentially reuse a sampling cup. In this respect, availability of spare parts is a quality issue. In addition, the auditor did not indicate if the facility has a parts inventory control system that would ensure an adequate supply of disposable sampling equipment.

Checklist B6-2, Item 36: The auditor did not indicate the presence of a log that documented the daily area inspection.

Checklist B6-2, Item 37: The auditor did not indicate where the balance calibration was documented and when the calibration was performed.

Checklist B6-2, Item 40: The auditor did not indicate what mechanism is used to assign and track sample numbers to ensure that all sample containers are uniquely identified.

Checklist B6-2, Item 41: The reference to sample appearance in bullet number 1 is a reference to the last bulleted item in section B1-4 regarding the documentation on sample tags. The sixth bullet is a clarification of the B1-4 requirement to identify the sample matrix. The requirement for the laboratory identification number on the sample tag is not consistent with the requirements of B1-4. A permit modification could be submitted to clarify this checklist question.

Checklist B6-2, Item 47: The permit does not allow preservation requirement exemptions for metals.

Checklist B6-2, Item 49: Failure to document a requirement for trip blanks associated with VOC samples appears to be a deviation from the permit. The permit does not contain provisions that exempt the collection of trip blanks for VOC samples.

Checklist B6-2, Item 55 and 57: VOC and SVOC Totals analysis of waste is required by permit. In addition, the auditor did not indicate if procedures and mechanisms are in place to meet the requirements of Items 55 and 57.

Checklist B6-2, Item 56 and 58: VOC and SVOC Totals analysis of waste is required by permit. In addition, the auditor did not indicate if procedures and mechanisms are in place to meet the

requirements of Item 56 and 58. The section citation in the checklist question could be modified to also cite Section B3-1.

Checklist B6-2, Items 60-63: QAOs are more appropriately evaluated at the project level. Individual data packages would only contain QAO data for that data package.

Checklist B6-2, Item 65: The audit report should include a copy of the referenced memorandum. In addition, the auditor did not indicate if the facility had a mechanism such as a tracking database to ensure that field duplicates were collected at the appropriate frequency.

Checklist B6-3

Checklist B6-3, Item 1: The required documentation listing is much more thorough than the brief listing provided in the checklist, and includes numerous background or other documents that support any summary documents. Ensure that the checklist includes a thorough listing of all applicable documents.

Checklist B6-3, Item 2: It is unclear whether the referenced documents actually demonstrate whether the logical sequence of information is presented; ensure that all such listings include all necessary information and that no documents or linkages are excluded.

Checklist B6-3, Items 3, 4, 6, 7, 9, 10, 20, 23, 36: All procedures and examples of implementation referenced should include detailed section and page numbers to facilitate checklist review. It also appears unlikely that the few procedures and documents listed in this checklist item 3 are sufficient to ensure that CAO has performed a thorough analysis of the requisite procedures. Also, the intent of the examples of implementation requirement is to ensure that audits examine actual data, samples, etc., which show that when procedures are implemented, the appropriate answer is achieved. Ensure that, whenever possible, actual acceptable knowledge data and information, including data sources referenced in any acceptable knowledge summary reports, are examined during audit and are presented in the checklists. In addition, the checklist should include specific results of the example of implementation analysis on a container and/or waste stream basis (whichever is appropriate); alternatively, specific, applicable pages of documents examined which support the AK question could be provided on a container/waste stream basis.

Checklist B6-3, Item 5: While headspace gas confirmation of acceptable knowledge will be performed, this checklist item also includes requirements for initial RCRA hazardous waste code assignments and waste stream assignments performed during initial waste stream identification via acceptable knowledge. Also, example waste stream information, including supporting information, should be included to show that waste stream identification and hazardous waste code assignment is appropriately performed.

Checklist B6-3, Item 8: The example of implementation must include a specific, documented example (if available) of how discrepant waste matrix code assignments were recorded and how hazardous waste code changes are recorded. It is not clear whether the referenced example of implementation includes this information.

Checklist B6-3, Item 11: The newly generated designation is most certainly required for those wastes generated after approval of the audit report. While it might not be possible to view an example of implementation because newly generated waste will not be created until after the audit has been approved, this aspect should be indicated in the checklist and procedures should be assessed for acceptability with respect to WAP requirements.

Checklist B6-3, Item 12: It appears that procedures have been identified for each bulleted item in the checklist, but the specific procedure sections which identify the questioned element are not specified, and the example of implementation must be of sufficient detail to identify where specific procedural elements are addressed. In addition the checklist should either include a more detailed discussion of audit results with respect to compliance, or it should attach appropriate sections of referenced documents that specifically address the examples of implementation.

Checklist B6-3, Items 13, 14: The types of supplemental information obtained and assessed by the site should be specified under the example of implementation, and the use of this information in the acceptable knowledge process should be clearly identified and traceable. The checklist should specify the specific supplemental information used to assemble the acceptable knowledge report(s), and should indicate how this information was used in the acceptable knowledge process. Further, the checklist must provide enough information to ensure that the CAO has assessed all supplemental information obtained and has determined whether all of the necessary supplemental information was assembled, and should also indicate whether the CAO has determined, upon audit, if all necessary information was obtained and information that was obtained was appropriately used.

Checklist B6-3, Item 15: The example of implementation must identify discrepant data that were identified and should also show how hazardous waste code assignments were made. Any non-conservative waste code assignments must be identified on audit, and the viability of alternative waste code assignments (i.e. justification for alternative assignments) should be clearly identified and available in the auditable record. This audit process, including all supporting documentation, should be included in the audit checklist.

Checklist B6-3, Item 16: Ensure that all training records for representative individuals are cited as examples of implementation, and that actual training records for individuals are examined to ensure that the appropriate training has been implemented.

Checklist B6-3, Items 17, 18, 19: Any reference to previously performed audits should be more specific and detailed, and should include the specific example of implementation examined during that audit (i.e. AK records examined for a give waste container/waste stream which shows that AK information is appropriately assembled and compiled, and that unacceptable wastes were identified and containers were segregated). The example of implementation should examine specific waste stream(s) for each of these required elements to demonstrate that the AK procedure has been appropriately implemented and that hazardous waste codes are appropriately assigned. This must also include specific confirmation data to ensure that the confirmation process is appropriately performed, including waste stream/container-specific AK confirmation data and auditor's analysis of whether this confirmation process was performed adequately. It would be appropriate to attach example documentation which proves that the complete AK characterization

process was adequately implemented, including any cross reference lists or “computer screens” showing requisite information.

Checklist B6-3, Items 20, 21: Both of these requirements reference visual examination procedures; it would be appropriate to cross reference other portions of the checklist that also deal with visual examination if audits to support these other checklists provide applicable information.

Checklist B6-3, Items 22, 24, 27, 28, 29: Specify the AK discrepancy reports reviewed (including identification of any applicable sections/page numbers) and the general discrepant information identified and resolved. Ensure that the referenced report or other objective evidence ensure that written documentation for each of the visual examination/ radiographic discrepancies is available and was examined during the audit for an example waste stream. Also provide a specific example of the AK confirmation process with respect to headspace gas data and/or sampling data, including how these data were used to confirm the initial acceptable knowledge process. This may be presented in different documents and may be confirmed upon interview; if interviews are used as part of the audit process, documentation of interviews should be included in the audit report. Specify any “reassessment memos” examined, and discuss, in the checklist, what these memos revealed with respect to compliance. Alternatively, attach appropriate documentation to the audit report.

Checklist B6-3, Item 30: The checklist item references “various building books”, but should specify those books examined and the specific section/page numbers examined for example waste streams.

Checklist B6-3, Items 31, 32, 34: Examination of WSPFs will not show whether the specific mean concentrations are appropriately calculated, whether the UCL 90 is appropriately determined, and whether elevated MDLs are handled appropriately. Section B4 requires that appropriate procedures be in place to assess these and other related requirements, and the checklist should reflect the auditor’s examination of appropriate procedures and specific examples of implementation (i.e. data) to determine checklist compliance. If this examination was done under a different checklist requirement, this process should be cross referenced at the B6-3 checklist location.

Checklist B6-3, Item 35: Accuracy, completeness, comparability, and representativeness of AK information should be audited by CAO; procedures to assess these elements should be examined, and AK data examined to determine whether these QA elements have been met. The checklist must specify all data examined to this end (including any detailed data reports, etc., referenced in any general AK documentation), and the checklist should indicate how and whether the QA elements have been addressed.

Checklist B6-3, Items 39, 40: The results of all AK data traceability analysis should be completely documented on the checklist(s), including all data sources examined to perform the traceability analysis for waste streams from each waste summary category group. Each data source should be specified on the checklist with the information obtained from that data source. Alternatively, the specific traceability analysis performed (i.e. for container XX in waste stream YY of Summary

Category Group ZZ) should be discussed in terms of what was performed, and then *applicable* pages of documents examined as part of the analysis should be attached to the report so that the NMED can clearly follow the AK knowledge data process from assembly through confirmation. In terms of reviewing all procedures necessary to assess the AK process (item 40), this should be done in conjunction with the traceability analysis (batch reports referenced in this checklist element may also suffice for element 39). Item 41 should be reported in the body of the audit report, as should checklist item 42.

Checklist B6-3, Item 46: The checklist should indicate whether any containers were identified as having unresolved discrepancies, and that the appropriate documentation is in place to ensure that these containers will not be shipped to WIPP until the discrepancies are resolved. Example containers with discrepancies should be identified.

Checklist B6-3, Item 48: The checklist should more completely address the toluene issue by specifying what arose and how this was resolved (this can be summarized in the checklist); the associated supporting documentation should be attached to the checklist.

Checklist B6-3, Item 49: Review of the WSPF by the auditors does not show that the site has performed the requisite review of the WSPF. This review should be required by procedure, and performance of the required review, including review results, should be appropriately documented.

Checklist B6-4

General: Checklist responses 5, 8, 9, 10, and 22, in which the auditor observed actual sampling events, did not reference the waste container or IDC that was sampled.

Checklist B6-4, Item 1: The permit does not exempt any waste from headspace gas sampling. In addition, the contention that ensuring headspace gas results for all containers is best controlled by the QAPjP is incomplete. Section B3-11 indicates that the Site Project Manager must verify the number of samples collected for headspace gas and Section B3-12 indicates that headspace gas sampling results must be reported for all drums, so other procedures should include this requirement.

Checklist B6-4, Item 2: There is no evidence that the audit included verification that the drum age criteria or temperature equilibrium criteria were met. In addition, it is unclear if the data packages reviewed to obtain this information were referenced. Also, the checklist comments section indicated that the equilibrium time can be adjusted for short shipments outside the temperature range. A permit modification is required for this allowance which clearly states the purpose of this exemption and provides justification for the exemption.

Checklist B6-4, Item 4: Provide more specific information to document the source of the objective evidence for the sample container volume and the holding temperature. For example, auditors should specify that the information was contained in the chain-of-custody records and the storage temperature logs for the data packages referenced.

Checklist B6-4, Item 7: It is unclear how verification of the type of sampling canister or sampling system can be adequately verified through review of data packages. This information appears to be more appropriately verified through observation of a sampling event.

Checklist B6-4, Item 8: In addition to not providing the observed drum identification number, it is unclear if the Building 776 log book documents the verification of the manifold evacuation, field blank collection, and calculated headspace volume for each sampling event.

Checklist B6-4, Item 9: Identify specific documents within the files for canister batches 563, 564, and 565 that would contain gauge leak check records and OVA measurements/ calibration records.

Checklist B6-4, Item 10: The standards identification number associated with the certificates of analysis should be identified as part of the verification process. Reference the documentation that demonstrates the purity of the humidifier water, and attach appropriate pages.

Checklist B6-4, Item 11: Indicate the observed measurement ranges and resolution of the pressure/vacuum gauges.

Checklist B6-4, Item 12: Indicate the document or evidence that was reviewed to verify temperature sensor calibration results (calibration sticker or log) and indicate the date of calibration.

Checklist B6-4, Item 14: The comment section or the report section 5.2.4 should describe the sampling procedure in more detail. If the procedure deviates from the method specified in the permit (as it appears to), then a permit modification would be required. In particular, the modification should indicate the processes that were used to ensure that sampling equipment is not contaminated and that a representative sample can be collected. The modification should also provide the appropriate justification for the use of the alternate method.

Checklist B6-4, Item 17: Identify specific documents or page numbers within the data packages that document the adequate collection of field QC samples (and/or attach these pages). In addition, the auditor should have determined if there is a programmatic mechanism to ensure that the field QC samples will be collected at the proper frequency. Verification through a small sampling of data packages only ensures that the frequency was met for those data packages.

Checklist B6-4, Item 18: Specify what information within the data package was reviewed to ensure that the site project QA officer reviewed field QC results and found the results to meet acceptance criteria.

Checklist B6-4, Item 20: Identify specific documents or page numbers with the data packages that indicate that field duplicates were collected in a representative manner. It appears that this question is more adequately addressed through the observation of a sampling event and an inspection of the sample manifold system to determine how duplicate samples are collected. In addition, the auditor should have determined if there is a programmatic mechanism to ensure that

the field QC samples will be collected at the proper frequency. Verification through a small sampling of data packages only ensures that the frequency was met for those data packages.

Checklist B6-4, Item 22: In addition to not indicating the waste containers that were observed during the sampling event, it appears that the auditor did not observe logbooks or lab sheets that documented leak checks, canister cleaning records (equipment blank results, cleaning certification, and cleaning logs), field blank results, and canister evacuation records.

Checklist B6-4, Item 23: The auditor did not indicate how PID verification is equivalent to manifold heating. For example, there was no indication as to the detection limit of the PID to ensure that the instrument is sensitive enough to verify manifold cleanliness. The author also did not indicate how maintaining the manifold at a vacuum is equivalent to maintenance at a positive pressure.

Checklist B6-4, Item 24: Indicate the dates of calibration and identification for each sensor or gauge reviewed.

Checklist B6-4, Item 25: Indicate what data packages were reviewed in conjunction with verification of the custody information.

Checklist B6-4, Item 31: The auditor should have examined the laboratory log in forms and procedures to verify that documentation is available to identify problems with samples upon receipt at the laboratory.

Checklist B6-4, Item 32: The response should more clearly identify where and how records are stored.

Checklist B6-4, Item 33: Indicate what documents or pages within the data packages were reviewed to verify that sample custody was appropriately maintained.

Checklist B6-4, Item 39: The response to this question should be more descriptive to include the following types of information:

- Indication of precision and accuracy results and a statement positively indicating that all criteria were met
- Indication of the range of MDLs and a statement positively indicating that all criteria were met
- Indication that blank results were reviewed and found to be acceptable

Checklist B6-4, Item 40: The auditor should have been able to produce some type of documentation that the laboratory has participated in and passed the PDP program. The procedure would be for laboratory selection to ensure that prior to shipment or delivery there is evidence that the laboratory is in compliance with the PDP requirements.

Checklist B6-4, Item 41: The auditor needs to provide more detail to describe how the TIC criteria were met and what mechanisms are in place to ensure that TICS are properly identified

and reported. Examination of a small sample of data packages only provides evidence that those data packages complied with the TIC criteria. Examples of additional detail would include:

- Indicating that sample results in the data packages were reviewed to determine if TICS were found
- If TICs were found, what steps were taken to evaluate the impact of the TIC on reporting requirements
- What mechanisms are in place to track TICs found for a particular waste stream.

Checklist B6-4, Item 42: The permit clearly specifies that all drums require headspace gas sampling. The stated exception for molten salts should have been identified as a deficiency in the body of the report. In addition, the permit does not allow sampling under the rigid polyliner, only in the headspace of a drum in which the polyliner has been vented. The report and checklist did not provide adequate documentation or justification for a determination that adequacy had been achieved for the sampling frequency and sampling procedures used by RFETS. The permit does not include provisions that allow for a determination of adequacy in lieu of performing headspace gas sampling on all containers or for sampling under the polyliner in the event the liner is not vented. Therefore, the deviations identified in this checklist question should have been subject to appropriate corrective action.

Checklist B6-4, Item 43: Indicate where in the data package this information is contained. In addition, the auditor did not address the programmatic mechanisms that would ensure that the field duplicate frequency requirements are maintained (e.g., sample tracking logs).

Checklist B6-4, Item 44: Data packages are not the appropriate example of implementation for this checklist question, unless duplicate RPD were exceeded in the data packages examined. If none were exceeded, the auditor would have no way of determining if appropriate corrective actions are available. Alternately, the auditor should have examined corrective action reporting systems to determine if RPDs have been exceeded in the past and what action was taken to alleviate the condition adverse to quality.

Checklist B6-4, Item 45: Indicate where, in the data package, this information is contained. In addition, the auditor did not address the programmatic mechanisms that would ensure that the field reference standards and field blank frequency requirements are maintained (e.g., sample tracking logs).

Checklist B6-4, Item 46: Data packages are not the appropriate example of implementation for this checklist question, unless reference standard or blank results were outside of acceptance criteria in the data packages examined. If none were exceeded, the auditor would have no way of determining if appropriate corrective actions are available. Alternately, the auditor should have examined corrective action reporting systems to determine if blank or reference standard criteria have been exceeded in the past and what action was taken to alleviate the condition adverse to quality.

Checklist B6-4, Items 47, 48, 49, 50, and 51: All of these questions pertain to waste stream level determinations that cannot be appropriately made at the data package level. It seems unlikely that

the auditor could have made an appropriate determination of waste stream completeness, comparability, and representativeness based on a review of a small set of data packages. The auditor should instead evaluate the mechanisms that are in place at the project level to verify QAOs for a waste stream and take any appropriate actions in the event QAOs are not met.

Checklist B6-5

General: For a number of the Table B6-5 Radiography Checklist items, the checklist indicates that various batch reports or batch data reports were reviewed to obtain the objective evidence of implementation of a requirement. This very general reference to the review of batch data reports does not provide enough information to allow a reviewer of the audit report to easily verify the audit results. The information provided in the checklist should be specific enough to allow the reviewer of the audit report to locate the objective evidence within the attachments to the audit report. The audit report checklist should reference the specific batch data report sections, documents, forms, etc. where the information verifying the implementation of the checklist item was found. If the form or document included in the batch data report has a specific area where a yes/no answer is required, or specific information is to be entered, then this should be identified in the checklist. For example, the checklist should state “The such and such box of Form XYZ was reviewed to determine whether the container was checked for the presence of a lead liner and a lead liner was not found to be present.” This general comment applies to Item Nos. 2, 4, 5, 6, 11, 12, 13, 14, 32, 34, 35, 36, 38, 39, 43, 47, 48, 50, and 52 of the Table B6-5 Radiography Checklist.

Checklist B6-5, Items 4 and 11: The item reviewed column of the checklist indicates that batch data reports were reviewed and operations were observed to obtain objective evidence of the implementation of these requirements. The checklist should specify whether any of the batch reports reviewed or operations observed included a container(s) with a lead liner, which would have allowed actual verification of the implementation of the requirement.

Checklist B6-5, Items 5, 14 and 15: The item reviewed column of the checklist indicates that batch data reports were reviewed to obtain objective evidence of the implementation of these requirements. The audit checklist should specify whether or not any of the batch reports reviewed included the discrepancies described in the checklist.

Checklist B6-5, Item 6: The item reviewed column of the checklist indicates that batch data reports were reviewed to obtain objective evidence of the implementation of this requirement. The checklist should identify the specific part the part of the batch data reports where the training of the radiography operators is documented. Alternatively, state that the names of the radiography operators identified in each batch data report were compared to a list of trained operators to obtain objective evidence of this requirement.

Checklist B6-5, Item 8: The item reviewed column of the checklist indicates that the RTR Units in Buildings 569 and 664 were inspected to obtain objective evidence of the implementation of this requirement. The audit report should include (as an attachment) an example of the documentation (i.e., audit log book page) that shows what equipment was inspected.

Checklist B6-5, Item 9: The item reviewed column of the checklist indicates that the RTR Units in Buildings 569 and 664 were inspected to obtain objective evidence of the implementation of this requirement. The checklist should clearly indicate whether the observations included radiography operations for high-density material and/or low density material.

Checklist B6-5, Item 16: The objective evidence of implementation of this requirement should have been supplemented by a review of the batch data reports to ensure that the names of the radiography operators identified in each batch data report were compared to a list of trained operators to verify the requirement was met.

Checklist B6-5, Items 18, 19, 20, 21 and 27: The item reviewed column of the checklist indicates that operator training records were reviewed to obtain objective evidence of the implementation of these requirements. The checklist should specify the particular part of the operator training records that contained the objective evidence and identifies how many records were reviewed during the audit.

Checklist B6-5, Item 21: The item reviewed column of the checklist indicates that the training course material was reviewed to obtain objective evidence of the implementation of this requirement. The checklist should describe the level of detail for the course material review (e.g., did the review include only a check of the table of contents for the training, or was the accuracy and appropriateness of the training material reviewed)

Checklist B6-5, Item 22: The item reviewed column of the checklist indicates that observation of a tape of the training drum was observed to obtain objective evidence of the implementation of this requirement. The checklist should identify the training drum and training drum tape that were observed.

Checklist B6-5, Items 24 and 25: The item reviewed column of the checklist indicates that observation of the items in the training drum was observed to obtain objective evidence of the implementation of this requirement. The checklist should identify the training drum observed and provide a statement that the test drum was representative of the waste matrix code(s) for which waste stream profile form approval is sought.

Checklist B6-5, Items 26 and 30: The item reviewed column of the checklist indicates that the training course material was reviewed to obtain objective evidence of the implementation of these requirements. However, an individual's training records should also include information to verify this requirement and this information should have been reviewed during the audit and documented on the checklist. The audit checklist should also include a statement of whether an individual's performance was determined to be unsatisfactory and, if so, was the individual disqualified until they could be retrained.

Checklist B6-5, Item 31: The item reviewed column of the checklist indicates that the RTR logs for Buildings 664 and 569 were reviewed to obtain objective evidence of the implementation of this requirement. The checklist should describe how the RTR logs provide evidence that the videotape of the training drum scan was reviewed by a supervisor to ensure that the operator's interpretations remain constant and accurate. In addition, an individual's training record should

include information to verify that this requirement has been met and these records should be reviewed during the audit.

Checklist B6-5, Item 40: The item reviewed column of the checklist indicates that RTR visual feedback file was reviewed to obtain objective evidence of the implementation of this requirement. The checklist should specify the particular part, or how much, of the RTR visual feedback file was reviewed during the audit.

Checklist B6-5, Items 41, 42, 43 and 44: The item reviewed column of the checklist indicates that operating log books for buildings 664 and 569 were reviewed to obtain objective evidence of the implementation of these requirements. The checklist should document the operating log book time frames (or page numbers) and specify whether the review consisted of a spot check of equipment maintenance and testing requirements or a very detailed check of all of the requirements.

Checklist B6-5, Item 51: The item reviewed column of the checklist indicates that batch data reports were reviewed to obtain objective evidence of the implementation of this requirement. The verification that all electronic and video data are stored appropriately to ensure that the data is readily retrievable would be better verified by observing the operation of the storage and retrieval system. Ensure that the checklist includes a description of the activities conducted to verify the appropriateness of the data storage and retrieval operations.

Checklist B6-6

General: For a number of the Table B6-6 Visual Examination Checklist items, the checklist indicates that various batch data reports, RTR visual feedback files, and sample selection reports were reviewed to obtain the objective evidence of implementation of a requirement. This very general reference to the review of reports and files does not provide enough information to allow a reviewer of the audit report to easily verify the audit results. The information provided in the checklist should be specific enough to allow the reviewer of the audit report to locate the objective evidence within the attachments to the audit report. The audit report checklist should reference the specific files or report sections, documents, forms, etc., where the information verifying the implementation of the checklist item was found. If the form or document included in the reports or files has a specific area where a yes/no answer is required, or specific information is to be entered, then this should be identified in the checklist. For example, the checklist should state, "The such and such box of Form XYZ was reviewed to determine whether the container was checked for the absence of prohibited items and that prohibited items were not found." This general comment applies to Item Nos. 2, 3, 5, 6, 7, 8, 11, 18, 19, 21, 22, 24, 25, 28 and 29 of the Table B6-6 Visual Examination Checklist.

Checklist B6-6, Item 1: The item reviewed column of the checklist indicates that video of visual examinations was observed to obtain objective evidence of the implementation of this requirement. The checklist should identify the actual video, including the specific time sections of the video, that was observed and the containers that were undergoing visual examination in the video. In addition, the auditor did not indicate what mechanisms are in place to ensure that the correct number of randomly selected drums are subject to visual examination.

Checklist B6-6, Item 2: The item reviewed column of the checklist indicates that batch data reports were reviewed to obtain objective evidence of the implementation of this requirement. The checklist should specify whether any prohibited items were found in any of the containers covered by the batch reports reviewed.

Checklist B6-6, Items 3 and 5: The item reviewed column of the checklist indicates that RTR visual feedback files were reviewed to obtain objective evidence of the implementation of these requirements. The checklist should specify how the RTR file information provides evidence regarding the role of visual examination data in calculating the miscertification rate.

Checklist B6-6, Item 4: See the evaluation of the Table B6-6, Items 3, 4 and 5 Issue. In addition, the audit checklist refers to a 2% initial miscertification rate. This rate has been changed to 11% in the permit.

Checklist B6-6, Item 5: Note that the language in Item 5 has been completely revised in response to revised language in the Final Permit and that a new checklist item will be inserted after Item 5.

Checklist B6-6, Item 6: See the evaluation of the Table B6-6, Item 6 Issue.

Checklist B6-6, Items 12, 13, 14, and 15: The item reviewed column of the checklist indicates that the training course material was reviewed to obtain objective evidence of the implementation of these requirements. The checklist should describe the level of detail for the course material review (e.g., did the review include only a check of the table of contents for the training, or was the accuracy and appropriateness of the training material reviewed).

Checklist B6-6, Item 14: The item reviewed column of the checklist indicates that the training matrix and training course material was reviewed to obtain objective evidence of the implementation of this requirement. However, an individual's training records should also include information to verify this requirement and this information should have been reviewed during the audit and documented on the checklist.

Checklist B6-6, Item 16: The item reviewed column of the checklist indicates that operator training records were reviewed to obtain objective evidence of the implementation of this requirement. The checklist should specify the particular part of the operator training records that contained the objective evidence.

Checklist B6-6, Item 17: The item reviewed column of the checklist indicates that this requirement was verified by an adequacy review of the QAPjP. The checklist should describe the standard or criteria that was used to verify the adequacy of the QAPjP requirements for the visual examination expert.

Checklist B6-6, Item 18: The comments section of the checklist states that the decisions documented on the cited batch reports are correct. The checklist should provide an explanation for why the auditor concluded that the decisions documented in the batch reports are correct.

Checklist B6-6, Item 20: The item reviewed column of the checklist indicates that the requirement was verified by observation of tapes. The checklist should identify the actual tapes, including what portion of the tapes, that were observed and the containers that were undergoing visual examination in the tapes.

Checklist B6-6, Items 22 and 25: The item reviewed column of the checklist indicates that batch data reports were reviewed to obtain objective evidence of the implementation of these requirements. The checklist should specify whether or not any of the containers covered within the batch data reports reviewed included bags that were not opened. In addition, the auditor did not indicate if the historical weight tables were reviewed.

Checklist B6-6, Item 23: The item reviewed column of the checklist indicates that the requirement was verified by observation of tapes for "Visual Exam FY99". The checklist should identify what portion of the Visual Exam FY99 tapes were observed during the audit.

Checklist B6-6, Item 25: The item reviewed column of the checklist indicates that the requirement was verified through a review of the batch data reports. The checklist should clearly indicate where these criteria are identified in the package or indicate what mechanism or documentation is used to ensure that the criteria were applied.

Checklist B6-6, Item 27: The item reviewed column of the checklist indicates that the requirement was verified by observation of VE operations. The checklist should identify the specific visual examination operations that were observed during the audit, including which waste stream and which containers were undergoing visual examination during the audit observations.

Checklist B6-6, Item 29: The item reviewed column of the checklist indicates that batch data reports were reviewed to obtain objective evidence of the implementation of this requirement. The checklist should specify whether or not liquids were found in any of the containers covered by the batch reports reviewed.