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December 12, 1994

Mr. George Dials, Manager
U. S. DOE Carlsbad Area Office
P. O. Box 3090
Carlsbad, NM 88221-3090

Dear Mr. Dials:

RE: NMED Comments on TRU Waste Characterization Quality Assurance Program Plan (QAPP), Revision B, July 8, 1994

Thank you for the opportunity to review the Draft TRU Waste Characterization QAPP (CAO-94-1010). Enclosed are our comments for your consideration.

This QAPP contains many components which the NMED considers relevant to waste characterization and would therefore need to be included in the application for disposal of TRU mixed wastes at the WIPP site. NMED believes the QAPP should be a stand-alone document which provides the direction and framework to develop Quality Assurance Project Plans (QAPjP) at each TRU mixed waste generator site. These QAPjPs must meet all the characterization criteria established and incorporated under the QAPP which satisfies NMED's waste analysis plan requirements in the RCRA permit.

While this QAPP covers many of the required elements, it also contains such differing levels of detail that portions could be considered a QAPjP rather than a broader QAPP. We have identified those comments which might be deemed "detailed" for a QAPP by an asterisk (*), and have retained them for your consideration. Some of these detailed comments may be more useful when applied to other documents which we did not review. However, NMED believes a sufficiently detailed QAPP will enhance our ability to adequately evaluate your Waste Analysis Plan

and other components of your RCRA Part B Application during the technical review phase.

If you need further information on this issue, please contact Mr. Steve Zappe of my staff at (505) 827-4308.

Sincerely,

Benito J. Garcia, Bureau Chief
Hazardous and Radioactive Materials Bureau

cc w/enclosure:

Mark Matthews, NTPO/CAO
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Larry Weinstock, EPA/ORIA
David Neleigh, EPA Region 6
Barbara Hoditschek, HRMB
Steve Zappe, HRMB
File: WIPP Red '94

GENERAL COMMENTS

1. The Quality Assurance Program Plan (QAPP) should be revised to include additional information regarding Quality Assurance (QA) objectives (see bulleted items below). Also, Section 1.0 of the QAPP is somewhat confusing and poorly organized, and is missing important program information. It is possible that the Quality Assurance Program Description (QAPD) referenced in this document contains some of the missing information, but since the QAPD was not reviewed and the QAPP should be "stand alone" (to the extent possible), the necessary information should be included. The major areas of concern are:

   - There are no "hard" QA objectives for the program presented in the QAPP. Although the QAPP does indicate that information acquired from the sampling will be used to support compliance, the document could more specifically state the facilities that this will apply to, etc. Furthermore, the DQOs should be as quantitative as possible.

   - The QA program organization chart includes only one QA person, and then only at the lowest level on the chart. This is not appropriate, since members of program management should not have QA roles. QA functions should be performed by qualified QA staff, separate from project management to ensure independent and unbiased results. Additionally, approval of a document needs to come from a party independent of the author. All QA documents produced by participating facilities should be reviewed by WIPP QA staff. Clear lines of accountability regarding QA responsibilities also need to be presented.

   - The required analytical parameters for waste entering the WIPP system are not clearly presented or justified in this document. The QAPP does not address analysis for RCRA characteristics other than toxicity (e.g., ignitability, corrosivity, and reactivity), nor does it address analyses relative to land disposal restriction requirements (or why these analyses are not proposed). Also missing is the justification for the selective volatiles and very limited semivolatiles target lists presented within the QAPP.

2. The Quality Assurance Objectives (QAOs) listed in the technical sections of the QAPP require additional clarification and discussion (see Specific Comments on these Sections for additional detail). All QAOs should be as quantitative as possible and in those cases where this is not feasible, a clear independent review system is needed. The basis for all QAOs should be given.

3. The data validation requirements presented in the QAPP require modification (see Specific Comments on Section 3.0 for additional detail). The premise of the QA program is that variability among generator facilities will be addressed through program-wide QAOs, validation of resulting data are key to determining whether QAOs have been met. However, according to the QAPP, validation may not be uniform throughout the program, thus compromising comparability of data between sites. Once the QAOs have been clearly identified, a data validation system must be developed, including specific checklists, for use throughout the program. The validation must be performed and reviewed by qualified QA staff independent of project management.

4. The QAPP relies upon process knowledge for waste characterization in most instances. While the use of process knowledge can be acceptable under RCRA, it must be accompanied by analytical data supporting the process knowledge assumptions. Typically, periodic analyses is performed at the disposal facility to confirm manifest information. Since WIPP intends to conduct no such analyses, the adequacy and consistency of process knowledge information across the DOE spectrum is critical. Additional information regarding the use of process knowledge in this capacity is highly warranted, to ensure that this activity results in accurate and verifiable information. Key to this is the comparison of analytical/visual examination information with process knowledge to confirm that process knowledge is adequate.

5. The QAPP should clearly indicate documentation intended for future generated waste, and specifically how waste characterization information obtained during environmental restoration or decommission/decontamination activities will be used to characterize this waste. Often, detailed characterization information is acquired during the RFI/CMS process which will be critical to establishing the hazardous nature of waste intended for disposal in WIPP.

6. The discussion pertaining to the audit program (Section 2.0) is vague. Specifically, it should be clear that the disposal facility QA representatives from the Carlsbad Area Office (CAO) will be involved with the audits and have responsibilities in accepting/denying waste. Because DOE intends to conduct no confirmatory sampling at WIPP, DOE proposed an audit program as part of its Test Phase Permit Application, which was included in the Draft Test Phase Permit for the WIPP. This audit program ensured that the disposal facility had responsibilities for evaluating characterization procedures at the generator sites, to ensure that adequate characterization data were being obtained. As part of this audit, container integrity should be assessed to ensure that

containers transferred to WIPP can be safely managed from the TRUPACT to the disposal room.

7. The QAPP contains only example forms, although the actual forms are usually required. If the participating facilities are allowed to create their own forms, the forms must be submitted to WIPP QA staff for approval, as part of the site-specific QAPjP. It is strongly recommended that consideration be given to the creation of system-wide forms.

8. The QAPP does not address remote handled waste. Is it the intention of DOE to only permit the WIPP site for contact handled waste? This should be clarified.

9. Several of the sections within the QAPP imply that significant modification of the QAPP could occur without any provisions for Agency approval of these changes. Modifications of critical elements of the QAPP (e.g., removal of headspace gas analysis requirements for all drums) could require modification of the Part B Permit application (or the permit), and subsequent approval by the Agencies (NMED and/or EPA). It is not acceptable to modify some elements of the QAPP by internal approval within the DOE organization without Agency review and approval, particularly if this document is a decision document/permit application submittal or reference, that was submitted and reviewed as part of RCRA compliance documentation.

10. Throughout the QAPP document, statements are made such as the one found on page 19, Section 1.3 which states "to evaluate potential migration of hazardous constituents before closure of the repository." Closure has different meaning to different agencies (e.g., RCRA closure vs. closure relative to performance assessment). Also, evaluation of the potential for migration of hazardous constituents (No Migration Variance) must be complete prior to issuance of a permit by NMED (unless waste treatment prior to disposal is intended), not before closure, although data will be used to demonstrate continued compliance and permit/variance renewal. Please review the QAPP document completely to evaluate such statements.

11. * The QAPP fails to address critical laboratory custody procedures, such as: laboratory custody procedures for sample receiving and log-in; sample storage and numbering, tracking during sample preparation and analysis; and storage of laboratory data. Laboratory custody procedures include:

- Chronological sequence from sample log-in through sample analysis and disposal;

- Detailing log-in procedures (including determining whether samples were properly preserved);
- Identifying the sample custodian;
- Detailing internal sample tracking and numbering systems;
- Detailing transfers of custody within the laboratory;
- Providing examples of internal custody documents (with instructions for completing);
- Specifying how and where samples are stored;
- Specifying how and when samples, extracts and digestates are disposed;
- Specifying how custody of analytical data is maintained; and
- Specifying how analytical data and custody records are "purged" from the custody of the lab to the final evidence file.

SPECIFIC COMMENTS

1.0 PROGRAM MANAGEMENT

1. Section 1.1, Program Organization, pages 6-12, all lines

The overall Quality Assurance (QA) organization presented in the Quality Assurance Program Plan (QAPP) is difficult to understand as it does not clearly indicate who has Quality Assurance responsibilities and at what level. In fact, it appears that multiple approval of the QAPP is required, but discrepancy resolution and "final" approval is not clear. The roles for implementing the QA program and the organizational responsibilities for development of policies and procedures require additional clarification.

The roles and responsibilities of the National TRU Program Office (NTPO) as a day-to-day QA/QC (Quality Control) management organization for the WIPP site are very unclear. It is not clear if a NTPO manager will be located at the WIPP site, whether this manager would function in the role of day-to-day QA manager, and how the NTPO QA manager would interface with the various Carlsbad Area Office (CAO) chiefs. If the NTPO QA manager is not located at the WIPP site, then this role would be even more difficult and complex. In addition, it appears that the NTPO QA manager is responsible for both preparation and review of QA documents, which would require the NTPO QA manager to QA review his/her own work product.

The program organization needs to clearly identify and delineate Quality Assurance responsibilities for all the DOE organizations specified in Section 1.0 and in Figure 1-1. The organization presented in the QAPP indicates numerous review/approvals of the QAPP, but clear lines of authority and responsibility are not adequately defined.

The QAPP lists several organizations within DOE that are responsible for review and approval of the QAPP. However, not all of these organizations are responsible for signing the title page to ensure that they have reviewed the document. Specify why organizations and individuals such as the CAO Experimental Programs Branch Chief, CAO WIPP Site Branch Chief, and the DOE Field Offices are not responsible for also signing the title page to signify complete document approval within the DOE system. In addition, the QAPP should provide a list of key individuals (names and titles) that are responsible for ensuring the collection and validation of data within the QA Program.

2. Section 1.2.3, Document Review, Approval and Control, page 13, line 24

The QAPP states that the generator site shall develop and implement procedures for approving and controlling the QAPjP and SOPs. Procedures for the control, review, and approval of these documents should be specified in the QAPP. A flow diagram presenting the review process should be provided.

3. Section 1.3, Problem Definition and Background, page 17, line 32

On page 17, the QAPP refers to "future-generated" TRU waste. The procedure(s) used to characterize this waste is not clearly specified in the QAPP. Include additional detail within the appropriate portion of the QAPP regarding characterization activities planned for future generated waste, including use of data collected under the remediation (RFI/CMS) process.

4. Section 1.3, Problem Definition and Background, page 18, line 4

The QAPP refers to "knowledge of process" as a method to obtain waste characterization information. The definition of this term is unclear. Also, since there are several sites which will be transporting the waste to WIPP, it is not clear if the term "knowledge of process" is defined in the same way at each of the generator sites. In addition, the use of "process knowledge" to characterize waste which has been in storage at the various sites for a long period of time may be questionable and requires elaboration. Although RCRA allows the use of process knowledge for waste characterization, an initial chemical analyses of a waste stream to determine a "baseline" should be performed. Further, on-site verification of waste (e.g., periodic chemical sampling of accepted waste) at the generator site is typically conducted. Since DOE does not intend to perform on-site analyses and only limited waste analyses at the generator site, verification of process knowledge relative to RCRA waste/ constituents requires significant elaboration within the QAPP.

For example, provide how "knowledge of the process" will be documented. Also include in the QAPP the guidance and training which is provided to site personnel to ensure that each site uses the same "knowledge of process" for consistency of identification. Discuss process knowledge verification procedures using analytical and other examination (e.g., RTR) methods.

In later sections of the QAPP, the term "process knowledge" (Section 5.0) and "knowledge of material process" (Section 5.2) are used. The distinction between these two terms is not clear, nor is whether the terms refer to different or similar process procedures

at the WIPP site or at the waste generating site(s). The use of these various terms imparts confusion.

5. Section 1.3, Problem Definition and Background, pages 18-19, line 27

The use of a 90% confidence limit for Toxicity Characteristic (TC) analysis appears low and is not justified within the QAPP. This is especially critical since DOE has in previous reviews of the RCRA Part B application by NMED, been informed that a 90% UCL was not acceptable and that the use of a 95% upper confidence limit is normally required.

The QAPP indicates that a 90% UCL is sufficient to determine the potential for migration of hazardous constituents from these types of waste, but this is not elaborated upon or justified. Again, the 90% UCL is low and a 95% UCL should be used, unless sufficient justification can be provided.

6. Section 1.3, Problem Definition and Background, page 19, line 12

The QAPP uses the term "hazardous constituents" in several instances in this section, but does not define this term.

7. Section 1.4, Program Description, pages 21-25, Figures 1-3a to 1-3d

The flow diagrams presented in Figures 1-3a to 1-3d do not address visual examination of the waste. Yet, according to the narrative and another flow diagram (Figure 1-4), visual examination is conducted. In addition, these flow diagrams appear to be inconsistent with the information and diagrams presented in Section 5.0. Clarify whether the diagrams in Sections 1.0 and 5.0 are intended to present the same (or different) information. Also include the headspace gas analysis on Figure 1-3c.

8. Section 1.4, Program Description, pages 26-28, Table 1-3

The constituents listed in the summary table are not consistent with those shown in tables presented in Sections 12.0 and 13.0 of the QAPP. For example, formaldehyde and hydrazine listed under "Headspace Gases" are not listed in Table 12-2 in Section 12. In addition, formaldehyde, hydrazine, 1,2,4-trimethylbenzene and 1,3,5-trimethylbenzene are not listed under "Volatile Organic Compounds" in Table 13-1 in Section 13. Pyridene is listed in Table 13-1, but is not presented as a parameter in Table 1-3. The tables presented in the QAPP should be consistent, or differences between the tables clarified.

It does not appear that all constituents specified in 40 CFR 268.6 have been included in Table 1-3. If the waste accepted by WIPP

would be readily expected to contain constituents listed in 40 CFR 268.6, then these constituents should be specified in Table 1-3. Justification for the reduced parameter list presented in this table is required.

9. Section 1.7, Documentation and Records, page 36, lines 20-26

It appears that several program documents have been classified by DOE as non-permanent and are not maintained by the facility through the RCRA post-closure period. Even though RCRA only requires that operating records be maintained for only three years, the period may be extended by the request of the NMED Secretary at any time. Because of the complex nature of waste characterization and management associated with WIPP, it is quite possible that hazardous waste records may be required to be maintained after the post-closure period. Strong justification should be provided regarding why computer-generated data, calibration records, etc. are not considered permanent records. Alternatively, these records should be retained.

2.0 ASSESSMENT AND OVERSIGHT

10. Section 2.1.1, Audits, pages 1-2, lines 26-30, and 10-30

This section specifies that annual audits will be conducted and that an Audit Plan will be developed. Since independent audits are a significant part of the QAPP, the audit process must be more fully developed and included in the QAPP. For example, it is not explicitly clear how or if the Audit Program applies to all of the sites that are sending waste to the WIPP. Auditing of generator sites was required under the draft WIPP Test Phase permit, which has since been remanded back to the NMED. Formal audits performed by DOE/CAO at waste generating sites (INEL, Rocky Flats, Hanford, etc.) will be a necessary procedure and should be incorporated into the QAPP. The CAO must have direct access to, involvement with, and authorization to, deny waste shipment should an audit reveal noncompliance. Further, the role and involvement of the NTPO relative to the CAO manager should be clarified.

11. Section 2.1.2.1, Nonconformance, page 3, line 13 and lines 14-20

The QAPP uses the term "nonconforming waste" but does not provide a definition of the term. Also, disposition of nonconforming waste in accordance with the QAPP requires additional detail.

The QAPP does not address the impact that a nonconformance would have relative to management of this waste. Would further changes be made in the QA procedures for the site which generated and shipped nonconforming waste?

12. Section 2.1.5, Independent Assessments, page 5, lines 23-31

The section infers that additional independent audits will be performed, but goes on to imply that the audits may be performed by organizations within DOE. Clarify the term "independent," and provide additional information as to how these independent audit teams will be selected. Clarify whether individuals on the Audit Team will be truly independent of the DOE organization, or only independent of the site QA program.

13. Section 2.3, Performance Demonstration Program (PDP), pages 6 and 7, lines 28-30 and 1-13

This section references the PDP Plan which, according to the QAPP, includes a detailed description of the requirements of the PDP. Since these sections of the QAPP provided no information on the PDP other than to reference the document, the PDP should be provided for review.

3.0 DATA VALIDATION, USABILITY AND REPORTING

14. Section 3.1, Data Review, Validation and Verification Requirements, page 1, line 12

It is unclear what procedures will be used for reducing data. Procedures for reducing both field and laboratory data should be clearly outlined in the QAPP, and the procedures that may be used to check for errors in reduction should also be provided.

15. Section 3.1.1, Data Generation Level, page 1, lines 23-25

Part of the data review process should include review of the proper sample preservations. It is unclear what "changes to the original data" may be made, as referenced in line 23. Any changes to the data must be justified and the criteria for such changes must be provided.

16. Section 3.1.1, Data Generation Level, page 2, lines 4-6, and 12-13

The QAPP should clearly provide the criteria for the selection of the independent technical review team. Describe how the data will be reviewed if any variances in the methods used are not properly justified. To ensure data comparability, a discussion of the criteria for the approval of any method deviations should be included in the QAPP; would these be considered operational variances?

17. Section 3.1.1, Data Generation Level, page 2, lines 21-22 and page 4, line 1

An outline of the acceptance criteria for radiography data should be provided that will be used to more fully evaluate comparability (see comments, Section 10.0). It is unclear how the review of radiography data against the reported data will ensure that the data are correct and complete, unless the reported data are those acquired through visual examination. Otherwise, this may constitute comparison of records that may reflect RTR operator evaluations with tapes that could still result in correct and incomplete assessment.

18. Section 3.1.1, Data Generation Level, page 2, lines 4-36 and page 3, lines 1-9

Describe what actions may be taken if 100% of the data do not meet the specified criteria.

19. Section 3.1.2, Project Level, page 3, line 19 and lines 26-27

To ensure that a consistent data review is employed for each site, examples of the data review checklist should be included in the QAPP. A discussion of which analyses will include field QC checks should be outlined, and the established Quality Assurance Objectives (QAOs) for field QC samples must be provided in the QAPP. Also, the rate at which field blanks, as applicable, are to be collected should be included in the QAPP.

20. Section 3.1.2, Project Level, page 4, lines 4-18

The QAPP states that a repeat of the review, validation and verification processed will be performed on one waste container from each generator every three months. Clarify if this process will take place regardless of the number of containers submitted by a facility, or whether this number could increase as more drums are submitted. Also, justify why this number will be sufficient.

21. Section 3.2, Data Validation Methods, page 5, lines 6-29

The data validation guidelines provided are very general and do not provide enough specific criteria to verify the validity of either qualitative or quantitative data. The specific data validation procedures to be used for each analyses must be provided or referenced in the QAPP. Include all criteria for the acceptance, rejection or qualification of all data and define qualifiers that may be applied to the data during the validation. Discuss corrective action measures that may be taken on all unusable data.

* The data validation guidelines for field QC samples should also be included in the QAPP. The QAPP should also identify the contents of the data validation package. Discuss what actions will

be taken if all necessary paperwork to perform data validation is not included in the data package. Also, to ensure consistency in the reports between each generator site, the components of the validation checklist should be included in the QAPP.

The specific visual parameters that will be used to validate the radiography data should be included in the QAPP. Clarify herein whether one hundred percent of the radiography data will undergo validation and if so, revise the QAPP to indicate that all containers are visually examined. Finally, the QAPP should discuss how the radiography data will be qualified based on visual parameters (see Comment No. 18).

22. Section 3.2, Data Validation Methods, pages 6-7, all lines

The QAPP must provide the acceptance control limits for field duplicate precision, accuracy and completeness. Discuss how representativeness will be ensured in the field. This may include the analysis and assessment of field duplicates or meeting holding time requirements.

23. Section 3.2.5, Comparability, page 8, lines 5-9

There is an overall concern regarding acquisition of "comparable" data using the information outlined in this QAPP. The text states that "comparability is the degree to which one data set can be compared to another." However, the QAPP does not provide exact analytical methods that each site must use. If each site is able to use a different method, comparison of data sets will then become difficult.

* The QAPP should detail how comparability of field QC checks will be maintained.

24. Section 3.3.1, Reconciliation at the Project Level, page 9, lines 17-18

It is unclear how an average miscertification rate of less than 14 percent was selected (see comments, Section 5.0).

25. Section 3.3.1, Reconciliation at the Project Level, Table 3-1, page 10

Table 3-1 presents the regulatory threshold limit (RTL) values for TC volatile and semi-volatile contaminants. It is unclear why several volatiles and semi-volatiles, while listed in Tables 13-1 and 14-1 and shown in 40 CFR 261.24, Table 1, are not included on Table 3-1. The RTL values for all TC organic compounds are necessary for the characterization of wastes, unless otherwise justified.

26. Section 3.3.2, Reconciliation at the DOE/CAO Level, page 11, line 4

Discuss what actions will be taken if the DOE/CAO has determined that insufficient data has been collected to meet the determinations listed in this section. Also, it is unclear what corrective action measures are to be taken if DQOs are not met. Discuss who will implement corrective action in such cases. While it is true that information acquired during the characterization process will be used to support compliance, much of the necessary information cannot be obtained through waste characterization. Instead, results of experimental programs/ Systems Prioritization (SP) process will presumably dictate many compliance needs, which may or may not be attainable at the site level (e.g., solubility data).

27. Section 3.4.1, Data Generation Level, page 11, lines 30-31

* The QAPP should include examples of the referenced "approved forms," and ensure that each site uses the same form(s). Also, describe the procedures to be used to report compounds detected at concentrations less than reporting limits, or reference where this is discussed in the document.

28. Section 3.4.2, Project Level, page 13, line 16

The text states that the DOE/CAO summary "shall include all of the waste stream information..." To ensure consistent information between each site, an outline of the necessary waste stream information should be provided, if different from that listed in Section 3.3.1.

29. Section 3.4.2, Project Level, page 16, Table 3-2

* The information fields for total VOC data, total semi-volatile data, and total metals data should also include the date prepared and if cleanup was necessary (i.e., yes/no). Also provide field Data Validation (DV) results for all analytes.

4.0 MEASUREMENT AND DATA ACQUISITION

30. Section 4.2, Methods Requirements, page 1, lines 18-21 and 24-25

Clarify how the Methods Manual provides necessary information to this section. The QAPP should clearly identify the "prescribed testing, sampling and analytical techniques" that are to be followed by the generators. Describe the criteria used to determine if supplies/consumables are "critical" to the quality of the data. If this information is included in the Methods Manual, it should be sufficiently detailed within this document to ensure

consistency between sites and waste streams/waste profiles at a given site.

31. Section 4.4, Equipment Testing, Inspection and Maintenance Requirements, page 2, lines 5-15

* The QAPP should outline the acceptance criteria for the testing of equipment and the conditions that will require retesting. A discussion of who is responsible for maintenance activities and how testing and maintenance activities are documented should also be provided. All field equipment should be cleaned, fit for its intended use and properly sealed and stored in a secured location. Preventative maintenance procedures for all field and laboratory equipment should be provided in the QAPP. This information should include the preventative maintenance schedule. Also, define how often "routine" maintenance must take place.

32. Section 4.5, Equipment Calibration and Frequency, page 2, lines 16-28

* The QAPP should provide more detail regarding how the field instruments will be calibrated. For example, the concentrations of all reference standards could be provided. Discuss the frequency that continuing calibrations are performed on field instruments.

Ensure that accuracy and traceability of the calibration standards used are properly documented. Also, include the acceptance criteria for calibration of all field equipment. Discuss what physical reference standards may be used for calibration.

33. Section 4.6, Data Management page 3, line 22

* Examples of the approved forms that will be used for reporting data should be included in the QAPP.

5.0 SAMPLING PROCESS DESIGN

34. Section 5.0, Sampling and Process Design, page 1, lines 6-15

Process knowledge waste characterization procedures are not well described. Characterizing TC wastes requires not only that the presence of certain hazardous constituents be identified but that their concentration levels also be known. It is not clear how process knowledge will accomplish this task for highly variable and non-homogenous wastes, such as debris. In the case of listed wastes, detailed understanding of constituent concentration is not (always) a factor when determining if a waste is hazardous (mixture and derived from rules); however, concentration is important in determining compliance with 40 CFR 268. Process knowledge determination of listed waste contents therefore requires further definition. The QAPP does not provide any information on what

documentation will be used to backup process knowledge determinations and does not describe how such determinations will be quality assured prior to being received at the WIPP disposal facility.

Since no sampling and analysis is proposed for debris waste, it is not clear what contingencies will be used in the event that there is little or no process knowledge available for a particular waste type.

35. Section 5.0, Sampling and Process Design, page 1, line 17

How should wastes that are generated by a particular process or waste stream on a batch basis be grouped for sampling? Should the groupings be selected so as to maximize the number of sampling events? Clearly, the need to sample and analyze wastes could be minimized by making a batch or process waste stream as large or as inclusive as possible. An alternative approach would be to require that a certain percentage of waste containers be sampled, regardless of the number of containers grouped into a particular waste stream or batch. Additional discussion should be provided on procedures to segregate wastes.

36. Section 5.0, Sampling and Process Design, page 1, lines 23-25

The association between "waste streams", "waste matrix codes", and "waste material parameters" (mentioned in Section 1.0) is not clear, although defined somewhat in associated documentation (e.g., Baseline Inventory Report). Since the statistical sampling will be based on segregating wastes into "waste streams," clear, standardized procedures for waste stream identification should be provided so that the data from all DOE sites will be of comparable detail and quality.

37. Section 5.0, Sampling and Process Design, pages 2 and 3, Figure 5-1 and Figure 5-2

The flow charts state that only average concentrations will be reported when determining whether a particular waste stream is RCRA hazardous or non-hazardous. It would be more meaningful if all data were reported so that summary statistics could be evaluated. This information would provide an indication of the variability of the data and the concentration ranges of various hazardous constituents (thereby providing some indication of how well wastes are being segregated into different waste streams).

Without standardized procedures, it is not clear how variability that is associated with a particular waste stream will be differentiated from variability that occurs as a result of improper waste segregation that combines several waste streams together.

This issue is not included in the discussion of a statistical analysis of data from waste sample collection.

Step three of the Figure 5-1 and step four of the Figure 5-2 characterization processes start with assigning waste streams an acceptable, established Waste Matrix Code. It is not clear, therefore, why the last step of the process involves developing a description of each Waste Matrix Code. Since, presumably different waste streams can comprise the same Waste Matrix Code, shouldn't the last step be developing a description of the particular "waste stream" rather than "Waste Matrix Code?"

38. Section 5.2.1, Solid Process Residues and Soils, page 4, lines 29-30

As discussed in Comment No. 26, it is not clear why several toxicity characteristic (TC) volatile and semi-volatile organics are not included in the referenced Tables 13-2 and 14-1. The levels of all TC organics is important to proper characterization of wastes, and the omission of several of these constituents should be specifically discussed and justified.

39. Section 5.2.2, Debris Waste, page 5, lines 6-14

It is not clear how process knowledge will be determined to be adequate to characterize all debris in all instances. Moreover, process knowledge that a particular hazardous waste is present does not always ensure that the waste has been properly characterized. To determine compliance with both the toxicity characteristic (i.e., RCRA "D"-code wastes) and the Land Disposal Restrictions (40 CFR Part 268), the concentration levels of organic and inorganic constituents is typically required.

40. Section 5.3, Sampling Plan, page 5, lines 22-23

The basis for determining that only one waste container needs to be resampled per waste stream per year or per batch for newly-generated wastes is not provided. This would suggest that future waste streams generated on a non-batch basis are expected to be, across the board, highly homogenous. Justification of the sampling frequency should be included to address this issue.

41. Section 5.3, Sampling Plan, page 6, line 4

How will the "quantities of physical waste parameters" be estimated? Clarify what physical parameters are being referred to. Since physical parameters are typically such items as waste form (liquid, solid, gas), color, consistency, etc., it is not clear how these quantities can be estimated. Specific estimation procedures should be provided so that the quality and consistency of these estimates can be validated and compared between different DOE sites shipping wastes to WIPP for disposal. Also, confirmation of waste

streams--which compromise waste matrix codes rather than these codes--must be discussed.

42. Section 5.3, Sampling Plan, page 6, line 9

More detailed procedures should be specified for randomly selecting waste drums from a waste stream for visual and chemical analysis. Random selection does not necessarily mean validation of representativeness will be achieved if the population sampled is not compared for the same waste stream at different DOE facilities. Guidance should be provided to the site project managers, including processes to validate sample representativeness and procedures to document the process.

43. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 6, line 27

The basis for selecting 10 waste containers per waste stream during phase one sampling should be provided.

44. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 7, Figure 5.3

The difference between a waste "population" and a "waste stream" (if any) should be provided for clarity.

45. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 8, lines 1-14

The basis for selecting the UCL_{90}, LCL_{90}, and μ^* = ½RTL should be provided. For large samples, EPA uses a higher confidence limit of UCL_{95}. Justification for using a less conservative approach should be provided. NMED provided commentary on previous Part B Permit applications expressing the need to use a UCL_{95} for sampling of process residues.

46. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 8, equation 5-5

The source of the method used to calculate "n" (number of additional samples required) should be provided, since it deviates from the method included in EPA SW-846 (Chapter 9). Of particular concern is the use of ½ the regulatory threshold (RTL) for μ^*; SW-846 indicates that the calculated mean concentration should be used for μ^*.

47. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 9, line 4

The text states that the final results of the sampling are used to conclude "at the desired level of confidence" whether or not a particular waste stream may be considered hazardous waste. This is

a vague statement. The accepted level of confidence should be definitively stated, and the selection of that level should be justified and the source provided.

48. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 10, line 7

Justification should be provided for selecting ½ the method detection limit (MDL) as the concentration value for those constituents that are not detected during analysis. A more conservative and commonly accepted approach would be to use the MDL value directly.

49. Section 5.3.1, RCRA Characterization of Retrievably Stored Solid Process Residues and Soils, page 10, lines 12-13

The statement that actual error levels and confidence levels may differ from the nominal levels discussed in the QAPP implies that higher error and confidence levels may be apparent that could significantly impact results. Additional clarification is warranted.

50. Section 5.3.2, Visual Examination of Solid Process Residues, Soils, and Debris Waste, page 10, lines 24-27

What are the visible parameters that are to be noted during the visual examination? How will the results of the examination be documented? Since the results of the examination are to be used to calculate an "acceptable confidence" level, these parameters should be consistent and not vulnerable to the subjectivity of a particular inspector. Procedures on the visual examination and documentation required for recordkeeping should be provided to ensure standardization across DOE sites.

51. Section 5.3.2, Visual Examination of Solid Process Residues, Soils, and Debris Waste, page 10, line 28

Additional discussion should be added regarding whether the INEL miscertification rate of 2% is likely to be representative of other DOE sites.

52. Section 5.3.2, Visual Examination of Solid Process Residues, Soils, and Debris Waste, page 11, lines 1-5

It is not clear how often facilities will be required to recalculate their miscertification rates after the first year of program activities.

53. Section 5.3.2, Visual Examination of Solid Process Residues, Soils, and Debris Waste, page 11, lines 6-10 and 19-20, Table 5-1

It is unclear how Table 5-1 and the statement regarding the 14 percent miscertification rate relate to one another. Does this mean that if a hypothetical facility that has a historical miscertification rate of 3% visually confirms 26 out of every 500 drums, then the facility can be only 90 percent confident that ideally up to 86% of the drums are actually properly classified? Justification should be provided for selecting the UCL_{90} and the 14 percent miscertification rate as acceptable levels.

It is unclear how the assumption that 98% of the waste containers were properly characterized in order to perform the calculations to prepare Table 5-1 corresponds with the statement that up to 14% of the containers may be miscertified. Additional clarification and discussion is requested.

54. Section 5.3.2, Visual Examination of Solid Process Residues, Soils, and Debris Waste, page 12, Table 5-1

Figures 5-1 and 5-2 indicate that every container selected for sampling and analysis will also undergo a visual analysis. Table 5-1, however, implies that only a certain percentage of characterized waste containers are to be visually examined for possible miscertification. This discrepancy should be addressed.

Clarify why there are "NA" (Not Applicable) values for certain miscertification rates at the 50 container level. Further, Table 5-1 shows that nearly the same number of drums will be examined for a given miscertification rate; justification for this is required.

The progression of the numbers of containers to be visually examined versus the number of containers undergoing characterization doesn't appear logical. For example, only 29 containers must be visually examined at the 50 container level (6% miscertification rate). As the container level doubles to 100 container level, the visual examination rate rises by eleven to 41 containers requiring visual examination. However, as container level progresses from 200 to 300 to 400, only one additional container requires examination at each subsequent level (i.e., 52 to 53 to 54 containers respectively). Finally, when moving from the 400 to 500 container level, there is a sudden increase of nine additional containers requiring examination (i.e., a move from 54 to 63 containers). Methods to generate the table and example calculations should be provided and discussed in greater detail.

55. Section 5.3.2, Visual Examination of Solid Process Residues, Soils, and Debris Waste, page 13, lines 16-23

The last paragraph of this section is difficult to follow. It implies that a hypergeometric probability distribution, or a binomial distribution, or a normal distribution can be used to determine what proportion of drums ought to be sampled from a given finite population of waste drums. It is not clear how allowing for such variation in statistical methods will ensure that procedures are consistent from one DOE site to another. Guidance on statistical methods should be provided, and instances where variation to the methods are allowed should be identified.

6.0 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

56. Section 6.1, Field Documentation, pages 1 and 2, lines 8-27, and lines 1-18

* Sampling documentation should also include procedures to obtain contaminant-free sample containers, and quality assurance samples collected (e.g., equipment blanks, field blanks, etc.).

57. Section 6.1, Field Documentation, page 2, lines 8-9

The sentence should be revised to indicate that ambient temperature and pressure measurements will be recorded both prior to and following sample collection, as shown in Figure 6-1.

58. Section 6.2, Labelling, page 2

* None of the labelling requirements in this section and its associated subsections specifically require that all label entries be made with permanent ink.

59. Section 6.2.2, Innermost Layer of Confinement, page 3, lines 4-8

Section 6.2.2 describes a numbering system for sampling the innermost layers of confinement. It is not clear where this information is recorded, since example Figure 6-1 does not provide space for noting what inner layer was sampled. This discrepancy should be addressed and additional detail added on documenting samples from inner layers of confinement.

60. Section 6.2.3, Headspace Gas Sample Containers, page 5, lines 1-12

* The text requires that the waste container identification number be identified on the gas sample canister tag. The example tag provided as Figure 6-1 does not include this item. This discrepancy should be addressed.

61. Section 6.2.3, Headspace Gas Sample Containers, page 5, lines 18-20

* The text states that example Figure 6-1 provides space for the analytical laboratory to record canister pressure within 24 hours of validated time of sample receipt and immediately prior to sample preparation or analysis. Figure 6-1, however, provides space for analytical laboratory to note only one measurement, and the timing of that measurement is not specifically identified. This discrepancy should be addressed.

62. Section 6.2.3, Headspace Gas Sample Containers, page 5, lines 21-23

* The text states that example Figure 6-1 provides space for the analytical laboratory to record gas temperature at the time of analysis. Figure 6-1, however, does not provides space for analytical laboratory to note this measurement. This discrepancy should be addressed.

63. Section 6.2.3, Headspace Gas Sample Containers, page 5, lines 18-23

* The sentence beginning on line 19 states that "canisters must be thermally equilibrated to laboratory ambient temperature prior to measurement of their pressure". The sentence beginning on line 22, however, the QAPP (for QAPjPs) must ensure that the SOPs address thermal equilibrium relative to ambient temperature that SOPs may dictate.

64. Section 6.2.4, Solid Process Residues and Soils Sample Containers, page 6, line 17, Figure 6-2

* The text states that the type and number of sample containers must be recorded on the sample label. The example label Figure 6-2, however, does not provide space for recording this information. Clarify that the container identification designator serves this purpose. Also, the sample container label Figure 6-2 includes space for recording the "Sample ID" and the "Sample Container Identification Number." These two identification numbers are not separately discussed in the text of Section 6.2.4, and it is not clear how they differ.

Clarify whether space for a laboratory-specific sample number (which would be assigned by the laboratory upon sample log-in) should be included on the container label. This is an item included on a typical sample label.

65. Section 6.3.2, Sample Containers, pages 8-10, Figure 6-4

EPA SW-846 (Chapter 9) requires that at a minimum, the following items be included on a chain of custody form to properly trace

sample possession from the time of collection to delivery to the analytical laboratory. These items should be incorporated into the text of Sections 6.3.1 and 6.3.2 and the example Figure 6-4:

- Sample number;
- Signature of collector;
- Date and time of collection;
- Place and address of collection;
- Waste type;
- Signature of person involved in the chain of possession;
- Inclusive dates;
- Name of laboratory person receiving the sample;
- Laboratory sample number;
- Date and time of sample receipt at the laboratory;
- Sample allocation; and
- Analyses to be performed.

66. Section 6.3.2, Sample Containers, page 10, Figure 6-4

The example chain-of-custody form Figure 6-4 does not include space for other analyses that must be performed (i.e., hydrogen and methane analyses required of headspace samples) or blank columns for recording additional information. Additionally, Section 1.4 (page 1-31) states that DOE sites may opt to use the TCLP method rather than total analyses for hazardous waste determination. There is no space on example Figure 6-4 to request a TCLP or any other analysis.

67. Section 6.4.3, Solid Process Residues and Soils Sample Container, page 13, lines 14-16, Figure 6-5

EPA SW-846 recommends that the custody seal also contain information on the date and time of sampling and the place of sample collection. These items are missing from the QAPP discussion of custody seals.

68. Section 6.4.3, Solid Process Residues and Soils Sample Container, page 14, Table 6-2

The following deviations from recommended EPA SW-846 procedures should be justified in the QAPP document:

- Holding times begin when the sample is collected, not when the sample is received at the laboratory. The QAPP should specify acceptable holding time from collection in the field, through transportation to the laboratory, through completion of required analyses.

- SW-846 recommends a minimum of 200 grams of sample for metals determination.

- SW-846 recommends a maximum holding time of 28 days for mercury.

- SW-846 recommends a maximum holding time of 14 days for VOCs. VOC analysis does not require extraction. Therefore, it should be explained why 14 days are allowed for sample preparation with respect to VOCs.

69. Section 6.4.3, Solid Process Residues and Soils Sample Container, page 14, Table 6-2

* Further detail and clarification is needed with respect to the methanol extraction mentioned in the footnote for VOCs. Explain why a 40-day holding time is appropriate.

SECTION 7.0 HEADSPACE GAS SAMPLING

70. Section 7.2.3, Sampling Heads, page 14, line 14

What contingencies will be used if the lid of the drum's 90-mil polyethylene liner does not contain a hole for venting into the drum?

71. Section 7.2.3, Sampling Heads, page 14, line 15

* Procedures to seal the drum's carbon composite filter to prevent outside air from entering the drums should be provided.

72. Section 7.2.3, Sampling Heads, page 15, line 3

* Describe the contingencies that will be used if the lid of the drum is not free of dents and scratches that would affect a seal required for sampling.

73. Section 7.2.3, Sampling Heads, page 15, lines 20 and 30

* It has not been specified what flow of QC gases would be considered "excess." If the 208-liter poly bag is torn or breached, clarify whether there is an alternative headspace gas sampling location relative to the deteriorated area (e.g., next to the tear, opposite side of the poly bag, etc.). Also, discussion of headspace gas volume estimation should be included.

74. Section 7.4, Equipment Testing, Inspection, and Maintenance Requirements, page 19, lines 25 and 30

* Since canisters must be cleaned and certified on a batch basis, and since one canister per batch must be analyzed for VOCs as part of the headspace gas sample canister cleaning process, the size of the batch should be specified within the text of the QAPP.

75. Section 7.4, Equipment Testing, Inspection, and Maintenance Requirements, page 20, line 14

* Procedures for determining whether the sampling equipment has a leak are not provided.

76. Section 7.4, Equipment Testing, Inspection, and Maintenance Requirements, page 21, line 12

* Procedures for determining whether sampling heads have been properly cleaned are not provided.

8.0 SAMPLING OF SOLID AND PROCESS RESIDUES AND SOILS

77. Section 8.0, Sampling of Solid Process Residues and Soils, page 1, lines 13-29

The QAPP indicates that a single core will be collected, and a random sample collected within this core of a relatively small volume. However, it is not apparent that this methodology will provide a representative sample of waste within the container. Previously submitted Part B Permit applications indicated that three cores would be collected within the vertical plane, with partitioning of each core to obtain an upper, middle, and lower sample that are analyzed and then assessed for comparability. Additional justification of the proposed sampling scheme is warranted.

The QAPP indicates that the solid process residues and soils will be packaged in 55-gallon drums or smaller containers. However, the document goes on to indicate that samples will be collected from 55 gallon poly bags--is this reference to internal bag(s) within the 55-gallon container, or a different containment system? Also, documentation indicates that these are not the only containers that may contain said wastes (e.g., boxes may also be present at some facilities). Clarify how any other containers will be sampled to ensure collection of representative samples, if these types of containers will be repackaged prior to shipment in TRUPACT-II containers, and whether sampling would occur before or after repackaging.

The QAPP is not written clearly relative to the sample collection location. As worded in this introductory section, the QAPP implies that two cores, a horizontal and vertical core, will be collected and sampled, although later the document indicates that a single vertical core will be collected.

The QAPP goes on to state that one randomly selected inner container will be sampled and analyzed for those drums containing smaller receptacles. However, if process knowledge, headspace gas analyses, or RTR results indicate that these containers may contain

many different hazardous constituents, additional sampling of internal containers within a drum is warranted. Further, if a drum includes several smaller containers with sludge/soil, sampling of a single container may not be (statistically) significant.

The QAPP indicates that tables within Sections 13, 14, and 15 include all parameters to be analyzed for, yet the justification for these parameter listings is not provided or referenced if discussed elsewhere within the QAPP. (See comments on previous sections regarding completeness of these tables relative to TC analyses.)

78. Section 8.1, Quality Assurance Objectives, pages 2 and 3, lines 27-28 and lines 1-9

Representativeness of the samples using the proposed sampling method is questionable relative to contents of the entire drum. Collection of a single core without compositing of samples, rather than the three vertical core method proposed in the past, indicates that the sample content will likely not be representative of the entire drum (or waste stream). Additional justification of the core frequency, lack of compositing (or multiple sample collection/analysis in the case of VOCs), and sample size is necessary. Even though the apparent intent of this procedure is to minimize the quantity of investigation-derived waste, it is not clear whether this trade-off with sample representativeness is appropriate. Further, quality assurance objectives need additional detail (e.g., completeness).

79. Section 8.2, Method Requirements, page 3, lines 11-18

As indicated in Comment No. 79 above, the proposed sampling strategy is not clearly or consistently discussed within the document. Further, the sample size, turn around time, etc., in Table 6-2 appear inadequate (see comments on Section 6.0). The origin of table contents is not referenced upon the table.

80. Section 8.2.1, Core Collection, page 6, lines 4-16

* The QAPP indicates that the coring device sleeve material must be of a rigid material that is "unlikely to affect the composition and/or concentrations of target analytes in the sample core." Provide a list of acceptable sleeve materials within the QAPP, including references for these assessments and how these determinations will be made prior to any sampling of the waste. It is presumed that the sleeve length will be determined by examination of radiographic information.

81. Section 8.2.2, Sample Collection, page 7, lines 34-42

* Define what constitutes a "representative subsection" of the core as it pertains to samples collected for analyses of semi-VOCs, PCB, and metals.

82. Section 8.3, Quality Control, page 8, lines 8-15, 17-18, 28-32

* It is presumed that the co-located core methodology is a duplicate sample collection methodology intended to collect samples from almost the same location within the drum, but clarification is warranted. Also, justification for the one out of 20 duplicate sample and equipment blank collection is not included in the QAPP.

83. Section 8.3, Quality Control, pages 8-9, lines 18-32 and lines 1-16

* The QAPP indicates that if equipment blank analyses shows contamination is present above the MDL, the particular "batch" of coring tools will be cleaned again and inspected prior to use. However, the turn-around time for this analyses is likely not sufficient to preclude the use of contaminated equipment for sample collection, thereby compromising the quality of the sample collected using contaminated equipment. Usually, equipment blanks are collected prior to sample collection and if found to be contaminated, samples collected using the equipment are disregarded and repeat samples are collected.

84. Section 8.3, Quality Control, page 9, lines 20-23

* Provide the specific EPA protocol for decontamination referenced within this section (e.g., rinsate material and procedures). It is also unclear, in lines 24-35, how the equipment blank collected at a frequency of "one tool per batch" coincides (or does not coincide) with the equipment blank collection presented in the previous subsection.

85. Section 8.4, Equipment Testing, Inspection, and Maintenance Requirements, page 10, lines 20-23

In typical sampling situations, coring devises (e.g., split spoons) are kept in separate areas and within protective coverings (e.g., covered with aluminum foil) to prevent contamination. As described in this section, it is implied that sampling equipment (which has presumably been decontaminated) could be placed within a sample area under circumstances that would allow for secondary contamination to occur following decontamination procedures. Later paragraphs (lines 33-35) indicate that packaging will be placed around cleaned equipment, but this appears to contradict what is implied in lines 20-23. Clarification that equipment discussed in this section will not become contaminated is warranted.

9.0 NONDESTRUCTIVE ASSAY

86. Section 9.0, Nondestructive Assay, page 1, lines 22-27

Revision of the QAOs could impact how Non Destructive Assay (NDA) is used relative to WIPP Performance Assessment (PA). For example, a revision to the Minimum Detectable Concentration (MDC) at a given sight could impart variability between sites, and could significantly impact facility performance if PA concerns are not taken into account. Also, discuss why radiochemistry methods are not included.

87. Section 9.0, Nondestructive Assay, page 2, lines 1-11

The QAPP indicates that, for the purposes of the Program (presumably the QAPP), determination of only total alpha activity and the activity of the individual isotopes present are required. Clarify whether this will satisfy all data needs for the PA program, including any assumptions relative to RCRA compliance (268.6 and 264) that could be impacted by radionuclide considerations (e.g., impact of radiolysis on hazardous waste). Clarify what constitutes "supportable process knowledge."

88. Section 9.1, Quality Assurance Objectives, page 2, lines 12-19

The QAPP does not clarify the criteria which must/must not be met to mandate NDA or the level of process knowledge that would be considered satisfactory to potentially disallow the need for NDA. Further, statements within Section 9.1 contradict with footnotes on Table 9-1 which state that "valid radioassay data is required for all waste containers", implying that actual radioassay--not process knowledge determination of isotope ratios--is required.

89. Section 9.1, Quality Assurance Objectives, page 3, Table 9-1

The origin of the precision values within this table are unclear and require additional justification. Further, the specific bias and uncertainty values are unsubstantiated, and the required accuracy is not listed.

90. Section 9.1, Quality Assurance Objectives, page 5, lines 1-11

Clarify how the minimum detectable concentration will be practically achieved. Also, the assumptions relative to the equations presented herein require additional clarification.

91. Section 9.1, Quality Assurance Objectives, page 6, lines 7-15

The use of an expert panel to determine total uncertainty requires additional clarification regarding how, specifically, the panel will selected, criteria for determining uncertainty (so that it is applied in a standard and universal manner), etc.

92. Section 9.1, Quality Assurance Objectives, page 6, lines 17-18

The definition of acceptable Radioassay (RA) data needs to be more clearly specified. As written, it is not clear whether all drums/containers will undergo RA as part of the QA program, or whether RA performed prior to initiation of the QAPP will be deemed acceptable. Also, it is unclear whether validation of RA data will occur prior to waste shipment.

93. Section 9.1, Quality Assurance Objectives, page 6, lines 19-28

The QAPP does not include any indication of the specific actions that will be taken if a measurement device is found to not meet QAO objectives, particularly if the problem is detected after a number of drums have been analyzed. Also, the document does not provide sufficient discussion of the "relevant, inter-laboratory comparison programs" relative to what these comparisons mean regarding "corrective actions." How a program is deemed inadequate is unclear (unless the document means that a program is inadequate when any of the element listed in Table 9-1 is not met).

94. Section 9.2, Methods Requirements, pages 7-8, lines 26-30 and 1-6

Although the QAPP provides standard guidance to determine and implement appropriate NDA methodologies, the acceptance criteria must be standard enough between the various facilities to ensure consistency. Without these assurances, uncertainties could be introduced on a site-specific basis that could significantly impact consistency of data acquired. The discussion pertaining to disposition/use of assays needs to be clarified to indicate that no shipment of waste to WIPP will be allowed unless the issue is resolved (determination of adequate resolution needs to be discussed more fully).

95. Section 9.3, Quality Control, page 9, line 29

* Clarify what is meant by "established performance specifications."

96. Section 9.3.1, Measurement System Checks, page 11, lines 9-21

The second sentence of this section implies a broader scope of responsibilities for the site project QA officer shall be required than to only compare replicate results with actual results. It is suggested that the full responsibilities of the site project QA officer as they pertain to NDA be clarified in this section (or in the appropriate portion of the QAPP).

Additional discussion of the measurement comparison program is warranted. Also, clarify how the results of the inter-comparison

program will be used to modify existing programs, and whether standardization of programs between sights will be sought.

97. Section 9.3.3, NDA Operator Training, page 11, lines 23-30

Clarify who will develop the training program, whether biannual or annual certification (of training) is appropriate, and whether recertification will be required as new instrumentation is added.

98. Section 9.4, Instrument Testing, Inspection, and Maintenance requirements, page 12, lines 1-6

* Section 9.4 does not provide discussion of the calibration, maintenance schedules, etc. While it is recognized that this may vary depending upon approved equipment, minimum standards for instrument testing, inspection, and maintenance requirements could be established within the QAPP.

99. Section 9.5, Calibration Procedures and Frequencies, page 12, lines 17-18

Clarify the minimum annual recalibration requirements; provide justification for this minimum value. List the commonly accepted techniques of transmission and live-time corrections to compensate for matrix variations in the container that are considered acceptable. Further, shouldn't the programs used be as standard as possible to allow for comparability?

100. Section 9.6, Data Management, page 14, lines 19-26

The QAPP states that "reduction of RA data may be accomplished using software" and the "software may vary from site to site." To ensure proper data review and consistency between sites, the DOE should identify the acceptable software that is allowed to be used rather than allowing each site to choose, unless it can be demonstrated that this software will not introduce error.

101. Section 9.6, Data Management, page 15, lines 1-2, 10, and 22

The specific instrument control parameters should be listed in the QAPP. It is unclear why a total of 15 replicate counts are needed to demonstrate precision and bias compliance; justify the selection of fifteen counts.

102. Section 9.6, Data Management, page 16, lines 3-8, and 17-28

The QAPP should precisely state what an "appropriately sized" waste container may be. A discussion of the criteria needed for the selection of the independent review panel should be included in the QAPP.

103. Section 9.6, Data Management, page 17, lines 1-30

Clarify how an uncertainty determined by an expert panel--which will (could) be more qualitative than quantitative--will be determined to the 95% confidence level.

10.0 RADIOGRAPHY

104. Section 10.0, Radiography, page 1, lines 1-4

Clarify whether the confirmatory visual examination performed as part of the radiography is the same process described in Section 5.0, or whether this visual examination is performed independent of that referenced in Section 5.0.

105. Section 10.1, Quality Assurance Objectives, page 1, lines 18-28

The QAPP should include in this section, a brief discussion pertaining to how radiography is used as part of the miscertification process, as discussed in Section 5.0. Clarify whether 100 percent accuracy relative to waste stream/waste matrix code determination is a quality assurance objective.

Although precision (lines 18-22) cannot be statistically addressed, a qualitative estimate of precision based upon visual examination results should be included in data collection/ reduction activities. Also clarify reporting requirements relative to reporting of corrective actions.

106. Section 10.2, Methods Requirements, page 3, lines 1-31

The QAPP indicates that standardization of procedures relative to radiography and operator qualification is a "must", but detail regarding implementation of this standardization is lacking.

Clarify how variations in radiographic technologies could potentially impact data quality and comparability. For example, 3D tomography can enhance image resolution, but the technique does not allow for determination of liquids via "sloshing" that can be achieved by "standard" RTR techniques. Clarify whether the operator will identify the nature/form of material parameters, which could impact additional testing (e.g., the presence of inner bags requiring sampling, or solidified sludges within smaller containers that also require sampling).

107. Section 10.3, Quality Control, pages 4 and 5, lines 10-26 and 6-13

Clarify why Supplement 2S-2 does not apply; this would appear to be applicable since the supplement provides amplified requirements for

the qualification of personnel who perform non-destruction examination. Clarify the standards for unsatisfactory performance (e.g., specific miscertification rate), as discussed in line 12. Will the training drum accuracy be "scored", with a minimum score required?

Justify the 1/20 replicate scan requirements; will this number be modified for a given waste stream/waste matrix code depending upon how "certifiable" the stream is?

* Clarify who will perform the independent drum replicate audits (personnel other than that who performed the first examination is vague). Be sure that responsibilities of the site project QA officer relative to nondestructive examination (radioassay) are clearly outlined in the appropriate section of the QAPP.

Clarify who will develop and implement the training program specified on page 5, line 12. The program must be consistent throughout all generator sites; since generator training is cited as the only way to ensure quality control of radiography, this is a very important issue. Clarify how a visual examination expert is identified and trained. Is this different that the RTR expert (Lines 14-22)? What are the programmatic objectives that govern whether a visual examination expert determines the extent to which waste segregation should be performed? The criteria used for this methodology could be determined in a standardized fashion for all DOE facilities, and inclusion of basic standards of determination within the QAPP would ensure consistent visual examination methodologies.

108. Section 10.4, Instrument Testing, Inspection, and Maintenance Requirements, page 7, lines 1-4

Although manufacturer's requirements impact testing and inspection, it would appear that "minimum standard requirements" could be included within this document pertaining to these issues.

109. Section 10.5, Instrument Calibration and Frequency, page 7, lines 6-10

This section is unclear and could include more "standardized" requirements that are not necessarily dependant upon manufacturer's recommendations to ensure consistency between generator sites relative to equipment calibration and frequency.

110. Section 10.6, Data Management, page 7, lines 11-30

Include an example of the approved standard form(s) for reporting Non-Destructive Examination (NDE) results. These forms can--and should--be consistent at all generator sites in terms of content, although some allowances can be made to account for site-specific equipment variations. It is also unclear what is meant by a

"batch"; it is presumed that individual container forms will be submitted that could be further compiled on a daily (or some other criteria) basis, but clarification is warranted. Also, waste stream verification as determined by radiography and confirmed by visual examination should be included. It might also be a helpful to repeat any RCRA hazardous waste/constituent information available upon the standardized form that are available via process knowledge.

11.0 HYDROGEN AND METHANE ANALYSIS

111. Section 11.2, Methods Requirements, page 3, lines 18-23

It is not clear why the methods for analysis are based on ASTM method 2650-83. Method 2650-83 is intended for the analysis of gas mixtures for or from petroleum refining processes. Justify the selection of this method.

112. Section 11.5, Instrument Calibration and Frequency, page 7, lines 7-9

In addition to the Laboratory Control Sample, the QAPP should indicate what other standards may be appropriate for continuing calibration.

12.0 GAS VOLATILE ORGANIC COMPOUND ANALYSIS

113. Section 12.1, Quality Assurance Objectives, page 2, Table 12-1

The text and table should discuss the rationale for the selection of the target compound list presented in Table 12-1. Also, the table should be revised to include the precision, accuracy, MDL, program required quantitation limit (PRQL) and completeness limits for the compounds listed.

114. Section 12.2, Methods Requirements, page 5, lines 1-5

The QAPP should provide more guidance on the appropriate GC/MS and GC/FID methods that may be selected for the analysis of gas VOCs. For example, reference the specific SW-846 methods that may be used, particularly if these are not included in the Methods Manual.

115. Section 12.5, Instrument Calibration and Frequency, page 9, line 29

The text should reference Table 12-4, not Table 12-1, for the calibration criteria.

13.0 TOTAL VOLATILE ORGANIC COMPOUND ANALYSIS

116. Section 13.1, Quality Assurance Objectives, page 2, Table 13-1

Justification for the selected targets for analysis listed in Table 13-1 should be included. Also, it is unclear why laboratory control samples are required for the analysis of VOCs. According to the SW-846 methods, a laboratory control sample (LCS, QC check sample) is required only if the MS/MSD recovery exceeds specified ranges (although more stringent methodologies can be applied). The QC check sample must then be analyzed and must fall within the required ranges.

Table 13-1 should be revised to include precision, accuracy, MDL PRQL and completeness limits for all of the compounds listed in the table. The following compounds are listed on Table 13-1, but are not included on the compound list in the referenced SW-846 methods: cyclohexane, 2-nitropropane, 1,1,2-trichloro-1,2,2-trichloroethane, n-butanol, cyclohexanone, ethyl ether, 2-ethoxyethanol, ethyl acetate, and methanol. It is unclear which methods should be used to analyze these compounds. The precision and accuracy limits listed in the table are not consistent with the limits in the SW-846 methods. Indicate where these limits came from and ensure that accurate QC limits have been provided.

* Table 13-1 should also distinguish between the different accuracy and precision parameters and limits. For example, a separate column for matrix spike recoveries and surrogate recovery limits should be included relative to accuracy. Since the recovery limits for both of these QC sample analyses are different, it is not clear from the table why one set of recovery limits has been listed for accuracy.

* The matrix spike and matrix spike duplicate samples should be spiked with five TCL compounds, as per SW-846 requirements. The recoveries for these five compounds, along with the associated VOC compounds, should be provided. This should also be done for surrogate recovery compounds (see comment below).

117. Section 13.1, Quality Assurance Objectives, page 1, lines 18-22

* As per the referenced SW-846 methods, a surrogate sample should also be analyzed to measure accuracy. Table 13-1 should include the following recovery limits for surrogate compounds:

Compound	Soil Control Limits
Toluene-d8	81-117%
Bromofluorobenzene	74-121%
1,2-Dichloroethane-d4	70-121%

118. Section 13.2, Methods Requirements, page 3, lines 28-29

It is unclear why preparation methods are necessary for VOC samples and which preparation methods the QAPP is referring to (other than those within the methods themselves). It is, however, recommended that all sediment/soil and waste samples be screened prior to analysis. If this is what is intended, please clarify and reference SW-846 Method 3810 (headspace method) or Method 3820 (hexadecane extraction and screening).

119. Section 13.2, Methods Requirements, page 4, lines 9-10

* Since methanol should not be used for standard preparation, it is unclear which solvent will be used.

120. Section 13.3, Quality Control, page 6, Table 13-2

* Table 13-2 should also include the recovery limits and guidelines for internal standards and surrogate analysis.

121. Section 13.5, Instrument Calibration and Frequency, pages 8 and 9, Line 22, Table 13-3

According to SW-846 methods, the acceptance criteria for the continuing calibration should be $\leq$25% of the initial calibration, not $\leq$30%, as stated in the text and Table 13-3.

14.0 TOTAL SEMI-VOLATILE ORGANIC COMPOUND ANALYSIS

122. Section 14.1, Quality Assurance Objectives, pages 1 and 5, lines 22-29

Discuss and justify the selection limited number of target compounds for analysis. Also, it is unclear why laboratory control samples are required for the analysis of semi-volatiles. According to the SW-846 methods, a LCS (QC check sample) is required only if the MS/MSD recovery exceeds specified ranges. The QC check sample must then be analyzed and must fall within the required ranges.

The accuracy measurements should also include the analysis of surrogate compounds. This information should be included in Table 14-1.

123. Section 14.2, Methods Requirements, pages 2 and 3, lines 12-28, Table 14-1

* The precision, accuracy, MDL, PRQL and completeness limits for all semi-volatile compounds listed on Table 14-1 should be included. Also, the matrix spike and matrix spike duplicate samples should be spiked with eleven TCL compounds for BNA analysis and one compound for PCBs analysis, as per SW-846 requirements.

The recoveries for these compounds, along with the associated semi-volatiles compounds, should be provided. This should also be done for surrogate recovery compounds.

124. Section 14.2, Methods Requirements, page 3, lines 22-24

* The QAPP should provide more specific guidance on the appropriate preparation methods that may be used for the semi-volatiles.

125. Section 14.3, Quality Control, page 6, Table 14-2

* Table 14-2 should also include all control limits for internal standard and surrogate analyses.

126. Section 14.5, Instrument Calibration and Frequency, page 8, lines 1-2

The QAPP should ensure that the initial calibration was performed in the proper sequence for the GC/ECD analysis.

15.0 TOTAL METALS ANALYSIS

127. Section 15.1, Quality Assurance Objectives, pages 1, 7, and 9, lines 13, 30, and 6, Table 15-1

It is unclear how the target analyte list on Table 15-1 was selected and why the specific metals are included.

It is unclear why matrix spike duplicate analysis will be performed on metals samples, since it is not required by the analytical method. As a check for precision, laboratory duplicates must be analyzed.

On Table 15-1, all accuracy, precision and completeness control limits should be provided for all analytes. Also, since matrix spike recovery limits are 75-125% and the laboratory control sample recovery limits 80-120%, the accuracy limits column should be expanded to include both LCS and MS recoveries. The table should also include all accuracy and precision control limits for AA analysis.

128. Section 15.2, Methods Requirements, pages 3 and 4, lines 24-25 and lines 6-7

A discussion of which appropriate sample preparation methods may be used for each analyte and associated analytical method should be included in the QAPP.

129. Section 15.2, Methods Requirements, page 6, line 26

* A discussion of when a method of standard additions (MSA) may be required should be included.

130. Section 15.3, Quality Control, page 7, lines 15-17

The QAPP states that all laboratories must demonstrate "acceptable performance" prior to analysis of the samples. The QAPP should discuss what corrective action measures may be taken if acceptable performance is not achieved. Also, initial and continuing calibration blank samples must also be analyzed as a part of the QC analysis.

131. Section 15.3, Quality Control, page 8, Table 15-3

The origin of the provided matrix spike accuracy limits should be discussed, since according to SW-846 methods, the matrix spike limits should be 75-125%. Also, accuracy recovery limits for AA analytical spikes (85-115%), and precision limits for duplicate injections ±20%, should also be included on the table. If MSA analysis is required, the control limits should also be presented.

132. Section 15.3, Quality Control, page 9, lines 2-7

The QAPP states that the LCS may be of a different matrix than the sample. In such cases, it is unclear how the LCS results will monitor sample preparation and analysis if it is a different matrix.

133. Section 15.6, Data Management, pages 10-12, Table 15-4

According to SW-846 methods, the initial calibration for ICP analysis should be a three point calibration (three standards and one blank). It is unclear why a one-point initial calibration is suggested.

The table should also include the calibration blank requirements. For example, initial calibration blanks should be analyzed immediately after blank verification; the continuing calibration blanks should be analyzed every 20 samples or per analytical batch, whichever is more frequent. Also, according to SW-846 method, the interference correction verification must be at the beginning and end of the run or twice during an eight-hour shift, whichever is more frequent.

Table 15-4 should also include a CRDL analysis for ICP-ES analysis. The lowest standard after calibration must be reanalyzed and the result must be ±5% of true value.

134. Section 15.6, Data Management, page 13, lines 2-4, Table 15-1

Data validation guidelines must include the different quality control limits applied to the various analytical methods (i.e., for ICP-MS, GFAA, etc.) Also, Table 15-1 does not include all QAOs for the proposed analyses. For example, ICP serial dilution duplicate and analytical spike analyses for furnace AA methods have not been included on the Table. The QAPP should indicate or reference how validation of this data will be performed and should be revised to specify the guidelines or criteria that will be used to validate total metals data.