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FAX TRANSMISSION COVER SHEET

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*Date: Oct. 12, 1994  
To: John Parker  
Fax: 505 827-4361  
Subject: QAPP Comments  
Sender: Lynne Wilson*

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YOU SHOULD RECEIVE 24 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202-233-9290.

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

Dear Mr. Dials:

Thank you for providing the United States Environmental Protection Agency (EPA) with the opportunity to review and comment on the July 1994 TRU Waste Characterization Quality Assurance Program Plan (QAPP), CAO-94-1010. The Agency recognizes the significance of quality assurance and appreciates the Department of Energy's (DOE) on-going efforts to design a program that ensures the quality of the data used in support of a compliance application. In an effort to expedite any unresolved issues, the EPA recommends that the DOE forward for review other Quality Assurance Program Plans as soon as possible. Quick resolution of issues will undoubtedly shorten the compliance certification schedule of the Waste Isolation Pilot Plant determination.

The EPA's most significant comments are discussed below and the detailed comments are included as an enclosure. The Agency believes that the resolution of issues raised by these comments is crucial to the success of the Department's compliance demonstration program and must be addressed prior to the submittal of a compliance application.

**1. The program organization deviates significantly from the basic requirements of ASME NQA-1, and as such, lacks independence and organizational freedom.**

Although the QAPP reflects a considerable amount of thought in description of methods and includes many elements of industry-accepted standards, such as ASME NQA-1 (II-1), the overall organizational scheme for this Quality Assurance Program is inadequate.

The organizational hierarchy (as shown in Figure 1-1) reveals management ambiguity between the Office of Waste Management (EM-30) and the Carlsbad Area Office (CAO). For example, the chart identifies no Quality Assurance manager at the CAO level. In fact, the first designated Quality Assurance title is the QA Officer at the DOE field office level, which is quite

far removed from centralized control.

The ambiguity between EM-30 and the CAO is further compounded by the assignment of the day-to-day QA operations management to the National TRU Program Office (NTPO). This office is responsible for the development of TRU Waste Acceptance Criteria and for the interface with EM-30 on national radioactive waste management; therefore, it is difficult to see how the TRU Waste Characterization QA program will be sufficiently independent from other priorities, such as the cost and scheduling plans of other waste management programs. Moreover, the CAO Compliance Branch, which contains the majority of WIPP-related quality assurance functions (QAPD development, QA audits, etc.) is only peripherally involved in the daily operations of quality assurance management.

The establishment of a centralized QA management program is complicated by the fact that the Waste Isolation Pilot Plant TRU Waste Characterization Program is a multi-site operation, with considerable variability in waste characterization and quality assurance practices. Therefore, it is puzzling that the Office of Quality Assurance (EM-20) has no identified role in this program. When multiple organizations are involved, ASME NOA-1 (IS-1) requires clearly established and documented responsibilities and authority for quality assurance.

The above observations constitute a significant deviation from the basic requirements of ASME NOA-1 (II-1, Organization). The EPA views this with great concern and feels that the overall QA program organization for TRU waste characterization should be simplified and strengthened into a centralized management program, sufficiently independent of cost, scheduling, and/or priority conflicts and demonstrating organizational freedom.

**2. The formulation of data quality objectives for demonstration of compliance with 40 CFR Part 191 through Performance Assessment is seriously incomplete and may result in waste characterization data being insufficient.**

The EPA document, "Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process" (EPA QA/G-4), outlines a seven step logical process for development of data quality objectives. The first step in the process is identification of problems requiring additional data by end users of the data, followed by identification of the decision to be made using the data, identification of inputs to the decision, definition of study boundaries, development of a decision rule, specification of limits on decision errors, and finally, optimization of the design for obtaining data. Critical to this process is the integral involvement of the end user of the data. The purpose of

the process is to obtain all data which is needed for the decision, but not more data nor more precise data than is actually needed. This is defended to prevent unnecessary expense and to ensure that additional measurement is not required. The development of DQOs for the TRU waste characterization program would conform well to this process for reasons including the high cost of waste characterization and the complex needs of the PA group.

EPA's current knowledge of the PA suggests that a number of topical areas should be considered in the development of DQOs: 1) gas generation rates, which are influenced by the content of cellulose and corrodible metals, as well as radiolytic activity in the waste; 2) actinide solubility, which currently has 14 orders magnitude of uncertainty and is affected by a large number of waste parameters; 3) content of transuranics in cuttings, which is a function of the distribution of curie content in drums; 4) criticality, which is affected by the choice and uncertainty of the upper limit for TRU in individual containers and the load management scheme; and 5) thermal response of the repository, which is affected by the loading of individual containers with alpha heat sources. Moreover, Sandia has identified a number of "very important" and "important" parameters used in the PA which are properties of the TRU waste itself. These include initial liquid saturation, radionuclide solubility limits, and the metal, glass, and cellulosic content of the waste. While the EPA's current plans do not require the use of EPA QA/G-4, it is clear that the problem areas above must be considered in order to form the basis for Data Quality Objectives using some type of process similar to that outlined in EPA QA/G-4.

Unfortunately, not one of these topic areas appears to have been used to develop a data quality objective for the waste characterization QAPP. Based upon this, it appears that the end users of the data (Sandia PA group) have not been effectively involved in the process of development of Performance Assessment-based DQOs. In fact, the EPA contends that none of the DQOs specified in Section 1.5 are true data quality objectives associated with an analysis of the Performance Assessment. The first example mentioned (radioassay - distinguishing with 95% confidence between TRU and low level waste) may be considered a DQO, but is not related to regulatory compliance. For instance, compliance could still be achieved even if some or all of the well-characterized waste emplaced in WIPP is low-level. The distinction between TRU and low-level waste is primarily an economic concern for DOE since the cost of disposal at WIPP is several orders of magnitude higher than the cost of disposal at a low-level waste site. The second example listed in Section 1.5 (radioassay to confirm the inventory) is a valid data goal of the PA, though it is not presented as a DQO since no quantitative limits of precision, accuracy or other quality objective are

specified. Finally, the third example (radiography to confirm the waste matrix and material parameters), calls for qualitative descriptors (no quantitative limits are specified); and therefore, will have little impact on the PA.

On several occasions, the EPA has raised the issue of involving the end users of the data in the development of the DQOs, but to date, there has been no resolution. Waste characterization is a vital link to performance assessment and the PA represents the primary means of compliance certification with 40 CFR 191. Any failure in the development of data needs and DQOs in this area may ultimately require significant, costly, and time consuming re-measurement of waste parameters in order to meet EPA's criteria for WIPP certification.

**3. The EPA is concerned that the QAPP is not adequately addressing site-to-site differences in the development of quality assurance objectives. Site-to-site comparability of data may be compromised as a result.**

During site visits, EPA was made aware that numerous differences exist among the waste generators in regard to the segregation and management of waste. These differences are evidenced in the handling of existing waste streams, in plans for the generation of future waste, and in the definition and use of "process knowledge." It appears as if these site differences have not been considered in the development of QAOs. For example, the development of a waste matrix coding system appears to be heavily influenced by segregation practices applied at the Rocky Flats Plant, but will have little meaning for waste generated at Hanford and the Savannah River site, where waste segregation has not been employed, or at Oak Ridge and Los Alamos, where relatively large volumes of laboratory waste (as opposed to production waste) have been produced. Based upon these differences and upon the likely differences in the character of production waste, decontamination/decommissioning waste, treated waste, repackaged waste, etc., it may be appropriate to find a more suitable basis for comparison than that of the waste matrix code.

Similarly, the EPA has observed site-to-site variability in the definition, use, and justification of "process knowledge." Therefore, a criteria for standardization (quality objectives) is needed in the QAPP. It is insufficient to introduce the concept of "knowledge of processes" as a means of grouping waste, selecting samples, and even characterizing newly generated waste without establishing a controlling mechanism to ensure site-to-site comparability.

4. The EPA is concerned that the QAPP makes statements regarding the characterization of to-be-generated waste without including descriptive information on the nature of future waste streams. As a result, the methods which are proposed for characterization may be inappropriate.

From site visits, the EPA has assessed that future waste streams will quite likely result primarily from non-production processes such as decontamination/decommissioning, waste repackaging/treatment, waste retrieval, etc. These processes often have priorities other than waste characterization. For example, in decontamination/decommissioning, there is a high priority on rapidly containerizing waste and an inherently low priority on making measurements to characterize the material. The approach proposed in the QAPP, which is to characterize waste using process knowledge after it has been placed in containers is not likely to be an effective method since there is no assurance of process control in the waste generation. It would be useful to have a comprehensive system of administrative controls and requirements that have been adapted to each of the new processes for generation (particularly to D/D activities) and that documents process control at every step. In addition, this system should be implemented through training so the waste is effectively characterized before it is containerized. The QAPP fails to address this need because it does not attempt to describe the processes associated with future generated waste or take into account the likely differences from past production processes.

5. The term "process knowledge" is inadequately defined and used inconsistently in this document.

An apparent distinction is made among three (3) terms:

- "process knowledge" (Section 5.0);
- "knowledge of process" (Section 1.3); and
- "knowledge of materials and processes that generate the waste" (Section 1.4).

What is the distinction among these three terms? Definitions are not provided in this document. This is best illustrated by comparing Figures 1-3a, 1-3b and 1-3c with Figures 5-1 and 5-2; the figures in Section 1 list "knowledge of process" and the Section 5 figures list "process knowledge."

Section 5.2.2 states that "[k]nowledge of the materials and operations that generated these waste streams is sufficient to determine if they contain RCRA-regulated metals. Similarly, knowledge of the original organics used and the operations that generated these waste streams is sufficient to determine if the waste is hazardous or contains PCBs and other hazardous

constituents. Therefore, RCRA waste characterization of debris wastes shall be accomplished using process knowledge instead of the sampling and analytical methods described in Sections 8.0, 13.0, 14.0, and 15.0." This indicates that "process knowledge" will be used as a measurement technique in the same manner as Radioassay, Headspace Gas Analysis, etc.. However, "process knowledge" is not covered under any of the controlling mechanisms that are presented for the other measurement techniques. For example:

- it is not defined;
- it is not subject to Quality Assurance Objectives (QAOs) and Data Quality Objectives (DQOs) (Sections 4.1 and 1.5, respectively);
- it is not subject to data review, validation and verification methods (Section 3.2);
- it is excluded from method-specific training and qualification requirements;
- it is not subject to Quality Control Requirements (Section 4.3);
- it is excluded from the requirements of data review, reporting and management (Sections 3.1, 3.4, and 4.6, respectively); and
- it lacks stated acceptance criteria comparable to those for the other characterization techniques (Section 3.3).

Requirements for documentation and verification of "process knowledge" are not presented in the QAPP. Further, the information this document does provide is internally inconsistent. Figure 5.2 requires a verification that "processes generating waste have operated within established and documented administrative controls" for newly generated wastes, but does not specify how the verification will occur or what controls would be in effect for this verification process. Section 9.0 allows for the incorporation of "supporting data from process knowledge, such as isotope ratios or scaling factors, when such data can be supported by auditable records." Page 2 of this section allows for "supportable process knowledge" to be used for the determination of total alpha activity, but provides neither a definition nor guidance for this concept. However, verification is apparently not required for using process knowledge on existing Waste Matrix Code Series 5000 wastes, as evidenced by Sections 5.2.1 and 5.2.2. This requires clarification.

This document presents "process knowledge" as an official characterization technique for hazardous waste determinations for Waste Matrix Code Series 5000 wastes, yet it excludes it from QA controls as listed above. The approach for Waste Matrix Code 5000 samples is to make the determination whether a sample is hazardous based solely on "process knowledge." Given the lack of QA controls on the use of "process knowledge" for waste

characterization presented in this document, this is not a conservative approach. The QAPP needs to acknowledge this without ambiguity by presenting "process knowledge" as an integral part of waste characterization and incorporating the appropriate Quality Assurance aspects, as is done for the other waste characterization techniques.

**6. The term "waste stream" should be defined since it appears to affect the actual number of waste containers selected for sampling and analysis.**

As stated in Section 5.3.1, "a minimum of ten containers per waste stream must be sampled and analyzed..." With unlimited latitude regarding waste stream definition, the waste generator sites can drive the actual number of containers to be sampled up or down. The vagueness of this document prevents a complete understanding of what DOE intends to do regarding waste stream composition and makes an independent evaluation of the process impossible. Section 5.0, page 1 defines a waste stream as "waste material generated from a single process or activity" that can either be "process" or "batch." Both definitions require that the material be "substantially uniform," which is subjective and not further defined or explained. Earlier on the same page it states that the waste streams will be created by DOE sorting containers based on "process knowledge." This allows for subjectivity on DOE's part with regard to determining which wastes are grouped together. It also allows for the possibility of biasing the number of containers to be sampled by maximizing waste stream size. Section 5.3 states that newly generated "waste streams of solid process residues and soils must be sampled annually or once per batch." What percent of these must be sampled annually and what is a "batch?" By not providing a clear definition or guidance regarding the number of containers to be sampled and allowing the use of an undefined quantity (batch), DOE prevents an independent evaluation of their compliance. In addition, the absence of a definition makes the term "waste stream" meaningless and undermines the quality and usefulness of the data collected.

**7. This document does not discuss the protocol for soliciting expert panels.**

This document refers to the use of expert panels with no discussion of a protocol or procedure for the selection, qualification and use of experts. This issue needs to be clarified and expanded within this document.

**8. The document does not address remote-handled waste.**



Because DOE has two waste characterization program plans, one entitled Waste Characterization Program Plan for the Waste Isolation Pilot Plant and the other entitled Remote-Handled Transuranic Waste Study Plan, it is unclear whether or not the QAPP intends to cover the characterization efforts of both contact-handled and remote-handled waste types.

Should you have any questions regarding the above issues or the enclosed comments, please contact Larry Weinstock, Chief of the Radioactive Waste Management Branch, (202) 233-9310 or Reid Rosnick, Office of Solid Waste (703) 308-8758.

Sincerely,

J. William Gunter, Director  
Criteria and Standards  
Division

Matthew Hale, Jr. Deputy Director  
Permits and State Programs  
Division

Attachment

cc: Jill Lytle  
Stephen Schneider  
Paul Davis

## EPA REVIEW OF THE TRU WASTE CHARACTERIZATION QUALITY ASSURANCE PROGRAM PLAN

At the request of the Department of Energy, the Environmental Protection Agency's Office of Radiation and Indoor Air and Office of Solid Waste reviewed the Revision B Draft of the *TRU Waste Characterization Quality Assurance Program Plan*. The following report is the compilation of specific comments presented by chapter and referenced to the applicable page, figure and/or line(s).

### Specific Comments

#### Chapter 1 - Program Management

- 1.) Page 1-1, lines 2-14. Identification of specific data needs for each program requires more emphasis.
- 2.) Page 1-1, line 16. The term "state" should be included as it is the New Mexico Environmental Department (NMED) that issues RCRA permits.
- 3.) Page 1-1, line 31. Please state what exceptions might be allowed to NQA-1.
- 4.) Page 1-2, lines 15-19. The detail is not sufficient for the reader to understand the division of labor between HQ EM-30 and CAO.
- 5.) Page 1-2, line 16. EM-30 is given a formal role in the organization of the QA program. The role of EM-20 (Office of Quality Assurance) should be clarified.
- 6.) Page 1-6, figure 1-1. Dotted lines are shown between EM-30 and CAO, and between the Manager, National TRU Waste Program Office and the DOE field offices. The nature of these relationships needs clarification. Also, there is no identified Quality Assurance Manager for the NTPO. Since this is a multi-site program, it is recommended that this position be established.
- 7.) Page 1-8, line 23. The description of the duties of the NTPO Manager and the overall management of the waste characterization program is not under the direction of the CAO Manager, but rather follows DOE Headquarters priorities. This ambiguity should be clarified.
- 8.) Page 1-10, lines 1-14. There is ambiguity in the discussion of the responsibilities (e.g., Operational variance approval,

Analytical data verification/validation, Laboratory/Testing facility assessment) listed under the DOE Site Project Manager and the DOE Site Project Quality Assurance Officer. Please clarify.

9.) Page 1-12, line 20. Please provide the schedule set for the development of the SOPs.

10.) Page 1-12, line 21. This seems to imply that virtually any document can qualify as a Standard Operating Procedure (SOP), and then it specifies a format for the SOPs. Please clarify.

11.) Page 1-14, Table 1-2. The responsibilities of "Change Approval" and "Change Control" of the QAPjPs appear only to reside with the DOE Field Office. There should be a procedure for ensuring that changes made to the QAPjPs (at the field level) do not result in the generation of data which no longer conform to the TRU-QAPD (or are otherwise unusable) prior to CAO review.

12.) Page 1-15, lines 8-9. The criteria for changes requiring NTPO approval is vague and appears to allow for site interpretation. More specific guidance which demonstrates centralized control is recommended.

13.) Page 1-17, line 31. Details are needed to demonstrate how the inventory will reflect future generated quantities of TRU waste, since much of future generated waste will be produced by processes other than that of production. Estimating practices in the past involved projecting previous production trends. This is a serious flaw in the quality of DOE estimates of the total waste inventory.

14.) Page 1-18, lines 26-29; Page 1-20, lines 4-8. "DOE generator/storage sites must determine if their waste exhibits a toxicity characteristic (TC) by comparing the upper 90-percent confidence limit ( $UCL_{90}$ ) values for measured contaminant concentrations to the regulatory levels specified in 40 CFR Part 261, Subpart C, expressed as total values...QAPP."

- Please clarify the process used in selecting the  $UCL_{90}$  value for comparison to the TC levels cited at §261.24, Table 1. §261.24 states that "[a] solid waste exhibits the characteristic of toxicity if...the extract from a representative sample contains any of the contaminants listed in Table 1 at the concentration equal to or greater than the respective value given in that table." Thus, unless the sample size is very large and EPA allows the use of an average value (e.g., greater than 20), any value over the TC limit will cause the waste to be hazardous. In cases where the sample size is very large, EPA typically uses the  $UCL_{95}$ .

- Wastes also can be classified as RCRA hazardous wastes if the subject waste material is either a listed waste or is derived-from and/or mixed with a listed waste -- 40 CFR Part 261, Subpart D. The determination of hazardous waste under RCRA is not limited only to the characteristic of toxicity.

15.) Page 1-19, lines 12-18. "To evaluate the potential for migration...the types and average quantities of hazardous constituents contained in the waste streams classified as solid process residues and soils will be determined using sampling and analysis and reported with a 90-percent confidence interval. For waste streams classified as debris wastes, knowledge of process will be used to estimate the types and quantities of hazardous constituents present."

- To evaluate the potential for migration of each constituent, will DOE use the average of all the UCL<sub>90</sub> results from each of the sampling events for the specific constituent in the modeling exercises? Please clarify what is meant here and discuss/support the validity of using an average of the UCL<sub>90</sub>s. The EPA believes that the UCL<sub>90</sub> (or the UCL<sub>95</sub>) should be calculated using all the data from all of the sampling events.
- For the purposes of determining whether the debris waste either exhibits the TC or is within the "waste acceptance envelope," the use of process knowledge to determine the concentration of constituents found in debris may be inadequate.

16.) Page 1-21, figure 1-3a. It does not appear that performance-based waste acceptance criteria (PBWAC) have been accounted for in the development of this QAPP. The EPA's concept of PBWAC anticipates several data requirements based upon waste parameters described in chapter 3 of the 1992 Performance Assessment, which are not included in this figure. As noted in number 2 of the general comment section of this review, there are many problems associated with the PA which have not been considered in this QAPP. This is indicative of an inadequate involvement of the data end user in this process. It is disconcerting that so few actual data requirements are specified related to compliance with 40 CFR 191, given that Sandia has identified so many problem areas in the PA. From examination of the data needs identified in figures 1-3a - 1-3d, one would be inclined to conclude that the WIPP TRU waste characterization program is being driven exclusively by data needs associated with RCRA and transportation requirements. EPA considers this QAPP incomplete without a thorough analysis of data needs of the Performance Assessment associated with compliance with 40 CFR Part 191.

17.) Page 1-22, Figure 1-3b and Figure 1-3c. This figure does not include the Toxicity Characteristic Leaching Procedure (TCLP) as one of the elements under "Data Requirements" necessary to answer whether or not the waste exhibits the TC. The TCLP should be added as one of the Data Requirements.

18.) Pages 1-27/28, Table 1-3 (Continued). Table 1-3 presents a summary of the waste characterization requirements. 40 CFR Part §268.6 requires that the petitioner collect and analyze representative samples for all of the constituents that may present a threat to human health and the environment. 40 CFR Part 268 also requires DOE to analyze for the following: Nitrobenzene, 1,2 Dichloroethene, and 4-Methyl-2- Pentanone. EPA believes that the list of metals should be expanded to include antimony, vanadium, zinc, and cyanide, unless DOE can show why these metals should not be analyzed. Lastly, as noted above (Page 1-19, lines 12-18), DOE should be collecting and analyzing samples of debris.

19.) Page 1-30, lines 18-19. The QAPP states that debris wastes will be characterized by process knowledge. As stated previously, the EPA believes this to be inappropriate, since the contamination present in the debris may have occurred over a period of decades, with little assurance that the "processes" involved in producing the contamination have been kept under control. In fact, such debris waste would seem unlikely to have any reliable record associated with it. EPA believes that it will be difficult to provide the detailed justification for the use of process knowledge in order to adequately characterize this type of waste.

20.) Page 1-31, lines 18-20. The term "data quality objective" is defined in the QAPP. The definition given departs somewhat from EPA's definition on page 1 of EPA-QA/G4: "Data quality objectives are qualitative and quantitative statements derived from the outputs at each step of the DQO Process that: clarify the study objective, define the most appropriate type of data to collect, determine the most appropriate conditions from which to collect the data and specify acceptable levels of decision errors that will be used as a basis for establishing the quantity and quality of data needed to support the decision." G4 continues with the definition of the DQO Process: "a series of planning steps based on the Scientific Method that is designed to ensure that the type, quantity and quality of environmental data used in decision making are appropriate for the intended application."

The QAPP definition of DQOs does not reference the process which EPA recommends for use in creating them (i.e., G4 or a similar method). This omission may explain why the process of development of DQOs is not evident in the QAPP, and why there appears to be no connection between the DQOs for Performance Assessment and the potential end uses of the data by the PA

group.

21.) Page 1-31, line 27. A fundamental data quality objective for performance assessment would be to confirm waste characteristics assumed for use in the performance assessment. Unless a clear correspondence can be demonstrated between all performance assessment waste characteristic parameters and waste acceptance criteria, the EPA will likely view a compliance application as incomplete.

22.) Page 1-32, lines 1-3. In order not to identify TRU waste as low-level waste, the accuracy with which measurements in the 60-80 nCi/g range must be demonstrated.

23.) Page 1-33, lines 21-23. It is not clear from this discussion how a set list of analytes is sufficient for each of the DOE Field Offices? Is it possible for differing processes and operations, site and environmental conditions to be present at each of the field offices? If so, there should be a provision for allowing the field offices to analyze for other potential contaminants or Table 1-3 should be made as comprehensive as possible.

24.) Page 1-37, table 1-5. The Performance Demonstration Program should include analytical results, training/qualification records, calibration records, and procurement records should be considered "non-permanent" as opposed to "lifetime" records, especially in the light of the difficulties currently being encountered in retrieving adequate quality records to qualify existing data. Justification should be provided for making these categories non-permanent.

## Chapter 2 - Assessment and Oversight

1.) Page 2-1, line 13. This should be changed to read that corrective action shall be taken if any condition, or significant condition, adverse to quality is detected at any time, not just during an audit or assessment.

2.) Page 2-1, line 20. It is unclear as to whether or not all "site Program activities" at each DOE TRU waste generator sites must have a formal audit prior to shipping any waste and each year thereafter.

3.) Page 2-3, line 17. The term "nonconforming wastes" is used, but not defined.

4.) Page 2-4, lines 1-10. Documentation of each nonconformance event should include a discussion of the potential ramifications and overall useability of the data.

5.) Page 2-7. The Performance Demonstration Program is described. Single blind samples are to be prepared and distributed to participating laboratories. The mechanism for maintaining single-blindness needs to be described, since the program management and the participants are all DOE or DOE contractor staff. Also, it is doubtful that qualification of the analytical laboratories participating in the PDP exclusively on the basis of performance with single blind samples is sufficient. Comprehensive audits (including unscheduled audits) of the laboratory's organization, management, qualifications and training, operations and records, and internal QA/QC, etc. are also necessary. The QAPP needs to address this, identifying the criteria by which each laboratory will be qualified.

### Chapter 3 - Data Validation, Usability, and Reporting

- 1.) Page 3-1, lines 10-17. DOE's plans for verifying and validating data remains unclear. Please indicate whether or not double testing is planned.
- 2.) Page 3-1, lines 19-33. Reasons for changes should be provided. In addition, applicable sample identification numbers should be provided.
- 3.) Page 3-2, lines 4-6. Please indicate the kind of criteria to be used in selecting the independent technical review team. Also, it remains unclear as to the criteria to be used by site project managers to determine that there exists a sufficient amount of data.
- 4.) Page 3-2, line 21. It is not clear how a review of radiography tapes indicate that other data are correct and complete. Radiography data can indicate that other data are not correct by showing the presence of items that are at variance with the reported results from other investigations or other nonconforming items (free liquids, etc.). However, the lack of disagreement with radiographic results does not necessarily indicate agreement with other analytical data.
- 5.) Page 3-4, line 1. The lack of clearly defined acceptance criteria for Radiography data is a concern. Please refer to the comments in section 10, below.
- 6.) Page 3-4, line 4. From this discussion it appears that one (1) waste container at each TRU waste generator site will undergo a repeat of the process outlined in this section every three months, regardless of the number of waste containers submitted by the site. Please clarify.
- 7.) Page 3-5, line 14. The radiographic data should be validated at a frequency that is consistent with the program's

QAOS and should be determined prospectively. However, if the visual examination is the means used to assess the radiography data, the extent of radiographic data validation is limited or determined by the number of containers that undergo visual examination.

8.) Page 3-8, lines 5-9. The definition of "comparability" appears more applicable to the definition of "completeness" (percent of useable data). The importance of comparability of data sets collected from different sites is obscured by this definition. Site to site comparability is an important concern and needs to be addressed explicitly in the QAPP.

9.) Page 3-9, lines 16-18. The text states "...whether a sufficient number of waste containers have been visually examined to determine with a reasonable level of certainty that the  $UCL_{90}$  of the average miscertification rate is less than 14 percent." Please state the means by which DOE decided the use of the  $UCL_{90}$  and 14 percent as acceptable measurements for miscertification.

10.) Page 3-9, lines 23-24. "The procedure, which calculates  $UCL_{90}$  and  $LCL_{90}$  values, should be used to assess compliance with the DQOs in Section 1.5 as well as with RCRA regulations." DOE should justify its use of the  $UCL_{90}$  and  $LCL_{90}$  values.

11.) Page 3-10, Table 3-1. Table 3-1 presents the TC levels expressed as RTL values (i.e., 20 times the TC level) in the waste. DOE should recognize that either the TC levels may be adjusted or new TC contaminants will be listed in the future. DOE, therefore, should have a procedure for updating the RTL values listed in Table 3-1.

12.) Page 3-13, lines 10-13. "Electronic data...The electronic data package must be capable of conversion to and from ASCII format without loss of information. The required report elements, data fields, and field types are presented in Table 3-2." This language suggests that the DOE Field Offices will not be using the same electronic data packages. It would appear more efficient for the field offices to use the same electronic data package to facilitate data processing and to ensure that the required information is encoded.

#### Chapter 4 - Measurement and Data Acquisition

1.) Page 4-1, line 18-19. Please indicate whether or not these procedures are available for review.

2.) Page 4-3, line 15. This line should state that any piece of equipment requiring recalibration due to failure in meeting continuing calibration must be certified to be in calibration prior to reuse.



## Chapter 5 - Sampling Process Design

- 1.) Page 5-2, figure 5-1. Figure 5.1 indicates that "process knowledge" is used to assign wastes to a waste stream and to determine if the wastes in the stream are hazardous. Process knowledge must be quality assured before it is used.
- 2.) Page 5-3, figure 5-2. The design for characterization of newly generated waste begins with waste already containerized. The design needs to start with a thorough understanding of the processes (especially non-production processes) by which future wastes will be generated; followed by the development and application of administrative controls before and during the processes to assure that the processes have operated within established and documented administrative controls. Also, the statistical selection of waste containers for visual examination would seem to be unnecessary if the process of visual examination were built into the waste generating process.
- 3.) Page 5-3, Figure 5-2. DOE should justify its statement "based on results, determine if wastes....and report average concentrations of hazardous constituents." DOE should report the data so that summary statistics, representative of the entire sample population, can be generated.
- 4.) Page 5-4, lines 19-20; Page 5 of 13, lines 22-23. The document states "[n]ewly generated waste streams of solid process residues and soils must be sampled and analyzed once per year or once per batch." Determining if a newly generated waste stream is homogeneous without more frequent testing than once per year may be inadequate. Variation in constituent concentrations is likely to be exhibited, even by process wastes, in a much smaller time window than one year.
- 5.) Page 5-5, lines 5-27. The notion is put forward that debris wastes can be easily and adequately characterized for RCRA constituents by process knowledge. As mentioned above, EPA fails to see how this can be easily done, since debris would seem to have a highly uncertain history, and debris associated with future generated waste would seem likely to be associated with decommissioning activities. This needs to be clarified.
- 6.) Page 5-6, line 19 and elsewhere. The notion of segregating wastes by waste streams appears to be a critical part of the process for obtaining statistically acceptable sampling. The QAPP needs to explain how drums will be segregated by waste stream at sites such as Hanford, Savannah River, Oak Ridge, Los Alamos, and others, where waste stream segregation has not been practiced.
- 7.) Page 5-6, lines 22-23. Section 5.3.1 states that the "site

project manager shall validate that the samples collected from within a waste stream are representative of that waste stream." Please provide the guidance used for this validation process, particularly in regard to its use, documentation, and control.

8.) Page 5-6, lines 26-29. The document states "[i]n Phase One, a minimum of 10 waste containers per waste stream must be sampled and analyzed to obtain a preliminary estimate of the mean concentration and variance of each RCRA-regulated contaminant..." EPA typically requires a minimum of 20 samples before it allows petitioners to use mean concentrations; therefore, DOE should justify its selection of a minimum of 10 containers. In addition, when the number of waste containers is much larger, sampling of a minimum of 10 wastes containers may be non-conservative. DOE should provide a consistent procedure for determining how many samples must be collected. Alternatively, DOE could rely on stratified random sampling predicated on the collection of X samples every Y events (e.g., ten samples per every 50 containers). Clearly, such methodology should consider both the size of the waste container and the time period represented by the material.

9.) Page 5-7, figure 5-3. Figure 5-3 shows waste streams being segregated into "populations which contain similar waste" and then shows a random selection of "ten waste containers from each waste stream." For the sake of clarity, the term population should be defined.

10.) Page 5-7, figure 5-3; Page 5-8, lines 1-14. As noted above, DOE should justify its use of the  $UCL_{90}$  and  $LCL_{90}$  values for mean measurements. In addition, DOE should explain how it selected the values for alpha, beta, and  $\mu^*$ .

11.) Page 5-9, lines 1-16. DOE should discuss and justify the following: (1) "defined levels of acceptable error," (2) "desired level of confidence," and (3) the use of 90-percent confidence.

12.) Page 5-10, lines 4-11. DOE should make every attempt to obtain actual numeric values for each measurement. Alternatively, the data can be evaluated using the detection limit -- this is very conservative. The estimation of concentrations between 0 and the detection limit are sometimes arbitrary. This may artificially increase variance. Also, the evaluation of estimated data points often corroborates the use of 1/2 the detection limit -- especially if the data are normally distributed.

13.) Page 5-10, line 30. The miscertification rate of 2%, which is typical of the INEL experience is proposed as a system-wide baseline rate for all sites to use. This needs to be justified since virtually all of INEL's experience has been with Rocky Flats waste where segregation practices were driven by relatively

tight nuclear materials accountability. Much of the rest of the DOE system appears to have had much looser practices (no segregation, acceptance of wastes generated offsite with little documentation, legacy wastes, etc.).

14.) Page 5-11, line 1. Page 11 states that the site specific miscertification rate must be determined during the first year of "Program activities," which is assumed to mean the first year that the WCOAPP is in effect. However, this section is vague regarding the requirement to recalculate this rate annually.

15.) Page 5-11, lines 7-10. "The number of waste containers requiring visual examination will ensure the Program is 80-percent confident that if the indicated number of waste containers is examined, the  $UCL_{90}$  of the miscertification percentage will be less than 14 percent...." DOE needs to justify its selection of 80 percent confidence, the use of the  $UCL_{90}$  and the acceptability of and statistical basis for a 14 percent miscertification rate.

16.) Page 5-11, line 19-20. The assumption that 98% of the waste containers will be properly certified is highly questionable for system-wide applications for the reason cited above in comment number 13.

17.) Page 5-11, line 21-22. The assumption that "the certification process is uniform for all waste containers and is therefore unbiased regardless of waste stream" requires comment. Please state if this includes consideration of the difficulties associated with lead and other materials/items that have historically been problematic for radiography. Additionally, this statement raises questions regarding the definition and composition of a "waste stream."

#### Chapter 6 - Sample Handling and Custody Requirements

1.) Page 6-14, Table 6-2. DOE should clarify whether the minimum quantity of sample required includes adequate sample for Quality Assurance and Quality Control (QA/QC) samples. Note:

- SW-846 recommends a minimum of 200 grams of sample for metals determination (Volume 1A, page Three-3);
- SW-846 recommends a maximum holding time of 28 days for mercury (Volume 1A, page Three-3);
- SW-846 recommends a minimum of 112 grams of sample for VOCs analysis of soil/sediment and sludges and 224 grams of sample for VOCs analysis of concentrated waste samples (Volume 1B, Table 4-1, page Four-5).

SW-846 recommends a minimum of 224 grams of sample for Semi-VOCs analysis of soil/sediment and sludges, and concentrated waste samples (Volume 1B, Table 4-1, page Four-6).

### Chapter 7 - Headspace Gas Sampling

1.) Page 7-3, line 4. Please clarify how DOE is planning to accurately evaluate the headspace gases of all innermost layers.

### Chapter 8 - Sampling of Solid Process Residues and Soils

1.) Page 8-1, lines 16-22. The sampling procedure described here is not sufficient to adequately characterize both the temporal and spatial variations in constituent concentrations of the drummed waste.

2.) Page 8-1, lines 26-29. As previously noted, DOE should justify its selection of target analytes and expand the list to allow for the complete characterization of the waste.

3.) Page 8-2, section 8.1. Specific requirements/acceptance criteria for the QAOs precision, completeness, and comparability (as listed in this section) are not provided.

4.) Page 8-3, lines 2-3. The statement "[t]he entire depth of the waste must be cored and the core recovery must be 50 percent, or greater..." conflicts with the statement on Page 8-1, lines 16-22, "...the waste is first cored at a location randomly selected in the waste's horizontal plan and the core collected at that location must have a length greater than or equal to 50 percent of the depth of the waste. Then, the core is removed from the waste, a location is randomly selected along the core's length...."

5.) Page 8-11, lines 18-32. Section 8.6 should include the requirement for the report to document the total time of sample acquisition (e.g., coring, filling sample containers, and placing sample containers on ice).

### Chapter 9 - Nondestructive Assay

1.) Page 9-1, line 26. The notion that requirements may be imposed in place of the stated QAOs based upon site specific conditions needs to be clarified, as it gives the impression that the QAOs are not constant and that site-to-site comparability may be further compromised.

- 2.) Page 9-2, line 2. Please distinguish the meaning of the phrase "individual isotopes" as compared to individual alpha emitting isotopes or TRU isotopes.
- 3.) Page 9-2, line 11. The term "supportable process knowledge" is introduced here and variations of this concept are used elsewhere (please refer to general comment number 5). This term should be defined and how and when it can be used described. The Department needs to address this either with a guidance document or a position statement. If this is not done, the EPA is concerned that this concept will be used inconsistently from site to site, giving rise to additional comparability problems.
- 4.) Page 9-3, line 17. Please distinguish the meaning of the phrase "uncertainties in the assay" as compared to the total uncertainties for the assay (e.g., sampling error, systematic measurement errors, etc.). Also, please indicate how these are calculated.
- 5.) Page 9-2, line 29. Accuracy is not addressed here. The term "known quantity" is an insufficient description for a test waste container, especially for heterogeneous wastes.
- 6.) Page 9-4, lines 17-18. The relevant detection limits for the specific waste types and methods should be provided with justification.
- 7.) Page 9-6, line 9. It is agreed that the ability to achieve the QAO for uncertainty is not demonstrated on the basis of specific measurements. However, to put the responsibility for this determination on an "expert panel" seems inadequate. Will each site have a separate panel? What are the qualifications for panel members? Can personnel involved with actual measurements at one site be panel members at the same or different sites? This issue needs to be clarified and addressed more thoroughly in the WCQAPP, or appropriately referenced.
- 8.) Page 9-6, lines 25-28. The term "interlaboratory comparison program" is introduced. This needs to be defined and distinguished from Performance Demonstration Program used elsewhere. Also, the criteria used for determining the adequacy (or perhaps inadequacy) of existing programs need to be specified.
- 9.) Page 9-11, lines 19-21. The description given of intercomparison participation for sites using NDA methods is fairly vague and indefinite. Since NDA has so much uncertainty associated with it, and since it may be very difficult to determine site-to-site comparability, it is essential that the program for establishing this comparability be clear and specific.

- 10.) Page 9-11, line 26. Please provide the rationale for the exclusion of Supplement 2S-2.
- 11.) Page 9-13, line 7. Please indicate how data comparability will be maintained if each site determines and documents the range of waste types to which it will apply any given calibration as well as the set of correction factors it uses.
- 12.) Page 9-15, line 18. Are the replicates discussed in this paragraph the "verification standards" mentioned on page 4 under Bias? If so, the term should be used in this section.
- 13.) Page 9-16, line 7. Any reference for the requirements listed for documentation of the justification and demonstration of any alternate protocols should be provided here.
- 14.) Page 9-16, line 17. As stated, the uncertainty calculation must include the uncertainty from the "isotopic ratios." Please clarify how this type of uncertainty will be estimated and incorporated in the overall uncertainty determination.

#### Chapter 10 - Radiography

- 1.) Page 10-3, line 12. While there is currently no EPA method outlining a procedure for radiography as it is used in waste characterization, there are other industries that use radiography on a routine basis for purposes equivalent to this program. For example, Section 10.3, page 4 states that training requirements must be "based upon existing industry training requirements." The lack of direct EPA reference does not preclude the use of protocols from a comparable industry.
- 2.) Page 10-4, line 10. Please provide the rationale for the exclusion of Supplement 2S-2.
- 3.) Page 10-4, lines 19-26. This section is vague regarding the acceptance criteria for key aspects of this analytical technique, "requalification of operators" and "satisfactory performance."
- 4.) Page 10-5, line 5. Please clarify the meaning of "semi-quantitative." As stated in comment 10-1 above, do not other industries have procedures/protocols, acceptance criteria, standards, etc. that would be applicable here? This section would be strengthened by the inclusion of industry accepted techniques for this type of radiographic examination. The absence of EPA protocols does not preclude the application of standard protocols from a different but comparable industry.
- 5.) Page 10-5, line 15. Please indicate what constitutes a "visual examination expert" and how the "decision-making criteria" for the "expert" will be determined. Also, state

whether or not there will be an "expert" at each site.

### Chapter 12 - Gas Volatile Organic Compound Analysis

1.) Page 12-2, Table 12-1. Table 12-1 should be expanded to provide information on precision, accuracy, MDLs, PRQls, and completeness for all of the constituents listed. In addition, DOE should clarify whether the suggested MDLs for a specific method are performance criteria (i.e., DOE Field Offices can use any method as long as the meet the referenced MDL).

2.) Page 12-4, Table 12-2. DOE should justify its selection of the analytes listed on Table 12-2 as being complete and sufficient for completely characterizing the waste.

- General comment applying to entire section. Each of the DOE Field Offices should be held to the same exact protocols to ensure consistent data reporting and to facilitate data analysis. In addition, analytical methodologies and information on the necessary precision, accuracy, MDLs, PRQls, and completeness for all of the target constituents should be explicitly provided.

### Chapter 13 - Total Volatile Organic Compound Analysis

1.) Page 13-2, Table 13-1. Table 13-1 should be expanded to provide information on precision, accuracy, MDLs, PRQls, and completeness for all of the constituents listed. In addition, DOE should clarify whether the suggested MDLs for a specific method are performance criteria (i.e., DOE Field Offices can use any method as long as the meet the referenced MDL).

2.) Page 13-2, Table 13-1. DOE should justify its selection of the analytes listed on Table 13-1 as being complete and sufficient for completely characterizing the waste.

- General comment applying to entire section. Each of the DOE Field Offices should be held to the same exact protocols to ensure consistent data reporting and to facilitate data analysis. In addition, analytical methodologies and information on the necessary precision, accuracy, MDLs, PRQls, and completeness for all of the target constituents should be explicitly provided.

### Chapter 14 - Total Semi-Volatile Organic Compound Analysis

1.) Page 14-2, Table 14-1. Table 14-1 should be expanded to provide information on precision, accuracy, MDLs, PRQls, and completeness for all of the constituents listed. In addition, DOE should clarify whether the suggested MDLs for a specific method are performance criteria (i.e., DOE Field Offices can use

any method as long as they meet the referenced MDL).

2.) Page 14-2, Table 14-1. DOE should justify its selection of the analytes listed on Table 14-1 as being complete and sufficient for completely characterizing the waste.

- General comment applying to entire section. Each of the DOE Field Offices should be held to the same exact protocols to ensure consistent data reporting and to facilitate data analysis. In addition, analytical methodologies and information on the necessary precision, accuracy, MDLs, PRQs, and completeness for all of the target constituents should explicitly be provided.

#### Chapter 15 - Total Metal Analysis

1.) Page 15-2, Table 15-1. Table 15-1 should be expanded to provide information on precision, accuracy, MDLs, PRQs, and completeness for all of the constituents listed.

2.) Page 15-2, Table 15-1. DOE should justify its selection of the analytes listed on Table 15-1 as being complete and sufficient for completely characterizing the waste.

- General comment applying to entire section. Each of the DOE Field Offices should be held to the same exact protocols to ensure consistent data reporting and to facilitate data analysis. In addition, analytical methodologies and information on the necessary precision, accuracy, MDLs, PRQs, and completeness for all of the target constituents should explicitly be provided.