Steve F
WIPP File

Department of Energy
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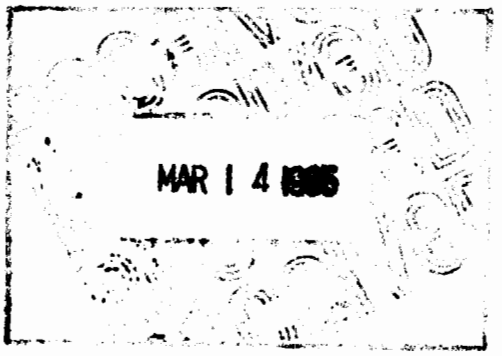
MAR 13 1995



Mr. Benito J. Garcia, Bureau Chief
Hazardous and Radioactive Materials Bureau
State of New Mexico-Environment Department
P.O. Box 26110
Santa Fe, NM 87502

Dear Mr. Garcia:

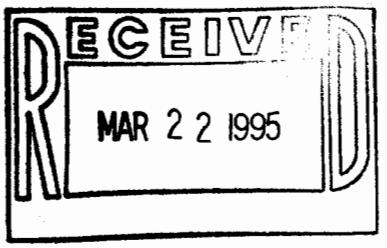
We have completed our review of your letter of December 12, 1994 transmitting your comments on the draft TRU Waste Characterization Quality Assurance Program Plan (QAPP), Rev. B, July 8, 1994.

Please find enclosed our response to your comments. The delay in transmitting our response to you was due to the need to ensure a consistent response was provided to the distinct sets of comments we received from you, the U.S. Environmental Protection Agency (EPA), and the Environmental Evaluation Group (EEG). We are proceeding with incorporating our response to the comments in the QAPP in order to meet our objective of completing the QAPP for its initial publication by May 1995. This objective is necessary to support the submittal of the No Migration Variance Petition for Disposal (to EPA in May 1995) and the Revised Resource Conservation & Recovery Act (RCRA) Part B Application (to NMED in June 1995). Future delays in issuing the initial QAPP will adversely affect the completion of the Quality Assurance Project Plan (QAPjP) at the individual generator sites. Completion of the QAPjPs is scheduled for September 1995, but this milestone is predicated on having an issued QAPP upon which to base the QAPjP.

If you have any questions regarding this letter, please contact me at (505)234-7467 or John F. Suermann of my staff at (505)234-7475.

Sincerely,

Mark L. Matthews, P.E.
Manager
National TRU Program



Enclosure

cc w/o enclosures:
P. McCasland, NMED-Carlsbad
C & C File

RESPONSE TO NMED COMMENTS ON THE *TRANSURANIC WASTE CHARACTERIZATION QUALITY ASSURANCE PROGRAM PLAN, REVISION B*

General Comments

#1 The QAPP follows the guidance provided by EPA in *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA/R-5)*. It is difficult to include extensive detail in the QAPP without greatly increasing the size of the document. The QAPP states repeatedly that the TRU Waste Characterization Program (TWCP) requirements apply to TRU waste generator/storage sites and the WIPP facility. The "QA Objective" of the document is stated on page 1-1, line 1, as; "...identifies the quality of data necessary, and the techniques designed to attain and ensure the required quality, to meet the specific objectives associated with the [DOE WIPP TRU] Waste Characterization Program (the Program)." The QAPP also includes information concerning the specific compliance programs and regulatory requirements that are to be addressed with the data collected. These compliance programs include: Performance Assessment (40 CFR Part 191), RCRA General Waste Analysis (40 CFR Part 270), RCRA Land Disposal Restrictions (40 CFR Part 268), and Transportation of Radioactive Waste (10 CFR Part 71).

In *Guidance for the Data Quality Objectives Process (EPA QA/G-4)*, DQOs are defined as; "qualitative and quantitative statements." The DQOs presented in Section 1.5 of the QAPP are quantitative statements when appropriate. For example, the DQO for radioassay under the "Performance Assessment" section provides for a "95-percent confidence that the total TRU activity is less than 100 nCi/g." Other DQOs refer to specific regulations that contain quantitative requirements. In addition, the discussion refers to the Quality Assurance Objectives (QAOs) contained in later sections (page 1-33, lines 26-29). The QAOs are stated in quantitative terms such as Precision determined as %RSD<30.

Section 1.1, Program Organization, will be modified to show clear lines of authority between DOE/HQ and DOE/CAO with respect to quality assurance. A separate and detailed description of the DOE/CAO QA Manager has been added with associated responsibilities for TWCP QA oversight and implementation. This position will be independent of cost, scheduling, and priority conflicts while retaining sufficient involvement with these functions to ensure QA is incorporated into all TWCP activities. Associated information such as document hierarchy and review/approval/implementation/control responsibilities for TWCP documents will also be modified to reflect an emphasis on centralized QA control of the TWCP.

A revised QAPP Figure 1-1, "Program Functional Organizational Chart" and QAPP Figure 1-2, "Program QA Document Hierarchy" are included with these responses.

The list of TWCP-required analytes is based on the following sources: toxicity characteristic contaminants as listed in 40 CFR § 261.24, Table 1 (except pesticides); the F-listed solvents (F001, F002, F003, F004, F005) found in 40 CFR § 261.31 and known to be used at DOE sites; hazardous constituents included in 40 CFR Part 261, Appendix VIII and reported by DOE TRU waste generator/storage sites; and constituents listed in the Conditional No-Migration Determination for WIPP (55 FR 47700). Based on a review of the analyte list, certain VOCs, specifically certain F-listed solvents may be deleted from the target analyte list because it has been determined that only a limited number of F-listed solvents were routinely used in weapons production. However, there is a provision in the QAPP for the addition of analytes if they appear as "Tentatively Identified Compounds" during normal TRU waste characterization activities. Although it is not specifically stated in the QAPP, other requirements for TRU waste restrict the inclusion of RCRA characteristic waste for disposal at WIPP. These restrictions are included in the *Waste Acceptance Criteria for the Waste Isolation Pilot Plant* (WIPP-WAC). Quality assurance requirements for the WIPP-WAC are addressed in site-specific certification plans. The text of the QAPP has been clarified, where appropriate, regarding the rationale for selection of TWCP analytes.

#2 The basis of the QAOs is the DQO process. This is stated both in Section 1.5 (page 1-33, lines 26-29) and in Section 4.1 (page 4-1, lines 12-16).The QAOs are stated in quantitative terms for all techniques except for precision and accuracy for "Sampling of Solid Process Residues and Soils" (Section 8.0). Specification of numeric QAOs for soils sampling is problematic and is an area where DOE requests additional discussion with the regulators. It is not clear to DOE how to implement the requirement found in SW-846, Chapter 1, to collect field duplicates. The variability of the waste is not known at this time so it is difficult to specify an acceptance criteria. The precision (as measured by RPD or %RSD) between field duplicates is dependent on the waste matrix, the specific analyte, and the concentration of the analyte. DOE requests additional discussion with EPA and NMED concerning the collection and acceptance criteria for field duplicates.

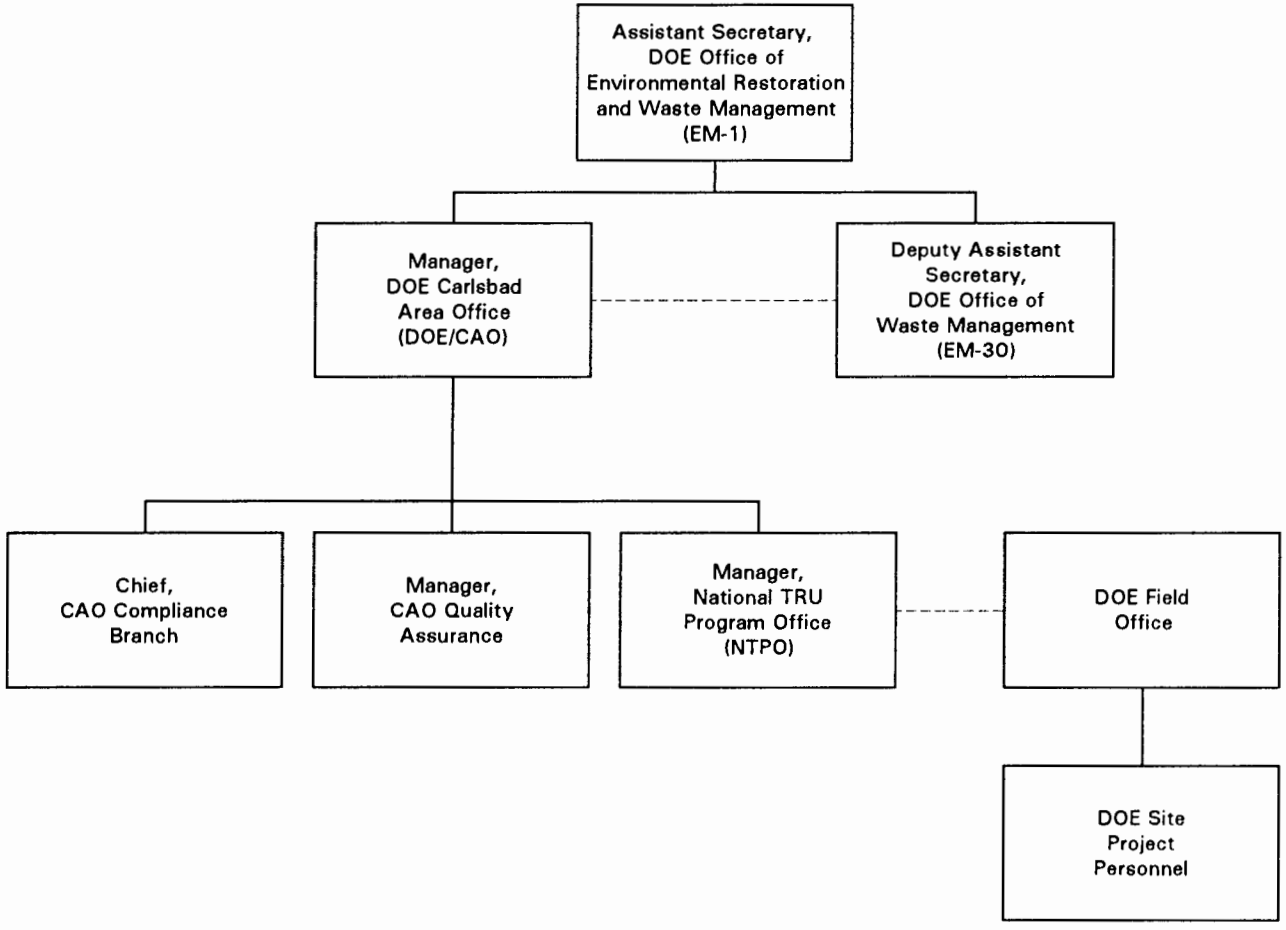


FIGURE 1-1

Program Functional Organizational Chart

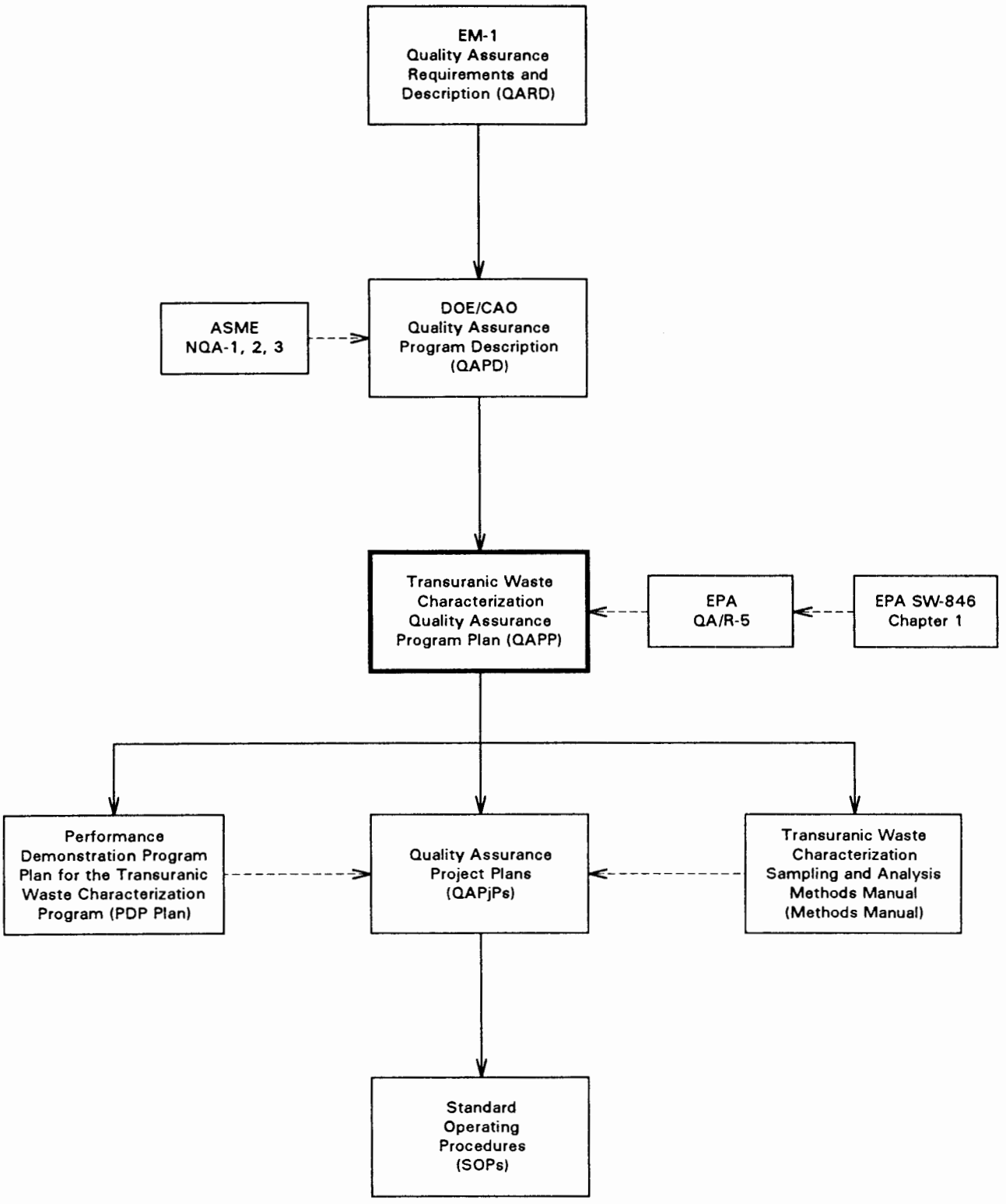


FIGURE 1-2

Program QA Document Hierarchy

#3 It unclear as to why NMED assumes that data validation will vary bet n sites. All sites (and sampling, testing, and analytical facilities) m follow the requirements for Data Review, Validation, and Verification outlined in Section 3.1. The QAOs have been developed and are included in Sections 8.0 through 15.0, as appropriate. Section 3.1.2 requires each site to develop a *Data Validation Summary* and a *Site Project QA Officer Summary*. Development and completion of these summaries involves the use of checklists while reviewing data on a per batch basis (see page 3-4, lines 7-18).

#4 The QAPP has been modified throughout to provide a definition of acceptable knowledge and use the term "acceptable knowledge" in a manner consistent with that provided by EPA in regulation and *Waste Analysis at Facilities That Generate, Treat, Store, and Dispose of Hazardous Wastes; A Guidance Manual*. All responses incorporate the term "acceptable knowledge" in place of the term "process knowledge."

Acceptable knowledge is used in TWCP activities in three ways; 1) to delineate waste streams, 2) to make all hazardous waste determinations for "debris waste" and 3) to determine if solid process residues and soils are RCRA-listed wastes. (Solid process residue and soil waste streams will be statistically sampled and analyzed in order to determine if they exhibit a toxicity characteristic.) Used for these purposes, acceptable knowledge balances the requirements for providing definitive chemical and physical characterization of waste streams with those circumstances where sampling and analysis is not feasible or necessary. Acceptable knowledge therefore can be used for RCRA characterization of waste streams for which it is difficult to obtain a representative sample because of physical form and/or heterogenous composition (e.g., metal, glass, combustibles). In these instances, acceptable knowledge will be supported (or verified) by radiography. Radiography will confirm the physical form of debris waste and by association, the RCRA constituents.

DOE will use its knowledge of the materials in debris waste and information regarding the processes that generated TRU waste (i.e., acceptable knowledge), in conjunction with nondestructive testing and headspace gas analysis to characterize these materials. Acceptable knowledge will be applied to identify the composition of base materials (e.g., lead in shielding). Results of headspace gas analyses will be used as a fingerprint or screening technique (e.g., to verify that flammable concentrations of VOCs are not present in the drum headspace). The text of the QAPP has been clarified, where appropriate, regarding this issue.

Contrary to the assertion that there are no quality controls on acceptable knowledge, there will be process flow diagrams and other types of supporting documentation included in compliance documents submitted to EPA and NMED. These quality controls will be subject to approval by the regulatory agencies. Additionally, decisions regarding waste characterization programs, as outlined in site-specific sampling plans, will be subject to review during audits and assessments. Waste that is not properly and completely characterized, whether by sampling and analysis or acceptable knowledge, will not be accepted for disposal at WIPP.

#5 The QAPP places requirements on the characterization of future generated wastes which are directly analogous to the requirements for characterizing existing wastes. Statements which seem less precise in their descriptions of future generated wastes are recognitions of unique factors associated with these wastes. By their nature, future generated wastes are less predictable and characterization requirements must accommodate this uncertainty. Generators have the opportunity to design process controls (both physical and administrative) to minimize resources required to characterize these wastes. Each site must develop applicable programs to meet the requirements of the QAPP when characterizing newly generated waste. The QAPP can not anticipate all of the possible scenarios that may be encountered during characterization of newly generated waste.

Future waste generation processes will be designed with waste characterization as a priority. A system of administrative controls is presently required for the characterization of newly generated waste in the QAPP (see Figure 5-2). Information from many sources may be used for the characterization of future generated waste, including the RCRA Facility Investigation/Corrective Measures Study (RFI/CMS) process, if applicable. For future generated waste, the most efficient means of gathering the required information will be designed into the waste generation process. The QAPP has been modified to require that these processes be described in site QAPjPs, SOPs, and sampling plans. This information will require approval prior to implementation of TWCP activities at each site.

#6 Section 2.1.1 indicates that a representative from DOE/CAO will be in charge of the audit program that reviews waste characterization activities at sites. This section has been clarified with the audit responsibilities being assigned to the CAO QA manager. The text has been further clarified to read; "Formal audits of Program activities at each site shall be performed before shipment of waste from that site and at least annually thereafter." The responsibilities assigned to the CAO QA manager include identifying; "the scope, requirements, personnel, activities to be audited, organizations to be notified, applicable documents and schedule." The QAPP goes on to say; "Formal audits must include evaluations of the site-specific field and laboratory activities and analytical laboratory protocols specified in the QAPjPs."

Container integrity will be assessed as part of the transportation requirements associated with TRU waste. These requirements are beyond the scope of the QAPP and will be addressed as part of other DOE TRU waste certification programs (e.g., WIPP-WAC, TRAMPAC).

#7 It was decided not to include specific forms in the QAPP because each site may have internal requirements for these items. In addition, sites may wish to develop a form that addresses not only TWCP requirements but also requirements associated with agreements with the state or other regulatory agencies. The QAPP specifies the content of the forms and the required information to meet TWCP needs without being so prescriptive that sites will have to develop multiple forms to meet the requirements of overlapping programs. Site-specific documentation must include approved forms. This documentation will be reviewed/approved as part of the QAPjP document control process or audit process.

#8 It is DOE's intention to have only one TWCP. This program is to address both contact-handled and remote-handled TRU waste. The DQO process will be applied in the determination of remote-handled waste characterization requirements. The DQO process will be used in order to address the relative impact of remote-handled waste to compliance issues (e.g., performance assessment, no-migration). When the remote-handled waste characterization requirements have been finalized, they will be incorporated into the QAPP during an annual review and revision. Section 1.2 of the QAPP has been clarified as follows; "This QAPP currently addresses only contact-handled TRU waste characterization activities. Future revisions will include requirements for both contact-handled and remote-handled TRU waste." Section 1.5 of the QAPP has been revised as follows; "During the annual review of the QAPP, the DQO Process will be employed to ensure the QAPP remains current with respect to the needs of the end users of data generated from Program activities."

#9 DOE understands that information provided as part of compliance documents, such as the permit application, cannot be changed without notification and, in some cases, approval of the responsible regulatory authorities. However, DOE also recognizes, and NMED must appreciate, that the implementation of a successful waste characterization program at ten different DOE facilities requires that the QAPP provide a mechanism to make changes to protocols, as necessary. All changes require review and approval by the site project manager. In order to avoid making changes to TWCP elements that may affect compliance documents, changes that may affect quality assurance/quality control requirements specified in the QAPP require approval of the respective DOE field office and the NTPO. NTPO will coordinate with other DOE/CAO offices and regulatory agencies, as appropriate, to ensure that compliance documents are not affected by the changes. The text of the QAPP has been clarified on page 1-15, line 8, as follows; "No changes that affect performance criteria or data quality; such as sample handling and custody requirements, sampling and analytical procedures, quality assurance objectives, calibration requirements or quality control sample acceptance criteria; shall be made without prior approval of the DOE field office and NTPO."

#10 DOE recognizes that in order to accept untreated mixed waste at WIPP, it must demonstrate no-migration of hazardous constituents through submittal of a no-migration variance petition to EPA. DOE plans to submit its petition in accordance with a schedule that considers the review of the petition by EPA as well as the RCRA permit application by NMED. DOE understands that the no-migration variance and permit must be issued by regulatory authorities prior to receipt of TRU mixed waste at the WIPP facility.

The DQO associated with VOC headspace gas sampling and analysis indicates that data will be obtained in support of a no-migration demonstration. In Section 1.3, "Land Disposal Restrictions," (page 1-19, lines 1-18) closure refers to completion of the WIPP operational phase and initiation of final closure of the repository (i.e., sealing of the shafts), when long-term performance evaluations are initiated. DOE intends to coordinate compliance programs for the operational phase and disposal phase to avoid conflicts in compliance activities. The QAPP has been reviewed to ensure that references to closure of the repository are specific to the no-migration demonstration requirements.

#11 T. uggested requirements have been incorporated into Section 6.3 of th APP as follows; "Participating laboratories must have a documented s le custody program that includes procedures for sample receiving and log-in, sample storage and numbering, sample tracking in the laboratory and storage of laboratory data. At a minimum, this program must include written procedures for the following:

- Chronological sample number sequencing
- Sample log-in (including determination of proper sample preservation)
- Identification of sample custodian
- Internal sample numbering and tracking systems
- Transfers of custody within the laboratory
- Example sample custody forms, with instructions for use
- Sample storage
- Sample disposal
- Analytical data maintenance and custody"

Section 1.0 - Program Management

#	Page	Lines	Response
1	6-12	all	Section 1.1, Program Organization, has been modified to show clear lines of authority between DOE/HQ and DOE/CAO with respect to quality assurance. A separate and detailed description of the DOE/CAO QA Manager has been added with associated responsibilities for TWCP QA oversight and implementation. This position will be independent of cost, scheduling, and priority conflicts while retaining sufficient involvement with these functions to ensure QA is incorporated into all TWCP activities. Associated information such as document hierarchy and review/approval/implementation/control responsibilities for TWCP documents will also be modified to reflect an emphasis on centralized QA control of the TWCP. Specifically, Section 1.1 has been clarified as follows; "Responsibility for Program quality is shared between DOE Headquarters, DOE/CAO and participating DOE generator/storage sites. The DOE Office of Environmental Restoration and Waste Management (EM-1) provides policy guidance and centralized management for DOE waste operations. The CAO manager ensures that program plans and operations are coordinated, integrated and consistent with Headquarters programs, policies and guidance. DOE/CAO has responsibilities to oversee the specific activities being performed at participating DOE generator/storage sites and ensure that Program requirements are met with regard to TRU waste testing, sampling, analysis, sample handling and custody and associated data management." Section 1.1.3 has been clarified as follows; "The DOE/CAO manager is responsible for overall implementation of DOE Headquarters programs, policies, and guidance for the National TRU Waste Program Office (NTPO) activities. The DOE/CAO manager is responsible for providing policy direction and oversight for waste characterization activities at participating DOE generator/storage sites. Authority for execution of the NTPO function, which ensures TWCP requirements are met with regard to TRU waste testing, sampling, analysis, sample handling and custody, and associated data management, is delegated to the NTPO manager. Overall responsibility for the development and implementation of the DOE/CAO quality assurance program belongs to the DOE/CAO manager. Authority for execution of the QA function, which ensures effective implementation, is delegated to the CAO QA manager. A new section (1.1.5) has been added to the QAPP describing the responsibilities of the Manager, Quality Assurance. This section will include the following description; "The CAO QA manager is responsible for verifying TWCP compliance at participating DOE generator/storage sites through audits. The CAO QA manager is responsible for approving the participation of all audit team members and observers. He also has responsibility for ensuring that through periodic audits at DOE generator/storage sites, waste characterization activities comply with applicable QAPjPs and implementing standard operating procedures (SOPs), as described in Section 2.1 of this QAPP." Section 1.1.3.5 has been renumbered as Section 1.1.6 and clarified as follows; "The National TRU Program Office manager is responsible for identifying issues that need to be addressed to properly manage TRU waste. The NTPO manager will develop options and recommendations, and propose priorities and guidelines for TWCP activities at participating DOE generator/storage sites. The NTPO manager is responsible for identifying data collection needs, establishing a TRU Waste Characterization Program Plan, and technical oversight. The NTPO manager is responsible for development and management of the planning process for the National TRU Program and waste characterization. In association with these activities, the NTPO manager has responsibility for review and approval of this QAPP." A revised Figure 1-1, "Program Functional Organizational Chart" is included with these responses. All applicable portions of the QAPP have been modified to be consistent with these changes. The QAPP limits descriptions of TWCP responsibilities to applicable positions. It is inappropriate to name individuals in these positions. Position titles only should be included in controlled documents since individuals change frequently in organizations.
2	13	24	Each site operates under requirements developed in response to needs associated with that site and in accordance with system-wide DOE QA requirements. Sites have organizations and procedures in place to develop and implement a variety of quality documents. In addition, all participants in WIPP or NTPO programs must comply with the requirements contained in the QAPD (see page 1, lines 17-18). The QAPP specifies a format and content for the QAPjPs and provides for an initial review and approval of QAPjPs by DOE/CAO. The text has been clarified as follows; "Each site must have a document control system to control the review and approval of controlled documents."

#	Page	Lines	Response
3	17	32	The QAPP places requirements on the characterization of future generated wastes which are directly analogous to the requirements for characterizing existing wastes. A system of administrative controls is presently required for the characterization of newly generated waste in the QAPP (see Figure 5-2). If information is available from other programs, such as the RCRA Facility Investigation/Corrective Measures Study (RFI/CMS) process, it will be used for waste characterization under the TWCP as well. Also see response to General Comment #5. The TWCP is equally applicable to existing and future generated waste, the only difference being that characterization of future generated waste may be more efficiently accomplished. For example, fewer containers may require intrusive sampling or visual examination to reach the TWCP confidence limits or waste streams may be more easily delineated. If it becomes apparent that the QAPP requires revision concerning future generated waste characterization activities, it will be revised to better reflect more appropriate techniques.
4	18	4	Acceptable knowledge will be used in TWCP activities to delineate waste streams and to make a hazardous waste determination on "debris" wastes. The QAPP has been modified throughout to provide a definition of acceptable knowledge and use the term "acceptable knowledge" in a manner consistent with that provided by EPA in regulation and *Waste Analysis at Facilities That Treat, Store, and Dispose of Hazardous Wastes; A Guidance Manual*. Acceptable knowledge refers to applying knowledge of the hazardous characteristic of the waste in light of the materials or processes used. This may include accompanying records; administrative, procurement, and quality controls associated with the processes generating the waste; and past sampling and analytical data. The major elements of acceptable knowledge include the process generating the waste, material inputs to the process, and the time period during which the waste was generated. Information required for characterizing waste using acceptable knowledge includes the physical form of the waste and documented changes to the process and/or material inputs. Also see response to General Comment #4, above. One of the goals of the TRU Waste Characterization Interface Working Group, led by the NTPO, is to develop and provide guidance concerning the use of acceptable knowledge in TWCP activities. This guidance will specify potential sources of acceptable knowledge and techniques that will be used in the course of TWCP activities to verify acceptable knowledge (e.g., radiography, headspace gas analysis). The guidance will ensure consistency in the use of acceptable knowledge among the various TRU waste generator sites. DOE does not believe that it is in the best interest of protecting human health and the environment to grind up radioactive materials to test for toxicity characteristics. Swiping the surfaces of materials will not provide a representative sample and result in increased exposure with no definitive data to make a hazardous waste determination. In addition, there will be process flow diagrams and other types of supporting documentation included in compliance documents submitted to EPA and NMED. This acceptable knowledge documentation will be subject to approval by the regulatory agencies. Additionally, decisions regarding waste characterization programs, as outlined in site-specific sampling plans, will be subject to review during audits and assessments. The text of the QAPP has been clarified throughout regarding this issue.
5	18-19	27	Because solid process residues and soils were not included in the test phase permit applications, there were no definitive discussions with NMED concerning acceptable confidence levels for data. DOE understood that NMED would defer to EPA concerning the acceptability of analytical results. In addition to specifying that sites must make a hazardous waste determination at the 90-percent confidence level, sites will be using data from total analyses to make this determination. Hazardous waste determinations based on data from total analyses will be conservative (see page 31, lines 1-6). A 95-percent confidence level does not seem necessary, especially in light of the fact that; 1) all TRU waste will be managed the same at the WIPP facility and 2) concerns over the level of exposure to radiation during TWCP activities.
6	18	12	Hazardous constituents are defined as those found under 40 CFR Part 261, Appendix VIII (see page 18, line 19).
7	21-25	Figs	Visual examination is used as a quality control check on radiography as described in Section 10.0. Therefore, visual examination is not a separate waste characterization technique, but is considered to be part of radiography. Figures 1-3a to 1-3d present the relationship between the specific compliance programs (i.e. Performance Assessment, RCRA General Waste Analysis) and the data requirements needed to answer questions associated with compliance. In contrast, Figures 1-4, 5-1, and 5-2 present the sequence of events and experimental design for the entire TWCP. Headspace gas sampling and analysis is not being performed as part of RCRA General Waste Analysis (Fig 1-3c). Information generated as part of headspace gas sampling and analysis (e.g., concentration of hydrogen, methane, and VOCs in the headspace) is not required to determine if a waste is hazardous.

#	Page	Lines	Response
8	26-28	Table	Formaldehyde and hydrazine are site-specific VOCs, so a decision was made to not include them in Tables 12-1 and 13-1. However, these compounds have been listed in the revised Tables 12-1 and 13-1 and footnoted as they are in Table 1-3. 1,2,4-trimethylbenzene and 1,3,5-trimethylbenzene were erroneously included in Table 1-3 under "Volatile Organic Compounds." The revised Table 1-3 does not include these two VOCs under this heading. Pyridine is listed in Table 13-1 but is footnoted that it can be analyzed as either a VOC or semi-VOC. In Table 1-3, pyridine is listed as a semi-VOC. The list of TWCP-required analytes is based on the following sources: toxicity characteristic contaminants as listed in 40 CFR § 261.24, Table 1 (except pesticides); the F-listed solvents (F001, F002, F003, F004, F005) found in 40 CFR § 261.31 and known to be used at DOE sites; hazardous constituents included in 40 CFR Part 261, Appendix VIII and reported by DOE TRU waste generator/storage sites; and constituents listed in the Conditional No-Migration Determination for WIPP (55 FR 47700). The text of the QAPP has been clarified, where appropriate, regarding the rationale for selection of TWCP analytes. Also see response to general Comment #1, above.
9	16	20-25	DOE understands the unique nature of the WIPP facility and the importance of retention of records associated with this facility. DOE is currently developing a long-term maintenance and control system for WIPP-related records. Records categories and retention requirements will be defined in Revision 0 of the QAPP.

Section 2.0 - Assessment and Oversight

#	Page	Lines	Response
10	1 2	26-30 10-30	The text has been clarified as follows; "Formal audits of Program activities at each site shall be performed before shipment of waste from that site and at least annually thereafter." In addition, the QAPP indicates that a final audit report must be prepared which includes the status and resolution of all conditions adverse to quality. If the report is satisfactory, the site will be given approval to participate in the TWCP (see page 3, lines 3-7). Specific responsibilities for TWCP audits will be clarified in the text as follows; "The NTPO Performance Assessment and Certification manager has overall responsibility for scheduling site audits, notifying sites of audit results, tracking and ensuring appropriate corrective action in response to audit findings, and coordinating the performance of the audits with the CAO QA manager. The CAO QA manager will select the Audit Team Leader and Audit Team members. When corrective actions are required, the site management shall provide a schedule that details all corrective action activities to the Audit Team Leader. The Audit Team Leader is responsible for the resolution of findings. The NTPO Performance Assessment and Certification manager will ensure that corrective action activities are being performed according to the schedule provided by site management.
11	3	14-20	The term "nonconforming waste" has been deleted from this discussion.
12	5	23-31	10 CFR § 830.120 does not require DOE facilities to establish outside organization audits as part of the QA program to demonstrate independence. Independence is maintained by having an individual not directly involved with the activity being audited conducting the audit. It is important to have audit team members with knowledge and experience of DOE operations and activities. Environmentel audits, a similar activity, are routinely performed by individuals from the same organization, but independent of the activities being audited. As per previous agreements, representatives from agencies external to DOE will be allowed on audits as observers.

#	Page	Lines	Response
13	6-7	Sec 2.3	The current PDP Plan was developed for the Experimental-Phase Waste Characterization Program and so is outdated. A new PDP Plan is being developed to reflect all of the waste characterization activities outlined in the QAPP.

Section 3.0 - Data Validation, Usability, and Reporting

#	Page	Lines	Response
14	1	12	The requirements for data reduction are provided in Sections 9.0 through 15.0 and the specifics of how to reduce data are provided in the Methods Manual. The text has been clarified regarding this point, as appropriate. It is beyond the scope of the QAPP to provide procedures to check for errors. Each participating testing and/or analytical facility must have SOPs that implement data review, validation, and verification as specified in the first paragraph of Section 3.0 (see page 1, line 6).
15	1	23-25	Line 20 on page 2 has been modified to read; "Sample holding time and preservation requirements were met, or exceptions documented." The text of the third bullet on page 1 has been clarified as follows; "A justification for changing the original data must also be included."
16	2	 4-6 12-13	The text has been clarified as follows; "Any nonconformance identified during this process shall be documented on a nonconformance report (Section 2.1.2.1)." The text has been clarified as follows; "This review shall be performed by an individual other than the data generator who is qualified to have performed the initial work." A reference to Section 2.1.2.2 (Operational Variances) has been added to line 13.
17	2 4	21-22 1	There are no acceptance criteria for radiography; DOE considers all radiography data useable. An independent reviewer will compare the data reported on the "Radiography Data Form" (see Section 10.0) with the radiography videotape. The text has been clarified as follows; "...against the data reported on the radiography form..." In addition to this videotape review of every tenth drum at the data generation level and one per batch at the project level, visual examination will be used as a quality control check on radiography as outlined in Sections 5.0 and 10.0. Section 10.0 has been revised, where appropriate, to require comparison and reporting of radiography and visual examination results. The comparison of results will be accomplished by calculating the percent difference between radiographically and visually determined Waste Material Parameter weights. There are no specific limits on allowable percent difference.
18	2 3	4-36 1-9	The text on page 2, line 2 has been clarified as follows; "Any nonconformance identified during this process shall be documented on a nonconformance report (Section 2.1.2.1)."
19	3	19 26-27	Because each participating site may wish to include information in addition to that required for the TWCP, example forms are to be included in site-specific documentation (see page 11, lines 30-31) and so will not be included in the QAPP. However, the text of Section 3.1.1 of the QAPP has been clarified regarding the use and content of checklists as follows; "Individuals conducting this data review, validation and verification must use checklists that address all of the items included in this section. Checklists must contain tables showing the results of batch QC samples, if applicable. Completed checklists must be forwarded with batch data reports to the project level." As specified in Sections 7.0 and 8.0, field QC samples will be included in every batch of samples sent for analysis. The sampling sections include the criteria for field QC sample collection and acceptance, including the QAOs applicable to these samples. A reference to Sections 7.0 and 8.0 has been added to the text on page 3, line 27.

#	Page	Lines	Response
20	4	4-18	The total number of waste containers characterized in a given quarter does not impact the number of waste containers chosen for this repeat exercise. One waste container per quarter will be chosen for this exercise regardless of the total number of waste containers characterized. Waste sampling activities will limit the number of samples that can be analyzed during a quarter. Data review, validation and verification is a three-stage process where each level routinely checks the data for errors. The "repeat exercise" is only a check on the data generation level review, validation and verification process. In addition, both sites and sampling, testing and analytical facilities will be routinely audited as described in Section 2.0 and elsewhere. Therefore, in combination with these additional checks on data quality, a review of one drum per quarter at the project level is sufficient.
21	5	6-25	The data validation "procedures" are provided as equations for calculating precision, accuracy, method detection limit and completeness (see equations (3-1) to (3-8)). The results of these quantitative determinations will then be compared to the QAOs specified for each analyte in Sections 11.0 through 15.0. The text of the QAPP has been clarified as follows; "...according to the conventional procedures outlined below (Equations (3-1) to (3-8)). These quantitative determinations will be compared to the QAOs specified in Sections 11.0 through 15.0." Participating sampling, testing and analytical facilities are required to forward nonconformance reports along with batch data reports to the site project office (see "Data Reporting" portion of Sections 7.0 through 15.0). In addition, the text of the QAPP has been modified to require a nonconformance report to be filled out during the data review, validation and verification process at both the data generation and project levels (in the event a nonconformance is identified during this process). Appropriate corrective action is to be determined at the data generation level and/or project level as part of the nonconformance disposition (see Section 2.1.2.1). Summarized data reports sent to DOE/CAO must include a narrative that, "...describes any problems or other noteworthy items of interest associated with the data (e.g., nonconformance reports, [operational] variances)" (see page 12, lines 22-26). Data validation requirements for field QC samples are specified as QAOs in Section 7.0 and 8.0, as applicable. The precision, accuracy, and completeness for field QC samples are determined the same way as for analytical QC samples. Section 3.4, Data Reporting Requirements, outlines the contents of the data package, which includes data validation information to be forwarded to the site project QA officer. Section 3.4 also refers the reader to Sections 7.0 through 15.0 for the details of the information to be reported for each sampling, testing, or analytical technique. The QAPP states; "The report forms and checklists used must contain all of the information required by the testing, sampling, and analytical methods described in Sections 7.0 through 15.0 of this QAPP, as well as the signature releases to document the review, validation, and verification as described in Section 3.1" (see page 11, lines 27-29). The second paragraph in Section 3.2 has been clarified to indicate that both the Waste Matrix Code and Waste Material Parameter weights for existing waste will be determined by both radiography (100% of waste containers) and visual examination (statistically selected number of containers) and compared to verify the results of radiography. A reference to Section 10.0 has also been added to this paragraph. One hundred percent of the radiography data will be validated according to the procedures outlined in Section 3.1 (i.e., independent review of radiography tapes). The selection of containers for visual examination is outlined in Section 5.0, and is based on the WIPP-WAC miscertification rate for each site. Also see response to Comment #17, above. Radiography/visual examination will not be required for newly generated or repackaged waste. In these instances, the goals of radiography/visual examination will be accomplished during the packaging operations. The text of the QAPP has been clarified, where appropriate, regarding this point. Section 10.0 has been revised, where appropriate, to require comparison and reporting of radiography and visual examination results. The comparison of results will be accomplished by calculating the percent difference between radiographically and visually determined Waste Material Parameter weights. There are no specific limits on allowable percent difference.
22	6-7	all	The acceptance criteria for headspace gas field duplicate results are presented in Section 7.0. Representativeness for field samples is discussed in Sections 7.0 and 8.0. The issue of acceptance criteria for field duplicates of solid phase waste is more problematic. It is not clear to DOE how to implement the requirement found in SW-846, Chapter 1, to collect field duplicates. The variability of the waste is not known at this time so it is difficult to specify an acceptance criteria. The precision (as measured by RPD or %RSD) between field duplicates is dependent on the waste matrix, the specific analyte, and the concentration of the analyte. DOE requests additional discussion with EPA and NMED concerning the collection and acceptance criteria for field duplicates.

#	Page	Lines	Response
23	8	5-8	Key quality criteria for all analytes and testing, sampling and analytical methods are given in the QAPP in Sections 7.0 through 15.0. These criteria include specification of QAOs, QC sample frequency, equipment calibration and cleaning, and acceptable methods found in the Methods Manual or SW-846. In addition, if a site chooses a method that is not included in the Methods Manual or SW-846, the QAOs must still be met, and the method must be submitted to DOE/CAO for approval. In this way, data will be comparable between sites. Section 3.2.5 has been revised as follows; "Comparability of data generated at different sites will be assured through the use of standardized, approved testing, sampling and analytical techniques, and by meeting the QAOs specified in Sections 7.0 through 15.0. The techniques presented in Sections 7.0 through 15.0 of this QAPP, and provided in greater detail in the Methods Manual, are acceptable and will meet Program requirements."
24	9	17-18	The 14 percent miscertification rate has been accepted as part of the certification programs associated with WIPP-WAC and TRAMPAC requirements. Visual examination is used in the TWCP only as a quality control check for radiography. The TWCP is using the WIPP-WAC/TRAMPAC certification programs as a way to determine the number of containers that will be visually examined. At this time, given the lack of certainty regarding the importance of the Waste Material Parameters to long-term performance assessment, there is no reason to make TWCP requirements more stringent than those associated with WIPP-WAC/TRAMPAC certification.
25	10	Table	The list of TWCP-required analytes is based on the following sources: toxicity characteristic contaminants as listed in 40 CFR § 261.24, Table 1 (except pesticides); the F-listed solvents (F001, F002, F003, F004, F005) found in 40 CFR § 261.31 and known to be used at DOE sites; hazardous constituents included in 40 CFR Part 261, Appendix VIII and reported by DOE TRU waste generator/storage sites; and constituents listed in the Conditional No-Migration Determination for WIPP (55 FR 47700). Also see response to general Comment #1, above. VOCs and semi-VOCs listed in Tables 13-1 and 14-1 and not found in Table 3-1 are not TC contaminants; they are hazardous constituents found in 40 CFR Part 261, Appendix VIII. The concentrations of Appendix VIII constituents will be reported, but do not need to be compared to a regulatory limit to determine if a waste exhibits a toxicity characteristic.
26	11	4	At this time the overall purpose of the QAPP is to support the collection of data for inclusion in compliance documentation. DOE/CAO is compiling all waste characterization data and will summarize it as part of the WIPP No-Migration Variance Petition, RCRA permit application and 40 CFR Part 191 Certification Application. If insufficient data is collected, the action required is to ensure that the generator/storage sites continue to collect additional data. It is correct that other information, such as solubility data, is necessary for a compliance demonstration; however, the QAPP only addresses waste characterization data. In some instances, data needs are being addressed by other programs. For example, gas generation data will be provided by the Enhanced Laboratory Program and actinide solubility data will be provided by the Source Term Test Program. When sufficient data are collected, DOE will prepare compliance documents for review and approval by regulatory agencies. Corrective actions are required at the generator/storage sites when data does not meet the QAOs (e.g., precision and accuracy for specific measurements). DQOs describe how the data will be used to address specific programmatic needs (e.g., does a waste exhibit a toxicity characteristic). Reconciliation of DQOs, such as achieving the required confidence for determining if a waste exhibits a toxicity characteristic, is done at the project level prior to transmitting the data to DOE/CAO. As indicated (page 9, line 19), if insufficient data have been collected to make a specific determination, additional data must be collected.
27	11	30-31	Sites must develop forms that; "...contain all of the information required by the testing, sampling, and analytical methods described in Sections 7.0 through 15.0 of this QAPP" (see page 11, lines 27-28). Sections 11.0 through 15.0 also include data flags to use when reporting analytical data. One of these flags, 'J,' is for analytes less than the PRQL, but greater than the MDL.
28	13	16	The waste stream information required from each site is outlined in Section 3.3.1, as stated on page 13, line 17.
29	16	Table	The electronic data package includes the date sampled and the date analyzed. The date of sample preparation and if cleanup was necessary is not relevant to the QAOs. All analytical methods, including sample preparation and cleanup techniques, must be approved by DOE/CAO prior to use. The electronic data package has a field; "Data Validation Summary completed? (yes/no)" (see page 17). The actual summary is provided to DOE/CAO in hard copy. It is not necessary to provide this information in electronic format because the information is not used in compliance documents. All data must be validated in accordance with the requirements in the QAPP. The summary provides documentary evidence that the data validation was completed.

Section 4.0 - Measurement and Data Acquisition

#	Page	Lines	Response
30	1	18-21 24-25	Section 4.0 provides a general discussion of information found for each testing, sampling and analytical technique provided in Sections 7.0 through 15.0 of the QAPP. The "Methods Requirement" portion of Sections 7.0 through 15.0 provides the specific requirements for each technique. In the case of analytical techniques (Sections 11.0 through 15.0) the specific SW-846 or ASTM method (or modified method) is referenced. The text of the QAPP has been clarified as follows; "Sections 4.1 through 4.6 follow the format of Sections 7.0 through 15.0 of this QAPP and provide a general discussion of the information provided for each testing, sampling and analytical technique. All of the requirements included in Sections 4.2 through 4.5 must be implemented at the testing, sampling and analytical facilities with site-specific SOPs." Criteria critical to the quality of a particular technique is provided in the QAPP (e.g., QAOs, QC sample acceptance and frequency, equipment calibration). However, the detail of specific methods and procedures is reserved for the Methods Manual and SW-846.
31	2	5-15	It is difficult to specify the equipment testing, inspection and maintenance requirements for all of the equipment that may be used for TWCP activities. This level of detail is best reserved for individual facilities to develop in response to needs associated with the equipment used and the waste samples being collected, tested or analyzed. The text of Section 4.0 has been modified as follows; "All of the requirements included in Sections 4.2 through 4.5 must be implemented at the sampling, testing, and analytical facilities with site-specific SOPs."
32	2	16-28	It is difficult to specify the equipment calibration and frequency requirements for all of equipment that may be used for TWCP activities. This level of detail is best reserved for individual facilities to develop in response to needs associated with the equipment used and the waste samples being collected, tested, or analyzed. The text of Section 4.0 has been modified as follows; "All of the requirements included in Sections 4.2 through 4.5 must be implemented at the sampling, testing, and analytical facilities with site-specific SOPs."
33	3	22	The content of the forms is specified in the QAPP, but actual development of forms will be left up to the individual sites. Often, reporting forms must conform to site-specific requirements. Also, certain sites may wish to combine reporting requirements from additional programs (e.g., WIPP-WAC) on one form.

#	Page	Lines	Response
34	1	6-15	The QAPP has been modified throughout to provide a definition of acceptable knowledge and use the term "acceptable knowledge" in a manner consistent with that provided by EPA in regulation and *Waste Analysis at Facilities That Generate, Treat, Store, and Dispose of Hazardous Wastes; A Guidance Manual.* Acceptable knowledge refers to applying knowledge of the hazardous characteristic of the waste in light of the materials or processes used. This may include accompanying records; administrative, procurement, and quality controls associated with the processes generating the waste; and past sampling and analytical data. The major elements of acceptable knowledge include the process generating the waste, material inputs to the process, and the time period during which the waste was generated. Information required for characterizing waste using acceptable knowledge includes the physical form of the waste and documented changes to the process and/or material inputs. Contrary to NMED's assertion that there are no quality controls on acceptable knowledge, there will be process flow diagrams and other types of supporting documentation included in compliance documents submitted to EPA and NMED. These quality controls will be subject to approval by the regulatory agencies. Additionally, decisions regarding waste characterization programs, as outlined in site-specific sampling plans, will be subject to review during audits and assessments. Waste that is not properly and completely characterized, whether by sampling and analysis or acceptable knowledge, will not be accepted for disposal at WIPP. Section 5.0 describes the sampling process design for solid process residues and soils. The QAPP states that generator/storage sites will use acceptable knowledge to sort wastes into waste streams (page 1, lines 6-15). After sorting, waste streams of solid process residues and soils will then be sampled and analyzed for toxicity characteristic contaminants and hazardous constituents. If sites do not sort the waste adequately, (e.g., if a waste generated over time varies but is not segregated by time), then the analytical results will indicate a large degree of variability in constituent concentrations. The site will then have to collect and analyze additional samples from the waste stream to obtain the required confidence. The more acceptable knowledge that is available to segregate waste streams, the less sampling will be required. In any case, all sites must collect sufficient data to determine with the required confidence if the waste exhibits a toxicity characteristic. To determine if a waste is listed, sites must use acceptable knowledge. Concentration is never a factor in determining if a waste is listed, including the application of the mixture or derived from rules. DOE is seeking a variance from the land disposal restriction to dispose of untreated mixed waste at WIPP. Therefore, it is not required to test waste to demonstrate that the treatment standards are met. DOE is collecting data regarding the average total concentrations of hazardous constituents in TRU waste to comply with the waste characterization requirements for a no-migration demonstration. With regard to debris waste forms, DOE is following EPA guidance regarding the use of acceptable knowledge as provided in *Waste Analysis at Facilities that Generate, Treat, Store, and Dispose of Hazardous Waste*. EPA suggests situations where it may be appropriate to apply acceptable knowledge, including: • Hazardous constituents in wastes from specific processes are well documented (e.g., F-listed wastes) • Health and safety risks to personnel would not justify sampling and analysis (e.g., radioactive mixed waste) • Physical nature of the waste does not lend itself to taking laboratory samples (e.g., debris waste) DOE will use its knowledge of the materials in debris waste forms and information regarding the processes that generated TRU waste (i.e., acceptable knowledge), in conjunction with nondestructive testing and headspace gas analysis to characterize these materials. Acceptable knowledge will be applied to identify the composition of base materials (e.g., lead in shielding). The Waste Material Parameters will be confirmed using radiography and visual examination. In plutonium fabrication, weapons production and weapons research operations, solvents are used for cleaning and degreasing and therefore are identified as F-listed solvents. The concentrations are not applicable, therefore sampling is not required to make this determination. Results of headspace gas analyses will be used as a fingerprint or screening technique (e.g., to verify that flammable concentrations of VOCs are not present in the drum headspace). DOE generator/storage site missions have been well-defined and limited. TRU waste is containerized and managed in a controlled manner to prevent the release of radioactivity. DOE is not aware of waste for which no acceptable knowledge is available. At a minimum, records exist regarding the point of generation (e.g., the site and building). Additional records exist regarding the operations and processes conducted at each site and building.

#	Page	Lines	Response
35	1	17	The definition of a waste stream is included in the QAPP (see "Definitions," page 7). This definition has been added to the QAPP, where appropriate. Grouping of wastes for the purposes of sampling and analysis is left up to the sites to decide. However, if a site disregards consistency and similarity of wastes when grouping into waste streams, many more samples will be required in order to achieve the required level of confidence. It is in the best interests of the sites to limit the variability of waste in a waste stream in order to achieve the required level of confidence with a minimum of sampling and analysis. Also see the second paragraph of the response to Comment #37.
36	1	23-25	The text of the QAPP has been clarified throughout concerning the definition of a waste stream and the association between waste streams and Waste Matrix Codes. Also see response to Comments #35 and #37.
37	2-3	Figs	As stated in Sections 1.5 and 3.4, confidence statements about the average will also be reported. Although the confidence statements reflect the variability observed in the waste stream, the QAPP has been modified, where appropriate, to require that the standard deviation and the number of observations also be reported. The sampling scheme accounts for the estimated variability in the waste stream, no matter how the waste stream has been defined. The calculated number of samples to be collected from the waste stream increases as the estimated variability increases. To avoid potentially excessive sampling that results from elevated variability, similar wastes are grouped into waste streams and waste streams should not be combined. The description of appropriate grouping of wastes for characterization has been clarified throughout Section 5.0 to emphasize that waste streams should be relatively homogeneous in nature. The last step in both Figure 5-1 and 5-2 has been changed to; "From the waste stream characterization data, develop a description of each waste stream."
38	4	29-30	VOCs and semi-VOCs listed in Tables 13-1 and 14-1 and not found in Table 3-1 are not TC contaminants; they are hazardous constituents found in 40 CFR Part 261, Appendix VIII. The concentrations of Appendix VIII constituents will be reported, but do not need to be compared to a regulatory limit to determine if a waste exhibits a toxicity characteristic. The list of TWCP-required analytes is based on the following sources: toxicity characteristic contaminants as listed in 40 CFR § 261.24, Table 1 (except pesticides); the F-listed solvents (F001, F002, F003, F004, F005) found in 40 CFR § 261.31 and known to be used at DOE sites; hazardous constituents included in 40 CFR Part 261, Appendix VIII and reported by DOE TRU waste generator/storage sites; and constituents listed in the Conditional No-Migration Determination for WIPP (55 FR 47700). Based on a review of the analyte list, certain VOCs, specifically certain F-listed solvents may be deleted from the target analyte list because it has been determined that only a limited number of F-listed solvents were routinely used in weapons production. However, there is a provision in the QAPP for the addition of analytes if they appear as "Tentatively Identified Compounds" during normal TRU waste characterization activities.
39	5	6-14	Acceptable knowledge is adequate to characterize debris waste. TRU wastes contain very few D-coded solvents. In the cases where solvents are found that are not listed wastes, either the site will conservatively include the D-code or will have documentation to prove the waste does not exhibit the toxicity characteristic. Debris wastes are generated from the same processes as homogenous waste streams (e.g., plutonium reprocessing). The RCRA regulated contaminants associated with these processes are well documented, and so the contaminants associated with debris wastes are also well documented. For example, graphite debris generated as part of "Process X" will contain only those hazardous constituents known to be used in "Process X." If hazardous constituents 'A & B' are known to be used in "Process X," these hazardous constituents will be assumed to be present in all debris waste streams generated from "Process X." Metals are associated with base materials (e.g, cadmium plated tools or lead bricks). The sites have included the appropriate D-code if the TC metal is present. DOE does not believe that it is in the best interest of protecting human health and the environment to grind up radioactive materials to test for TC metals. Swiping the surfaces of materials will not provide a representative sample and will result in increased exposure with no definitive data to make a hazardous waste determination. DOE is seeking a variance from the land disposal restrictions and, if successful, will not be required to provide documentation that TRU mixed wastes meet the treatment standards under 40 CFR Part 268 (i.e., the concentration of Appendix VIII constituents).

#	Page	Lines	Response
40	5	22-23	Generator sites use acceptable knowledge to determine the RCRA-regulated constituents present in newly generated waste streams of solid process residues and soils and to determine if these waste streams are hazardous. The once per year or once per batch sampling and analysis of these waste streams is meant to verify this information. Both existing and newly generated debris waste streams will be characterized for RCRA constituents using acceptable knowledge, not sampling and analysis. The following has been added to line 23; "Sampling frequency of once per year is only allowed if a process has operated within established and documented administrative controls for the previous year. Otherwise the waste must be considered as 'batches.'"
41	6	4	Section 10.0 indicates that sites must compile an inventory of waste items, residual materials and packaging materials and also develop look-up tables to assist in estimating weights and volumes (see pages 10-3 and 10-4, lines 27-2). Additional detail is provided in the Methods Manual and a reference to the Methods Manual has been added to the QAPP. The text has been modified to read; "...visual examination to confirm the Waste Matrix Code and Waste Material Parameter weight estimates as determined by radiography."
42	6	9	Representativeness is validated if it is documented that a true random sample was taken. This has been clarified; "Representativeness of drums subjected to visual examination and sampling and analysis will be validated through documentation that a true random sample was collected." This issue has been clarified throughout the QAPP. It is not necessary to compare samples from the same waste stream from different DOE facilities because the intent is to document whether a waste stream from a particular DOE facility is hazardous.
43	6	27	Section 5.0 of the QAPP has been modified to accommodate a more general requirement regarding Phase One sampling. Instead of a specified number (10) of samples being required, a preliminary estimate for mean and variance, with justification, will be required for the purposes of determining sample size. To obtain a preliminary estimate of mean and variance, data will be generated through preliminary sampling and analysis of a waste stream, or data from previous sampling and analysis of the waste stream can be used, if available. As a result, the Phase One decision process has been omitted and the decision of hazardous or nonhazardous will be made on the basis of the upper confidence limit after sufficient random sampling of the waste stream has occurred. The revised text also includes a procedure for examining the sampling precision for suitability prior to decision making.
44	7	Fig	The term "waste population" has been changed to "waste stream" for consistency.
45	8	1-14	Because the decision process has been changed (see response to Comment #43), only the UCL_{90} for the mean will be calculated. The UCL_{90} is desirable because it accounts for the variability in the sample mean. For an UCL_{90}, the interpretation is that there is a 90% chance that the true mean is less than the UCL_{90}. The error rate of 10% is acceptable because the consequences of an error are relatively small. Despite the TC determination, the waste will be shipped to WIPP and handled in the same manner. The operational phase no-migration demonstration (prior to final repository closure) is evaluated using headspace gas concentrations and not total or TCLP concentrations. The disposal phase no-migration demonstration (after final repository closure) will be evaluated assuming liquid/gas phase equilibrium for VOCs and the maximum solubility for semi-VOCs and metals in brine. Safety analyses use conservative exposure scenarios that are not impacted by the TC decision. Therefore, a determination that hazardous waste is nonhazardous (or vice versa) has minimal impact. DOE is not aware of EPA or NMED requirements to make hazardous waste determinations at a specified confidence level. DOE requests that such information be provided, if available. The value of μ^* must be between zero and RTL for this application; the closer the value is to the RTL, the smaller the Type II error rate will be and the greater the required number of samples. The value of μ^* was selected to be 1/2 RTL in order to have a reasonable Type II error rate and at the same time achieve a reasonable sample size determination. The sample size formula has been changed to one that ensures a constant relative precision in the results based on acceptable Type I and Type II errors when the true value is 1/2 RTL but does not now include the parameter μ^*. The reasoning for the 1/2 RTL basis for the relative precision is the same as for μ^*, however.

#	Page	Lines	Response
46	8	Eq (5-5)	The sample size formula has been changed to that given in Cochran (1977), page 77 for reasons cited in response to Comment #45. The source has been added to the QAPP (see; William G. Cochran. 1977. *Sampling Techniques*, New York, John Wiley & Sons). The source of the method used to calculate "n" has been added to the text, where appropriate, and refined to accommodate cases of unknown variance and small sample sizes. The selection of 1/2 RTL for μ^* in the previous formula is addressed in the response to Comment #45. The parameter μ (not μ^*) in SW-846 refers to the population mean, and so is estimated by the sample mean, but in the QAPP, μ^* does not refer to the mean and so is not estimated by the sample mean.
47	9	4	The text of the QAPP has been modified to reflect a 90-percent confidence level. The required confidence levels are also stated in Section 1.5, "Data Quality Objectives." As stated in the response to Comment #45, the text has been clarified with respect to selection of the confidence level.
48	10	7	The use of the 1/2 MDL may be less conservative than MDL for less-than-detectable measurements, but it is a commonly acceptable approach. Furthermore, although more sophisticated estimation methods exist, 1/2 MDL performs better than the MDL in simulations described in the cited references.
49	10	12-13	Actual error levels and confidence levels may differ from nominal levels for several reasons, such as: 1) many compounds are being evaluated to determine whether or not a waste stream is hazardous, 2) estimates for the mean and variance are used to determine sample size, 3) preliminary random sample data, if collected, may be included in the calculations, 4) the distributions are only approximately normal, as assumed in the sample size calculation, and 5) approximate methods for transformations and treatment of less-than-detectable measurements. The text has been clarified as follows; "...actual values will be somewhat different because the distributions are only approximately normal, estimates will be used to determine sample size, many compounds will be evaluated to determine whether a waste stream is hazardous and data transformations and substitutions are approximate. The impact of these items is that either a lower or higher confidence level could result, that is, the error rate may not be exactly 10 percent. Such potential impacts are not atypical of similar studies."
50	10	24-27	The QAPP states (page 5-10, line 26) that the determination of miscertification is based on; "...WIPP-WAC and TRAMPAC criteria..." WIPP-WAC and TRAMPAC are defined elsewhere in the QAPP as *Waste Acceptance Criteria for the Waste Isolation Pilot Plant* and *TRUPACT-II Authorized Methods for Payload Control*, respectively. The specific criteria to be determined are enumerated in these documents. Radiography and visual examination requirements, including reporting requirements, for the TWCP are detailed in Section 10.0 of the QAPP as stated on page 5-10, line 21, and elsewhere.
51	10	28	The 2 percent rate is used in the first year to ensure a required minimum of containers are opened and visually examined the first year. The text has been modified as follows; "The site project manager shall evaluate whether the assumed miscertification rate (2 percent in the first year) is consistent with the miscertification rate observed during visual examination. If the assumed rate is inconsistent with the observed rate, Table 5-1 will be consulted to determine whether or not additional containers must be visually examined. This requirement will apply for each yearly selection of containers for visual examination."
52	11	1-5	The text has been clarified as follows; "This miscertification rate must be determined each year based on results of certification activities over a minimum of 12 months."

#	Page	Lines	Response
53	11	6-10 19-20	The text has been clarified as follows; "If the number of containers listed in Table 5-1 are visually examined, it is simply guaranteed that the UCL_{95} of the miscertification percentage will be less than 14 percent; 14 percent is a worse case. In actuality, when the UCL_{95}s have been calculated from sample data, most of them will be much smaller than 14 percent." The text at line 19 has been clarified as follows; "The percent of waste containers that will be properly certified is based on site experience to date with the certification program or 98 percent if no site experience is available (the first year only)." A statement has been added to the text after line 23 as follows; "The assumptions regarding the miscertification rate will be evaluated after visual examination." Also see response to Comment #51, above. The strategy for determining the number of samples for visual examination and confidence associated with waste material parameter estimates are based on the existing certification program for WIPP. Visual examination of waste for the determination of waste material parameter weights is not part of the certification program. It is assumed in the QAPP that requirements for visual examination of waste for the determination of waste material parameter weights need not exceed those for existing certification programs. Regarding the apparent discrepancy between assuming 98 percent (or other site-specific percentage) are properly characterized and allowing 14 percent to not be properly characterized, the following should be understood; the 14 percent miscertification rate is only a worst case allowable rate for the UCL_{95} for the miscertification proportion for the purposes of sample size calculation. Much lower actual rates for the UCL_{95} will typically be observed, and the observed miscertification proportion will be even lower.
54	12	Table	There is no discrepancy between Figures 5-1 and 5-2, and Table 5-1. Figures 5-1 and 5-2 instruct the sites; "Statistically select waste containers from waste streams in all the Waste Matrix Codes (3000, 4000, and 5000 series) for visual examination in accordance with Section 5.3.2." These figures indicate that all waste containers will be considered for selection, but that only a statistical subpopulation will undergo visual examination. Some sample sizes in Table 5-1 were designated "NA" because it is impossible to have exactly 1 percent, 3 percent and 5 percent of 50 drums miscertified, i.e., a noninteger number of containers would be indicated to be miscertified. The "NA" designation has been replaced with recommended sample sizes based on the next higher error rate and footnoted with an explanation of the source of the replacement and the reason for the replacement. The values in Table 5-1 are based on the equation and calculation process given in the text, and do not require further justification. Because of the discrete nature of the hypergeometric distribution, the progression of the numbers of containers to be visually examined will not appear "logical." The value of 54 should be and has been replaced with 62, however. The methods to generate the table are provided in the text. To expedite future sample size calculations and further understanding of the derivation of Table 5-1, an appendix has been added to the QAPP that explains in detail how the calculations are performed.
55	13	16-23	The paragraph does provide statistical guidance, by stating the conditions under which each distribution assumption is acceptable or not acceptable. As stated in response to Comment #53, the requirements for visual examination need not exceed those for existing certification programs.

Section 6.0 - Sample Handling and Custody

#	Page	Lines	Response
56	1 2	8-27 1-18	It is unclear why NMED wants the information recorded during sampling to contain procedures for obtaining contaminant-free sample containers. The requirements for obtaining contaminant-free sample containers are found in Section 7.4 for canisters and Section 8.3 for vials and jars. However, the text of the eighth bullet on page 1 has been clarified as follows: "Type of sample container used (e.g., 40 ml VOA vial) and the QC batch number assigned to that container." Sections 7.0 and 8.0 also provide procedures for obtaining QC samples (e.g., equipment blanks, field blanks, etc.).

#	Page	Lines	Response
57	2	8-9	The text of the bullet on page 2, line 8 has been clarified as follows: "Ambient temperature and pressure measurements at the time of sample collection" Ambient temperature and pressure is not expected to change during the few seconds it takes to fill a canister. Therefore, the measurements need to be recorded only once at about the time the samples are collected. The canister tag shown in Figure 6-1 has been revised accordingly.
58	2	Sec 6.2	It is not appropriate to require permanent ink for all field records since the generator sites may choose to record sampling information in a digital format. However, Section 6.0 has been revised to require permanent ink for recording information on the canister tags and the labels of the vials and jars. Specific revisions are as follows: (page 3, line 23): "...prior to shipment to the field. All information recorded on the tag must be made in permanent ink." (page 6, line 13): "...must be recorded in permanent ink on each sample label."
59	3	4-8	The designation for which innermost layer of confinement was sampled is not to be recorded on the Gas Sample Canister Tag (Figure 6-1). Recording this information on the tag would compromise the "blindness" of the sample to the laboratory. The requirement to record which innermost layer of confinement was sampled is specified in Section 6.1.
60	5	1-12	The requirement to record the waste container identification number on the canister tag has been deleted.
61	5	18-20	The text of the bullet on page 5, line 18 has been clarified as follows: "In the analytical laboratory, canisters must be thermally equilibrated to laboratory ambient temperature for a minimum of 24 hours prior to measurement of their pressure and canister pressure must be measured and recorded on the canister tag immediately prior to sample preparation or analysis." Figure 6-1 (canister tag) has been changed from "Analytical Laboratory" to "Lab - Prior to Sample Analysis."
62	5	21-23	The text of the bullet on page 5, line 21 has been clarified as follows: "In the analytical laboratory, ambient temperature must be measured and recorded on the canister tag immediately prior to sample preparation or analysis."
63	5	18-23	See responses to Comments #61 and #62, above.
64	6	17	The waste container ID does not need to be recorded on the sample container label. The sample number will be referenced to the waste container ID in the field logs. Figure 6-2 has been revised as follows; "Waste Container ID" changed to "Laboratory ID" and left blank when the sample is collected. The lab will use this space to record their laboratory-specific sample number; "Sample Container Identification Number" changed to "Sample Container QC Batch Number" so the container can be traced back to its cleaning procedure, if necessary. The first paragraph in Section 6.2.4 has been clarified as follows: "Twelve alpha-numeric characters; two alpha characters must designate the sampling site (ZZ), and the remaining ten numeric characters must indicate the chronological sequence of solid process residues and soils sample collection."
65	8-10	Fig 6-4	The text has been clarified to incorporate sample matrix and place and address of sample collection.
66	10	Fig	Figure 6-4 is an "Example Only" form, DOE sites must develop, and document in QAPjPs, site-specific chain-of-custody forms.
67	13	14-16	A custody seal is designed to detect tampering. The chain-of-custody form(s) accompanying a sample shipping container will adequately document sampling date, time and location.

#	Page	Lines	Response
68	14	Table	Table 6-2 has been revised to indicate holding times are measured from the time of sample collection. Due to the complexities of shipping and handling radioactive samples, DOE would like to further discuss this issue. Sample quantities have been reduced to the absolute minimum required to perform analysis, thereby, reducing investigation derived radioactive waste. A footnote has been added to Table 6-2 to indicate holding times are consistent with SW-846. Table 6-2 has been revised to require a 28 day holding time for mercury. Methanol extraction for VOCs is detailed in SW-846 Method 8240B. Table 6-2 has been clarified with respect to holding times (14 days) for non-extracted VOCs.
69	14	Table	Methanol extraction for VOCs is detailed in SW-846 Method 8240B. The holding time for VOCs has been changed to 14 days.

Section 7.0 - Headspace Gas Sampling

#	Page	Lines	Response
70	14	14	The WIPP-WAC requires that all waste container 90 mil liners be vented prior to shipment. The text has been clarified as follows; "If headspace gas samples are collected prior to venting the 90 mil liner, a nonconformance report must be prepared, submitted and resolved."
71	14	15	The text of the bullet on page 14, line 15 has been clarified as follows: "For sample collection, the drum's carbon composite filter must be sealed as specified in Procedures 110.1 through 110.4 of the Methods Manual, or equivalent, to prevent outside air from entering the drum and diluting and/or contaminating the sample."
72	15	3	The text has been clarified as follows; "The seal between the drum lid and sampling head must be designed to minimize intrusion of ambient air." At the time of sample collection through the drum lid the rigid liner will also be breached and the sample collected from within the rigid liner.
73	15	20 & 30	The text has been clarified as follows: "...downstream of the drum punch and operated in the same manner as the flow indicating device described in Section 7.2.1." To minimize subjective field evaluation, all 55-gallon poly bags must be sampled regardless of condition and the poly bag condition and sampling location noted in field logs. All 55-gallon poly bags, regardless of available headspace gas volume must be sampled.
74	19	25/30	It is unnecessary to specify batch size requirements for canister cleaning operations because the canisters are loaded into an oven where they are baked clean. The number of canisters in an oven does not affect the level of cleaning accomplished. The text has been clarified as follows: "...on a batch basis. A batch is the number of canisters cleaned together under the same conditions."
75	20	14	The text has been clarified as follows: "...checked for leaks in accordance with the cleaning and leak check procedures described in Procedures 110.1 and 110.2 of the Methods Manual, or equivalent. The procedures must be conducted after headspace gas..."
76	21	12	The text has been clarified as follows: "...sampling heads must be cleaned in accordance with the cleaning procedures described in Procedures 110.1 and 110.2 of the Methods Manual, or equivalent. After sampling collection, a sampling head must be disposed of or cleaned in accordance with the Methods Manual procedures, or equivalent, prior to reuse."

Section 8.0 Sampling of Solid Process Residues and Soils

#	Page	Lines	Response
77	1	13-29	The solid process residues and soils sampling technique is designed to characterize waste on a waste stream basis. Individual waste containers serve as convenient units for characterizing the combined mass of waste from the waste stream of interest. The variability of waste stream composition is addressed as described in Section 5.0, page 1. Waste will be segregated into waste streams and individual drums will be randomly chosen from those waste streams for sampling and analysis. Waste stream determination and random sampling will account for spatial and temporal changes in the waste stream and provide for a representative sample. The purpose of selecting containers from a waste stream for representative sampling is to characterize the waste stream, not an individual container. The text has been revised to indicate a drum instead of a poly bag. The sampling technique is applicable for use on waste boxes as well as drums. The text has been clarified throughout Section 8.0 regarding this issue. Only one core will be collected from each drum. The core is to be randomly located in the horizontal plane of the waste, and a sample from within the core will be randomly selected in the vertical plane. The text has been clarified, where appropriate, regarding this issue. The text has been clarified as follows: "...(55-gallon) drums, the smaller containers must be grouped according to waste stream and a representative sample must be collected from one randomly selected inner container of each waste stream." Also see response to Comment #37, above. For a discussion of the rationale for TWCP analyte selection, see response to General Comment #1. Also see response to Comment #25.
78	2 3	27-28 1-9	The solid process residues and soils sampling technique is designed to characterize waste on a waste stream basis. Also see response to Comment #77, above. The objective of collecting three cores as proposed in the waste analysis plan associated with DOE's RCRA Part B permit application was to characterize a small number of drums comprising the contents of a bin for DOE's Bin-scale Test Program. Compositing samples may invalidate these samples for certain analyses, especially VOC analysis. The QAPP does not require compositing. However, DOE sites may choose to composite samples to reduce variability associated with a waste container and thus reduce the number of waste containers that must be characterized within a waste stream. The text has been modified to specify 90 percent completeness for solid process residues and soil sampling. This is consistent with the completeness requirements for all other techniques.
79	3	11-18	The text has been clarified as follows; "Procedure 120.1 in the Methods Manual is an acceptable method for the collection of solid process residues and soils samples." Table 6-2 has been clarified as indicated in the response to Comment #68, above.
80	6	4-16	The QAPP provides and example; "(e.g., Teflon)." The text has been clarified as follows; "Site QAPjPs must document that analytes of concern are not likely to be present in sleeve material."
81	7	34-42	Sites must ensure representativeness according to the ASTM method quoted in the QAPP.
82	8	8-32	It is not clear to DOE how to implement the requirement found in SW-846, Chapter 1, to collect field duplicates. The variability of the waste is not known at this time so it is difficult to specify an acceptance criteria. The RPD between field duplicates is dependent on the waste matrix, the specific analyte, and the concentration of the analyte. DOE requests additional discussion with EPA and NMED concerning the collection and acceptance criteria for field duplicates. The QAPP has been clarified, where appropriate, to reference SW-846 for the justification for the 1 out of 20 duplicate and equipment blank collection.
83	8 9	18-32 1-16	The QAPP recommends "...equipment blank results for the coring tools, sleeves, and sampling equipment be reviewed prior to use," and recommends that "...a sufficient quantity of these items should be maintained in storage to prevent disruption of sampling operations" (see page 9, lines 14-16).

#	Page	Lines	Response
84	9	20-23	The QAPP specifies that equipment blanks must not contain analytes at concentrations greater than the MDLs specified in Tables 13-1, 14-1 and 15-1. Any decontamination procedure that supports these performance objectives is acceptable. Lines 24-30 are specific to coring tools. Coring tools are described in Section 8.2.1. The text has been clarified as follows: "...requirements specified above. The results of the equipment blank analysis for the batch in which each coring tool was cleaned must be submitted to the sampling site with the identification numbers of all coring tools in the batch."
85	10	20-23	The text has been clarified as follows; "All sampling equipment must be stored in protective wrapping prior to sample collection."

Section 9.0 - Nondestructive Assay

#	Page	Lines	Response
86	1	22-27	This entire paragraph addresses the concern of the Nondestructive Assay/Nondestructive Examination Interface Working Group (NDA/NDE IWG) that the QAPP acknowledge the right of management, customers, or other parties to place additional or substitute requirements on the NDA measurement systems at any given site. It was not intended that other parties be able to modify requirements for compliance with the QAPP, only that the QAPP not be interpreted as voiding site specific requirements implemented for other purposes. The text has been clarified as follows: "Parties responsible for determining the acceptability of NDA measurement systems for purposes other than TRU waste characterization for WIPP may establish requirements in addition to or in lieu of the QAOs for the Program. Such requirements do not affect the obligation to meet the QAOs of the Program for systems generating waste characterization data for WIPP." Earlier versions of this section had attempted to include any measurement system capable of performing the required measurements in compliance with the stated QAOs, including radiochemistry. Technical reviewers from the Nondestructive Assay/Nondestructive Examination Interface Working Group (NDA/NDE IWG) found this approach to be confusing because of differences in terminology and instrument operating principles. To alleviate this concern a decision was made to separate NDA and destructive radiochemistry into distinct sections. Since no site was known to be proposing radiochemistry methods, the section covering this method may never be needed and was postponed until a need was demonstrated. NDA methods were addressed immediately in the existing Section 9.0 because of their virtual universal usage for radioassay of waste drums.

#	Page	Lines	Response
87	2	1-11	The general phrase "individual isotopes" is used intentionally in this paragraph and has its natural meaning, i.e., the set of individual, specific radioisotopes without restriction to a particular group by virtue of characteristic or atomic number. Its use is intended to avoid limiting the discussion or application of the principles therein to only the alpha emitting or only the TRU isotopes. The QAPP must be applicable to a wide variety of sites across the DOE system. At an individual site there may be significant quantities of radioisotopes which do not fall into either of these classifications which nevertheless affect radiolytic gas generation or contribute to other calculated quantities, e.g. projected inventories. These isotopes might include alpha emitting non-TRU isotopes or beta emitters with alpha emitting daughters. The use of the more general term extends the application of the QAOs to any isotopes which may contribute to the phenomena of interest and which can be analyzed by the applicable NDA techniques. The use of the more inclusive term is thus appropriate to ensure that all relevant needs for radioisotopic data can be satisfied. By requesting specific data on individual radioisotopes, the QAPP ensures that derived values, such as fissile grams equivalent or wattage can be calculated whenever needed. To date, no data users have indicated a need for any values which can not be derived from quantitative concentration data on individual radioisotopes. DOE is unaware of any assumptions with respect to radioisotope concentrations which affect RCRA compliance issues that would require additional radioactivity concentrations. In this section, acceptable knowledge is acknowledged as a possible means of specifying isotopic composition. Note that a measurement is required if there is any possibility that a "...waste stream may be contaminated with radioactive material of variable or unknown composition..." (Page 9-2, Lines 5-7). Therefore, acceptable knowledge can only be used for isotopic composition when the waste stream is of consistent and known composition. The use of "...supportable..." is a reference back to Line 9, where it is required that the "...bases for the isotope ratios which are used be documented and supported." The requirement is that the basis for the ratios be documented, i.e., the processes by which they were derived and all supporting data. Documentation of only the isotope ratios themselves would not be sufficient. Furthermore, the requirement for an analysis of the uncertainty entailed in the use of these isotope ratios is also contained in this section. While the subject paragraph is broad and introductory in nature, a later section (Page 9-16, Lines 11-30) discusses at length a required propagation of uncertainty for all parameters used in the calculation specifically including the isotope ratios (Line 18). A standard of proof is implied in the requirement to pass review by an expert review team (Lines 27-29). The preponderance of evidence supporting the isotopic ratios must be convincing to a team of experts who are independent of the site and knowledgeable of the subject. Finally, the limit on total uncertainty in the aggregate places an upper limit on the uncertainty associated with the isotopic ratios. We conclude that the use of the term "acceptable knowledge" is clear, narrowly defined, and appropriate in the NDA section of the QAPP.
88	2	12-19	This comment appears to stem from a misreading of the situations in which the QAPP allows the use of acceptable knowledge in NDA. In no case does the QAPP allow the substitution of acceptable knowledge to the exclusion of NDA for radioassay. However, some NDA methods return a measurement value which is essentially the summation of a group of isotopes. For example, active neutron methods measure the total of isotopes which can be induced to fission by the interrogating neutron flux while passive neutron methods return the total of spontaneously fissioning isotopes. In theory, either of these responses can be converted to activities of individual isotopes if the ratios of the contributing isotopes are known. That is, if the ratios of the isotopes are constant, only one combination of activities can sum to the observed total of fissionable or spontaneously fissioning isotopes. The QAPP recognizes this possibility and allows that in specific instances it may be possible to obtain the required data on individual isotopes from the "summation" type measurements and known isotopic ratios. The acceptable knowledge referred to in this section may be used only for the isotopic ratios and not for the total radioassay measurement. The response to Comment #87 discusses at length the criteria by which this acceptable knowledge will be judged as "supportable". The substitution of acceptable knowledge for measured isotopic ratios is likely to be used only for wastes which were generated from processes which demonstrably handled only a single grade of plutonium, e.g. only weapons grade plutonium or only heat source plutonium. Note that the two key requirements are on page 9-2, lines 5 to 7, "If a waste stream may be contaminated with radioactive materials of variable or unknown isotopic composition , a method independent of waste acceptable knowledge must be used to determine the isotopic ratios" and also page 9-2, line 13, "Each participating generator/storage site must use one or more RA techniques". The requirement for "...valid radioassay data..." in Table 9-1 means data obtained by methods in compliance with the QAOs in the QAPP. Therefore, use of a method which includes constant isotopic ratios in the calculation is a valid radioassay measurement if the ratios used are supported by the documentation required by the QAPP.

#	Page	Lines	Response
89	3	Table	The precision and bias QAOs presented in Table 9-1 are the result of an extended consensus process consisting of reviews of existing requirements; formal presentations at open project meetings; meetings with small groups of data users and generators; meetings within the QAPP generation team; reviews of this specific chapter of the QAPP by technical experts from the NDA IWG; raview and comment cycles of the full QAPP; and, a comment resolution process which included key representation from the QAPP generation team, technical experts, and data users. At this time the participants in the process have reached a consensus that there is no single controlling rule, order, or application which can be used to define the requirements for NDA. There is also consensus that the QAOs are reasonable and there exists no compelling rationale for either relaxing or tightening the proposed values. In particular, the data users have indicated that the data generated under the QAOs listed in Table 9-1 should be adequate to their needs and will not be controlling with respect to uncertainties in the performance assessment. Because the values were arrived at through the described consensus process and are not specified in any other published document there is no reference which can be used to substantiate or justify the values. The specification for bias replaces the specification for accuracy in Section 9.0 of the QAPP. This is discussed on page 9-4, in the subsection entitled "Bias". Bias was used in Section 9.0 in response to comments from NDA IWG reviewers that bias is the more common and accepted term in the NDA community. In this section the bias is approximated by the determination of the parameter which is termed "accuracy" elsewhere in the document. If there were a separate specification for accuracy, it would be defined, calculated, and compared to the same numerical limit as the "bias"; a situation which would be redundant and confusing. The terms are internally consistent within Section 9.0 and are defined sufficiently to permit a clear understanding of the usage.

#	Page	Lines	Response
90	5	1-11	As stated on line 6 there are a number of parameters under operator control which can be varied to affect the MDC. The most practical and likely parameter to be varied on a routine basis is the count time. Individual sites may specify minimum count times as a function of waste stream and/or package weight. However, the QAPP does not specify the parameters to be varied. In fact, the QAPP does not even specify the exact methods to be used, so it would be impractical to specify the parameters to be varied for every potential method. Instead the QAPP strives to ensure that all sites will define the MDC consistently and meet the same numerical values. Beginning on page 9-5, line 27, the QAPP addresses the issue that no one equation can accommodate all the potential methods of calculating detection limits. There are many ways of determining the variance of the background and a wide array of calculational methods available to the sites. The background and its variance can be affected by physical changes in the vicinity of the measurement system (e.g., shielding), adjustments to instrument response parameters, or by varying the count time. It was necessary to allow the sites some flexibility to implement measurement systems in a manner consistent with their design and capabilities. However, in the sentence beginning with "Such alternate methods..." on the bottom of Page 9-5, the QAPP clearly requires that the same risks of Type I and Type II errors be included in the sites' calculations as were included in the QAO in Table 9-1. Further, the QAPP goes on to specify the use of "...typical or average values for the parameters comprising K_2 in Equation 9-1." These are the parameters which relate the response of the measurement system to activity concentration in the waste. These two conditions are the key determinants that the MDCs calculated for two different systems be comparable. That is, they must be based on the same assumptions of acceptable errors and they must include realistic values for the system in question for each of the factors included in the calculations. By meeting these conditions the sites will produce consistent determinations of the MDC. As already stated, for a given measurement system, the counting time is the most likely parameter to be varied on a routine basis to meet the QAO for the MDC. With respect to clarifying assumptions, earlier drafts of the QAPP addressed the question of equations, generalized calculations, and definitions of terms at great length. At one time the section included a significant amount of material on radiochemical methods. It was obvious from the comments from various members of the NDA/NDE IWG that this was distracting and confusing to the reviewers. Comments indicated that there was too much emphasis on material that was of little relevance to NDA. Comments also indicated that the derivation of the equations for detection limits were unnecessary and readily available elsewhere. Since most of this material was only background discussion, a decision was made to eliminate most of this text and to limit discussion in the QAPP to requirements, definitions, and methods of demonstrating compliance. Background text would be supplied only to the extent that it was relevant to NDA and only to the extent required to make the requirements understandable. The text included in this draft of the QAPP was negotiated in meetings with technical experts of the NDA/NDE IWG. It eliminated the material they found either misleading or irrelevant while retaining the definitions and specifications essential to the MDC requirement. There are four references included in this section on the MDC which are the classical references on this subject and are readily available. Considering the historical development of this section, it was concluded that it was not essential to include the derivation of the equation in the QAPP text and to do so would unnecessarily void the concurrence already reached with the expert technical reviewers of this section. It was also not felt to be appropriate to include the derivation of the MDC equation as an Appendix. The QAPP covers a broad range of technical subjects. While readers not expert in any given subject would benefit from more background material in that area, including such background material would have the effect of greatly increasing the volume of the document. The ratio of background to requirements meterial would also become much larger. Again, there has been a conscious decision to concentrate the QAPP on the QAO requirements and on the definitions and methods of demonstrating compliance which are essential to meeting those requirements. This decision includes a desire to avoid diluting the QAPP with reference and background material available elsewhere.

#	Page	Lines	Response
91	6	7-15	This is only the first reference to an "expert panel". A later reference (page 9-16, Lines 27 - 30) contains a fuller although still incomplete description of the role played by the review panel. The term "expert panel" has been changed to "expert review team" to avoid confusion with the expert panels which may be convened to support or review other parts of the WIPP program. It was not felt appropriate to define the makeup of the expert teams too precisely in this document because of possible problems in scheduling, funding, and conflicts of interest. Additional wording is proposed to be added to page 9-16 to resolve confusion. The paragraph on page 9-6 already references the relevant section, 9.6. The text has been clarified by replacing all "expert panel" with "expert review team" and all uses of "panel" with "team" where appropriate and relevant to this discussion. The text has been clarified as follows: "...in the field. The most probable source of members for the review teams is the existing NDA/NDE Interface Working Group and their associated staff. These individuals have the required theoretical and practical expertise as well as backgrounds in the TRU waste characterization area. Members of the IWG who are measurement staff at one site may serve as expert reviewers of measurement systems at other sites but not at their own site. The makeup, selection method, and role of the review team will be defined in a QA procedure by CAO." The discussion on page 16, line 11-26, discusses at length the parameters and general methods to be used to determine total uncertainty. Evaluation by the expert review team will be based on this discussion and any additional guidance supplied in the CAO procedure.
92	6	17-18	The text has been clarified as follows: "...characterized for disposal. Acceptable radioassay data shall consist of data on the radioactivity content of the waste package obtained from measurement systems which have been demonstrated to have met all the relevant QAOs for radioassay." The QAPP is silent on the issue of acceptability of RA data obtained prior to the official issuance of the QAPP. A prior version of the QAPP was issued for the Experimental Program and the probable values for radioassay QAOs in the Waste Characterization QAPP have been discussed for several years. It is possible that some systems will be able to be proven to have met QAPP QAOs prior to their issuance. It was not judged appropriate to reject out of hand all data obtained prior to an arbitrary issuance date. The acceptability of such data will be considered as part of CAO's evaluation of the individual site's waste certification program. Notwithstanding this possibility, it is most likely that all sites will incorporate a new radioassay measurement into any waste characterization program developed in response to the new QAPP requirements. This will present an integrated program at the site and also recognizes that retrospective proof of the validity of existing assay data may be more difficult than simply reassaying the drums. Section 3.0 of the QAPP discusses data review, validation and verification requirements for all data to be submitted for waste characterization. At this time data is being reported to satisfy all the objectives listed in Section 1.0. All such data will be validated and submitted well in advance of any planned shipment. Timing and details of submission of data associated with a scheduled shipment will be discussed in later revisions of the QAPP. The text has been clarified as follows: "...in Section 9.6 prior to shipment of the waste to WIPP."

#	Page	Lines	Response
93	6	19-28	Data produced using measurement systems which have not been demonstrated to meet the QAPP QAOs will not be acceptable for use in characterizing wastes intended for disposal at WIPP. This is stated throughout the document and is the crux of QAPP enforcement. If a site had previously been performing measurements and is subsequently shown to not meet QAOs, all of the data generated prior to the time QAOs are shown to have been met will be treated as non-conforming items. These data will be subject to examination and disposition under the provisions of the corrective actions required under the site's Non-Conformance Procedure which is a general requirement of the QAPP. The term "interlaboratory comparison program" has its common meaning, i.e., any program wherein more than one laboratory makes measurements of the same material and reports the results of these measurements for the purposes of determining the comparability of the methods used by the various laboratories. No effort is being made to exclude any possible intercomparison measurement from evaluation except on the basis of relevance to the TWCP. DOE/CAO wishes to encourage participation in and evaluate the data from any relevant program. In this context, "relevant" means the measurement in any environmental or waste media of any parameter required in the TWCP using a measurement system or method planned for use in the waste characterization program. The PDPs are the "...new programs [which] will be developed to ensure that an appropriate program is available for each general class of RA." No formal criteria have been established for determining the adequacy or inadequacy of potential programs. Since no formal, ongoing intercomparison program exists for the NDA measurements planned for use in WIPP waste characterization, CAO has proceeded directly to the development of a PDP for NDA. Evaluation of candidate programs other than the PDP will be conducted if any are proposed for use in the TWCP. The text has been clarified as follows: "...comparison programs. In this context, "relevant" means the measurement in any environmental or waste media of any parameter required in the Program using a measurement system or method planned for use in the Program."
94	7 8	26-30 1-6	DOE disagrees that this is a valid concern. DOE has established the overall common acceptance criteria for the NDA measurement systems by publication of the performance based QAOs in this section. The "acceptance criteria" in the lines which are the subject of this comment refer specifically to instrument performance checks and associated criteria. The QAPP requires that SOPs document the limits of acceptance on instrument performance checks as well as the required corrective actions if the criteria are not met. This is required in instrument specific SOPs precisely because there is no reason to assume that these criteria will be comparable between measurement systems. The operating limits for each system will be established as part of the setup and calibration of the measurement system and will be further defined by the method performance demonstration required in the QAPP. The QAPP requires that these performance acceptance criteria be established in association with demonstrating compliance with the QAOs and that these criteria be subsequently adhered to for all WIPP related waste characterization measurements. Comparability for limits on instrument operating parameters between sites is not required in order for the data generated from the instruments to be comparable. For example, two instrument systems could produce identical results even if the control limits on background counts and counting efficiency were completely different for the two systems. There is no reason for the QAPP to require any such comparability.
95	9	29	The text has been clarified by replacing; "established performance specifications," with; "the performance specifications established for that measurement system to demonstrate compliance with QAPP QAOs."
96	11	9-21	The text has been modified by deleting the sentence "The site project QA officer...when necessary." The site project QA officer's responsibilities are the same for NDA as for all other characterization measurements. They are discussed in Section 3.0 of the document. The referenced lines are not intended to be a description of the intercomparison program. The first sentence is a clear and unambiguous requirements statement. Paraphrasing, it simply states that the sites are required to participate in any intercomparison program which the NTPO chooses to make a requirement. Note that the sentence is a "shall" statement denoting an absolute requirement. The second sentence is a clarification of the "endorsed" reference. It is intended to make it clear that the formal PDP is not the only program which CAO/NTPO may choose to use for purposes of obtaining an intercomparison. If the statement can be interpreted as vague, it is only because NTPO wishes to reserve for itself the right to require future participation in programs that may not as yet exist. For programs which the NTPO sponsors, e.g., the PDP, documents will be published describing the programs in great detail and providing ample opportunity for comment and discussion among the technical experts, management, and data users.

#	Page	Lines	Response
97	11	23-30	Each individual site will establish its own program of training and qualificetion under the guidance of DOE/CAO. The QAPP does not go into deteil on the program requirements to avoid conflicting with well established site training programs, of which the NDA training may be only a part. The QAPP establishes only the general requirement and the applicability of the ASME NQA-1 standard. The QAPP establishes a minimum requalification requirement of every two years. Sites are free to establish a more frequent requirement if they so choose. Addition of new instrumentation will trigger requalification requirements depending on its similarity to existing systems. Requalification may not be required for new systems which are identical to existing systems in measurement principle and operation. In that case, calibration and establishment of operating parameters of the system may be sufficient to familiarize qualified operators with the new system. Any acquisition of a new measurement system which is substantially different from existing systems will trigger all applicable QAPP requirements, not just training and qualification.
98	12	1-6	The concept of including proposed minimum schedules was included in earlier versions of the QAPP. Comments from technical experts of the NDA/NDE IWG on these drafts argued that a simplistic, conservative listing would be confusing because of the wide variability in system requirements. It was further argued that these requirements were available in the applicable third party consensus standards. These standards provide a much fuller discussion of the requirements than could possibly be included in the QAPP. These comments were accepted and the requirement to conform to applicable ANSI, ASTM, and other applicable standards was inserted in the QAPP. Considering the historical development of this section, it was concluded that to attempt to include specifications for calibration and maintenance schedules would unnecessarily void the concurrence already reached with the expert technicel reviewers of this subject.
99	12	17-18	This requirement to verify calibration of a instrument system for one geometry/sample matrix forces a verification that the system operating characteristics have not changed significantly since the initial, complete calibration of the system. This type of verification will be more complete than the routine performance checks used to verify performance on a more frequent schedule. Only one sample configuration is required since a problem due to changes in instrument performance should manifest itself regardless of the waste geometry. No consensus standard requires recalibration on a more frequent basis. Many do not require a recalibration unless a significent change in instrument operating performence is noticed or there is an intentional change in operating parameters. Going into greater detail on techniques such as transmission or live-time corrections would introduce an inappropriate level of detail to the QAPP. The intention of the statement is simply to recognize their usage in calculation routines and to note that these routines are subject to documentation and verification under calibration and software documentation requirements. All such techniques are included in the requirement and discussion in depth of any individual technique is not required. The programs for operation of measurement systems and for calculating radioassay results are intimately dependent on the herdware usage, the methods of calibration, and the nature of the correction algorithms. No standardization of the software itself is feasible. However, minimum specifications for documentation and validation are possible and are required in this section. Comparability of the radioassay data is ensured by the QAOs specified for overall system performance and not on the specification of eny individual parameters. See, for example, the response to Comment #94.
100	14	19-26	The software for operation of measurement systems and for calculating radioassay results are intimately dependent on the hardware usage, the methods of calibration, and the nature of the correction algorithms. No standardization of the software itself is feasible. Software is developed for specific measurement systems and no standard software is available except for essentially identicel instruments. However, minimum specifications for documentation, verification, and validation are possible and are required in this section. Accuracy of the calculations performed by the software is ensured by the verification and validation process. Comparability of the radioassay data is ensured by the QAOs specified for overall system performance and not on the specification of any individual parameters. See, for example, the response to Comment #94.

#	Page	Lines	Response
101	15	1-22	The term "specific instrument control parameters" was not intended to mean that DOE/CAO would specify the parameters. It is recognition that the system performance depends on the parameters used to control the instrument during operation. The intention is that if these parameters have a specific value during a successful method demonstration, the same values must be used for routine operation of the instrument. The text has been clarified as follows: "...with all instrument control parameters set at specific values (e.g., specific count times). The values for all parameters ..." In addition, the following has been added: "Fifteen replicates were selected as an arbitrary number. It is a compromise between obtaining reasonable statistics on the performance demonstration and avoiding unnecessary measurements. At fifteen replicates statistics are adequate. Significantly more replicates would pass the point of diminishing returns and needlessly consume measurement resources and staff time. Significantly less would diminish the statistical confidence in the results. The value has generally been accepted by a consensus compromise by technical reviewers."
102	16	3-8 17-28	Some sites discriminate between low level and TRU waste by measuring waste as removed from process lines in 5 gallon pails or other containers. This provision in the QAPP simply permits the determination of the required MDC based on measurements for other than 55 gallon drums. An "appropriately sized waste container" is one which is the same size as those which the site uses to perform the actual measurements for assay of actual wastes. See the response to Comment #91.
103	17	1-30	The uncertainty will not be "determined" by the expert panel. Each site is required to perform a complete error propagation analysis for each measurement system in use. As stated on page 9-16, lines 11-26, all contributing sources of uncertainties are to be quantified and propagated to a total uncertainty term. The role of the independent technical review team is to evaluate this error propagation to ensure that the values used for the individual uncertainties are supported by the documentation and that the uncertainties are properly combined. The site's analysis is expected to be quantitative. The expert team's evaluation will be performed on this quantitative analysis based on their knowledge of statistical error, the NDA measurement systems characteristics, and the support documentation provided by the site. The total uncertainty is intended to include all quantifiable uncertainties but an expert review is the only feasible means of evaluating uncertainty propagation for systems that are unique and must by their nature include terms and correction factors not universally applied to all NDA methods. Also see response to Comment #91.

Section 10.0 - Radiography

#	Page	Lines	Response
104	1	1-4	The confirmatory visual examination performed as part of radiography is the same process described in Section 5.0. The text has been clarified as follows: "...as described is Section 5.3.2."
105	1	18-28	Section 10.1 cites Section 5.0 for details of how radiography is used as part of the certification process. 100% accuracy is not a QAO for radiography. The results of radiography and visual examination will be compared to provide a qualitative measure of uncertainty. See Section 5.0 for the discussion of allowable miscertification rates. The results of visual examination cannot be used to provide a qualitative estimate of precision. Precision is a measure of repeatability of a specific measurement system. It is not a measure of agreement between two different measurement systems. Section 2.0 presents requirements for reporting nonconformances and operational variances.
106	3	1-31	The requirements specified in the QAPP are the minimum requirements to assure standardization of procedures. Standardization of procedures will be implemented through development of site QAPjPs and SOPs that meet the requirements specified in the QAPP. Radiography operators can identify nature/form of materials within a waste container. The identification of inner bags of solidified material in small containers during radiography will not necessarily impact requirements for additional testing. Both headspace gas sampling of inner bags and solidified materials sampling are performed on statistically selected containers that comprise portions of waste streams.

#	Page	Lines	Response
107	4 5	10-26 6-13	Existing training programs for radiography have been deemed adequate for determining waste matrix codes and identifying waste material parameters. Compliance with Supplement 2S-2 is typically used for radiography used in verifying safety related parameters, such as welding, where quantitative comparisons can be utilized. Supplement 2S-2 for training of radiography personnel is not considered necessary or appropriate for the TWCP. NQA-1 is designed for the nuclear power industry. As such, it is not entirely applicable to waste management. Individual sites may take exception to other requirements as well, but must document any exceptions in site QAPjPs. The QAPP requires that performance criteria be specified and documented in site QAPjPs. The QAPP does not set specific standards for unsatisfactory performance. Because of variation in the radiographic technologies utilized, this level of detail should be included in site QAPjPs. The 1/20 replicate scan is based on an analogy with collection of field duplicate samples as specified by EPA in SW-846. Independent drum replicate audits will be performed by a qualified radiography operator. The experts referred to in the QAPP are specific to the assigned roles of the TWCP. The text has been clarified, where appropriate, regarding this issue. The modified text addresses the specific selection, qualification, and responsibilities of any expert reviewers. The terminology used in the modified text is consistent with other TWCP and DOE documents that address this issue.
108	7	1-4	To assure proper equipment operation, DOE has determined that manufacturer's minimum requirements for radiography testing, inspection, and maintenance are adequate for the TWCP.
109	7	6-10	DOE assumes NMED reference is to Section 10.4. Determination of calibration and frequency requirements are not based solely on manufacturer's procedures and instructions. It is difficult to specify the equipment calibration and frequency requirements for all of radiography equipment that may be used for TWCP activities. This level of detail is best reserved for individual facilities to develop in response to needs associated with the equipment used and the waste being tested.
110	7	11-30	The content of the forms is specified in the QAPP, but actual development of forms will be left up to the individual sites. Often, reporting forms must conform to site-spacific requirements. Also, certain sites may wish to combine reporting requirements from additional programs (e.g., WIPP-WAC) on one form. Waste stream verification as determined by radiography and confirmed by visual examination is included in the batch report sent to the project office (see page 7, lines 25-26). RCRA hazardous waste and constituent information determined using acceptable knowledge will not be included on the radiography data form. The following definitions have been incorporated into the QAPP: ANALYTICAL BATCH -- A suite of samples of similar matrix (i.e., gas or solid) processed as a unit, using the same analytical method, within a specific time period. An analytical batch can be up to 20 samples (excluding laboratory QC samples), all of which must be received by the laboratory within 14 days of the validated time of sample receipt (VTSR) of the first sample in the batch. EQUIPMENT CLEANING BATCH -- A number of sampling equipment items cleaned together at one time using the same cleaning method. PROCESS BATCH -- An amount of material subjected to a particular unit chemical process, unit physical mixing process or other short-term operation, resulting in a final product and/or waste stream that is substantially uniform. SAMPLING BATCH -- A suite of samples of similar matrix (i.e., gas or solid) collected consecutively using the same sampling equipment within a specific time period. A sampling batch can be up to 20 samples (excluding field QC samples), all of which must be collected within 14 days of the first sample in the batch. TESTING BATCH -- A suite of waste containers undergoing radioassay (Section 9.0) or radiography (Section 10.0) using the same testing equipment. A testing batch can be up to 20 waste containers without regard to waste matrix.

Section 11 Hydrogen and Methane Analysis

#	Page	Lines	Response
111	3	18-23	ASTM method 2650-83 was used as the basis for development of an acceptable hydrogen and methane analytical method for the TWCP because there were no applicable SW-846 methods available. Although the ASTM method is intended for use on petroleum refining related gas mixtures, it has been adapted for use in the TWCP. The method, included in the Methods Manual, has been optimized for the analysis of hydrogen and methane in samples of headspace gas from TRU waste containers.
112	7	7-9	The text of the QAPP has been clarified, where appropriate, with respect to continuing calibration requirements, including the types of standards to be used and the concentrations of analytes in those standards. The text of the QAPP has been modified as follows; "If the laboratory control sample is not used for continuing calibration, then [it] must be run as a sample during the analytical sequence."

Section 12.0 - Gas Volatile Organic Compound Analysis

#	Page	Lines	Response
113	2	Table	The text of the QAPP has been clarified with regard to the rationale of TWCP analyte selection (see response to Comment #38). The table has been revised to show QAOs for all analytes.
114	5	1-5	The text has been clarified as follows; "The procedures are based on SW-846 Methods 8240 and 8260 and *EPA Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, Method TO-14*." This information is also included in the Methods Manual in greater detail.
115	9	29	The text refers to the analyte list and applicable QAOs for this section of the QAPP. This information is included in Table 12-1, not 12-4.

#	Page	Line	Response
116	2	Table	The text of the QAPP has been clarified with regard to the rationale of TWCP analyte selection (see response to Comment #38). The table has been revised to show QAOs for all analytes. NMED is correct in stating that SW-846, methods 8240 and 8260 require a laboratory control sample only if the matrix spike and matrix spike duplicate recovery does not meet acceptance criteria established. However, for the purposes of demonstrating acceptable method performance, participating laboratories must analyze a laboratory control sample with each batch of samples. The following VOCs are included in either SW-846 Method 8240B or 8260A: 2-nitropropane, 1,1,2-trichloro-1,2,2-trifluoroethane, n-butanol, ethyl ether, ethyl acetate, and methanol. In addition, as stated in SW-846, Proposed Update II, Method 8240B, any organic with a boiling point less than 200 degrees C can be analyzed for using the referenced methods. If any of the compounds fail to meet acceptance criteria, then alternate methods must be utilized. GC/FID is one that is suggested in the QAPP and included in the Methods Manual. The precision and accuracy limits included in Table 13-1 were derived from method performance criteria included in SW-846 Method 8240B (see Table 6, page 35 of SW-846 8240B). The precision QAOs were determined by calculating the %RSD for each analyte as follows: %RSD = (s/smallest value for $\bar{x}$) • 100. The accuracy for each analyte was taken directly from Table 6 (see Range p, p_s). For compounds not listed in Table 6, the %RSD was specified as +/-50 and %R at 60-150 based on EPA Contract Laboratory Program requirements for VOCs. The accuracy acceptance limits in Table 13-1 are appropriate for matrix spike recoveries. Table 13-2 has been modified to include surrogate compound requirements. Table 13-2 will also be modified to require more stringent %Rs for both the laboratory control samples and surrogate compounds than those listed in Table 13-1 for analytes. These criteria have been specified as follows: 80-120 %R for laboratory control samples and %Rs calculated as indicated in the response to Comment #117, below, for surrogate compounds. The matrix spike and matrix spike duplicate spike compounds are only "suggested" in SW-846. SW-846 provides for the substitution of other compounds if they are more appropriate for the analytes present in the samples.
117	1	18-22	The QAPP has been revised to require surrogate compounds to be added to each QC and field sample. However, it will be the responsibility of the individual laboratory to choose the specific surrogate compounds based on the analytes and matrices. %Rs are somewhat dependant upon the matrix and should be determined as such. According to SW-846, Method 8240B, the upper and lower control limits for surrogate compounds should be plus or minus three standard deviations from the average percent recoveries from a minimum of thirty samples for a given matrix. This acceptance criteria has been added to Table 13-2.
118	3	28-29	In SW-846 Method 8240B, an extraction method using methanol is detailed. It is to be used for high concentration samples of soil and sludge, and is not just a screening technique. The text of the QAPP has been clarified as follows; "If needed, each site must decide..." The specification of sample screening is beyond the scope of the QAPP. This information is included in the Methods Manual and SW-846.
119	4	9-10	The text of the QAPP has been clarified as follows; "...other than methanol (e.g., propanol)."
120	6	Table	Table 13-3 (Calibration Requirements) has been modified to include acceptance criteria for both internal standards and surrogate compounds.
121	8 9	22 Table	The text of the QAPP and Table 13-3 has been modified to require %D for continuing calibration <20, in accordance with SW-846 Methods 8240B and 8260A.

Section 14.0 - Total Semi-Volatile Organic Compounds

#	Page	Lines	Response
122	1 5	22-29	The text of the QAPP has been clarified with regard to the rationale of TWCP analyte selection (see response to Comment #38). NMED is correct in stating that SW-846, Methods 8250 and 8270 require a laboratory control sample only if the matrix spike and matrix spike duplicate recovery does not meet acceptance criteria established. However, for the purposes of demonstrating acceptable method performance, participating laboratories must analyze a laboratory control sample with each batch of samples. Tables 14-2 and 14-3 has been modified to include acceptance criteria for surrogate compounds.
123	2 3	Table 12-28	The table has been revised to show QAOs for all analytes. The matrix spike compounds are not required and should be determined based on the analytes of interest. The %Rs for the matrix spike and surrogate compounds are very matrix and method dependant and should be determined on matrix by matrix and method by method basis. The matrix spike and matrix spike duplicate compounds are only "suggested" in SW-846. SW-846 provides for the substitution of other compounds if they are more appropriate for the analytes present in the samples.
124	3	22-24	It is difficult to specify sample preparation methods for all of the potential waste types that may be characterized under the TWCP. The Methods Manual refers to several SW-846 methods for semi-volatile analysis (i.e., 8250 and 8270) which provide guidance on sample preparation depending on sample matrix and other parameters. A procedure for PCB analysis in the Methods Manual includes sample preparation procedures.
125	6	Table	Table 14-2 (QC Samples) has been modified to include acceptance criteria for surrogate compounds. Also see response to Comment #117. Table 14-3 (Calibration Requirements) has been modified to include control limits for the internal standards and surrogate compounds.
126	8	1-2	GC/ECD calibration requirements are outlined on page 8, lines 14-22. Detailed calibration requirements (including the sequence of calibration actions) is included in the Methods Manual and/or SW-846.

Section 15.0 - Total Metals Analysis

#	Page	Lines	Response
127	1 2	13 Table	The text of the QAPP has been clarified with regard to the rationale of TWCP analyte selection (see response to Comment #38). In SW-846, Final Update I, Method 7000A, it states that a matrix spike and a matrix spike duplicate shall be included in each analytical batch. This section relates to atomic absorption methods. In Method 6010A of the same revision, a spike replicate must be run and meet acceptance criteria. Table 15-1 has been revised to show QAOs for all analytes. Table 15-3 shows that acceptance criteria for both matrix spikes and laboratory control samples is 80-120 %R, which is consistent with the accuracy QAO specified in Table 15-1 for all analytes. The QAOs specified in Table 15-1 are applicable to all analytical methods. This is stated on page 4, line 22.
128	3 4	24-25 6-7	It is difficult to specify sample preparation methods for all of the potential waste types that may be characterized under the TWCP. However, the text of the QAPP has been clarified as follows; "The Methods Manual includes an acceptable sample preparation procedure based on microwave-assisted hot acid digestion." Table 15-2 provides guidance on the specific SW-846 analytical methods to be used for each analyte. Each SW-846 method provides additional guidance on acceptable sample preparation procedures.
129	6	26	The use of MSA, including when it may be appropriate for use, is outlined in the specific methods contained in SW-846 and referenced in the QAPP. The text of the QAPP has been clarified as follows; " The analytical methods referenced in Table 15-2 provide guidance concerning the use of MSA."

#	Page	Lines	Response
130	7	15-17	Corrective action in response to laboratory failure to demonstrate acceptable performance is left up to the individual participating laboratory. However, it is clearly stated that no laboratory will participate in the TWCP until such time as acceptable performance is demonstrated (see page 7, line 15). Table 15-3 specifies the analysis of a laboratory blank at the frequency of one per batch. Initial blank analysis is included in initial calibration (see Table 15-4). For example, the ICP-MS 1-pt initial calibration is shown as (1 standard and a blank).
131	8	Table	The acceptance criteria for matrix spikes is stated as 80-120 %R (see Table 15-3). This is more stringent criteria than that suggested by SW-846 and is consistent with the accuracy requirements for all analytes as stated in Table 15-1. DOE understands "analytical spike" to be a post digestion spike as included in SW-846 AA methods. The QAPP addresses post digestion spike acceptance criteria in Table 15-4. The acceptance criteria is stated as "Recovery within +/- 15% of expected value. The acceptance criteria has been changed to 85-115 %R. DOE does not recognize the term "duplicate injection" as this is not included as a requirement in SW-846 with regard to metals analysis by AA.
132	9	2-7	In some cases, a clean matrix cannot be obtained for a laboratory control sample. The laboratory control sample is a check to determine if the sample preparation and analytical methods are in control and determine the loss/recovery values. For very complicated matrices, the use of e laboratory control sample of a different matrix is the only way to determine control. It is true that a different matrix does not fully represent the sample matrix, but in some cases, the use of an alternative matrix is the only option.
133	10-12	Table	There are two ICP based analytical methods included in the QAPP; ICP-MS and ICP-AES. SW-846 Method 6020 (ICP-MS) specifies a one-point calibration curve (one standard and a blank). SW-846 Method 6010A (ICP-AES) specifies that a three-point calibration curve should be used. In SW-846 the term "should" refers to suggested criteria, whereas the term "must" refers to mandatory criteria. Past work at DOE sites has shown that a one-point calibration curve is adequate for ICP-AES. Calibration blank requirements are included in Table 15-4 under "Continuing Calibration." In addition, laboratory blanks are run once per batch (up to 20 samples) as included in Table 15-3. The interference correction verification for ICP-AES has been changed to require twice per 8 hour shift. Table 15-1 includes the criteria for MDL and IDL for each analyte regardless of the specific analytical method used. These are the TWCP-required detection limits which are analogous to the CRDL.
134	13	2-4	Data validation requirements are included in Section 3.0, as stated in the QAPP, and apply to total metals data as well as all other data generated as part of the TWCP. Data validation procedures include a confirmation that all QC sample results are within established control limits (see page 3-2, line 18). Table 15-1 has been revised to show the QAOs for all analytes. ICP serial dilution and AA post digestion spike criteria are included in Table 15-4. All participating laboratories are required to meet the calibration requirements end analysis QC outlined in Table 15-4. Records documenting that calibration and analysis QC were properly performed must be kept in the laboratory files or forwarded to the site project office as appropriate (see page 13, lines 31-34 and page 14, lines 6-9).