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TECHNICAL SUPPORT DOCUMENT FOR SECTION 194.24: CONSOLIDATED COMPLIANCE REVIEW OF WASTE CHARACTERIZATION REQUIREMENTS

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TECHNICAL SUPPORT DOCUMENT
FOR SECTION 194.24: CONSOLIDATED REVIEW OF
WASTE CHARACTERIZATION REQUIREMENTS

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1.0 SUMMARY OF EPA FINDINGS

The purpose of this document is to provide a thorough discussion of the evaluation and decision-making process EPA followed to evaluate DOE's compliance with the waste characterization and quality assurance (QA) requirements of §194.24.

The Waste Isolation Pilot Plant (WIPP) Project was authorized by the National Security and Military Applications of Nuclear Energy Authorization Act of 1980. Its legislative mandate was to provide a research and development facility to demonstrate the safe disposal of radioactive waste resulting from United States defense activities and programs. In response to this Act, The Department of Energy (DOE) has developed the WIPP, an underground geologic repository, for the disposal of transuranic (TRU) waste currently stored or generated by DOE defense installations. The WIPP is intended to be the permanent disposal site for TRU wastes generated at various DOE sites after 1970 from defense activities of the United States, including weapons production, research and development, and disassembly.

The Land Withdrawal Act (LWA) of 1992 transferred jurisdiction of the land used for the WIPP Project from the Bureau of Land Management to the DOE and provided additional authorization to continue WIPP-related activities. The LWA included requirements to develop certification criteria for compliance with the long-term disposal regulations developed by the U.S. Environmental Protection Agency (EPA). These regulations are the environmental standards for management and disposal of TRU wastes as mandated in 40 CFR Part 191 and Part 194. Section 194.24 presents the waste characterization requirements DOE addressed in it's Compliance Certification Application (CCA)

EPA evaluated DOE's CCA submission and supplemental information, and attended site audits at LANL, RFETS, and INEL. In summary, EPA finds that DOE is in compliance with §194.24, and that LANL has demonstrated compliance with §§194.24(c)(3) through (5) for certain retrievably stored legacy debris waste streams and may therefore ship TRU waste for disposal at the WIPP (as such shipments relate solely to compliance with EPA's disposal regulations; other applicable requirements or regulations still may need to be fulfilled before disposal may commence). EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.

1.1 REGULATORY DRIVERS

DOE must demonstrate that WIPP operations are in compliance with several other statutes and regulatory requirements. Chapter 3 discusses the various regulations, including 40 CFR Part 191, that drive waste characterization.

WIPP was developed for the disposal of radioactive wastes. Therefore, the major regulatory drivers affecting waste characterization are those that regulate the management of radionuclides. These drivers include:

- Environmental Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes (40 CFR Part 191)

- WIPP Land Withdrawal Act (LWA), as amended

- Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations (40 CFR Part 194, Section 24)

- 40 CFR 194.24 Waste Characterization Compliance Requirements

- NRC Regulations for the Packaging and Transportation of Radioactive Waste (10 CFR Part 71)

Regulations governing the hazardous component of the wastes destined for WIPP also drive DOE's waste characterization program. These drivers are primarily found in the Resource Conservation and Recovery Act (RCRA) requirements and permit conditions related to that Act. These drivers include:

- Resource Conservation and Recovery Act (RCRA)
- RCRA Part B Permit Application
- Federal Facilities Compliance Act (FFCA) of 1992 (Public Law 102-386)

DOE's waste characterization program is also driven by other regulatory drivers that affect the parties involved in the program and that affect the waste components that must be addressed by the program. These drivers include:

- Agreement for Consultation and Cooperation-July 1, 1981

- U.S. Department of Transportation Regulations; 49 CFR Part 173-Shippers-General Requirements for Shipments and Packaging

- Toxic Substance Control Act (TSCA): 40 CFR Part 761 – PCB Manufacturing, Processing, Distribution in Commerce and Use Prohibitions.

- Variances, Permits, and Certifications that WIPP Must Acquire Prior to Waste Shipment

1.2 SECTION 194.24 REQUIREMENTS

Section 194.24(a) requires DOE to describe the chemical, radiological and physical composition of all existing and to-be-generated waste, including a list of waste components and their approximate quantities in the waste. DOE described the existing waste by combining similar waste streams into eleven final waste forms and waste stream profiles. A waste stream is defined by DOE as waste material generated from a single process or activity that results in a similar in material, physical form, isotopic make-up, and hazardous constituents. The waste stream profiles contained information on the waste material parameters, or components, that could affect repository performance. DOE extrapolated information from the existing waste streams to determine the amount of to-be-generated waste.

To satisfy requirements of 40 CFR 194.24(b), EPA required that DOE perform an analysis to identify and assess the impact on long-term performance of those waste characteristics that influence the containment of waste in the disposal system, including those waste components that affect the waste characteristics. A *waste characteristic* is defined by EPA as a property of the waste that has an impact on the containment of waste in the disposal system. A *waste component* is defined by EPA as an ingredient of the total inventory of the waste that influences a waste characteristic. The inclusion of select waste components and characteristics as parameters or portions of performance assessment models links WIPP waste with the overall evaluation of disposal system performance.

Waste components impact waste characteristics and are integral to disposal system performance. For example, the characteristic of gas generation is controlled, in part, by the type and amount of waste components present, such as metal waste containers and cellulosics, rubber, and plastic material in waste. The presence of these components and a sufficient amount of brine (salt water) leads to microbial degradation of cellulosics, corrosion of metals, and subsequent gas generation (i.e., CO_2, H_2, CH_4). The resulting gas pressure affects repository pressure, room closure rates, fracture development in near by markerbeds, as well as brine inflow and the possibility of waste entrainment in gas during a drilling event (spallings). All of these factors are important elements of disposal system performance and are modeled in performance assessment (PA). Radionuclide solubility in Salado and Castile brine partially[1] controls the quantity of radionuclides that are released in brine to ground surface through a direct brine release; radionuclides in brine also serve as the source term to the Culebra for potential long-term transport through this rock unit. Therefore, some waste characteristics and components influence aspects of disposal system performance.

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[1] Depending on the performance assessment model future, the volume of brine released as important as solubility.

EPA's regulations at 40 CFR Part 194.24 (c)(1),(e)(1)(2),(g) recognized that there may be waste components that could affect the ability of the WIPP to meet performance criteria. Section 194.24 requires DOE to evaluate the wastes destined for WIPP and determine whether maximum or minimum limits should be placed on these components. DOE imposed maximum limits on free water emplaced with waste and on cellulosics, rubber, and plastic. DOE also imposed minimum limits for ferrous and nonferrous metals. EPA evaluated the waste limits provided by DOE and determined that the appropriate components requiring limitation were identified and the waste limits applied were sufficient. EPA believes that DOE adequately addressed questions regarding uncertainties, the presentation of upper/lower limits, and plausible combinations of these limits.

As presented in Section 194.24(c)(2), EPA expected DOE to identify the method(s) that will be used to quantify each waste component. Chapter 4 of the CCA presents several waste characterization methodologies to identify the physical, chemical and radiological properties of the waste. Specifically, DOE proposed to use non-destructive assay (NDA), non-destructive examination (NDE) (i.e., radiography), visual examination (VE), headspace gas sampling and analysis, and solid waste sampling and analysis as the methods to quantify various waste components (Section 4.4). The first three methodologies are most important to compliance with § 194.24 because they pertain to waste components for which limits have been set and can be identified through radiological and physical waste characterization. The last two methodologies pertain to chemical waste characterization for hazardous waste components and are not pertinent to Section 194.24(c)(2).

EPA reviewed the waste characterization information and methods to quantify waste components as presented by DOE in the CCA, Section 4.4; QAPP, Chapters 9 and 10, and Section 5.4.2; and Methods Manual, Methods 310.1 and 310.2. In addition, EPA reviewed site-specific procedures at Los Alamos National Laboratory (LANL) and Rocky Flats Environmental Technology Site (RFETS) during waste characterization certification audits and Performance Demonstration Program (PDP) tests. The DOE characterization methods apply to contact-handled transuranic (CH-TRU) waste. DOE did not specify waste characterization methods for remote-handled transuranic (RH-TRU) waste.

Section 194.24(c)(3) includes requirements for use of acceptable knowledge (AK), which is a method which can be used in appropriate circumstances by waste generators, or treatment, storage, or disposal facilities to make preliminary physical and chemical waste determinations. Acceptable knowledge is defined in *Waste Analysis: EPA Guidance Manual for Facilities That Generate, Treat, Store and Dispose of Hazardous Waste* (EPA 1994) to include process knowledge, waste analysis data, and facility records of analysis. Acceptable knowledge, as an alternative to sampling and analysis, is typically used to meet all or part of the waste characterization requirements under RCRA (EPA 1994), but is also proposed as an initial characterization element to defining those waste characteristics and components important to performance assessment. Specifically, DOE proposes to use acceptable knowledge to initially define the individual radionuclides in a waste stream, and to identify physical components important to performance assessment. AK is also instrumental in identifying the origin or generation of TRU wastes. This information is needed to help NDA measurement personnel in selecting the appropriate correction or calibration factors for NDA. AK also will be used to address the presence of items or conditions that are prohibited by the WIPP Certification Plan. Examples of such items are: reactives, corrosives, ignitables, pyrophorics, compressed gases, free liquids, and the maximum number of confinement layers.

Acceptable knowledge is one of a number of techniques used to characterize TRU waste. It is used in conjunction with radiography, VE, and NDA to define important waste components important to performance assessment, including radionuclides, cellulosics, rubbers, plastics, and liquid (water) content in waste. It should be noted that acceptable knowledge will also be used to determine some hazardous wastes that may be present and will be used in conjunction with headspace gas sampling and analysis, and solidified waste sampling and analysis to meet the requirements of the RCRA Waste Analysis Plan (WAP).

As required at §194.24(c)(4), a system of controls must be implemented that tracks and measures the waste components destined for the WIPP to ensure that the generator sites ship only waste that conforms with the waste component limits. This system of controls must also comply with the QA requirements of §194.22. The fundamental objective of EPA's review of DOE's waste characterization at waste generator sites is to assure that the proposed system of controls can quantify and track both the radionuclides and the waste component limits important for the repository performance. Because DOE's defense missions varied at the sites, the waste generated and the methods to characterize waste vary accordingly.

Further, Sections 194.24(c)(4) and (5) require DOE to demonstrate that a system of controls has been and will continue to be implemented to confirm that the waste components emplaced in the WIPP will not exceed the upper limit or fall below the lower limit calculated in accordance with §194.24(c)(1). EPA expected DOE to provide a description of all Performance Demonstration Program (PDP) tests used to certify the capability and comparability of measurements at waste generation sites, and to provide standardized waste characterization methodologies. EPA also expected DOE to cite objective evidence of the status of current implementation methods or procedures. Finally, EPA expected that the CCA would include documentation of QA for waste characterization activities from the point of generation (for to-be-generated waste) to the point of emplacement and disposal at the WIPP.

Waste characterization activities (WCA) are essential for the determination of whether the WIPP will comply with the radioactive waste disposal regulations. Therefore, EPA requires at §194.24(c)(5) that QA programs be applied to WCA to enhance reliability. WCA includes use of assumptions, analyses, sampling, computations, and computer codes; and therefore, relate to the site's compliance with the requirements of 194.22(a)(2)(ii) and (a)(2)(iv) (relating to sampling and analysis activities, and computations and computer codes).

To satisfy the requirements of 40 CFR 194.24(d) and (f), DOE had the option of implementing procedures to control the emplacement of TRU waste that would in turn affect the spatial distribution of the TRU waste within the disposal system. Otherwise, DOE was required to assume, for purposes of performance assessment and compliance assessment, random placement of waste in the disposal system. Further, DOE was required to ensure that waste emplacement conforms with the assumed loading conditions used in performance assessments and compliance assessments.

1.3 QUALITY ASSURANCE REQUIREMENTS

Prior to the Agency's allowing DOE to ship waste to the WIPP, DOE must demonstrate that the sites shipping the waste have established and executed the requisite Quality Assurance (QA) programs described in §§194.22(a)(2)(1) and 194.24(c)(3) and (5). In addition, due to the site specific nature of operations at each of the generator sites, DOE is required to establish and implement site-specific plans for waste characterization at each of the individual sites, including information on how process knowledge will be used for waste characterization of the waste stream(s) proposed for disposal at the WIPP. EPA also required DOE to implement a system of controls at each of the sites, in accordance with §194.24(c)(4), to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value. The DOE's implementation of such a system of controls includes a demonstration that the site has procedures in place for adding data to the WIPP Waste Information System ("WWIS"), and that such information can be transmitted from that site to the WWIS database; and a demonstration that measurement techniques and control methods can be implemented in accordance with §194.24(c)(4) for the waste stream(s) proposed for disposal at the WIPP.

Compliance Evaluation Findings
The remainder of this summary section outlines the premise (EPA Rulemaking), the finding (EPA Final Determination), and the steps connecting these start and end points for each component of 40 CFR 194.24. These summaries are further amplified in the corresponding sections of this document. Exhibit 2-1 provides a cross reference table for this purpose.

1.4 SUMMARY OF EPA'S ANALYSIS: 194.24(a)

EPA Rulemaking: The regulations contained in 40 CFR part 194.24(a) required DOE to describe the chemical, physical, and radiological composition of all existing waste (and to the extent practicable) to-be-generated waste. The description also is to include a list of all waste components and their approximate quantities. EPA expected this description to be lengthy, and to be based on "best judgment" using, to the extent available, process knowledge, waste measurement data, and other information. EPA expected that this waste description would provide sufficient detail to enable EPA to confidently conclude that all waste components that could significantly affect the potential for release of radionuclides had been identified.

EPA Final Determination: EPA examined the data provided by DOE, including supplemental information acquired after the submission of the CCA pertinent to the waste inventory. EPA determined that DOE's waste inventory description contained appropriate specific information on the components and their approximate quantities for both existing and to-be-generated waste. Therefore, EPA determined that DOE was in compliance with §194.24(a).

<u>EPA Analysis Process:</u>

- EPA's analysis began with a detailed examination of the CCA and its contents, including Appendix BIR (Transuranic Waste Baseline Inventory Report, Revs. 2 and 3). EPA examined these documents to determine whether they provided a sufficiently detailed description of the chemical, physical, and radiological characteristics of existing and to-be-generated wastes.

- EPA's initial analysis of the CCA identified questions regarding DOE's submitted inventory information, including DOE's intended use of post-CCA inventory data (Docket A-93-02, Item II-I-17) and quantities of organic ligands used in Performance Assessment (Docket A-93-02, Item II-I-17). DOE responded to EPA's questions (Docket A-93-02, Item II-I-24), and EPA determined that DOE's responses were technically sufficient.

- EPA's initial examination of CCA waste inventory data indicated that a more detailed analysis of the Transuranic Waste Baseline Inventory Report (TWBIR) and the data compilation process was warranted. EPA used five separate criteria, including consistency, traceability, representation, uncertainty and effectiveness to evaluate DOE's waste inventory.

- EPA's detailed analysis began with an investigation into DOE's data compilation processes, and an examination of TWBIR and CCA/PA data to ensure consistent data use and transfer. EPA found that the BIR data were accurately represented in the CCA and PA. EPA also examined the TWBIR data with respect to its use in performance assessment, and its importance in DOE's sensitivity analysis. These assessments were done to ensure that DOE used appropriate data in performance assessment analysis.

- EPA's analysis included an evaluation of the traceability of CCA data back to generator site data submittal. EPA selected to evaluate a waste material parameter of special concern, cellulosics. EPA traced the inventory information contained in the TWBIR (and represented in the CCA) back to the original data sheets submitted by generator sites, and followed the data assembly process from the individual generator site data through the DOE inventory-wide summary tables.

- EPA reviewed the data contained in the TWBIR to determine if DOE provided sufficient documentation of its methodologies, and provided information at a level of detail that would enable the Agency to have a high level of confidence that DOE had accurately represented the inventory, and that all components of the waste that could significantly affect repository performance had been identified.

- EPA concluded that the TWBIR contains the best information available to DOE to date regarding the WIPP waste inventory. Traceability of waste material parameters was evident, and the existing inventory summarized in the TWBIR and CCA is sufficiently detailed. EPA also concluded that DOE used a systematic and appropriate approach to assemble generator site inventory information. EPA noted that the scaling factor used by DOE to predict the quantity of waste material parameters in a "full" repository was calculated incorrectly, but the error was so slight that it did not impact performance assessment.

- EPA also examined DOE's EPAUNI document (Sanchez, 1997, WPO#43843) which was submitted after the CCA. This document presents waste stream-specific activities of the seven major actinides (in contact handled waste), decayed to the 2033 closure date. EPA concluded that DOE had used appropriately assembled and decayed actinide inventory data in performance assessment.
- As a result of this thorough analysis, EPA concluded that the waste inventory information is sufficient for performance assessment purposes.

1.5 SUMMARY OF EPA'S ANALYSIS: 194.24(b)

EPA Rulemaking: §194.24(b) required DOE to submit the results of an analysis which substantiates that all waste characteristics and associated components influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The DOE was also required to present any decision to exclude consideration of any waste characteristic or waste component because such characteristic or component is not expected to significantly influence the containment of the waste in the disposal system. EPA expected the compliance application to include: a detailed description of the analysis performed; a list of waste characteristics retained as a result of the analysis; a list of waste components influencing these characteristics that are retained as a result of the analysis; identification of all waste related inputs into computer models; and a list of all waste characteristics and components (tabular format suggested) that were considered and excluded, including the rationale for exclusion. In accordance with §194.27, a description of the scope of peer review of the waste characterization analysis is expected to be provided, along with a discussion of reviews of technical issues, evaluations and recommendations as to the adequacy of the analysis, and follow-up actions. Also, objective evidence supporting decisions (peer review process documentation, conclusions.) and the location of the evidence should be cited.

EPA Final Determination: EPA concluded that DOE performed a thorough and well documented analysis, adequately identified all waste characteristics and components, and appropriately assessed these and included them (as appropriate) as PA input parameters. In the case of actinide solubility, EPA believes that DOE assumed the incorrect solubility controlling mineral phase. However, the error lead to the use in the CCA of higher actinide solubilities than EPA believes will be the case, which is a conservative assumption.

EPA Analysis Process:

- EPA performed an extensive technical analysis of DOE's submission pertaining to waste characteristics. CCA references were examined, to determine whether DOE presented logical arguments for all characteristic and associated component identifications. EPA considered whether all relevant waste characteristics and components were identified and evaluated. Screening procedures were used to determine whether waste characteristics and components were examined for reasonableness and consistency of application. Results of DOE experimental programs as they pertain to identified characteristics and components were also examined in detail to determine whether conclusions drawn by DOE, based upon experimental program results, were sound. In addition, DOE's sensitivity analysis, as well as applicable bounding analysis, were examined to determine whether the sensitivity analysis includes all applicable components and to review the application of sensitivity analysis results.

- EPA has conducted a thorough evaluation of the conceptualizations and methodology used by DOE to calculate the solubilities of actinides under equilibrium conditions (Docket A-93-02, Item V-B-17). EPA performed a detailed analysis of the actinide oxidation states that may be present in the repository, recognizing that actinides can exist in oxidation states ranging from +3 to +6, depending on the specific actinide under consideration and prevailing redox conditions. EPA's analysis showed that DOE's sampling of oxidation distribution states is appropriate, and that the redox conditions of the repository will likely be reducing rather than oxidizing. EPA also agrees that chemical equilibrium models are appropriate for predicting the concentrations of actinides that might be reached in the brines infiltrating into the repository.

- EPA evaluated the use of MgO with respect to mineral species that will form in the WIPP and subsequent impact that these species will have on actinide solubility. EPA's detailed analysis indicates that hydromagnesite is the appropriate mineral phase to base solubility on.

- DOE used the computer code FMT to model the actinide solubilities in the repository. EPA identified that the thermodynamic database used by FMT was deficient. The results of DOE's FMT model were, for the most part, verified by EPA's independent modeling following the methodologies provided in support documents to the CCA. Small differences in calculated actinide concentrations were observed but are not considered significant enough to affect PA. Most importantly, errors in the FMT thermodynamic database identified by EPA have been corrected. The corrections resulted in more realistic predictions of actinide concentrations for the range of possible conditions that might be expected for equilibria with different magnesium carbonates.

- EPA's independent model runs indicate that the actinide solubilities calculated by FMT and used in the CCA performance assessment appear to be higher than what would be expected in the repository.

- The Performance Assessment Verification Test was run using values for hydromagnesite equilibria instead of the magnesite equilibria used in the CCA.

- EPA examined the viability of using a single concentration for representing U(VI) concentrations in the repository and calculated U(VI) concentrations that might be expected for equilibrium with potential solubility controlling solids such as schoepite, sodium uranate, and calcium uranate. As a result of it's analysis, EPA considered the concentration of U(VI) at 8.8×10^{-6} molal a reasonable upper bound for U(VI) concentrations in the WIPP brines.

- EPA also examined the methodology developed by DOE to assign uncertainty limits to the concentrations of actinides predicted from solubility calculations. These uncertainty limits were determined by DOE to range from 1.4 log units above to 2.0 log units below the actinide concentrations calculated from solubility expressions contained in the FMT model. Because the uncertainty distribution is based on direct comparisons between predicted and observed data from actinide solubility experiments, it is expected to provide a reasonable depiction of the uncertainty in calculations of actinide solubilities made with the FMT model.

- EPA reviewed DOE's characterization and parameterization of microbial, humic, actinide intrinsic, and mineral colloids. EPA concluded that the parameterization for actinide intrinsic and mineral colloids was adequate for use in performance assessment due to the low sensitivity of colloids in EPA's sensitivity analysis (EPA 1997a). Microbial and humic colloids were examined in detail by EPA.

- EPA's evaluation of microbial issues began with a consideration of the types of microbes likely to grow in the WIPP repository and the general lack of knowledge about their properties. Evaluations of parameters for microbial gas generation and development for microbially-mediated actinide transport was also performed. EPA finds that:

  1. DOE's approach to address the probability of gas generation is adequate for use in performance assessment although there are uncertainties in future microbial populations.

  2. DOE's simplified formulation of microbial actinide accumulation in the CCA is appropriate given EPA's knowledge of expected microbial populations.

  3. The experiments used as support to estimate actinide binding parameters have uncertainties associated with them due to limited data and projection to future populations. EPA recognizes the uncertainties associated with the parameterization of PROPMIC and CAPMIC, however, EPA finds that the approach used in the CCA reasonable given the data and the need to use existing populations to extrapolate to future populations.

- EPA's review of gas generation mechanisms and parameterization indicated that DOE's inundated corrosion-related gas generation rate is conservative and appropriate, based upon literature and available experimental data. Regarding the likelihood of microbial gas generation, EPA concluded that the 50% probability of microbial gas generation and subsequent 50% probability for plastic and rubber degradation is appropriate. EPA also reviewed DOE's CO_2 production rate data. EPA concluded that the CO_2 production values (high) are likely conservative overestimates of possible CO_2 production rates in the WIPP repository.

- EPA performed a detailed analysis of waste components associated with waste characteristics important to WIPP performance. EPA agrees that ferrous metals are important waste components relative to gas generation, and that iron will be present in abundance in waste containers shipped to WIPP. EPA also concurs with values used in PA for density of iron; see EPA Technical Support Document for Section 194.23: Parameter Justification Report (EPA 1997b) for EPA's evaluation of parameter values, and EPA Technical Support Document for Section 194.23: Sensitivity Analysis (EPA 1997a) for EPA's sensitivity analysis. EPA also agrees that DOE appropriately found that cellulosics will contribute to gas generation and that chelating agents (organic ligands) will bind to metals other than actinides. EPA's sensitivity analysis indicates that chelating agents and colloids are not important to performance. EPA Technical Support Document for Section 194.23: Sensitivity Analysis (EPA 1997a) provides EPA's PA-related sensitivity for related parameters such as cellulosic and plastic density. EPA Technical Support Document for Section 194.23: Parameter Justification Report (EPA 1997b) includes discussion of DOE's value selection for these parameters. EPA also notes that iron (via number of containers) and cellulosic content will be determined for each container intended for disposal in the WIPP by tracking the number of waste containers and through waste content evaluation using process knowledge and radiography and/or visual examination.

- EPA found that DOE appropriately identified radioactivity in curies of each isotope, ∝-emitting TRU radionuclides ($t_{1/2} > 20$ years) (with respect to TRU activity at closure), and radionuclides (with respect to redox state and solubility) as important waste components. EPA's review of the CCA indicated that DOE did not account for all waste when calculating the waste unit factor (which is based upon the total activity at closure), although the omission did not result in inventory modifications that impacted WIPP performance evaluations by EPA.

- EPA's evaluation of the waste inventory revealed that DOE had not adequately considered the entire waste inventory when determining the total curie content anticipated at closure. DOE provided supplementary information pertaining to this issue in which DOE concurred with EPA that the waste unit factor at closure (2033) was 3.59, not 3.44, as stated in Chapter 4 (p. 4-26). EPA concluded that these values did not result in a significant difference in CCDF curves and did not affect EPA's assessment of the WIPP's compliance.

- The CCA lists in Table WCA-4 those characteristics and components not considered in performance assessment, and references locations in Appendices SCR and WCA where supporting justification is contained. EPA concludes that DOE has considered the effects of each appropriately.

- EPA conducted an independent evaluation of the effects of organic ligands by conducting modeling runs to examine the effects of EDTA on the aqueous speciation of Th(IV) and the solubility of ThO_2(am); see EPA Technical Support Document for Section 194.24: EPA's Evaluation of DOE's Actinide Source Term (EPA 1997e). The solid phase, ThO_2(am), is the expected solubility-controlling phase for Th(IV) in the repository environment. EDTA was considered because it has the greatest affinity for forming aqueous complexes with the actinides compared to acetate, citrate, and oxalate. The modeling runs indicated that the EDTA concentration would have to increase by at least 1,000 times the maximum concentrations expected for the repository to produce an appreciable change in the aqueous speciation of Th(IV) and solubility of ThO_2(am), and this range was limited primarily to acidic pH conditions. At the pH conditions of 9 to 10 that are relevant to the repository with magnesium oxide backfill, the EDTA was completed predominantly by calcium and magnesium ions. These results imply that the organic ligands are unlikely to affect the mobilities of the actinides.

- EPA evaluated DOE's assumptions, calculations and experimental results with respect to excluded waste characteristics and components, and had questions pertaining to assumptions and conclusions made by DOE which were posed in EPA's December 19, 1996, letter to DOE (Docket A-93-02, Item II-I-01). For example, EPA required DOE to provide additional information pertaining to computer codes used to calculate equilibrium constants for the organic ligands. DOE responded that the results of this modeling were not used in PA, although experimental data were used (Docket A-93-02, Item II-I-24).

1.6 SUMMARY OF EPA'S ANALYSIS; 194.24(c)(1), (e)(1),(2),(g)

EPA Rulemaking: Section 194.24(c)(1) requires DOE to specify numeric limits on significant waste components and demonstrate that, for those component limits, the WIPP complies with the numeric requirements of §§194.34 and 194.55. EPA expected DOE to establish either upper or lower limits were to be established for components that must be controlled to ensure that the PA results comply with the containment requirements. EPA also expected DOE to describe plausible combinations of upper and lower limits and their associated uncertainties and demonstrate that the combination of these selected limits would result in the greatest estimated release.

Sections 194.24(e)(1) and (2) require DOE to ensure that the total quantity of emplaced waste in the disposal system will not exceed the upper limiting value for waste components and will not fall below the lower limiting value for waste components. EPA expected the compliance application to describe DOE's system for maintaining centralized control over waste characterization activities, maintaining chain of custody over waste and waste records, the controls currently in place for receipt of waste at the WIPP, and the record keeping/accounting system for controlling limited waste components. EPA also expected current documentation on the WIPP Waste Acceptance Criteria (WIPPWAC).

Section 194.24(g) requires DOE to demonstrate that the total inventory emplaced in the WIPP will not exceed limitations on TRU waste described in the LWA. Specifically, the LWA defines limits for: surface dose rate for remote-handled ("RH") TRU waste, total amount (in curies) of RH-TRU waste, and total capacity (by volume) of TRU waste to be disposed. (LWA, Section (7)(a)) EPA expected the compliance application to: (1) describe the inventory of waste proposed for disposal at the WIPP in terms of the units specified in the limitations of the LWA, in addition to limits of important waste components; and (2) describe how these limitations will be assured through implementation of the required system of controls.

EPA Final Determination: EPA finds DOE in compliance with §194.24(c)(1). EPA concurred with DOE that it was not necessary to provide estimates of uncertainty for waste limits, so long as the PA demonstrated compliance at the fixed limits.

EPA finds that the WWIS, which will be used by DOE to track specific data related to each of the waste component limits and LWA limits, is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility and LANL; as discussed above, other waste generator sites will demonstrate WWIS procedures before they may ship waste for disposal at the WIPP. Therefore, EPA finds DOE in compliance with §§194.24(e) and (g).

EPA Analysis Process

- EPA examined key CCA documents including Chapter 4 of the CCA, Appendix WCL, and related analyses presented in Appendix SOTERM and Appendix SCR.

- EPA concurred that using the quantity of iron from the container itself as the minimum limiting value is an appropriate and easily traceable waste limit, and also recognizes that iron within waste will provide additional iron and other components.

- EPA believes that the WAC limitations will ensure that water within the waste is less than 1% by volume, and that the quantity of water in waste will likely be well below the maximum limit imposed by DOE.

- EPA concurred that limitations on radionuclides are not explicitly warranted at this time, although tracking of radionuclides within the inventory will be performed to ensure that the inventory is well defined for future recertification activities.

- EPA's sensitivity analysis indicated that PA is not particularly sensitive to humic and organic ligand parameters modeled, and limitations on these components are not warranted. EPA also noted that information gleaned through the waste characterization process will provide additional detailed information pertaining to waste inventory, and that modification of waste limits could be imposed as part of the recertification process if identified as necessary by a PA for purposes of recertification.

- EPA reviewed the CCA and initially determined that DOE did not provide the associated uncertainty for the waste component limits. In DOE's responses to an EPA completeness comment regarding the absence of associated uncertainties (Docket A-93-02, Item II-I-17, Enclosure 1), DOE stated the waste component limits are fixed values, and fixed values do not have uncertainties associated with them (A-93-02, II-I-24 and II-I-28). EPA examined DOE's logic surrounding the associated uncertainty issue and agreed with DOE's approach because a limiting value can be a fixed value without an associated uncertainty. That is, the limiting value itself is imposed to ensure compliance, and in fact represents the upper "end" of an uncertainty value. EPA believes that this approach captures the intent of the regulation.

- EPA reviewed the CCA and questioned whether DOE had addressed the issues of compliance with numeric requirements, plausible combinations of upper and lower limits of waste components and associated uncertainties, the rationale for the selection of these combinations, results of modeling run of the code, results of the analysis, and the combination of the selected limits resulting in the greatest estimated release. EPA stated its concerns in a March 19, 1997 letter to DOE (Docket A-93-02, Item II-I-17). DOE responded to EPA's questions, stating that the results of the WCA, SA, CCDFs and PAs established fixed-value repository-scale WCLs, and these also addressed Section 194.24(c)(1) (Docket A-93-02, Items II-I-24 and II-I-28). Furthermore, DOE stated that the plausible combinations of upper and lower limits are equivalent to the fixed values selected and included in the CCA PA calculations. Therefore, DOE asserted the combination of selected limits that result in the greatest estimated release was used in the analysis.

- EPA examined DOE's responses in concert with a detailed examination of the PA and PAVT results. EPA concluded that DOE adequately addressed the issue of plausible combinations of upper and lower limits and their associated uncertainties through implementation of the PA, wherein multiple combinations of parameters are used that capture the spectrum of plausible PA results and associated uncertainties.

- EPA concluded, given the quantity of ferrous iron in waste containers identified by DOE, that a number of parameters used in the PA -- including the oxidation state distribution parameter (Appendix PAR, page PAR-148) -- incorporated the effects of reducing conditions. Also, the quantity of drums (Parameter ID 3132, p. PAR-235) is input to PA, as is the fixed volume of the repository.

- Since the density of waste containers relative to ferrous and nonferrous metals was established by DOE (Table 4-4) and is input to PA (see Section 194.24(b)(2) of CARD 24 for specific values), the combination of fixed PA repository volume, drum content, and waste density captures the effect that ferrous metals would have on PA.

- A specific quantity of water was not included as a separate PA parameter, but the anticipated volume of water was incorporated in the initial brine saturation parameter (parameter SAT_BRN = 1.5%, Table PAR-38).

1.7 SUMMARY OF EPA ANALYSIS: 194.24(c)(2)

EPA Rulemaking: 40CFR 194.24(c) states "For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:

(2) "Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section."

EPA Final Determination: The CCA described numerous NDA instrument systems and described the equipment and instrumentation found in NDE and VE facilities. DOE also provided information about performance demonstration programs intended to show that data obtained by each method could meet data quality objectives established by DOE. EPA found that these methods, when implemented appropriately, would be adequate to characterize the important waste components. Therefore, EPA finds that DOE has demonstrated compliance with §194.24(c)(2).
EPA Analysis Process

- EPA reviewed the CCA, Sections 4.4.2 (p. 4-55) and 4.4.2.1 (pp. 4-56, 57) for NDA as the radiological waste characterization methodology to quantify radionuclides and their activity. EPA also reviewed the Transuranic Waste Characterization Quality Assurance Program Plan (QAPP, DOE/CAO-94-1010) for QA guidelines in Chapter 9 for NDA. After performing these reviews, EPA determined that DOE adequately identified NDA as the radiological waste characterization methodology used to quantify radionuclides and their activity.

- EPA reviewed the CCA and determined that DOE does not provide a discussion of instrument sensitivities for NDA within the CCA. EPA reviewed the QAPP, Section 9.1, for DOE's discussion of the MDC for NDA. EPA determined the MDC requires a minimum sensitivity given the variety of NDA instruments used by DOE, and that the 60 nCi/g MDC meets the intent of EPA's request in the Compliance Application Guide regarding instrument sensitivities. The 60 nCi/g standard provides a 95% confidence that any drum containing TRU waste at 100 nCi/g will be properly classified. This standard meets the requirements imposed through the WIPP performance assessment.

- EPA reviewed Chapter 4.4.2 (pp. 4-55 to 57) and the QAPP, Chapter 9.0. EPA determined that DOE provided sufficient information showing NDA could measure radionuclides and their activity. EPA will verify that waste generator sites can measure different waste matrices through inspections. The LANL NDA methods have been verified as capable of characterizing radionuclide activity using the combustible legacy debris waste stream as an example of the retrievably stored legacy debris waste streams for which the process of waste characterization has been approved.

- EPA conducted inspections during DOE waste characterization certification audits to verify DOE's ability to quantify radionuclides and their activity in WIPP waste components using NDA. During the LANL waste characterization certification audit (Docket # A-93-02, V-B-18, and Docket # A-93-02, II-A-51) of the passive active neutron (PAN) system in May 1997, EPA identified issues regarding software quality assurance and isotopic identification prior to using the PAN system. The LANL PAN system provides quantitative results for Pu-240 in passive mode, and fissile grams equivalent in active mode. Quantitative results for other nuclides are calculated using the ratios of the measured isotope's activity to the activity of the other isotopes present in the waste container. This ratio information must be provided either by Acceptable Knowledge or by another waste characterization method. LANL is using the PC-FRAM gamma spectroscopy system to provide the isotopic ratio information to the PAN system. During the LANL follow-up audit of the gamma system in August 1997, issues were identified with software quality assurance, calibration, equipment set-up, and the inability of the PC-FRAM system to identify the radionuclide Neptunium-237 (Np-237). EPA attended the LANL follow-up audit of September 1997, at which the software quality assurance, calibration, equipment set-up, and the PC-FRAM issues previously noted were adequately addressed.

- EPA performed NDA inspections at two generator sites, RFETS and LANL. LANL conclusively demonstrated their NDA system's ability to detect individual radionuclides for the combustible debris waste stream as an example of retrievably stored legacy debris waste. RFETS could not conclusively demonstrate their NDA system's ability to detect individual radionuclides. EPA therefore concluded that DOE has sufficiently demonstrated at LANL that the NDA systems can identify and quantify radionuclides and their activity for the combustible debris waste stream as an example of retrievably stored legacy debris waste, but not necessarily for all waste streams expected at LANL. In addition, EPA has concluded that DOE has not yet sufficiently demonstrated that NDA systems at RFETS can identify and quantify radionuclides and their activity.

- EPA evaluated the adequacy of NDE radiography methods to verify adherence with the compliance limits for ferrous metals, cellulosics, plastics, rubber, water, and nonferrous metals as specified in Appendix WCL of the CCA. EPA reviewed the CCA, Sections 4.4.1 (p. 4-50), 4.4.1.2 (p. 4-54), 4.4.1.3 (p. 4-55), and 4.2.2 (p. 4-29), and Appendix

BIR (Section 1, pp. 17-20; Section 2, pp. 6-7; Appendix M, pp. 1-3) to evaluate the adequacy of radiography as a physical waste characterization methodology. EPA determined that DOE adequately demonstrated that the ferrous metals content would not fall below the minimum waste limit based on the ferrous metal content of the containers emplaced in the WIPP. However, EPA believes DOE must track the number of waste containers emplaced in the WIPP. EPA also reviewed chapter 10 of the QAPP for QA guidelines and Method 310.1 of the Methods Manual for procedures in order to evaluate the adequacy of radiography as a method for quantifying cellulosics, plastic, and rubber waste components. After performing these reviews, EPA determined that DOE adequately identified NDE as an appropriate physical waste characterization methodology to quantify waste components (including cellulosics, plastics and rubber).

- EPA evaluated the adequacy of visual examination methods in verifying adherence to the compliance limits for ferrous metals, cellulosics, plastics, rubber, water, and nonferrous metals as specified in Appendix WCL of the CCA. EPA reviewed the CCA, Sections 4.4.1 (p. 4-50), 4.4.1.2 (p. 4-54), 4.4.1.3 (p. 4-55), and 4.2.2 (p. 4-29), and Appendix BIR (Section 1, pp. 17-20; Section 2, pp. 6-7; Appendix M, pp. 1-3) to evaluate the adequacy of radiography as a physical waste characterization methodology. EPA determined that DOE adequately demonstrated that the ferrous metals content would not fall below the minimum waste limit based on the ferrous metal content of the containers emplaced in the WIPP. However, EPA believes DOE must track the number of waste containers emplaced in the WIPP. EPA also reviewed the Transuranic Waste Characterization Quality Assurance Program Plan for QA guidelines in Section 10 (radiography) and the Transuranic Waste Characterization Sampling and Analysis Methods Manual for procedures in Method 310.1 to evaluate the adequacy of VE as a method for quantifying cellulosic, plastic, and rubber waste components. After performing these reviews, EPA determined that DOE adequately identified visual examination as an appropriate physical waste characterization methodology to quantify waste components (including cellulosics, plastics and rubber).

1.8 SUMMARY OF EPA'S ANALYSIS: 194.24(c)(3)

EPA Rulemaking: §194.24(c)(3) required DOE to provide information which demonstrates that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance requirements found in §194.22. EPA expected the CCA to provide information used in connection with control of the use of process knowledge; cite objective evidence substantiating the degree of implementation of quality assurance (such as audit reports, status of corrective actions, etc.) for each generator site that is approved to use process knowledge for characterization; and provide an implementation plan for application of quality assurance requirements to process knowledge at remaining sites.

EPA Final Determination: EPA determined that DOE had adequately described the use of process knowledge for the retrievably stored (legacy) debris waste stream at LANL. EPA has confirmed establishment and execution of the required QA programs at that waste generator site through inspections. Therefore, the Agency determined that DOE has demonstrated compliance with the §194.24(c)(3) QA requirement for LANL. EPA did not find, however, that DOE has adequately described the use of process knowledge for any other waste streams at LANL (other than the retrievably-stored (legacy) debris waste streams discussed above). Furthermore, DOE has not demonstrated compliance with §194.24(c)(3) for any other waste generator site.

EPA Analysis Process:

- EPA conducted a thorough review of the waste analysis process that included DOE acceptable knowledge documentation presented in the CCA. Information reviewed included Chapter 4, Appendix WAP (and Appendix C8 of the WAP), and the QAPP included in the CCA.

- EPA found that the descriptions of AK in Chapter 4, Section 4.4.1.1 (p. 4-50), Appendix WAP, and the QAPP did not provide adequate documentation of the compilation, confirmation, and auditing of AK information and processes specifically for radioactive constituents. EPA requested additional information regarding acceptable knowledge for radioactive constituents in its December 19, 1996, letter to DOE (Docket A-93-02, Item II-I-01). DOE responded in a letter dated February 14, 1997, that the revised QAPP and the CCA contained the requested information (Docket A-92-03, Item II-I-08). EPA obtained a copy of the revised QAPP subsequent to receipt of the CCA (DOE 1996a).

- Based on this information, EPA prepared a checklist that detailed the AK requirements each site must meet, which was used on EPA audits of the generator sites to examine AK technical elements.

- EPA participated in site audits for INEEL, RFETS and LANL which included examination of the AK procedures in-house and implementation of these procedures. EPA shadowed DOE personnel at the audit and, using the EPA checklist, examined whether individual sites had the appropriate procedures and other processes in place to adequately characterize waste using acceptable knowledge.

- EPA concluded that LANL had sufficiently demonstrated that it could characterize waste using acceptable knowledge for the retrievably stored legacy debris waste stream.

1.9 SUMMARY OF EPA'S ANALYSIS: 194.24(c)(4),(5)

EPA Rulemaking: Sections 194.24(c)(4) and (5) require the implementation of a system of controls that will be used to ensure that critical waste components for which waste limits have been established (§194.24(c)(1)) are appropriately traced to confirm that the total amount of each component will not exceed these limits. Sections 194.24 (e)(1) and (e)(2) require that the total quantity of emplaced waste must not exceed the estimated upper-bound limits for waste components and will not fall below the estimated lower-bound limits for waste components, which is linked to §194.24(c)(4) in that the specified system of controls will ensure that the total quantity of emplaced waste will meet the limiting values. Section 194.24(g) requires DOE to demonstrate that the total inventory emplaced in the WIPP will not exceed limitations on TRU waste described in the LWA. Specifically, the LWA defines limits for: surface dose rate for remote-handled ("RH") TRU waste, total amount (in curies) of RH-TRU waste, and total capacity (by volume) of TRU waste to be disposed.

<u>EPA Final Determination:</u> The system of controls must also conform to the QA requirements specified in §194.22. With respect to the requirements in §§194.24(c)(4) and (5) DOE described a system of controls over waste characterization activities, such as the requirements of the TRU QA Program Plan ("TRU QAPP") and the Waste Acceptance Criteria ("WAC"). EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: (1) waste stream screening/verification (pre-shipment from waste generator site); and (2) waste shipment screening/verification (pre-receipt of waste at the WIPP). The tracking system for waste components against their upper and/or lower limits is found in the WIPP Waste Information System ("WWIS"). EPA believes that the TRU QAPP, WAC, and WWIS are adequate to control important components of waste emplaced in the WIPP. EPA audited DOE's QA programs at Carlsbad Area Office, Sandia National Laboratory and Westinghouse Waste Isolation Division and determined that DOE properly adhered to QA programs that implement the applicable Nuclear Quality Assurance standards and requirements. However, in the CCA, DOE did not demonstrate that the WWIS is fully functional and did not provide information regarding the specific system of controls to be used at individual waste generator sites.

After submission of the CCA, EPA subsequently received information regarding the system of controls (including measurement techniques) to be used at LANL. The Agency confirmed through inspections that the system of controls -- and in particular, the measurement techniques -- are adequate to characterize waste and ensure compliance with the limits on waste components and also confirmed that a QA program had been established and executed at LANL in conformance with Nuclear Quality Assurance requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. At the same time, DOE demonstrated that the WWIS is functional with respect to the WIPP facility -- i.e., that information incorporated into the central database can be retrieved at the WIPP and compiled to produce reports for tracking compliance with the waste limits. Therefore, EPA finds DOE in compliance with §§194.24(c)(4) and (5) for retrievably-stored legacy debris waste at LANL. (Docket A-93-02, Item V-B-15 and CARD 24.) EPA's decision is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at

LANL.[2] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

<u>EPA Analysis Process:</u>

- EPA conducted inspections during waste characterization certification audits to verify DOE's ability to quantify waste components using VE, radiography, and NDA (including cellulosics, plastics and rubbers, and radionuclides and their activity). EPA determined that DOE demonstrated the ability to quantify waste components (including cellulosics, plastics and rubber) by VE and radiography during the LANL audits of May 1997 and August 1997, and by radiography during the RFETS audit of July 1997. During the LANL waste characterization certification audit of the passive active neutron (PAN) system in May 1997, EPA identified issues regarding software quality assurance, and inadequate isotopic identification prior to using the PAN system. The LANL PAN system cannot identify individual radionuclides, but can quantify radionuclide activity after the radionuclide is identified by another waste characterization method. Therefore, inadequate isotopic identification prior to using the PAN directly impacts the PAN system's ability to quantify radionuclide activity.

- EPA attended the LANL follow-up audit of September 1997, at which the software quality assurance, calibration, equipment set-up, and FRAM issues previously noted were adequately addressed. During the RFETS audit of July 1997 of the mobile Canberra NDA unit, issues were identified by EPA regarding software quality assurance.

- EPA inspected audits that included NDA at only two generator sites, RFETS and LANL. LANL conclusively demonstrated their NDA system's ability to detect individual radionuclides for a legacy debris waste stream. RFETS could not conclusively demonstrate their NDA system's ability to detect individual radionuclides.

- After reviewing the CCA, EPA determined that DOE did not provide any waste characterization methods for RH-TRU waste, nor was there discussion specific to how DOE will quantify the RH-TRU waste. All of the waste characterization discussions in the CCA's Chapter 4 are geared toward contact-handled transuranic (CH-TRU) waste, except for Chapter 4, Table 4-13 (p. 4-49), which is entitled "Applicable CH- and RH-TRU Waste Component Characterization Methods." Furthermore, there was no discussion provided regarding the applicability of traditional CH-TRU waste characterization methods to RH-TRU waste. Therefore, EPA is not able to certify that DOE has demonstrated that the WIPP will comply with the radioactive waste disposal regulations for any RH-TRU wastes.

[2] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

- EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: (1) waste stream screening/verification (pre-shipment from waste generator site); and (2) waste shipment screening/verification (pre-receipt of waste at the WIPP).

- EPA reviewed the CCA and determined that in Section 4.4 (pp. 4-44 to 4-49), DOE provided an adequate description of the system for maintaining centralized control over waste characterization activities. During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed DOE/CAO auditors through their audit checklists and interviews, and determined that the auditors sufficiently examined the LANL waste characterization records center personnel qualifications, responsibilities, and activities, and the records themselves.

- EPA also inspected the waste characterization certification audits at Rocky Flats Environmental Technology Site (RFETS) (June 1997) and Los Alamos National Laboratories (LANL) (May, August, and September 1997), as well as the Performance Demonstration Programs (PDPs) at LANL (June 1997) and RFETS (November 1996). These are the only audits and PDPs that EPA inspected. EPA verified at the audits and PDPs that DOE had an adequate DOE's system for maintaining centralized control over waste characterization activities.

- EPA reviewed the CCA and determined that in Section 4.4 (p. 4-49) DOE did not provide adequate detail on the radiological waste characterization portion of the audit process, and that the audit checklist (as presented in Appendix WAP, Appendix C11) does not include a radiological waste characterization portion. However, through EPA's inspection of the waste characterization certification audits at LANL (May, August and September 1997), EPA reviewed DOE/CAO auditors' checklists and observed the auditors during interviews, and determined that the auditors sufficiently examined LANL's waste characterization program as it relates to radiological waste characterization. See EPA Technical Support Document for Section 194.24: Waste Characterization Status of INEL, LANL and RFETS (Docket A-93-02, Item V-B-15) for further discussion of the LANL inspection.

- EPA reviewed the records management and records storage information that DOE provided in Appendix WAP, Section C-5 (pp. C-46, 47), and found the information to be adequate. During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed that the LANL waste characterization records center exceeds the records management and storage guidelines previously noted. EPA also observed DOE/CAO auditors through their audit checklists and interviews, and determined that the auditors sufficiently examined the LANL waste characterization records center personnel qualifications, responsibilities, and activities, as well as the records themselves.

- EPA reviewed the CCA and determined that DOE provided generally adequate descriptions of the WWIS including documentation, data fields and features in Chapter 4.3.2 (pp. 4-35 to 4-39) and the WIPP Waste Information System Software Design Description (WWIS SDD) (DOE, 1996d). EPA submitted a request for additional WWIS information (i.e., automatic limits, range and QA checks; automatic report generation) in the completeness comment letter dated December 19, 1996 (Docket A-93-02, Item II-I-01). DOE responded on May 2, 1997 to EPA's completeness comment by referencing the information already provided in the CCA (A-93-02, II-I-28). EPA determined that DOE provided no additional information on the WWIS in its response and therefore did not demonstrate that the WWIS was functional.

- In September 1997, DOE demonstrated for EPA the operation of the WWIS at Los Alamos National Laboratory (LANL). EPA observed that LANL site operators were knowledgeable about the WWIS system and had procedures in place to ensure accurate entry of waste information into the system. EPA observed that the WWIS provides checks that are for repository-based limits (i.e., cellulosics in kilograms, total capacity of contact-handled (CH) waste in cubic feet or cubic meters). During the WWIS test, which occurred simultaneously at the WIPP and LANL, EPA also observed the nuclide reporting, waste container data reporting, and calculation of total cellulosics (including plastics and rubber).
- EPA determined that the WWIS tracks individual waste material parameters (WMPs) (i.e., cellulosics) and the weight of individual WMPs.

- EPA finds that the WWIS is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility; as discussed above, waste generator sites will demonstrate WWIS procedures before they can ship waste for disposal at the WIPP.

1.10 SUMMARY OF EPA'S ANALYSIS: 194.24(d) and (f)

<u>EPA Rulemaking</u>: §§194.24(d) and (f) required DOE to provide a final plan for waste loading that addresses the emplacement of radioactive waste and implements any assumptions about the distribution of the waste that were used in the performance assessments (PAs). The DOE was also required to cross-reference the resultant waste distribution assumptions from the waste loading plan with the waste distribution assumptions used in the PA. Lastly, EPA required DOE to describe how the planned distribution of waste (as assumed in the PA) would be achieved. This discussion also should identify both the acceptance criteria for implementation and the controls that will be in place to assure proper implementation of the plan.

<u>EPA Final Determination</u>: EPA determined that, because DOE had assumed random waste loading and also had found that potential non-random loading of waste would not affect releases, a final waste loading plan was unnecessary. EPA determined that DOE cross-referenced the resultant waste distribution assumptions from the waste loading plan with the waste distribution

assumptions used in PA, and accurately modeled random placement of waste in the disposal system. Since EPA concurred with DOE that a final waste loading plan was unnecessary, DOE does not have to further comply with §194.24(f), requiring DOE to conform with the waste loading conditions, if any, used in the PA and compliance assessment. EPA concluded that DOE complied with §§194.24(d) and (f).

EPA Analysis Process:

- EPA reviewed DOE's methodology for determining if a final plan for waste loading was necessary to control the emplacement of waste and/or implement any assumptions about the distribution of the waste.

- EPA reviewed the CCA to determine whether the waste distributions within the waste disposal system were accurately reflected (modeled) in DOE's methodology for determining whether a final plan for waste loading was necessary.

- EPA evaluated DOE’s assumption that containers of waste would be emplaced randomly according to the distribution of the 569 waste streams tracked in TWBIR, Revision 3, and concluded that DOE’s assumption that containers would be randomly placed in the WIPP did not account for the likely, “real world” scenario where a specific generator shipped a large shipment of a single waste stream. EPA also determined that the placement of these residue drums (stacked three-high) in a nonrandom manner was inadequately described by DOE's modeling (using the TWBIR distribution and random shipment/placement); therefore, the probability of subsequent penetration may be too low. As a result of these findings, EPA requested that DOE rework its assumptions and provide a supplemental analysis. EPA reviewed DOE’s supplemental analyses concerning the possible affects of non-random loading and concluded that DOE had correctly demonstrated that a loading plan was not necessary.

1.11 SUMMARY OF EPA’S ANALYSIS: QUALITY CONTROL

EPA Rulemaking: DOE is required to comply with §194.22, and with 194.24(c)(5) wherein DOE is to adhere to a detailed quality assurance program and to ensure that all waste characterization controls comply with the requirements of §194.22.

EPA’s Final Determination: After submission of the CCA, EPA subsequently received information regarding the system of controls to be used at LANL. The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. Therefore, EPA determines DOE to have demonstrated compliance with §§194.24(c)(4) and (5) for several waste streams in the category of retrievably stored legacy debris waste at LANL. EPA's final determination of compliance is limited to those retrievably stored (legacy) debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[3] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

EPA Analysis Process:

- EPA reviewed the Performance Demonstration Program (PDP) for non-destructive assay described in Chapter 4.3.3.1 (p. 4-40) and 4.4 (p. 4-44) of the CCA. The CCA in Chapter 4.3.3.1 describes the detailed elements that comprise the program, including test materials and analysis required.

- DOE did not include the PDP Plan for NDA in the CCA. However, DOE later provided the PDP Plan for NDA (DOE 1995). DOE has since updated the PDP Plan for NDA (DOE 1997b). DOE has provided results of Cycle 1 and Cycle 2 PDPs (DOE 1996e and DOE 1997a).

- NDA PDP Cycle 1 was completed in April 1996; Cycle 2 was completed in December 1996; and Cycle 3 was completed in June 1997. DOE presented the results of Cycle 1 at the September 1996 Technical Exchange meeting held in Washington, D.C., and the results of Cycle 2 at the January 1997 NDA/NDE Waste Characterization conference held in Salt Lake City, Utah (DOE 1996e and DOE 1997a). EPA reviewed DOE documentation pertaining to these activities, including the PDP plan and results reports, and participated in the Cycle 2 PDP at RFETS and the Cycle 3 PDP at LANL.

- The EPA inspections of Los Alamos consisted of one preliminary inspection of a CAO audit in May 12, 1997 and two full inspections of CAO audits during demonstrations of waste characterization in August 18-22 and September 10-12, 1997 (Docket Number A-93-02, Item II-A-51). EPA's inspections determined that the Los Alamos site had appropriately established and executed a QA program for WCA.

- After performing inspections of waste characterization activities, EPA is satisfied that DOE has controls in place to control the quality of data related to waste characterization. In the case of waste characterization, the TRU Waste Quality Assurance Program Plan (QAPP) (CAO-94-1010) describes controls that will enable generator sites to

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[3] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

demonstrate an acceptable level of assurance in the quality of their data. Specifically, the QAPP identifies data quality objectives for each type of measurement data

- EPA found that the TRU QAPP established appropriate technical quality control and performance standards.

- To date, only one WIPP waste generator site, Los Alamos National Laboratory ("LANL"), has been approved by EPA to have established adequate QA programs (encompassed in a QAPP and QAPjP) and to have properly executed QA procedures in accordance with the applicable NQA requirements. Prior to approval of LANL's site-specific QA program, EPA conducted an audit of DOE's overall WIPP QA program and approved its capability to perform audits in accordance with the requirements of NQA-1. EPA then inspected three DOE audits of LANL's QA program. Based on the results of the inspections, the EPA inspectors determined that the QA program had been properly executed at LANL. Therefore, EPA finds that the requirements of §194.22(a)(2)(I) have been met for the WID QAPD, the WWIS, and waste characterization activities at LANL.

- EPA also determined DOE to have adequately described the use of process knowledge for retrievably stored legacy debris waste streams at LANL. EPA has confirmed establishment and execution of the required QA programs at that waste generator site through inspections. Therefore, the Agency determines that DOE has demonstrated compliance with the §194.24(c)(3) QA requirement for LANL.

- After submission of the CCA, EPA subsequently received information regarding the system of controls to be used at LANL. The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. Therefore, EPA determined DOE to have demonstrated compliance with §§194.24(c)(4) and (5) for retrievably stored legacy debris waste at LANL. EPA's determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[4] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

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[4] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

1.13 CONCLUSIONS

Attachments 1 through 3 of Section 12 present the inspection reports prepared by EPA to summarize the activities observed during the three separate inspections and audits at the LANL site.

EPA finds that DOE is in compliance with §194.24, and that LANL has demonstrated compliance with §§194.24(c)(3) through (5) for certain retrievably stored legacy debris waste streams and may therefore ship TRU waste for disposal at the WIPP (as such shipments relate solely to compliance with EPA's disposal regulations; other applicable requirements or regulations still may need to be fulfilled before disposal may commence). EPA's final determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.

2.0 DOCUMENT PERSPECTIVE

2.1 PURPOSE

The purpose of this document is to provide a thorough discussion of the evaluation and decision-making process EPA followed in assessing DOE's compliance with the waste characterization and quality assurance (QA) requirements of §194.24. Although this document has been written as a stand-alone document, it references both CARD 24 and supporting Technical Support Documents (TSDs) as appropriate. It serves as a comprehensive reference document providing a concise description of EPA's certification actions for multiple reader interest levels. To the extent practicable, most of the remaining document sections (4-12) employ the following format:

- overview of regulatory requirements;
- summary of EPA's analysis procedure (from rulemaking to final determination);
- supporting technical documentation.

The structure and intent of this document is presented below.

2.2 STRUCTURE OF DOCUMENT

As discussed in <u>Section 3.0</u>, EPA, in its evaluation of DOE's Compliance Certification Application (CAA) and supporting documents, also recognized the waste characterization and QA requirements stipulated by other agencies, EPA offices, and legislation, including:

- Agreement for Consultation and Cooperation between the Department of Energy (DOE) and the State of New Mexico;
- The WIPP Land Withdrawal Act, as amended (LWA);
- Nuclear Regulatory Commission (NRC) regulations for the packaging and transportation of radioactive waste (10 CFR Part 71);
- relevant Department of Transportation regulations;
- Resource Conservation and Recovery Act (RCRA) and amendments;
- The Federal Facilities Compliance Act (FFCA) of 1992;
- The Environmental Protection Agency (EPA) Toxic Substance Control Act (TSCA) regulations; and,
- EPA 40 CFR Parts 191 and 194.

The Agency coordinated its review of DOE's waste characterization and QA programs with other agencies, as appropriate, and also solicited and evaluated input from stakeholders, ranging from the State of New Mexico and public research/interest groups to academia and members of the general public.

Section 194.24(a) requires DOE to describe the chemical, radiological and physical composition of all existing and to-be-generated waste. §194.24(a) also requires DOE to provide a list of waste components and their approximate quantities in the waste. EPA conducted an in-depth review and evaluation of DOE's TRU waste inventory to determine if DOE accurately represented the TRU wastes to be disposed in the WIPP. EPA presents the steps it followed to conduct its analysis, and findings.

In addition to a comprehensive waste description, DOE was required to submit a detailed analysis regarding how/if waste characteristics and components may impact WIPP performance. Specifically, 40 CFR 194.24(b)(1)-(3) requires that all waste characteristics and components influencing containment of waste in the disposal system be identified and assessed for their impact on disposal system performance. The characteristics to be analyzed include, but shall not be limited to: solubility; formation of colloidal suspensions containing radionuclides; production of gas from the waste; shear strength; compactability; and other waste-related inputs into the computer models that are used in the performance assessment. The components to be analyzed shall include, but shall not be limited to: metals; cellulosics; chelating agents; water and other liquids; and activity uncertainties in each isotope of the radionuclides present.

EPA also reviewed DOE's analysis of waste characteristics and components that might impact WIPP performance to determine if DOE's CCA presented a comprehensive analysis (e.g., study) that addressed the issues identified above. Specifically, EPA looked to see if the CCA presented:

- a detailed description of the analysis performed;
- a list of waste characteristics retained as a result of the analysis;
- a list of waste components influencing these characteristics that are retained as a result of the analysis;
- identification of all waste-related inputs into computer models; and
- a list of all waste characteristics and components (tabular format suggested) that were considered and excluded, including the rationale for exclusion.

EPA analysis of DOE's studies, including whether (1) a logical progression of rationales, arguments, etc., beginning with the description required in 194.24(a) and leading to the selection of the important or significant waste components that will be limited and controlled to assure compliance with disposal regulations was prepared, and (2) potential processes that involved waste and disposal system interaction were considered is presented in Section 5.0.

Section 6.0 discusses EPA's review and evaluation of the portion of the CCA (and supporting documentation) that relate to §§194.24(c)(1), (e), and (g) and the resulting linkage with §194.24(b) to determine if DOE fully documented the rationale for all waste-related modeling, including limitations used, and that the combination of waste-related limits selected resulted in the greatest estimated release. Specifically, §194.24(c)(1) requires DOE to specify numeric limits on significant waste components and demonstrate that, for those component limits, the WIPP complies with the numeric requirements of §§194.34 and 194.55. DOE may establish either upper or lower limits for components that must be controlled to ensure that the PA results comply with the containment requirements. Section 194.24(e) prohibits DOE from emplacing waste in the WIPP if its disposal would cause the waste component limits to be exceeded, and §194.24(g) requires DOE to demonstrate that the total inventory emplaced in the WIPP will not exceed limitations on TRU waste described in the LWA. Lastly, EPA expected DOE to (1) specify limiting values as either an upper or lower value, (2) discuss the uncertainty associated with each limiting value identified, and (3) clearly relate inputs to models to waste characteristics and components identified as part of this assessment (194.24(b)).

Section 194.24(c)(2) requires DOE to identify and describe the methods used to quantify the limits of important waste components identified in §194.24(b)(2). Section 7.0 discusses EPA's review and evaluation of the waste characterization and associated QA techniques (i.e., Non-Destructive Analysis, Non-Destructive Examination, and Visual Examination) used to characterize and quantify the characteristics and components of the wastes to be emplaced in the WIPP. This section also presents EPA's conclusions on whether DOE provided evidence that substantiates that waste components for which inventory limits were set in accordance with § 194.24(c) are monitored, controlled, and accounted for in a systematic and traceable manner...including waste that undergoes treatment or repackaging, remote-handled and contact-handled wastes, and to-be-generated waste.

Section 8.0 presents the steps EPA followed to determine if DOE demonstrated that its use of process knowledge to quantify components in waste for disposal conformed with the quality assurance ("QA") requirements found in §194.22, as stipulated in §194.24(c)(3). Specifically, EPA's analysis included the review of the CCA (and supporting documents) to see if DOE provided full documentation regarding control of process knowledge, quality assurance relative to process knowledge for generator sites approved to use process knowledge for characterization, and an implementation plan for application of quality assurance requirements for sites not yet approved.

Section 194.24(c)(4) requires DOE to demonstrate that a system of controls has been and will continue to be implemented to confirm that the waste components emplaced in the WIPP will not exceed the upper limit or fall below the lower limit calculated in accordance with §194.24(c)(1). EPA presents it evaluation and findings regarding the adequacy of DOE's system of controls to identify and track waste components in Section 9.0. Specifically, EPA reviewed the adequacy of (1) the WIPP Waste Information System (WWIS) to track metrics describing waste components to be emplaced in the WIPP and (2) the waste characterization techniques (i.e., Non-Destructive Analysis, Non-Destructive Examination, and Visual Examination) used to characterize and quantify the characteristics and components of the wastes to be emplaced in the WIPP. This section also presents the results of EPA's analysis.

Section 10.0 presents the steps EPA followed to evaluate the adequacy of DOE's QA program to meet the requirements stipulated in §194.24(c)(5), which requires DOE to demonstrate that the system of controls also conformed to the QA requirements specified in §194.22. This section also presents the results of EPA's analysis of DOE's performance demonstration program (PDP), which is designed to demonstrate that the various waste characterization techniques are operated and maintained properly and that DOE is capable of obtaining accurate characterization information for waste characteristics and components. EPA's review also considered whether DOE provided a complete discussion regarding quantification of waste limits (e.g., methods to quantify, scale, instrumentation, etc.), including quality assurance indicators.

Section 11.0 discusses EPA's evaluation of DOE's analysis of whether a load management plan is necessary to ensure compliance and that the waste emplaced does not exceed either upper or lower limiting values. This section also discusses EPA's evaluation of whether waste emplacement will conform to the assumed waste loading conditions, if any, used by DOE in its performance assessment conducted pursuant to §194.32 and compliance assessments conducted pursuant to §194.54. EPA also presents the steps it followed to determine if DOE correctly addressed the requirements stipulated by §§194.24(d) and (f) in this section.

Lastly, Section 12.0 discusses the authority granted by §194.24(h), which allows EPA to conduct inspections and record reviews to verify compliance with the waste characterization requirements. This section also discusses how EPA used audits and inspections at the WIPP site, as well as WIPP-related facilities, to verify DOE's (1) compliance with both the QA requirements and site-specific waste characterization plans, and (2) implementation of a system of controls. EPA also discusses the nature and findings of audits conducted at the LANL site, used by the Agency to determine that LANL could accurately implement the process used to characterize stored legacy debris waste. Finally, this section presents a discussion of how EPA will confirm both the execution of the waste characterization and QA programs and DOE's continued compliance with the requirements of §§194.24(c)(3) through (5) at each of the waste generator sites through future inspections and audits under its authority at §§194.21, 194.22(e) and 194.24(h).

A table showing where the §194.24 requirements for waste characterization and QA programs are discussed in the remainder of this document is presented in Exhibit 2-1.

EXHIBIT 2-1

ROAD MAP OF §194.24 CRITERIA AND SECTIONS

CITATION	CRITERIA	SECTION
§194.24(a)	Describe the following for all existing waste proposed for disposal: - Chemical composition - Radiological composition - Physical composition - Quantity	4.0
§194.24(a)	As practicable, describe the following for all to-be-generated waste proposed for disposal: - Chemical composition - Radiological composition - Physical composition - Quantity	4.0
§194.24(b)(1)	Provide analyses substantiating identity and impact of all waste characteristics on containment of waste in disposal system, including: - Solubility - Formation of colloidal suspensions containing radionuclides - Production of gas - Shear strength - Compactability - Any other inputs to computer model	5.0
§194.24(b)(2)	Provide analyses substantiating identity and assessment of all components for their impact on performance of disposal system, including: - Metals - Cellulosics - Chelating agents - Water and other liquids - Activity (in curies) of each radionuclide isotope	5.0
§194.24(b)(3)	Provide analyses substantiating any decision to exclude any characteristic or component from further consideration	5.0
§194.24©	Specify upper/lower limiting values of the volume of waste proposed for disposal and associated uncertainty of the total for each value, including - Mass - Volume - Curies - Concentration	6.0
§194.24(c)(1)	Demonstrate compliance with numeric limits of §§194.34 & 194.55 for each waste for all combinations of upper and lower limits that would result in greatest estimated release	6.0
§194.24(c)(2)	Identify and describe method(s) used to quantify limits of waste components	7.0

EXHIBIT 2-1 (Continued)

CITATION	CRITERIA	SECTION
§194.24(c)(3)	Demonstrate that the use of process knowledge to quantify components in waste streams conforms with QA requirements in §194.22	8.0
§194.24(c)(4)	Demonstrate a system of controls that ensures that upper and lower limits of amount of waste will not be exceeded, including: - Measurement - Sampling - Chain of custody records - Record keeping systems - Waste loading schemes	9.0
§194.24(c)(5)	Identify and describe the controls referenced in §(c)(4) and confirm conformance with QA requirements in §194.22	10.0
§194.24(d)	Include a waste loading scheme in compliance application, or conduct performance assessments pursuant to §194.32 and compliance assessments pursuant to §194.54 assuming random placement of waste	11.0
§194.24(e)(1) and (e)(2)	Methodology for tracking the total quantity of waste in the disposal system to ensure that the upper limiting value is not exceeded and lower limiting value is not fallen below	6.0
§194.24(f)	Methodology for determining parameters necessary to meet waste loading criteria	11.0
§194.24(g)	Demonstrate that the total inventory of waste emplaced in disposal system complies with limitations on TRU waste described in WIPP LWA	6.0
§194.24(h)	The Administrator will use inspections and record reviews, such as audits, to verify compliance.	12.0

3.0 WIPP TRU WASTE CHARACTERIZATION DRIVERS AND REQUIREMENTS

DOE must demonstrate that WIPP operations are in compliance with several other statutes and regulatory requirements. This chapter discusses the various regulations, including 40 CFR Part 191, that drive waste characterization, the ways in which waste characteristics can affect performance assessment, and the rationale for EPA's waste characterization requirements of the 40 CFR Part 194 rule.

3.1 REGULATORY DRIVERS AFFECTING RADIOACTIVE COMPONENT CHARACTERIZATION

WIPP was developed for the disposal of transuranic radioactive wastes. Therefore, the major regulatory drivers affecting waste characterization are those that regulate the management of radionuclides. These drivers include EPA's standards at 40 CFR Part 191, the WIPP LWA, and EPA's implementation at 40 CFR Part 194. They are individually discussed in the remainder of this subsection.

<u>Environmental Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes (40 CFR Part 191)</u>.

40 CFR § 191 provides environmental standards for the disposal of radioactive wastes. The EPA originally promulgated these standards in 1985 but following legal challenges in 1987 and rehearings, Subpart B was remanded to the EPA for further consideration. The LWA (see discussion below) reinstated the 1985 disposal standards except "the three aspects of §191.15 and §191.16 of such [standards] that were the subject of the remanded order".

40 CFR Part 191, as finalized in 1993, addresses individual and groundwater protection requirements (the subject of the remanded parts).

- Subpart A, Environmental Standards for Management and Storage, of this rule sets annual dose equivalent exposure standards for the maximum off-site individual during facility operation as follows (50 FR 38085):
  - whole body – 25 mrem;
  - thyroid – 75 mrem; and
  - other critical organ – 25 mrem

  The subpart A standards, coupled with DOE Order 6430.1 - General Design Criteria, were used as the basis for setting the upper limit on TRU waste packages received at the WIPP at

1,000 Curies of Pu-239 equivalent activity[5] (DOE 87). Inhalation dose calculations are based on particles that have a 1 μm Activity Median Aerodynamic Diameter. Assumed accident scenarios set the particle size distribution for drum handling mishaps which, in turn, lead to a particle size specification in the WIPP Waste Acceptance Criteria (WAC). Wastes not meeting the particle size specification will require treatment prior to shipment to the WIPP. Distribution of drums of waste with high curie contents may be important in analyzing release from drilling intrusions.

- Subpart B, Environmental Standards for Disposal, and Subpart C, Environmental Standards for Ground-Water Protection, of the amended rule (58 FR 66414) prescribe the long-term containment requirements which the WIPP must meet and defines performance assessment as the basis for assessing compliance with the cumulative release limits in Subpart B. Performance assessment will establish, through iterative calculations, an envelope of waste acceptance criteria. If met, these criteria will provide a reasonable expectation that the disposal standards can be achieved for the regulatory life of the repository.

WIPP Land Withdrawal Act (LWA)

The WIPP LWA did not specify a waste characterization program, but included definitions and limits that necessitate a waste characterization program.

Several items in the LWA relate to waste characterization including relevant definitions and limitations (particularly those involving RH-TRU waste). The following definitions from Section 2 of the LWA are important to waste characterization:

> "(20) TRANSURANIC WASTE — The term transuranic waste means waste containing more than 100 nanocuries of alpha-emitting transuranic isotopes per gram of waste, with half lives greater than 20 years, except for:
>
> (A) high-level radioactive waste;
>
> (B) waste that the Secretary has determined with the concurrence of the Administrator, does not need the degree of isolation required by the disposal regulations; or
>
> (C) waste that the Nuclear Regulatory Commission has approved for disposal on a case-by-case basis in accordance with Part 61 of Title 10, Code of Federal Regulations."[6]

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[5] Pu-239 equivalent curies are used to normalize the inhalation hazard of various transuranic nuclides to that posed by Pu-239.

[6] The apparent intent of exceptions (B) and (C) is to preclude shipment to the WIPP of wastes which meet the transuranic waste definition, but can be properly disposed in other than a geologic repository (e.g., greater than class C wastes (as defined in §61.55)).

"(3) CONTACT-HANDLED TRANSURANIC WASTE — The term “contact-handled transuranic waste” means transuranic waste with a surface dose rate not greater than 200 millirem per hour."

"(12) REMOTE-HANDLED TRANSURANIC WASTE — The term “remote-handled transuranic waste” means transuranic waste with a surface dose rate of 200 millirem per hour or greater."[7]

Section 7 of the LWA imposes the following waste-related limitations:

- Restrictions of RH-TRU waste
  - 1,000 rem/h maximum surface dose rate
  - surface dose rate less than 100 rem/h for 95% by volume of all RH-TRU
  - Canister activity limited to 23 Ci/liter (averaged over the canister volume)
  - Total RH-TRU radioactivity is limited to 5.1 x 10^6 Ci
- Repository capacity – 6.2 million cubic feet of transuranic waste

Most of the waste requirements in Section 7 are also included in the First Modification to the Agreement for Consultation and Cooperation between the DOE and the State of New Mexico (See section 3.3 below).

In Section 12, Congress made clear its intent that disposal at the WIPP be limited to TRU wastes by prohibiting the shipment and disposal of high-level radioactive waste or spent nuclear fuel.[8] In Section 16, it further specified that the TRU waste must be shipped to the WIPP in containers whose design is certified by NRC and whose quality assurance (QA) requirements meet NRC standards.

Section 8(c) of the LWA included requirements for EPA to develop certification criteria for compliance with the long-term disposal regulations at 40 CFR Part 191. The requirements at 40 CFR Part 194 (see discussion below), more specifically determine the nature and scope of the characterization activities for radioactive waste components.

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[7] According to the LWA definitions of CH-TRU and RH-TRU, waste with a surface dose of exactly 200 millirem per hour meets both definitions.

[8] These terms are defined in Section 2 of the Nuclear Waste Policy Act of 1982 as follows: 12. "High-level radioactive waste:" (A) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such waste that contains fission products in sufficient concentrations; and (B) other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation. 23. "Spent nuclear fuel" means fuel that has been withdrawn from a nuclear reactor following irradiation, the constituent elements of which have not been separated for reprocessing.

Criteria for the Certification and Re-certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations (40 CFR Part 194)

40 CFR Part 194 presents EPA's criteria for determining if the WIPP will comply with EPA's radiation protection standards for the disposal of radioactive waste as presented in 40 CFR Part 191. Promulgation of these criteria was also required by the LWA.

- Subpart A of 40 CFR § 194 includes general provisions such as definitions, communication requirements, conditions of compliance certification, publications to be incorporated by reference, alternative provisions, and the effective date of the regulations.

- Subpart B addresses compliance certification and re-certification applications, including required content, submission of reference material, and completeness requirements.

- Subpart C includes the technical requirements relative to the content of the compliance certification application, and includes requirements pertaining to inspections, quality assurance, computer modeling/codes, waste characterization, future state assumptions, expert judgement, peer review, containment requirements (scope of the performance assessment - PA, consideration of drilling events, results of PA), assurance requirements (monitoring, engineered barriers, consideration of the presence of resources, removal of waste), and individual and groundwater protection requirements (consideration of protection individuals/exposure pathways, scope and results of compliance assessments).
- Subpart D describes EPA's public participation process for its review of the CCA, and its rulemaking regarding certification and modifications or revocation of certification.

Waste characterization requirements are contained in §191.24 of Subpart C. These requirements are discussed in more detail below.

40 CFR 194.24 Waste Characterization Compliance Requirements

Section 194.24, Waste Characterization, requires DOE to identify the chemical, radiological, and physical characteristics of all existing waste, and to the extent practicable, to-be-generated waste, proposed for disposal at the WIPP. The DOE can use process knowledge, non-destructive examination/assay, and other methods to provide this waste description.

The DOE is further required to substantiate that all waste characteristics that could impact containment of wastes by the disposal system have been identified and their impacts assessed. Waste characteristics include, inter alia, radionuclide solubility, ability of radionuclides to exist in stable colloidal suspensions, gas generation potential, and shear strength. The DOE must also substantiate that all waste components which influence the critical waste characteristics are identified and their impacts assessed. Waste components include, but are not limited to, such items as the activity of each radionuclide, metals, cellulosics, chelating agents, and water and other liquids. The specific requirements of § 194.24 are summarized below in Table 2 and are discussed in detail below.

Using this information, DOE is required to set limits on those waste components judged to be important and to show that, when all of these components are set at the designated limits,[9] the disposal system will meet the numeric requirements of §191.34 and §194.55. It is then incumbent on DOE to ensure that the waste actually emplaced in the WIPP falls within these limits.

The EPA requires that the DOE submit a thorough discussion regarding the composition of all existing waste that DOE intends to emplace in the WIPP. Specifically, 40 CFR 192.24(a) states:

> *Any compliance application shall describe the chemical, radiological and physical composition of all existing waste proposed for disposal in the disposal system* [WIPP]. *To the extent practicable, any compliance application shall also describe the chemical, radiological and physical composition of to-be-generated waste proposed for disposal in the disposal system. These descriptions shall include a list of waste components and their approximate quantities in the waste. This list may be derived from process knowledge, current non-destructive examination/assay, or other information and methods.*

The EPA has indicated that this description should include approximate quantities of waste components. The physical description of waste is to include the types of items, articles, and material present in the waste, including descriptions of physical forms, initial liquids (free and bound) and the types and properties of containers to be used for disposal. Relative to chemical information, the EPA anticipates that this will include process chemicals likely to be present in the waste as well as added materials (neutralizers, etc.) (including total quantities) and chemical properties of other items that may be present in the waste. The radiological description is to include the species and quantities of radioisotopes present in the waste, expected curie distribution by container, surface radiation levels of containers and waste classification (contact versus remote handled). The EPA recognizes that the waste description is to be rather lengthy, but that the process should be detailed enough to ensure EPA that no component present in the waste that could impact facility performance has been overlooked.

In addition to a comprehensive waste description, EPA requires that the DOE submit a detailed analysis regarding how/if waste characteristics and components may impact WIPP performance. Specifically, 40 CFR 194.24(b)(1)-(3) requires:

> *(b) The Department* [DOE] *shall submit in the compliance certification application the results of an analysis which substantiates:*
>
> *(1) That all waste characteristics influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The characteristics to be analyzed shall include, but shall not be limited to: solubility; formation of*

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[9] In some cases, the upper limit on a component will produce the more conservative result while in other cases the lower limit will be controlling. For example, solubility of actinide elements generally increases as the pH of the solution is lowered. Thus, one would want to specify the minimum quantity of components which would tend to increase pH.

colloidal suspensions containing radionuclides; production of gas from the waste; shear strength; compactability; and other waste-related inputs into the computer models that are used in the performance assessment.

(2) That all waste components influencing the waste characteristics identified in paragraph (b)(1) of this section have been identified and assessed for their impact on disposal system performance. The components to be analyzed shall include, but shall not be limited to: metals; cellulosics; chelating agents; water and other liquids; and activity uncertainties in each isotope of the radionuclides present.

(3) Any decision to exclude consideration of any waste characteristic or waste component because such a characteristic or component is not expected to significantly influence the containment of the waste in the disposal system.

This requirement implies that the DOE is to submit, as part of the compliance application, a comprehensive analysis (e.g., study) that addresses the issues identified above. The EPA indicates, in its Compliance Application Guidance (CAG) (EPA, 1996) that the analysis should include:

- a detailed description of the analysis performed;
- a list of waste characteristics retained as a result of the analysis;
- a list of waste components influencing these characteristics that are retained as a result of the analysis;
- identification of all waste-related inputs into computer models; and
- a list of all waste characteristics and components (tabular format suggested) that were considered and excluded, including the rationale for exclusion.

As written in the CAG, EPA expects DOE to present a logical progression of rationales, arguments, etc., beginning with the description required in 194.24(a) and leading to the selection of the important or significant waste components that will be limited and controlled to assure compliance with disposal regulations. The EPA also expects to see a list of potential processes considered that involve waste and disposal system interaction. Relative to peer review conducted for waste characterization, EPA expects that this review present technical issues, evaluations/recommendations as to the adequacy of the analysis, and any follow-up actions that are required.

In addition 40 CFR 194.24(c) requires that any limiting values be identified, stating:

> *(c) For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting values (expressed as an upper of lower*

limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (.e.g margin of error) of each limiting value, of the total inventory of such waste proposed for disposal in the disposal system.

The EPA expects that these limiting values will be specified (including whether the value is an upper or lower value), and that DOE will also discuss uncertainty associated with each limiting value identified.   The EPA also expects that inputs to models be clearly related to waste characterization/components identified as part of this assessment (194.24(b)).

40 CFR 194.24(c) continues, requiring that any compliance application shall:

(1) Demonstrate that, for the total inventory of waste proposed for disposal in the disposal system, WIPP complies with the numeric requirements of §194.34 and § 194.55 for the upper or lower limits (including the associated uncertainties), as appropriate, for each waste component identified in paragraph (c)(2) of this section, and for the plausible combinations of upper and lower limits of such waste components that would result in the greatest estimated release.

(2) Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section.

(3) Provide information which demonstrates that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance requirements found in §194.22.

(4) Provide information which demonstrates that a system of controls has been and will continue to be implemented to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text paragraph (c) of this section. The system of controls shall include, but shall not be limited to: measurement; sampling; chain of custody records; record keeping systems; waste loading schemes used; and other documentation.

(5) Identify and describe such controls delineated in paragraph (c)(4) of this section and confirm that they are applied in accordance with the quality assurance requirements found in § 194.22.

The EPA states, in the CAG, that it expects the DOE to provide full documentation and rationale for all waste-related modeling including limitations used, and that the combination of waste-related limits selected should result in the greatest estimated release. In addition, full discussion regarding quantification of waste limits is required (e.g., methods to quantify, scale, instrumentation, etc.), including quality assurance indicators.

Relative to the use of process knowledge for waste characterization, EPA expects the Compliance Certification Application (CCA) to include full documentation regarding control of process knowledge, quality assurance relative to process knowledge for generator sites approved to use process knowledge for characterization, and an implementation plan for application of quality assurance requirements for sites not yet approved. The EPA has also requested that the CCA include a detailed description of the systems of controls in place to ensure that the upper/lower limiting bounds are met (i.e., waste characterization plan), to include a description of the certification program, chain of custody, waste receipt controls, record keeping, and identification of WAC requirements developed to meet 191/194 requirements. Specifically, the EPA states in the CAG that the DOE must provide "evidence that substantiates that waste components for which inventory limits were set in accordance with § 194.24(c) are monitored, controlled, and accounted for in a systematic and traceable manner...including waste that undergoes treatment or repackaging, remote-handled and contact-handled wastes, and to-be-generated waste." The EPA also expects that quality assurance controls to meet the requirements of 194.24(c)(4) be provided.

Waste characterization requirements set forth by EPA also require that the CCA include any waste loading schemes mandated to ensure compliance and that waste emplaced does not exceed upper or lower limiting values:

> *(d) The Department shall include a waste loading scheme in any compliance application, or else performance assessments conducted pursuant to § 194.32 and compliance assessments conducted pursuant to § shall assume random placement of waste in the disposal system.*
>
> *(e) Waste may be emplaced in the disposal system only if the emplaced components of such waste will not cause;*
>
> *(1) The total quantity of waste in the disposal system to exceed the upper limiting value, including the associated uncertainty, described in the introductory text to paragraph c of this section; or*
>
> *(2) The total quantity of waste that will have been emplaced in the disposal system, prior to closure, to fall below the lower limiting value, including the associated uncertainty, described in the introductory text to paragraph (c) of this section.*

The EPA indicates that waste emplacement will follow any identified waste loading scheme and that the DOE must demonstrate that the total waste inventory complies with limitations identified in the LWA (refer to Section II.A.1.b above). EPA also states that it will use inspections and records reviews (e.g., audits) to ensure that compliance with requirement 40 CFR 194.24 are met:

> *(f) Waste emplacement shall conform to the assumed waste loading conditions, if any, used in performance assessment conducted pursuant to § 194.32 and compliance assessments conducted pursuant to § 194.54.*

(g) The Department shall demonstrate in any compliance application that the total inventory of waste emplaced in the disposal system complies with the limitations on transuranic waste disposal described in the WIPP LWA.

(h) The administrator will use inspections and records reviews, such as audits, to verify compliance with this section.

NRC Regulations for the Packaging and Transportation of Radioactive Waste (10 CFR Part 71)

In 10 CFR Part 71, the NRC sets "(1) requirements for packaging, preparation for shipment, and transportation of licensed material; and (2) procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity"[10] (§71.0). Under this rule, packages must be approved for each specific use. Subpart D of the rule defines the contents of the application for approval of a transportation package. In the case of WIPP, the application approval package is the Safety Analysis Report (SAR) for the TRUPACT-II Shipping Package. Revision 0 was issued in February 1989. The latest revision is number 14 which was issued in October, 1994. The package description in the approval application must include the following information with regard to the contents of the shipping package (§71.33):

- Identification and maximum radioactivity of the radioactive constituents;
- Identification and maximum quantities of fissile constituents;
- Chemical and physical form;
- Extent of reflection, the amount and identity of nonfissile materials used as neutron absorbers or moderators, and the atomic ratio of moderator to fissile constituents;
- Maximum normal operating pressure;
- Maximum weight;
- Maximum amount of decay heat; and
- Identification and volumes of any coolants.

The DOE shipping package application for the TRUPACT-II Shipping Package has been assigned Docket No. 71-9218 by the NRC who issued a Certificate of Compliance No. 9218

[10] A Type A quantity is an amount of radioactive material which does not exceed certain isotope-specific limits stipulated in Appendix A of 10 CFR Part 71.

(DOE93) for use of this container to ship CH-TRU.[11] Revision 5 (June 9, 1994) of this certificate specifies the following limitations on the contents of the TRUPACT-II based on the items from §71.33 listed above:

- "Dewatered, solid or solidified transuranic wastes. Waste must be packaged in 55-gallon drums, standard waste boxes (SWB) or bins. Within a drum, bin, or SWB radioactive pyrophorics must not exceed 1 percent by weight and free liquids must not exceed 1 percent by volume. Flammable organics are limited to 500 ppm in the headspace of any drum, bin, or SWB." Radiography or visual examination shall be used to determine the presence of liquids and to estimate the quantity of liquid in retrievably-stored waste. Radiography or visual records shall include a description of the location of any liquid detected and an estimate of its volume. Headspace-gas analysis will be used to determine the level of flammable organics in the headspace of any drum, bin or SWB.

- Waste must be restricted to prohibit explosives, corrosives, nonradioactive pyrophorics, and pressurized containers. Documented procedures, radiography, or visual examination shall be used to ensure that individual CH-TRU waste payload containers contain no pressurized vessels. For newly generated waste, documented procedures shall be used to exclude explosive or corrosive items, compounds, or combinations of materials that could form explosive or corrosive constituents within the payload container. If explosive materials are present, they must be treated or diluted such that a detonation is not possible. Corrosive materials, if present, must be treated to render them noncorrosive.

- "Contents not to exceed 7,265 pounds including shoring and secondary containers, with no more than 1,000 pounds per 55-gallon drum and 4,000 pounds per SWB."

- "Fissile material not to exceed 325 grams Pu-239 equivalent with no more than 200 grams Pu-239 equivalent per 55-gallon drum and 325 grams of Pu-239 equivalent per SWB." Assay data shall be obtained in accordance with the TRU Waste Characterization Quality Assurance Program Plan (QAPP)-approved methods and shall be presented to show that the fissile gram equivalent contents complies with the limits for a CH-TRU waste payload container. For newly generated CH-TRU waste, documented procedures controlling the loading of contents into a payload container may be substituted for assay data.

- "Decay heat must not exceed values specified in Tables 6.1 through 6.3 of "TRUPACT-II Content Codes," (TRUCON), DOE/WIPP 89-04, Rev. 6."

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[11] As of the date of publication of this document, the most recent revision to the TRUPACT-II Shipping Package Application is Revision 14 submitted to NRC by Westinghouse (on behalf of DOE) on October 14, 1994. The current revision and revision date for other related documents are as follows:

- TRUPACT-II Content Codes (TRUCON) – Revision 8, October 1994
- TRUPACT-II Safety Analysis Report (SAR) – Revision 14, October 1994
- Certificate of Compliance No. 9218 – Revision 6, March 30, 1995

- The external dose rate of individual CH-TRU waste payload containers is limited to 200 mrem/hr on contact. The external dose rate of the loaded TRUPACT-II to be transported is limited to 200 mrem/hr contact dose rate and 10 mrem/hr at two meters distance as specified in Section 12.0 of Appendix 1.3.7 of the TRUPACT-II SAR.

- "Physical form, chemical properties, chemical compatibility, configuration of waste containers and contents, isotopic inventory, fissile content, decay heat, weight and center of gravity, radiation dose rate must be limited in accordance with Appendix 1.3.7 of the application, "TRUPACT-II Authorized Methods for Payload Control," (TRAMPAC)."

- Wastes must be evaluated to ensure that no adverse reactions could take place during the transport and that the chemical/material or any products of reaction are compatible with the TRUPACT-II construction materials. Documentation must show that chemicals, if present in a CH-TRU mixed waste are listed in Tables 5.1 through 5.6 of Appendix 1.3.7 of the TRUPACT-II SARP. A chemical compatibility analysis has been performed for the chemicals in these tables and ensures that these wastes meet the requirements for operations, TRUPACT-II, and environmental compliance.

- "Each drum, bin, or SWB must be assigned to a shipping category in accordance with Table 5, "TRUPACT-II Content Codes," (TRUCON), DOE/WIPP 89-004, Rev. 6, or must be tested for gas generation and meet the acceptance criteria in accordance with Attachment 2.0 of Appendix 1.3.7 of the application."

As noted above, the NRC Certificate of Compliance specifies that waste properties are determined and limited according to the specifications in TRAMPAC. TRAMPAC (Appendix 1.3.7 to the SAR) is the document which provides acceptable methods for the preparation and characterization of payloads for transport in TRUPACT-II. The parameters for which TRAMPAC specifically identifies restrictions are as follows:

- Physical and chemical form of the CH-TRU waste;

- Chemicals to ensure chemical compatibility between all constituents in a given shipment;

- Maximum pressure in a package during a 60-day transportation period;

- Amount of potentially flammable gases that might be present or generated in the payload during a 60-day transportation period;

- Layers of confinement (e.g., plastic bagging) in payload containers;

- Fissile material content for individual payload containers and the total package;

- Decay heat for individual payload containers and the total package;

- Weight of the individual payload containers and the loaded TRUPACT-II;
- Center of gravity for the payload assembly to be transported in TRUPACT-II; and
- Dose rate of individual payload containers, the total package, and three loaded packages on a truck trailer.

The foregoing discussion is specific to CH-TRU waste. Currently, there is no approved shipping container for RH-TRU waste. The DOE plans call for RH-TRU to be shipped in the RH-72B, which is a scaled down version (5/8 scale) of the NuPac 125B container certified by NRC and used to ship waste from Three-Mile Island Unit 2 (DOE93).

The TRAMPAC provides detail on how various parameters are to be tested. For example, Section 9.4, Methods of Determination and Control of Radionuclides, specifies five allowable methods for the identification and quantification of radionuclides in TRU waste including:

- passive gamma;
- radiochemical assay using alpha and gamma spectroscopy;
- passive neutron coincidence counting;
- passive-active neutron assay; and
- calorimetry

Attachment 3.0 to the TRAMPAC discusses each of the allowable methods including typical errors, sensitivities, calibration standards, assay procedures, and operator training. These topics are addressed further in the Transuranic Waste Characterization Quality Assurance Program Plan (Docket No. II-G-1, DOE96) and the site specific Quality Assurance Project Plans (QAPjPs).

3.2 REGULATORY DRIVERS AFFECTING HAZARDOUS COMPONENT CHARACTERIZATION

Regulations governing the hazardous component of the wastes destined for WIPP also drive DOE's waste characterization program. These drivers are primarily found in the Resource Conservation and Recovery Act (RCRA) requirements and permit conditions related to that Act.

Resource Conservation and Recovery Act (RCRA)

The Resource Conservation and Recovery Act of 1976 (RCRA) and the Hazardous and Solid Waste Amendments of 1984 (HSWA) provide the statutory framework for the regulation of hazardous wastes at the WIPP. Under HSWA, certain "listed" and "characteristic hazardous" wastes are prohibited from land disposal unless the wastes meet specified treatment standards or it can be demonstrated to a reasonable degree of certainty that there will be no-migration of hazardous constituents from the disposal unit for as long as the wastes remain hazardous. Migration of hazardous constituents outside the unit boundary must not exceed health-based limits (EPA92). The approach being taken by DOE at the WIPP was to seek a no-migration variance rather than meet the technology-based treatment standards.

Requirements of a petition to seek a no-migration variance are set forth in 40 CFR Part 268 — Land Disposal Restrictions (LDRs). Specific requirements (§268.6) which relate to waste characterization are:

- §268.6(a)(2) A waste analysis to fully describe the chemical and physical characteristics of the subject waste [must be provided];

- §268.6(b)(1) All waste ... sampling, test, and analysis data must be accurate and reproducible to the extent that state-of-the-art techniques allow;

- §268.6(b)(2) All sampling, testing, and estimation techniques for physical and chemical properties of the waste ... must have been approved by the Administrator; and

- §268.6(b)(3) Simulation models must be calibrated for the specific waste ... conditions and verified for accuracy by comparison with actual measurements.

The <u>No-Migration Variance to the Hazardous Land Disposal Prohibitions: A Guidance Manual for Petitioners</u> (EPA92) elaborates on the waste analysis dictated under §268.6(a)(2) noting that "proper management of wastes for as long as they remain hazardous requires that potential incompatibilities and waste transformation mechanisms be assessed." Some additional guidance provided in the No-Migration Guidance Manual for Petitioners regarding details of waste descriptions is summarized below:

- Waste types and sources
  - applicable waste codes (EPA and industrial)
  - waste-generating processes
  - hazardous constituents and their properties
  - quantities of waste to be disposed
  - rate of disposal
  - handling and storage practices

- Waste characteristics
  - potential for leachate formation
  - waste solubilities
  - hazardous-constituent vapor pressures
  - other factors affecting waste mobility

– analytical testing results for 40 CFR Part 261 Appendix VIII hazardous constituents reasonably expected to be present in the waste

- Waste incompatibilities
  - potential chemical interactions
  - identification and characteristics of reaction products

- Waste transformation mechanisms
  - biodegradation
  - photodegradation
  - hydrolysis
  - oxidation/reduction
  - volatilization

In 1990, EPA granted DOE a conditional no-migration variance to permit DOE to implement an underground test program with a limited quantity of actual TRU waste at the WIPP (55 FR 47700). The DOE subsequently canceled the test program so the no-migration variance was never exercised. However, some of the conditions imposed by EPA in this conditional variance are instructive as presaging future EPA requirements when DOE sought a final no-migration variance to dispose of TRU wastes in the repository.[12] It is recognized that the conditional variance was based on short-term no-migration considerations over a ten-year test phase with particular focus on air emissions. Thus, some of the conditions specified in granting the variance may not be indicative of requirements for permanent disposal. In granting the conditional variance, EPA imposed the following requirements relating to waste analysis:

> "To ensure that each waste container had no layer of confinement which contains flammable mixtures of gases or mixtures of gases which could become flammable when mixed with air, samples of gas from the head space in each container must be analyzed for hydrogen, methane, and volatile organic compounds. It must also be demonstrated that the headspace gas is representative of the gas within all layers of confinement in a container."

> "To ensure that the wastes to be emplaced are compositionally similar to the wastes on which the no-migration petition was based, representative samples of headspace gas must be analyzed and compared to compositions supplied with the petition. If the results are not comparable, the waste may not be shipped to WIPP (without treatment or modification)."

A key finding in the conditional no-migration determination was that "if adequate data are not collected, EPA will not be in a position to approve any no-migration petition for the operational or post-closure phase." The EPA clearly stated that further characterization of the waste would be required before a final no-migration petition could be considered by the Agency. The EPA noted that, at a minimum, wastes should be analyzed for 32 organic compounds and six metals

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[12] DOE submitted a final petition to EPA for a disposal phase no-migration variance in June, 1996.

(Cd, Cr, Pb, Se, Hg, Ag). Testing should include headspace analysis of all waste types for the organics and analysis of sludges for both organics and metals.

Although DOE submitted a final petition to EPA for a disposal phase no-migration variance in June 1996, the U.S. Congress passed and the U.S. President signed a bill in September 1996, which exempted DOE from the requirement to meet the Land Disposal Restrictions (LDRs) at the WIPP site, and therefore removed the need for a no-migration variance.

RCRA Part B Permit Application

Since the State of New Mexico is authorized by the EPA to permit facilities which treat, store and dispose of radioactive mixed waste, the RCRA Part B Permit Application must be submitted to, and approved by, the New Mexico Environment Department (NMED) before DOE may emplane hazardous waste in the WIPP. In February 1991, DOE submitted a RCRA Part B Permit Application for the Test Phase and in 1996 (Revision 6) for the disposal phase.[13]

The draft Part B Permit Application contains a Waste Analysis Plan (WAP) which was prepared in accordance with Waste Analysis at Facilities that Generate, Treat, Store, and Dispose of Hazardous Wastes: A Guidance Manual (EPA94). According to the Permit Application (Revision 6), the following waste is unacceptable for management at the WIPP facility:

- Ignitable, reactive and corrosive waste (Free liquids, explosives, compressed gases, oxidizers, and non-radioactive pyrophorics are prohibited);
- Headspace gas volatile organic compounds (VOCs) in concentrations resulting in emissions not protective of human health and the environment;
- Incompatible wastes (Waste must be compatible with container, cask, and TRUPACT II materials as well as other waste);
- Compressed gases;
- Free liquids (Residual liquids in well-drained containers must be less than 1% by volume);
- Waste with 50 parts per million or more of polychlorinated biphenyls (PCBs);
- Particulate waste not solidified, stabilized, or consolidated; and
- Wastes with EPA codes not listed in the RCRA Part A permit application.

The Waste Analysis Plan further specifies that all waste containers (for both newly-generated and retrievably-stored wastes) undergo headspace gas analysis for total VOC concentrations.

[13] New Mexico's RCA regulations (HWMR-7) mirror the Federal RCRA regulations.

Based on results and trends DOE may propose in the future to reduce the sampling frequency. Homogeneous solids and soil/gravel wastes will be sampled periodically for VOCs, semi-volatile organic compounds (SVOCs), and metals. Debris wastes, and homogeneous solids and soil/gravel will also be characterized by acceptable knowledge. The physical form of all retrievably-stored waste will be determined by radiography or visual examination. The physical form of all newly-generated waste will be determined by visual examination during packaging.

Federal Facilities Compliance Act (FFCA) of 1992 (Public Law 102-386)

The FFCA is an amendment to the Solid Waste Disposal Act (SWDA) (42 U.S.C. 6981) which, among other things, imposes certain restrictions on DOE regarding the storage of mixed wastes.[14] After October 6, 1995, DOE can store mixed waste without violation of Section 3004(j) of the SWDA only if a plan has been submitted to EPA, or to a state agency authorized by EPA to regulate the hazardous components of the mixed waste, and has been approved by the appropriate agency. An order requiring compliance with the plan must also have been issued. According to Sec. 102 (c) of the FFCA, the requirement does not apply to facilities subject to existing agreement, permit, administrative, or judicial order. For example, a tri-partite compliance agreement among DOE, EPA Region X, and the State of Washington exists for the Hanford Site which takes precedence (DOE94a). While the FFCA does not, per se, require waste characterization, the compliance plans may.

The FFCA does, however, require that DOE generate an inventory of mixed wastes. Some of the specified elements of this inventory include:

- a description of each type of mixed waste including the name of the waste stream;
- the EPA hazardous waste code for each type of mixed waste that has been characterized at each DOE facility[15];
- an inventory of each type of waste that has not been characterized by sampling and analysis at each DOE facility; and
- the basis of DOE's determination of the applicable hazardous waste code for each type of mixed waste and a description of whether the determination is based on sampling and analysis or on process knowledge.

The FFCA also requires that DOE develop and submit Site Treatment Plans for the development of treatment capacity and technologies for handling mixed waste. Required inventory reports and plans are described in Section 3021 of the FFCA. Mixed waste inventory reports have been completed (DOE94b) and Draft Site Treatment Plans have been summarized in a recent DOE

[14] Mixed wastes are wastes which contain a hazardous component regulated under the Resource Conservation and Recovery Act and a radioactive component regulated under the Atomic Energy Act.

[15] EPA Hazardous Waste Codes are found in 40 CFR Parts 261.21-33.

report (DOE94a). The National Summary Report (DOE94a) noted that about one-third of the existing mixed TRU waste can probably be shipped to the WIPP without further treatment, but the balance will require additional treatment to meet the expected waste acceptance criteria. Thus, at least implicitly, the FFCA requirements will result in increased understanding of the characteristics of the waste destined for the WIPP.

3.3 OTHER REGULATORY DRIVERS AFFECTING WASTE CHARACTERIZATION

DOE's waste characterization program is also driven by other regulatory drivers that affect the parties involved in the program and that affect the waste components that must be addressed by the program.

Agreement for Consultation and Cooperation-July 1, 1981

An Agreement for Consultation and Cooperation (the Agreement) between the State of New Mexico and the DOE was signed by the parties on July 1, 1981. Appendix B to this Agreement is entitled Working Agreement for Consultation and Cooperation (the Working Agreement). Article IV of the Working Agreement provides a basis for the State to comment on waste acceptance criteria as described in Article IV.E.1(c):

"The DOE has provided this documentation to the State. Any State comments as to public health and safety concerns shall be provided to the DOE WIPP Project Manager within __[16] calendar days after receipt of documentation from DOE. DOE shall respond to the State comments within __[17] calendar days after receipt of such comments. Nothing herein shall preclude further discussions of the matter or any updates prepared by DOE. Reasonable time frames for State comments and DOE response to any DOE updates shall be negotiated by the principal representatives of the parties."

The Agreement and the Working Agreement were modified in November 1984 under the First Modification to the July 1, 1981 "Agreement for Consultation and Cooperation" on the WIPP by the State of New Mexico and the U.S. Department of Energy (First Modification). Article VI.B of the Agreement was revised to set certain limitations on RH-TRU waste including the following maximum values for specified parameters:

- volume – 250,000 cubic feet;
- surface dose rate – 1,000 rem/h;

[16] To be negotiated in original agreement.
[17] To be negotiated in original agreement.

- volume with surface dose greater than 100 rem – 12,500 cubic feet;
- activity level (averaged over canister volume) – 23 Curies (Ci)/1; and
- amount of radioactivity – 5.1 million Ci

The First Modification further specified that the concentrations of radionuclides in the RH-TRU canisters would be determined by one or more of the following methods: "(1) materials accountability; (2) classification by source; (3) gross radioactivity measurements; (4) direct measurements of major contributing radionuclides; or (5) such other methods as the parties may agree to."

A second modification to the Agreement was implemented on August 4, 1987 which included, among other things, an amendment of Article VI.E to contain the following paragraph:

> "4. The transportation of radioactive waste to WIPP shall comply with the applicable regulations of the U.S. Department of Transportation and any applicable corresponding regulations of the U.S. Nuclear Regulatory Commission. All waste shipped to the WIPP will be shipped in packages which the Nuclear Regulatory Commission has certified for use."

U.S. Department of Transportation Regulations; 49 CFR Part 173-Shippers-General Requirements for Shipments and Packaging

The Department of Transportation (DOT) has jurisdiction over hazardous materials shipments affecting intrastate and interstate commerce (DOE 93). This authority is derived from the Hazardous Materials Transportation Act of 1975 as amended by the Hazardous Materials Transportation Uniform Safety Act of 1990. Subpart I of 49 CFR Part 173 sets out DOT regulations for the shipment of radioactive materials. Basically, the DOT regulations provide that any package which meets the applicable requirements of NRC regulation 10 CFR Part 71 is authorized for shipment (49 CFR 173.416(b)). The DOT regulations add no additional waste characterization requirements beyond those already imposed by the NRC.

Toxic Substance Control Act (TSCA): 40 CFR Part 761 – PCB Manufacturing, Processing, Distribution in Commerce and Use Prohibitions.

TSCA regulations limit the concentration of polychlorinated biphenyls (PCBs) that may be disposed. Unlike the RCRA regulations, the TSCA regulations do not provide the issuance of no-migration variances. Thus, waste containing PCBs must be treated to meet TSCA requirements before disposal (IDA94). Generally speaking, §761.60 — Disposal requirements — specifies that PCBs at concentrations of 50 ppm or greater must be treated in a licensed incinerator. Alternate methods of disposal which achieve the same level of performance in destroying PCBs as incinerators may be approved by EPA (§761.60(e)).

The Waste Analysis Plan, as part of the RCRA Part B Permit Application, indicates that transformer oils containing PCBs have been identified in a few waste streams included in the organic sludges summary category and consequently these streams must be examined for PCBs. The draft site treatment plans prepared by INEL and RFETS have noted that PCB-contaminated TRU waste at those facilities must be treated (IDA94 and RFP94). Therefore, DOE must characterize its wastes to determine the concentration of PCBs in the wastes in order to demonstrate compliance with TSCA regulations.

Variances, Permits, and Certifications that WIPP Must Acquire Prior to Waste Shipment

As discussed in Section II.A above, DOE must obtain a RCRA Part B Permit for the WIPP, and each site must certify that the waste meets the WIPP WAC prior to DOE Carlsbad Area Office (CAO) allowing any waste shipment to be emplaced in the WIPP. DOE is not required to obtain RCRA no migration variance petition for WIPP, as congress exempted WIPP from land disposal restrictions. The waste characterization requirements associated with the Part B Permit were previously discussed in Section II.A. For the purposes of this section, however, additional detail on the waste characterization and certification requirements of the WIPP WAC is provided in Table 3.

4.0 WASTE INVENTORY REVIEW

Section 194.24(a) requires the Department of Energy (DOE) to describe the chemical, radiological and physical composition of all existing and to-be-generated waste, including a list of waste components and their approximate quantities in the waste. DOE described the existing waste by combining like waste streams into eleven final waste forms and waste stream profiles. A waste stream is defined by DOE as waste material generated from a single process or activity that is similar in material, physical form, isotopic make-up, and hazardous constituents. The waste stream profiles contained information on the waste material parameters, or components, that could affect repository performance. DOE extrapolated information from the existing waste streams to determine the amount of to-be-generated waste.

4.1 SUMMARY OF EPA'S ANALYSIS

<u>EPA Rulemaking:</u> The Environmental Protection Agency (EPA) regulations contained in 40 CFR 194.24(a) required DOE to describe the chemical, physical, and radiological composition of all existing waste (and to the extent practicable) to-be-generated waste. The description also is to include a list of all waste components and their approximate quantities. EPA expected this description to be lengthy, and to be based on "best judgment" using, to the extent available, process knowledge, waste measurement data, and other information. EPA expected that this waste description would provide sufficient detail to enable EPA to confidently conclude that all waste components that could significantly affect the potential for release of radionuclides had been identified.

<u>EPA Final Determination:</u> EPA examined the data provided by DOE, including supplemental information acquired after the submission of the Compliance Certification Application (CCA) pertinent to the waste inventory. EPA determined that DOE's waste inventory description contained appropriate specific information on the components and their approximate quantities for both existing and to-be-generated waste. Therefore, EPA determined that DOE was in compliance with §194.24(a).

<u>EPA Analysis Process:</u>

- EPA's analysis began with a detailed examination of the CCA and its contents, including Appendix BIR (Transuranic Waste Baseline Inventory Report, Revs. 2 and 3). EPA examined these documents to determine whether they provided a sufficiently detailed description of the chemical, physical, and radiological characteristics of existing and to-be-generated wastes.

- EPA's initial analysis of the CCA identified questions regarding DOE's submitted inventory information, including DOE's intended use of post-CCA inventory data (Docket A-93-02, Item II-I-17) and quantities of organic ligands used in Performance Assessment (PA) (Docket A-93-02, Item II-I-17). DOE responded to EPA's questions (Docket A-93-02, Item II-I-24), and EPA determined that DOE's responses were technically sufficient.

- EPA's initial examination of CCA waste inventory data indicated that a more detailed analysis of the Transuranic Waste Baseline Inventory Report (TWBIR) and the data compilation process was warranted. EPA used five separate criteria, including consistency, traceability, representation, uncertainty and effectiveness to evaluate DOE's waste inventory. This analysis did not include a technical evaluation of information submitted by the generator sites, as this could not be conducted without traveling to each individual generator site and re-assembling and examining site-specific data.

- EPA's detailed analysis began with an investigation into DOE's data compilation processes, and an examination of TWBIR and CCA/PA data to ensure consistent data use and transfer. EPA found that the BIR data were accurately represented in the CCA and PA. EPA also examined the TWBIR data with respect to its use in performance assessment, and its importance in DOE's sensitivity analysis. These assessments were done to ensure that DOE used appropriate data in performance assessment analysis.

- EPA's analysis included an evaluation of the traceability of CCA data back to generator site data submittal. EPA selected to evaluate a waste material parameter of special concern, cellulosics. EPA traced the inventory information contained in the TWBIR (and represented in the CCA) back to the original data sheets submitted by generator sites, and followed the data assembly process from the individual generator site data through the DOE inventory-wide summary tables.

- EPA reviewed the data contained in the TWBIR to determine if DOE provided sufficient documentation of its methodologies, and provided information at a level of detail that would enable the Agency to have a high level of confidence that DOE had accurately represented the inventory, and that all components of the waste that could significantly affect repository performance had been identified.

- EPA concluded that the TWBIR contains the best information available to DOE to date regarding the Waste Isolation Pilot Plant (WIPP) waste inventory. Traceability of waste material parameters was evident, and the existing inventory summarized in the TWBIR and CCA is sufficiently detailed. EPA also concluded that DOE used a systematic and appropriate approach to assemble generator site inventory information. EPA noted that the scaling factor used by DOE to predict the quantity of waste material parameters in a "full" repository was calculated incorrectly, but the error was so slight that it did not impact performance assessment.

- EPA also examined DOE's EPAUNI document (Sanchez, 1997, WPO#43843), which was submitted after the CCA. This document presents waste stream-specific activities of the seven major actinides (in contact handled waste), decayed to the 2033 closure date. EPA concluded that DOE had used appropriately assembled and decayed actinide inventory data in performance assessment.

- As a result of this thorough analysis, EPA concluded that the waste inventory information is sufficient for performance assessment purposes.

4.2 EPA's WASTE INVENTORY REVIEW (194.24(a))

EPA required that DOE provide waste inventory information for use in performance assessments (PA), including the radionuclide content of waste and the physical and chemical components that may affect disposal system performance. EPA also required DOE to assess the impact that specific waste components have on waste characteristics and components (§ 194.24(b)), and provide sufficient overall waste inventory information for use in the PA, specifically for those components deemed important to repository performance. Section 194.24(a) of the Compliance Criteria presents the inventory reporting requirements that DOE must meet to ensure sufficient information is available for use in performance assessment.

EPA expected the compliance application to:

- Provide a description (chemical, radiological, physical) of existing waste;
- List approximate quantities of waste components in each description; and
- Provide similar descriptions for to-be-generated waste, to the extent practicable.

As stated in the Compliance Application Guidance for 40 CFR Part 194 (CAG) (p. 30), the physical description of waste may include: the types of items, articles, and materials present in the waste (including void space); a description of physical forms and initial liquids present in the category (both free and bound); and the types and properties of the containers to be used for disposal. The chemical description may include: process chemicals likely to be present in the waste; all added components (neutralizers, stabilizers, solidifiers, etc.) and approximate total quantities; and the chemical properties of other items present that could affect performance. The radiological description may include: the species and quantities of the radioisotopes present in the waste; information on the expected distribution of curie loading by container; the surface radiation levels of containers, including types of radiation; and the classification of the waste material, such as CH or RH TRU waste.

EPA expected that the waste description may be rather lengthy, due to the heterogeneous nature of transuranic waste and the presence of numerous components that are present in quantity and have the potential to affect solubility, gas generation, criticality, etc. EPA expected that the waste description would be detailed enough to enable EPA to have confidence that DOE did not overlook any component that is present in transuranic waste and has significant potential to influence releases of radionuclides. EPA also expected that the required descriptions would be semi-quantitative, based upon both waste measurement data and acceptable knowledge that are readily available at the waste generator sites and well documented, best-judgment estimates of what will be generated in the future.

4.2.1 Development of Waste Inventory Description

194.24(a) "Any compliance application shall describe the chemical, radiological and physical composition of all existing waste proposed for disposal in the disposal system. To the extent practicable, any compliance application shall also describe the chemical, radiological and physical composition of to-be-generated waste proposed for disposal in the disposal system. These descriptions shall include a list of the waste components and their approximate quantities in the waste. This list may be derived from process knowledge, current non-destructive examination/assay, or other information and methods."

4.2.1.1 Description of Chemical, Physical, and Radiological Description of Existing and To-Be-Generated Waste and Quantities of Waste Components

To describe and categorize the entirety of TRU waste that exists at various DOE facilities, DOE developed a descriptive methodology for grouping waste information obtained from each generator site. DOE first asked every TRU waste generator site to fill out waste profile forms describing the physical, chemical, and radiological constituents in each waste stream that generates or generated TRU waste at that site. Appendix BIR, Appendix P, contains for each waste stream both detailed, site-specific information and summary information (e.g. Appendix BIR, Table 1-2) concerning the chemical, physical, and radiological properties of existing and to-be-generated waste. Information regarding WIPP waste profile forms includes the following, for each waste stream at each generator site (Chapter 4, p. 4-14):

- Waste stream description;
- Waste stream source description;
- Currently used identification codes, including DOE TRU waste site matrix descriptions (waste matrix descriptions are described below);
- Final waste form assigned by the TRU waste generator and storage sites (final waste forms are described below);
- As-generated waste form volumes and final waste form volumes;
- Estimated minimum, maximum, average, and maximum weight of waste components per cubic meter of the final waste form (i.e. iron-base metal and alloys, aluminum-base metal and alloys, cellulosics, etc.);
- Identification of whether the waste is CH or RH TRU waste;
- Final waste form radionuclide inventory (activity of each radionuclide) in curies per cubic meter);

- Chemical constituent content (i.e. hazardous waste code identification); and
- Comments provided by the TRU waste generator site and storage sites to further explain the data provided.

This list was derived by the generator sites from acceptable knowledge, current nondestructive examination/assay, or other information and methods. See CARD 24, Section 194.24(c)(4) for further discussion of specific characterization methodologies.

Waste streams were categorized by DOE into waste matrix codes, and the waste matrix codes were grouped into final waste forms, based on similar physical and chemical properties (CCA Section 4.1.3.1, Table 4-2, page 4-15). The following eleven final waste forms intended for disposal at the WIPP were identified by DOE (CCA Table 4-2):

- Solidified Inorganics;
- Salt;
- Solidified Organics;
- Soils;
- Uncategorized Metal;
- Lead and Cadmium Metal;
- Inorganic Nonmetal;
- Combustible;
- Graphite;
- Heterogeneous; and
- Filters.

The chemical, physical, and radiological inventory was also grouped in other fashions by DOE and developed in detail from the waste stream profiles from each of the TRU waste generator and/or storage sites (CCA Appendix BIR, Appendix P). As previously stated, the BIR contains information, called a waste stream profile, on the radiological, chemical and physical properties of existing and to-be-generated waste for each waste stream at each generator site. DOE grouped these individual waste stream profiles into site-specific waste stream profiles, which were further grouped across the DOE generator sites to develop WIPP waste profiles (Figure 4-3, p. 4-19).

This categorization is a second type of waste descriptor parallel to the waste material code and final waste form descriptor.

Waste groupings (other than contact handled and remote handled designations) by DOE were based on the chemical and physical aspects of the waste, not the radiological content of the waste (Appendix BIR). However, the radiological constituents were identified and quantified (in Ci/m3 for each waste stream) on each waste profile form, and information from the forms was used by DOE to develop the radiological inventory for the WIPP. Table 4-6 (Chapter 4, p. 4-25) presents the radiological constituents expected in WIPP waste, including the inventory at the estimated time of disposal (year 2033), and anticipated EPA units for each radionuclide. Sanchez et al. (1997) presented the radionuclide content for each waste stream anticipated for shipment to WIPP.

Each WIPP Waste Profile contains information on the physical and chemical waste components (identified as waste material parameters, or WMPs), as well as radiological waste components, that DOE believes could affect the performance of the repository. Waste material parameters are not identical to waste material forms, but do share similar waste categories (e.g. soils). Waste material parameters are presented as density values, calculated by the average density of individual waste streams from a given waste form multiplied by the volume of the TWBIR waste stream and the total volume of the final waste form. Refer to CCA Appendix BIR, TWBIR, Revision 3 (p. 2-3) for DOE's detailed WMP calculation methodology. The approximate maximum, average, and minimum densities for twelve (12) waste material parameters were calculated by DOE, including iron based metals/alloys, aluminum based metals/alloys, other metal/alloys, other inorganic materials, vitrified materials, cellulosics, rubber, plastics, solidified inorganic matrix, solidified organic matrix, solidified cement, and soils (CCA Appendix BIR, Table 2-2, p. 2-5). WIPP Waste Profiles contain information on the WMPs, i.e., components that DOE determined to have the potential to impact repository performance. DOE identified the quantity of physical waste components such as cellulosics, rubber, etc., in CCA Appendix BIR (see TWBIR Revision 3, pp. ES-1 and ES-2). CCA Table 4-3 presents the anticipated nonradionuclide TRU waste inventory for the WIPP based upon the waste profile forms in CCA Appendix BIR, Appendix P. Also, in accordance with 40 CFR 194.24(a), DOE's waste profiles contain specific information on the species and quantities of individual radioisotopes in the waste. Additional information, such as curie distribution per container and surface dose rate, while not explicitly provided in the CCA, can be calculated using the information contained in Appendix BIR, Appendix P.

DOE described its inventory as "stored" and "projected," with the stored inventory generally equivalent to existing waste and projected waste generally equivalent to-be-generated waste. The projected inventory information was derived from each generator site from the waste stream profile forms, and reflects the site's best determination of the waste expected to be generated (CCA Appendix BIR, TWBIR Revision 3, pp. 1-3 through 1-8). The anticipated inventory is the sum of the stored and projected inventories (Appendix BIR, TWBIR, Revision 3, p. 1-3). Appendix BIR, TWBIR Revision 3, Table 2-1, summarizes DOE's projected and anticipated inventories based on final waste form.

DOE's estimates indicate that the total expected inventory volume for CH-TRU wastes will not reach the maximum disposal capacity of the WIPP for CH-TRU (calculated to be approximately 168,500 cubic meters or 5,950,000 cubic feet) (Chapter 4.1.3.21, p. 4-21). DOE employed a scaling approach to project the impacts of a full repository. This scaling methodology was not used on remote handled transuranic wastes, because DOE has reported inventory sufficient to meet the RH-TRU waste capacity defined in the WIPP Land Withdrawal Act (LWA) (approximately 7,080 cubic meters or 250,000 cubic feet). DOE developed a scaling factor based upon the approximately 54,000 cubic meters of projected inventory it expected would be generated, as DOE believed that any new waste generated to "fill" the outstanding WIPP space would probably be more similar to the projected rather than existing waste inventory (CCA Appendix BIR, TWBIR Revision 3, p. 2-3). This scaled CH-TRU inventory was described by DOE in TWBIR Revision 3 and was based on the projected TRU waste inventory (e.g., waste components, quantity, type of waste, species and quantity of radionuclides).

4.2.2 EPA's Analysis of DOE's Waste Inventory Description

EPA reviewed the CCA to determine whether it provided a sufficiently complete description of the chemical, radiological and physical composition of the existing and to-be-generated wastes proposed for disposal in the WIPP. EPA questioned in its March 19, 1997 letter to DOE whether any recently acquired information pertinent to the TWBIR would result in revision of the TWBIR and, hence, PA estimates (Docket A-93-02, Item II-I-17). DOE responded that EPA should consider the information contained in the CCA as the inventory description upon which the PA is based for the purposes of the initial compliance determination (Docket A-93-02, Item II-I-24). EPA's initial examination of CCA waste inventory data indicated that a more detailed analysis of the Transuranic Waste Baseline Inventory Report (TWBIR), Rev. 3 and the data compilation process was warranted.

The objectives of EPA's analysis of TWBIR Rev. 3 were to:

1. Obtain an understanding of the efficiency of TWBIR Rev. 3 in identifying all waste components that are destined for disposal at the WIPP; and to

2. Evaluate whether the information regarding waste components contained in the TWBIR are adequately portrayed in the CCA.

EPA's review of the inventory data contained in TWBIR Rev. 3 was restricted to DOE's process for gathering and representing the information obtained for the generator sites. EPA used five criteria to conduct its review of the TWBIR Rev. 3 to determine DOE's compliance with the requirements of §194.24(a).

- **Consistency:** EPA reviewed TWBIR Rev. 3 to ensure that DOE's description of wastes and waste components is adequate to allow the Agency to conduct a qualitative assessment of the adequacy of the chemical, physical, and radiological characteristics of the waste and waste components proposed for disposal at the WIPP.

- **Traceability:** EPA reviewed TWBIR Rev. 3 to ensure that the data contained in the TWBIR Rev. 3 are traceable to the data submitted by the generator/storage sites.

- **Representation:** EPA's analysis was designed to ensure that DOE provided a description of the chemical, physical, and radiological characteristics of the waste and waste components that truly represents the wastes currently stored, and to the extent practicable, the wastes to be generated that are proposed for disposal at the WIPP.

- **Uncertainty:** EPA reviewed the data contained in TWBIR Rev. 3 to determine if DOE provided sufficient documentation of its methodologies, and provided information at a level of detail that would enable the Agency to have a high level of confidence that DOE has accurately represented the inventory, and that all components of the waste that could significantly affect repository performance had been identified and characterized.

- **Effectiveness:** EPA reviewed TWBIR Rev. 3 to ensure that DOE had provided sufficient justification to the Agency that would allow EPA to determine how effective DOE has been in providing enough information for EPA to draw conclusions about the affect of waste components on repository performance.

4.2.2.1 Consistency of Use of Inventory Data

The first part of EPA's review of the TWBIR Rev. 3 included determining the extent to which data contained in the TWBIR Rev. 3 (related to waste characterization) were accurately represented in the CCA.

<u>Waste Matrix Codes and Anticipated Final Waste Forms</u>

EPA first evaluated whether the final waste forms described in the CCA consisted of the same waste matrix codes described in TWBIR Rev. 3. Final waste forms apply to both stored and projected inventories. Each final waste form for a waste stream consists of numerous waste matrix codes that have been grouped together. The volumes associated with these waste matrix codes are rolled-up to the final waste form level for purposes of the CCA. EPA determined that the series of waste matrix codes associated with a final waste form in both the TWBIR Rev. 3 and CCA are identical, with one exception. The TWBIR Rev. 3 contains waste matrix codes for excluded waste streams and unknown final waste forms. Excluded waste streams are not allowed to be disposed in the WIPP, and thus, this final waste form is not included in the CCA. For waste matrix codes associated with unknown final waste forms, the sites can change the waste matrix codes with adequate justification; however, if adequate information is not available, the waste streams remain as unknown and are prohibited from being disposed in the WIPP.

Non-radionuclide TRU Waste Inventory for WIPP

EPA next compared the non-radionuclide waste volumes in the TWBIR and CCA. CCA Table 4-3 and TWBIR Rev. 3 Table 2-1 contain data related to the stored, projected, and WIPP disposal volumes for each of the 11 final waste forms. EPA determined that the data contained in each of the tables for each of the CH-TRU and RH-TRU final waste forms are identical.

WIPP CH-TRU and RH-TRU Waste Material Parameter Disposal Inventory

EPA also conducted a comparison of the data presented in the CCA and TWBIR for waste material parameters. CCA Tables 4-4 and 4-5, and TWBIR Rev. 3 Tables 2-2 and 2-3 present the average density of each of the waste material parameters. The average density is reported because this value is used to generate certain waste-related inputs to PA. EPA found that the data contained in each of the tables for CH-TRU and RH-TRU waste material parameter disposal inventories, respectively, are identical in both the CCA and TWBIR Rev. 3.

4.2.2.2 Traceability of TWBIR Data to Generator Sites

As the second part of this analysis, EPA conducted an in-depth review of the traceability of the site submittal data related to final waste form volumes and waste material parameters (specifically, the waste material parameter cellulosics) was conducted.

Traceability of Final Waste Form Data

EPA evaluated the traceability of reported values for CH-TRU combustible final waste form volumes back to generator site data submittals (refer to Figure 4-1). A combustible final waste form volume of 1.4 E+04 m^3 was reported in Table 2-1 of TWBIR Rev. 3 and also reported in Table 4-3 of the CCA. Six different facilities reported either inventory quantities or projected final waste form volumes for combustibles. Data submitted by Los Alamos National Laboratory (LANL) were then further assessed, and two waste stream profiles (a total of approximately 4,200 m^3 of CH-TRU combustibles) were selected for further examination:

- LA-T004, CH-TRU Combustibles; and
- LA-W004, CH-TRU Mixed Combustibles.

EPA next examined the Waste Stream Profiles found in TWBIR Rev. 3 Appendix P for these waste streams. EPA's evaluation of LANL submittals to CAO regarding each of the waste streams showed that waste stream LA-T004 was based on an inventory volume of 1,555 m^3 and a projected volume of 1,677 m^3. Similar procedures were followed for waste stream LA-W004, which showed an inventory volume of 266 m^3 and a projected volume of 699 m^3. Waste projections for these waste streams were based upon constant annual projection rates by the site and were identical to the values reported in the CCA.

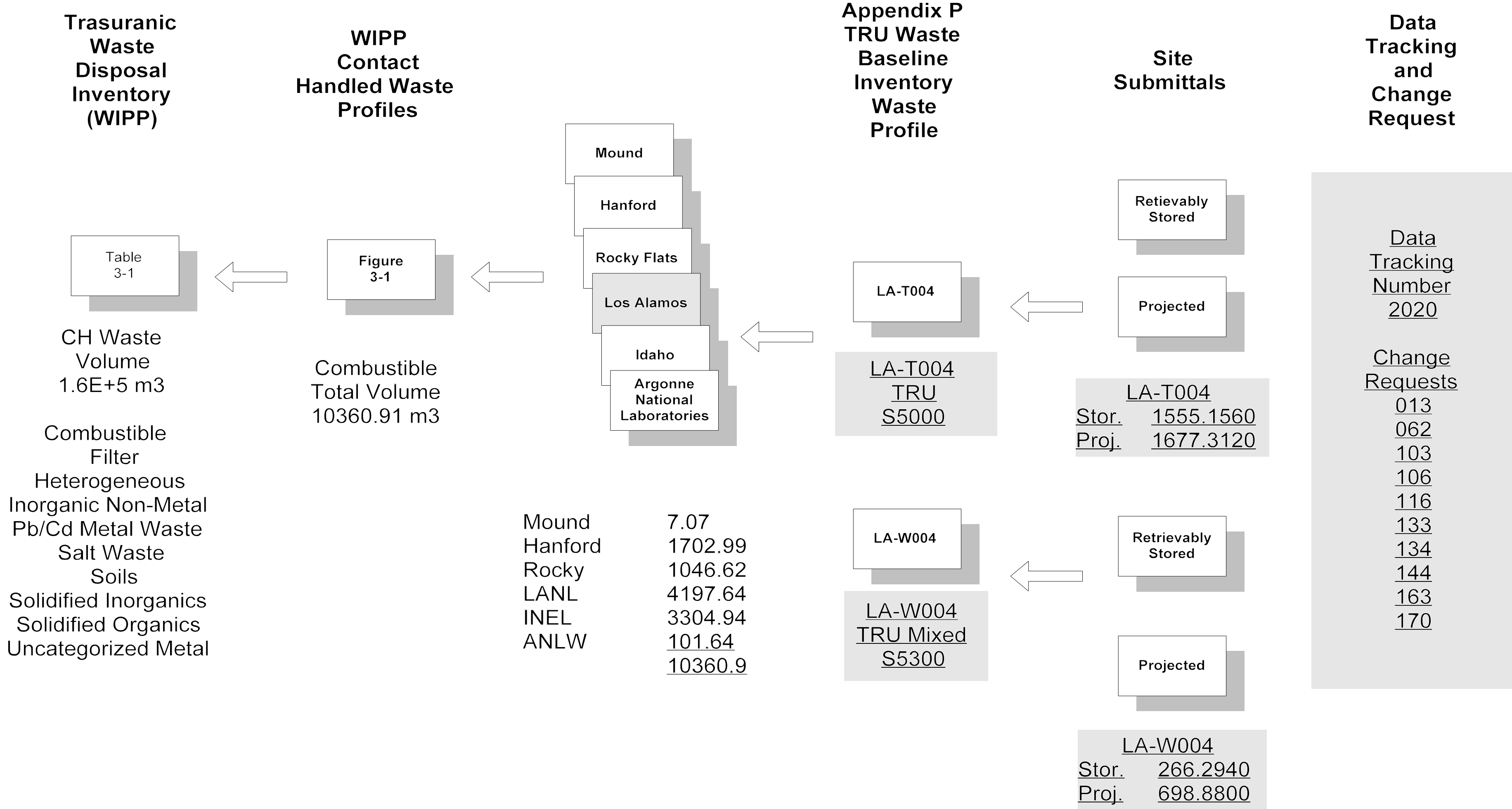
Several changes to the initial LANL data submittal occurred between the receipt of the original data call to publication of the TWBIR Rev. 3. Each of these changes were reviewed to assess the basis of change and to ensure traceability of site data. Upon review of waste stream profiles for LANL waste streams LA-T004 and LA-W004, the following changes were made to the original site submittals:

- Correction of data entry error for projected volumes;
- Correction to radionuclide calculations for stored volumes; and
- Changes to waste material container information and stored volumes.

EPA observed that all changes to site submitted data were documented. It was observed, while reviewing data change forms and in discussions with DOE representatives, that the reasons for many of the changes were known by the personnel managing the data base, although the reasons were not clearly documented.[18]

[18] Per conversation, P. Drez, January, 1997.

Figure 4-1: Baseline Inventory Report Review - Final Form Volume



Traceability of Cellulosics Waste Material Parameter Data

The DOE has expressed the non-radionuclide disposal inventory in terms of waste material parameters and additional packaging materials necessary as inputs to the PA models. The DOE selected these parameters because of their importance to PA. The DOE has identified (TWBIR, Rev. 3) 12 different waste material parameters and 3 different packaging materials:

Waste Material Parameters

- Iron-base metal/alloys;
- Aluminum-base metal/alloys;
- Other metal/alloys;
- Other inorganic materials;
- Vitrified materials;
- Cellulosics;
- Rubber;
- Plastics;
- Solidified inorganic materials;
- Solidified organic materials;
- Cement (solidified); and
- Soils.

Packaging Materials

- Steel;
- Plastic; and
- Lead (for RH-TRU waste only).

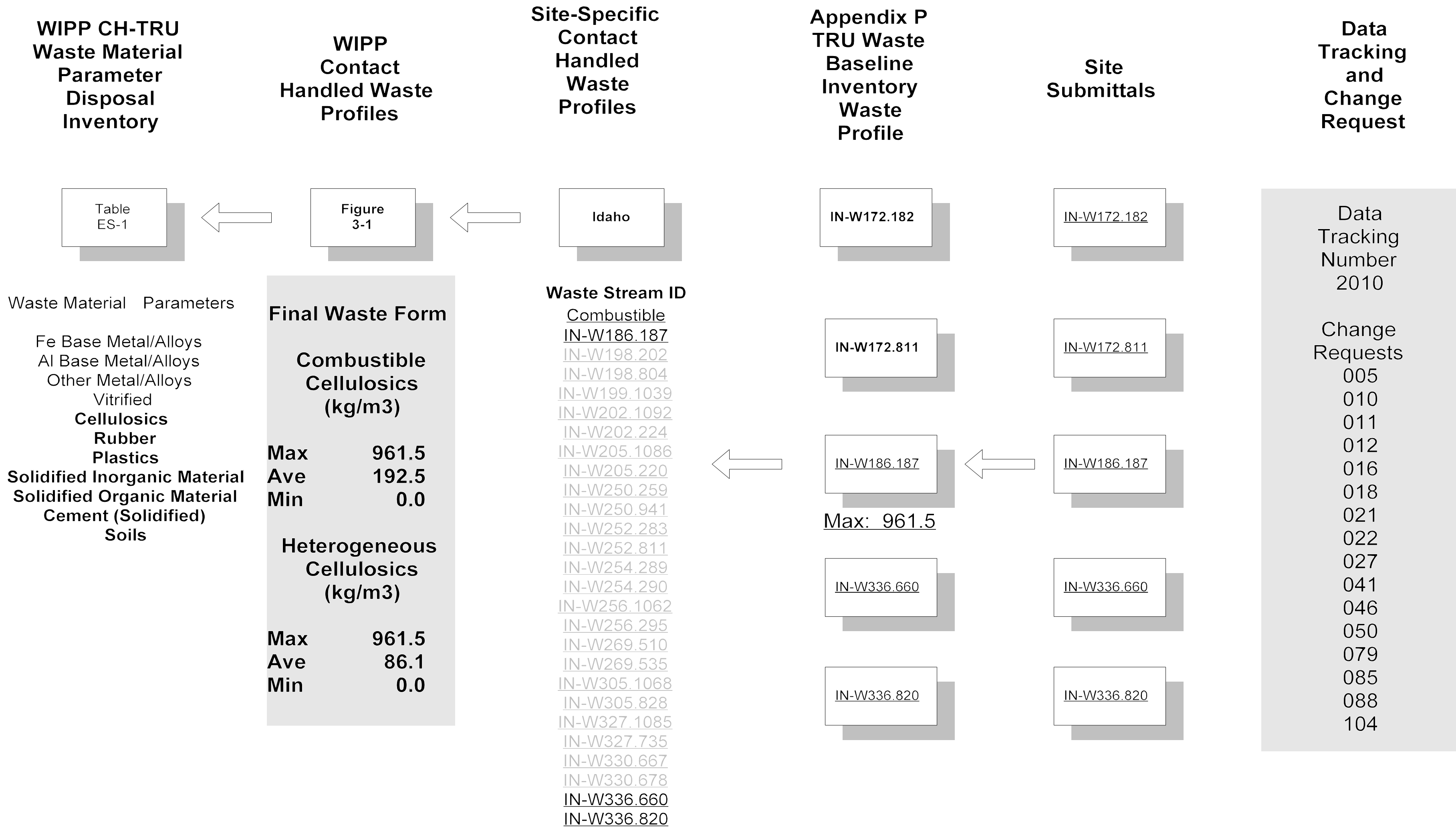
As part of the TWBIR Rev. 3 review, EPA examined the traceability of the maximum reported value for the CH-TRU cellulosic waste material parameter for combustible waste volumes (see Figure 4-2). Table ES-1 of TWBIR Rev. 3 reports a maximum waste material parameter disposal volume for cellulosics of 9.6E+02 Kg/m^3. As a first step, EPA reviewed the TWBIR to identify all waste stream profiles that could comprise the cellulosic WMP. EPA reviewed the WIPP CH-TRU Waste Stream Profile forms and identified six facilities that reported inventory volumes for cellulosics and final waste form volumes for combustible wastes; 16 facilities reported inventory volumes and final waste form volumes for heterogeneous wastes.

The next step of EPA's analysis included a review of the site-specific CH-TRU Waste Profile forms to identify the specific waste streams that reported the maximum value contained in TWBIR Rev. 3 Table ES-1. Based on this review, five waste streams at Idaho National Engineering Laboratory (INEL) were identified in TWBIR Rev. 3 Appendix P as reporting a maximum value for cellulosics of 9.6E+02 Kg/m^3.

- IN-W172.182;
- IN-W172.811;
- IN-W186.187;
- IN-W336.660; and
- IN-W336.820.

The Waste Stream Profile forms contained in TWBIR Rev. 3 Appendix P include information on the maximum, average, and minimum density for each of the 12 waste parameters associated with a specific waste stream at a specific site. EPA's evaluation of the original INEEL data submittals for the above referenced waste streams revealed that the site did not originally provide a density for any of the above referenced waste streams. Numerous data change requests were initiated by the DOE Carlsbad Area Office (CAO) to clarify data and to request that the site review and correct deficiencies after the initial submittal. EPA reviewed each of the change forms for the specified waste streams to ensure the traceability of the site data. EPA noted that through data change requests, EPA received the required density information.

Figure 4-2: Baseline Inventory Report Review - Waste Material Parameter



EPA found that all changes to site submitted data were adequately documented. EPA further found that the maximum density of 9.6E+02 Kg/m^3 was traceable from the change reports and the site submittals. EPA observed that for some changes examined, the specific reasons for the change were not presented.

4.2.2.3 Representativeness of Waste Inventory

EPA next evaluated the TWBIR Rev. 3 to determine the extent to which the final waste forms described by DOE in the CCA truly represented the TRU waste inventory and projected disposal volume. EPA reviewed the representativeness of DOE's inventory information for waste types, waste material parameters, radionuclides, and waste volume. EPA also evaluated DOE's use of a scaling factor for projecting the impacts of a full repository for CH-TRU waste.

Waste Types

The TWBIR Rev. 3 lists 151 different waste matrix codes (WMCs) that were identified by the waste's final waste form. In many instances, a single WMC may exist in several final waste forms. Table 1 provides a summary of WMC representation by final waste forms. Seven WMCs were omitted from a particular final waste form category. These seven WMCs are: X7100, Elemental Mercury; X7600, Explosive/Propellants; X7700, Compressed Gasses/Aerosols; X7900, Unknown/Other Special Waste; Z9000, Other Final Waste Forms; S5900, Unknown/Other Debris; and S9000, Unknown/Other Solids. These WMCs were not included within the final waste form categories because they are prohibited from being disposed at WIPP. The remaining WMCs have been adequately represented within TWBIR Rev. 3.

Table 4-1: WMC Representation by TWBIR Rev. 3 Final Waste Forms

Final Waste Form	Number of WMC's Represented
Solidified Organics	25
Solidified Inorganics	41
Inorganic Nonmetal	10
Combustibles	11
Filters	1
Salts	5
Graphite	0
Uncategorized Metal	4
Heterogeneous	7
Pb/Cd Metal	10
Soil	5
Multiple Final Waste Forms	25
No Final Waste Form Identified	7
Total	151

Note: WMCs for the graphite final waste form are included in the "Multiple Final Waste Form" category. The final waste form category "No Final Waste Form Identified" may be a result of excluded WIPP waste forms.

Waste Material Parameters

Based on a review of both DOE's methodology for obtaining and evaluating site inventories and the data quality obtained within the responses submitted by individual sites (change reports), it appears DOE has (1) a sufficient understanding of its waste for the purposes of PA, and (2) adequately represented the waste material parameters as presented in the TWBIR Rev. 3. Review of the information submitted by DOE/CAO in response to questions by EPA indicates that the majority of the information that was reported represents wastes that are currently stored. Table 4-2 shows that for both CH-TRU and RH-TRU stored wastes, over 96 percent of the reported waste volumes contained waste material parameter data. Conversely, Table 4-2 indicates that only 40 percent of the projected CH-TRU waste and 77 percent of the projected RH-TRU had reported waste material parameter data. This lack of information is understandable for future generated wastes, and reflects an uncertainty surrounding the to-be-generated wastes. However, EPA notes that all to-be-generated waste will be fully characterized prior to shipment, to ensure all waste limits are met. Therefore, this uncertainty will be eliminated through the required waste characterization activities.

Table 4-2: Percentage of Waste Volume with No Waste Material Parameter Data

Waste Type	Stored Volume % with No Data	Projected Volume % with No Data
CH-TRU Waste	3%	60%
RH-TRU Waste	1%	23%

Source: DOE Response to WIPP Compliance Review Questions, February 1997

Upon review of the data submittals, the percentage of stored and projected; and projected only waste streams was determined for CH-TRU and RH-TRU waste. The data indicate that 67 percent of the CH-TRU waste streams are identified as stored and projected; and only 16 percent of the RH-TRU waste streams are identified as stored and projected. Waste stream comparisons for CH-TRU and RH-TRU wastes are presented in Table 4-3.

Table 4-3: Waste Stream Comparisons

Waste Type	% Stored and Projected	% Projected Only
CH-TRU Waste	**67%**	**33%**
RH-TRU Waste	**16%**	**84%**

Source: DOE Response to WIPP Compliance Review Questions, February 1997

Based upon a review of the TWBIR Rev. 3 data, EPA concurs that the volume of cellulosics in CH-TRU waste is dominated by Hanford and INEEL wastes, as shown in Table 4-4. The average densities of this waste material parameter appear to be widely variable, ranging from 218.95 Kg/m^3 to as low as 2.5 Kg/m^3.

Table 4-4: Cellulosics Profile for Combustible and Heterogeneous Contact Handled Waste

Sites	Total Volume (m^3)	UL (Kg/m^3)	Avg (Kg/m^3)	LL (Kg/m^3)	Kg of Cellulosics (Avg)
Battelle	1.23E+02	20	6.99	0	8.62E+02
INEEL	1.04E+04	961.5	218.95	0	2.27E+06
LANL	4.23E+03	68.7	63.46	0	2.69E+05
Lawrence Livermore	8.63E+02	500	66.94	0	5.77E+04
Mound	1.04E+00	10	2.5	0	2.60E+00
NTS	6.22E+02	318	52.48	0	3.27E+04
Oak Ridge	1.56E+03	184.81	80.91	0	1.26E+05
Rocky Flats	9.32E+02	647.8	56.03	0	5.22E+04
Hanford	1.28E+04	-	52.68	-	6.76E+05
Sandia National Lab	1.12E+01	5	3	1	3.37E+01
Savannah River	7.96E+03	576.85	115.83	0	9.22E+05
Total	3.95E+04*	961.5	111.50	0	4.40E+06

* **Volumes do not represent the total amount of combustible and heterogeneous waste.**

Note: The Hanford site did not report upper or lower limits for the cellulosic WMP.

Radionuclides

In contrast to other waste material parameters, estimates of radioactivity obtained from the sites are for stored waste only. As described in TWBIR, Rev. 3, DOE assumed that the radionuclide distribution for projected waste would be the same as that for the stored waste inventory. DOE then assumed that the radionuclide distribution of the stored inventory would be uniform over the stored volume, thus allowing DOE to scale the activity of the stored radionuclide inventory to the full WIPP repository. DOE stated that this assumption was reasonable, as they do not expect any new waste forms or waste generating processes for future generated wastes and that they are confident in their knowledge regarding radionuclide distributions from their process knowledge. To assess this conclusion, data submittals were reviewed by EPA to understand how radionuclide concentrations were obtained, the sources of their information, and to identify whether any new waste streams will be introduced into the DOE system.

Table 4-5 provides an overview of methods used by DOE sites in collecting information regarding waste streams submitted for TWBIR Rev. 3. According to DOE, over 50 percent of all reported radionuclide concentrations were obtained from sampling and analysis. For the CH-TRU waste inventory, 69 percent of the waste stream totals were quantified using sampling and analysis, process knowledge, or a combination of both methods. For the RH-TRU inventory, 76 percent of the waste streams were quantified using sampling and analysis and acceptable knowledge. The remainder of the waste streams were quantified using information provided by the waste generator.

Table 4-5: Basis for Determining Waste Stream Radionuclide Concentrations

Categories	CH-TRU Waste Summary % of Waste Stream Totals	RH-TRU Waste Summary % of Waste Stream Totals
Both (Sampling & Analysis and Process Knowledge)	**44%**	**36%**
Generator Supplied	**31%**	**23%**
Process Knowledge	**11%**	**26%**
Sampling and Analysis	**14%**	**15%**
Total	**100 %**	**100 %**

Source:DOE Response to WIPP Compliance Review Questions, February 1997
Note: Totals may not add to 100 due to rounding.

Site-level inventory systems (or databases) were the most common source of information (72.4 percent) used by DOE in TWBIR Rev. 3. A summary of the data sources used in TWBIR Rev. 3 is provided in Table 4-6.

Table 4-6: Site Information Sources

Information Sources	% of Inventory
Operational Records	**0.5 %**
Databases	**72 %**
Reports	**26 %**
Other	**2 %**
Total	**100 %**

Source:DOE Response to WIPP Compliance Review Questions, February 1997
Note: Totals may not add to 100 due to rounding.

Table 4-7 provides the percentage breakout of stored volume data used in calculating the radionuclide inventory for emplacement at WIPP. As shown in this table, over 99.9 percent of the waste in inventory was used in determining radionuclide inventories for CH-TRU waste. This information was decayed to a common year and rolled-up from a TWBIR Rev. 3 waste-stream level to site-level data. Activity was then derived from the rolled-up data for use in the PA.

Table 4-7: Percentage of Stored Volumes Included in Radionuclide Inventory Calculations

Waste Type	Volume Included in Radionuclide Calculations	Volume not Included in Radionuclide Calculations
CH-TRU Waste	**99.96%**	**0.04%**
RH-TRU Waste	**83.28%**	**16.72%**

Source:DOE Response to WIPP Compliance Review Questions, February 1997

Within TWBIR Rev. 3, radionuclide inventories were estimated by DOE on a bin level (this could be a drum, or a series of drums or canisters) for RH-TRU wastes, whereas CH-TRU inventories were estimated on a waste stream basis. At the waste stream level, radionuclide representation was assumed using normalized distributions of the actinide spectrum. The actinide spectrum allows a signature to be determined that is specific to transuranic wastes only. DOE stated that this ensures complete representation of all potential actinides associated with WIPP waste streams.[19]

Site Inventories and Projections

Information regarding existing volumes of wastes was collected by DOE from 20 separate generator sites across the DOE complex. Wastes available for emplacement at WIPP encompass post-1970 generated volumes. Figure 4-3 graphically represents the cumulative CH-TRU waste volume in storage at the generator and storage sites. From 1970 through the late 1980's, the rate of CH-TRU generation was fairly constant, but was abruptly curtailed as weapons production within the DOE complex was stopped - initially for the correction of environmental and safety problems and later because of the end of the Cold War.[20]

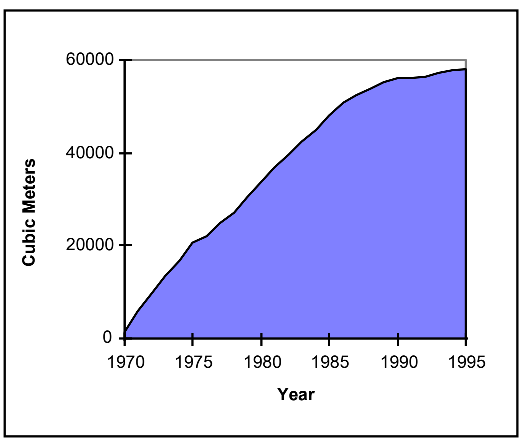


Figure 4-3: CH-TRU Waste Cumulative Storage Inventory

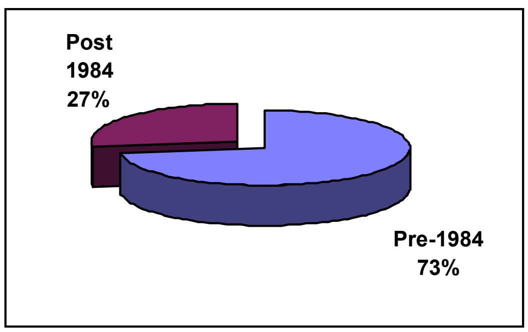
[19] Meeting Minutes. Waste Isolation Pilot Plant (WIPP) 194.24(a) Compliance Review, pp. 3-4. ICF Inc., January 30-31, 1997.

[20] *The 1996 Baseline Environmental Management Report*, U.S. Department of Energy, Office of Environmental Management, June 1996.

Information extrapolated from TWBIR Rev. 3

EPA observed that early practices for recording non-radioisotopic TRU waste inventory information were not as rigorous as current ones with regard to waste identification, categorization, and segregation. Consequently, earlier inventory records are largely based upon process knowledge and on various studies related to site-specific practices. The representative age of the stored inventory is shown in Figure 4-4. As shown in Figure 4-4, nearly 73 percent of the CH-TRU waste in storage was generated prior to 1984.

Figure 4-4: Age of CH-TRU Storage Inventory



DOE stated that updates will be made to the TWBIR based on new information received from on-going waste identification and characterization activities at the generator and storage sites. DOE further stated that new information will either be obtained as part of the annual update to the IDB or through specific data calls.[21]

Based on its review, EPA concluded that DOE has sufficiently represented the WIPP anticipated (stored and projected) inventory of TRU waste as the sum of retrievably stored waste plus currently projected TRU waste volumes. Excluded in waste projections are those wastes generated from future environmental restoration (ER) and decontamination and decommissioning (D&D) activities

[21] Meeting Minutes. Waste Isolation Pilot Plant (WIPP) 194.24(a) Compliance Review, pp. 3-4. ICF Inc., January 30-31, 1997.

due to the uncertainty in their projected amounts.[22] Projections of TRU waste generation have been made for a 25 year period, through 2020. However, all future generated waste will be characterized to ensure it meets waste acceptance criteria and waste limits.

Scaling Factors

The DOE employed a scaling approach to project the impacts of a full repository because the total anticipated inventory volume for CH-TRU wastes does not reach the maximum allowable CH-TRU disposal capacity for WIPP (calculated to be approximately 168,500 m^3 or 5,950,000 ft^3). The scaling methodology is not used on RH-TRU wastes, because DOE has reported inventory sufficient to meet the RH-TRU capacity defined in the Land Withdrawal Act (LWA) (approximately 7,080 m^3 or 250,000 ft^3). The approach used by DOE was to develop scaling factors based upon final waste forms, as it was not feasible to scale by waste stream due to variability at the site level for various waste streams. In the development of the scaling factors, DOE reviewed the information presented in the Baseline Environmental Management Report (BEMR) to determine if other sources of projected volumes were available. It is important to note that only projected volumes were used in the scaling process. DOE felt that the existing inventory was not representative, proportionally, to the final waste forms to be generated in the future. As such, these approximated values are to reflect the characteristics of approximately 85,000 m^3 of TRU wastes.[23]

As reported in the TWBIR Rev. 3, the scaling factor calculated by DOE for CH-TRU waste is 2.05. This factor is used in the following formula to project the makeup of the emplaced waste according to the LWA design limitations:

Stored Inventory + Projected Inventory * (2.05) = Disposal Inventory

Upon review of the calculations used by DOE in determining the scaling factor, EPA found that DOE miscalculated the scaling factor of 2.05 by not including data from several sites, including radionuclide data from Argonne East and West, and Teledyne Brown; stored waste volumes from Paducah, and some radionuclide data from Sandia National Laboratories that was coded as RH-TRU waste. The scaling factor has been revised by DOE to be 2.09.[24] As a result, the total TRU waste radionuclide inventory contained in TWBIR Rev. 3 and the CCA is slightly incorrect. The radionuclide inventory at the end of 1995 would be increased for three radionuclides, Pu-238, U-234, and Th-230. (See discussion of revisions to scaling factor contained in Memorandum, *"Assumptions and Methodology Involved in the Estimation of the WIPP Disposal radionuclide Inventory in the CCA.*) However, DOE concluded and EPA agrees that this very small error would not have any effect on performance assessment.

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[22] Per conversation, P. Drez, January, 1997.

[23] *The 1996 Baseline Environmental Management Report*, June 1996, U.S. Department of Energy, Office of Environmental Management.

[24] *"Assumptions and Methodology Involved in the Estimation of the WIPP Disposal Radionuclide Inventory in the CCA,"* SAIC, August 1997.

Also, based on this change to the scaling factor, EPA concluded that the calculation of the Waste Unit Factor (WUF) was slightly incorrect. In addition to the scaling factor, stored off-site CH-TRU waste streams from Savannah River were also mistakenly excluded in the calculation of the WUF. DOE has recalculated the WUF to be 3.59 instead of 3.44. Again, DOE concluded and EPA agrees that this revision will not impact performance assessment. (See discussion of revisions to the Waste unit factor contained in Memorandum, *"Recalculation of Waste Unit Factor with Corrected Radionuclide Inventory,"* Sandia National Laboratories, September 1997.)

4.2.2.4 Uncertainty in Waste Inventory Description

EPA also evaluated DOE's ability to define the level of uncertainty in its TRU waste inventory. As stated in the September 1995 audit report of the WIPP TRU waste baseline inventory reporting process, CAO failed to define acceptance criteria for the quality of data produced by the sites for use in developing the TWBIR Rev. 3.[25] CAO responded that no accuracy criteria could be established and that numeric confidence limits were not possible.[26]

Controls imposed by DOE on the assembly of TWBIR data emphasized information management rather than accuracy of the information submitted. Several quality control checks (e.g., review of data for outliers, verification that key fields were populated with data) were performed to assess the completeness of incoming information and the integrity of electronic file transfers.

During discussions with the TWBIR data team, DOE representatives indicated that the TWBIR is used to report current and projected transuranic inventories and not used to validate information from the field.

4.2.2.5 EPA's Analysis of the Effectiveness of Waste Inventory Description in Meeting §194.24(a) Requirements

As a final evaluation, EPA analyzed the effectiveness of the TWBIR Rev. 3 in providing a sufficiently accurate, complete description of the wastes proposed for disposal in the WIPP for the purposes of PA. The effectiveness of the TWBIR will not be known until feedback from the WIPP Waste Information System (WWIS) is available. That is, accuracy of TWBIR data will not be known until waste characterization information, transmitted by the WWIS, is available for comparison. From evaluation of the magnitude of the effort applied to the TWBIR, it appears that, percentage-wise, minimal changes have occurred in TWBIR numbers since Revision 1 (refer to Figure 4-5). This is an indication that DOE is refining its inventory rather than conducting whole-scale modifications.

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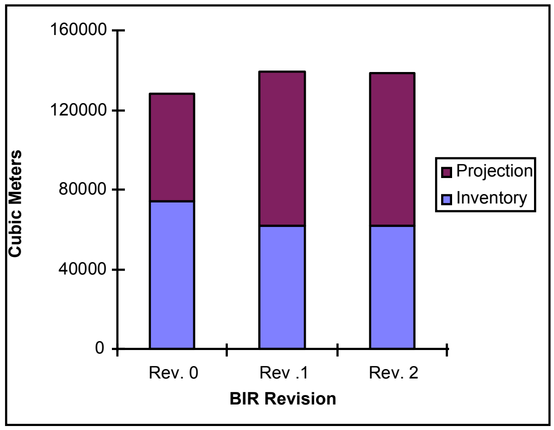
[25] *Audit Report Of National TRU Program Team, WIPP Baseline Inventory Report Database Management*, Audit A-95-04, U.S. Department of Energy, Carlsbad, New Mexico (September 1995).

[26] Memorandum, *Corrective Action Report (CAR) 95-054*, R. Bisping, Waste Certification Manager, U.S. Department of Energy, Carlsbad, New Mexico (January 1996).

Figure 4-5: TWBIR Projection History



EPA reviewed the CCA to determine whether it provided a sufficiently complete description of the chemical, physical, and radiological composition of the existing and to-be-generated wastes proposed for disposal in the WIPP. EPA also reviewed DOE's description of the approximate quantities of waste components (for both existing and to-be-generated wastes). EPA considered whether CCA's waste descriptions were of sufficient detail to enable the Agency to conclude that DOE did not overlook any component that is present in transuranic waste and has significant potential to influence releases of radionuclides. DOE described the waste in Volume 1 and Appendix BIR of the CCA. EPA also concluded that the use of projected waste inventory for scaling the CH-TRU waste inventory to meet the total WIPP capacity was acceptable.

4.2.3 EPA's Analysis of the Relationship of Inventory Data to DOE's Sensitivity Analysis

As described in Section 4.2.2, EPA traced those waste material parameters identified by DOE as related to key parameters of the PA to the original generator site submittals. EPA reviewed the relationship of inventory data to DOE's sensitivity analysis to ensure that those parameters considered to be key to the performance assessment were included. Key waste parameters of CH and RH-TRU waste identified by DOE as potentially important to the PA are divided into two categories:[27]

- Non-Radioactive Materials: Primarily those non-radioactive materials that influence brine and gas outflow and direct release to the accessible environment through disturbed conditions.

[27] DOE/CAO-95-1121, *Transuranic Waste Baseline Inventory Report,* Revision 3, June 1996.

- Radionuclides: As reflected in radioactivity in curies of each isotope, the TRU radioactivity at closure and actinide mobility.

The influence of each parameter was ranked, based on the results of the sensitivity analysis performed by DOE.[28]

Non-Radioactive Materials

DOE stated that, for undisturbed conditions, dominating variables for brine and gas outflow identified in the DOE's sensitivity analysis included[4]:

- Carbon dioxide generation from microbial degradation of cellulose;
- Brine and gas inflow/outflow as affected by halite porosity; and
- Hydrogen generation from corrosion rate for steel.

For disturbed conditions, the dominating variables identified in DOE's sensitivity analysis are related to the release of spallings, cuttings, and cavings. The volume of spallings, cuttings, and cavings that may be released is related, in part, to properties impacted by non-radioactive waste materials, including particle diameter, compressibility, and shear strength.

Waste material parameters used in the PA model for gas generation include the following:[29]

- Iron-Based Metals and Alloys;
- Cellulosics;
- Plastics; and
- Rubbers.

EPA determined that the cellulosic waste material parameter was reported in TWBIR Rev. 3 as being present in numerous final waste forms. Table 4-8 presents the final waste forms reported by DOE in TWBIR Rev. 3 to contain cellulosics, with the top of the list the final waste form that contains the most cellulosic material (e.g., combustible final waste form for CH-TRU waste).

Table 4-8: Final Waste Form Ranking Based on Cellulosic Content

[28] *Preliminary Summary of Uncertainty and Sensitivity Analysis Results Obtained in Support of the 1996 Compliance Certification Application for the Waste Isolation Pilot Plant*, December 1996.
[29] DOE/CAO-95-1121, pp B-2.

Contact Handled TRU Waste	Remote Handled TRU Waste
1. Combustibles	1. Heterogeneous
2. Heterogeneous	2. Uncategorized Metals
3. Inorganic Non-metals	3. Combustibles
4. Filters	4. Inorganic Non-metals
5. Salt Waste	5. Pb/Cd Metal Wastes
6. Uncategorized Metals	6. Solidified Organics
7. Solidified Inorganics	7. Solidified Inorganics
8. Solidified Organics	
9. Pb/Cd Metal Wastes	
10. Soils	
11. Graphite	

Ranking was calculated based upon maximum concentration values [Kg/m^3] contained in TWBIR Rev. 3.

Radionuclides

The DOE determined that seven isotopes, contained in waste proposed for disposal at WIPP, are the most important in assessing repository performance.[30] These seven isotopes are:

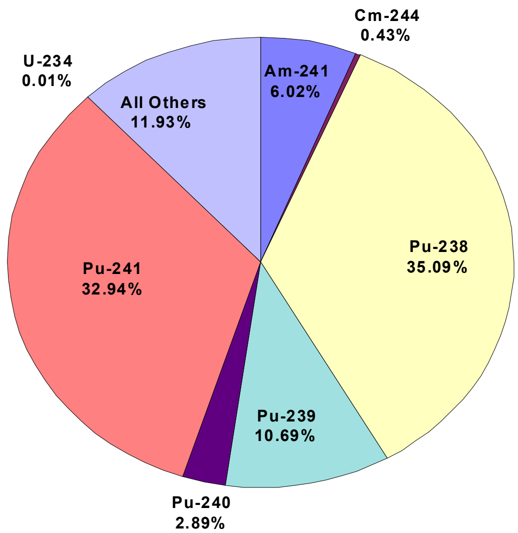
- Am-241;
- Cm-244;
- Pu-238;
- Pu-239;
- Pu-240;
- Pu-241; and
- U-234.

As shown in Figure 4-6, EPA determined that about 90 percent of the total 6.55E + 06 curies is expected to be contributed by these seven isotopes. Waste streams from three sites, Savannah River, Rocky Flats, and LANL, are expected to contribute over 85 percent of the total activity for the seven isotopes.

Figure 4-6: Percentage of Total Inventory Contributed

[30] *WIPP PA Analysis for EPAUNI: Estimating the Probability Distribution of EPA Unit Loading in the WIPP Repository for Performance Assessment Calculations, Version 1.01,"* WBS# 1.2.07.1.1.

by Significant Isotopes (Curies)



EPA determined that the isotope with the highest total activity is Pu-238. Four waste streams contribute about 60 percent of the total Pu-238 activity. These waste streams are from Savannah River (T001- 221F-HET and T001-221H-HET) and LANL (LA-T004 and LA-T005). The same four waste streams that contribute the most to the total Pu-238 activity are also the four largest waste streams in terms of volume, comprising nearly 50 percent of the total volume of waste at the eight sites that generate or store Pu-238. The four waste streams with the highest activity per cubic meter of Pu-238 (Ci/m^3) are from INEEL (IN-W213.252 and IN-W280.448) and Savannah River (W027-999-HET and W027-999-VIT).

EPA's evaluation of TWBIR data determined that the isotope with the second highest total activity is Pu-241. Four waste streams contribute nearly 50 percent of the total Pu-241 activity. These waste streams are from Rocky Flats (RF-RESIDUES and RF-MT-0335), Savannah River (T001-221F-HET), and Oak Ridge (OR-W044). Four waste streams comprise nearly 40 percent of the total volume of waste that contains Pu-241 at the eight sites. These waste streams are from Savannah River (T001-221F-HET and T001-221H-HET) and Hanford (RL-W377 and RL-T107). The four waste streams with the highest concentrations of Pu-241 (Ci/m^3) are from INEEL (IN-W211.249) and Rocky Flats (RF-MT0320, RF-RESIDUES, and RF-MT0801).

Similarly, EPA's analysis determined that the isotope with the third highest total activity is Pu-239. Four waste streams contribute over 60 percent of the total Pu-239 activity. These waste streams are from LANL (LA-W005, LA-W006, and LA-T005) and Rocky Flats (RF-RESIDUES). Four waste streams comprise over 33 percent of the total volume of waste that contain Pu-239 at the eight sites. These waste streams are generated at LANL (LA-T004 and

LA-T005), Savannah River (T001-221F-HET) and Hanford (RL-W377). The four waste streams with the highest concentrations (Ci/m^3) are from INEEL (IN-W211.249), Rocky Flats (RF-MT0320 and RF-RESIDUES) and LANL (LA-W005).

In summary, EPA determined that, based on the inventory information submitted by DOE, four single waste streams comprise about 45 percent of the total activity. These waste streams are from Rocky Flats (RF-RESIDUES), Savannah River (T001-221F-HET and T001-22H-HET) and LANL (LA-T004). Nearly 30 percent of the total volume of these waste streams is contributed by waste streams from LANL (LA-T004 and LA-T005), Savannah River (T001-221F-HET), and Hanford (RL-W377). The four waste streams with the highest concentrations (Ci/m^3) are from INEEL (IN-W213.252 and W211.249) and Savannah River (W027-999-HET and W027-999-VIT).

Table 4-9 provides a description of the processes that generated the wastes from the ten waste streams that contribute the majority of the total activity to the WIPP inventory.

Table 4-9

Stream ID#	Volume (m3)	Total Ci	Process	Conc. (Ci/m3)
IN-W211.249	22.46	3.07E+04	Cemented Insulation And Filter Media from Material Production/Recovery Effluents	1.37E+03
LA-T004	12491.82	5.31E+05	Combustible Waste from Facility/Equipment Operation and Maintenance Waste	4.25E+01
LA-T005	8794.14	1.14E+06	Non-combustible scrap Waste from Facility/Equipment Operation and Maintenance Waste	1.30E+02
LA-W005	4771.66	7.66E+05	Non-combustible Waste from Facility/Equipment Operation and Maintenance Waste	1.60E+02
RF-MT0320	128.94	1.83E+04	Scrap metals which are heavier than iron and steel. Mainly used tantalum crucibles	1.42E+02
RF-MT-0335	2612.21	2.51E+05	High efficiency particulate air filters used on glovebox air intakes and exhausts	9.60E+01
RF-MT0801	108.99	2.88E+03	Cemented solidified organics - Bldg 774	2.64E+01
RF-RESIDUES	4181.91	NA	Not Available at this time	NA
RL-T107	6156.09	2.20E+05	TRU Waste from the Plutonium Finishing Plant. Filters, paper, wood, gloves, piping, etc.	3.58E+01
RL-W377	6946.14	3.11E+05	324 Pb/Cd metal. Contains Lead, zircalloy, metal/galvanized sheet	4.47E+01
T001-221F-HET	11361.36	1.21E+06	Job control waste, sludges and resins, HEPA filters and large, metal equipment from 221F	1.06E+02
T001-221H-HET	6492.7	6.89E+05	Job control waste, sludges and resins, HEPA filters and large, metal equipment from 221H	1.06E+02

Source: TWBIR Rev.3 Appendix P

Radionuclide inventories obtained at the waste stream level and rolled-up to site level data are included in TWBIR Rev. 3. Activity was then derived from the rolled-up data for use in the PA. During discussions with DOE regarding the TWBIR Rev. 3, it was reported that radionuclide inventories could be increased by an order of magnitude without significant impact to the repository performance.[31]

To support its contention that the radionuclide inventory could be increased with no significant affect on the WIPP's performance, DOE conducted additional modeling. Specifically, DOE modeled the consequence of drilling through three stacked drums of the highest activity waste (from waste streams with at least 810 drums) on (1) spallings and (2) cuttings and cavings releases under an intrusion borehole scenario. DOE's work demonstrated that in the unlikely event that a bore hole passed through three drums of Rocky Flat's Residue waste stream (the highest activity waste stream with at least 810 drums), the WIPP remained in compliance even though a shift occurred in the CCDF. (These analyses are described in DOE's Response to EPA's March 19, 1997 request for additional information on the WIPP CCA, dated May 2, 1997, Enclosure 1, pages 8-18 (Docket No. A-93-02, II-I-28).)

EPA determined that DOE's waste inventory provided sufficient information on key waste material parameters is sufficient for PA purposes.

4.3 CONCLUSION: WASTE INVENTORY REVIEW

EPA examined the data provided by DOE, including supplemental information acquired after the submission of the CCA pertinent to the waste inventory. EPA determined that DOE's waste inventory description contained appropriate specific information on the components and their approximate quantities for both existing and to-be-generated waste. Therefore, EPA determined that DOE was in compliance with §194.24(a).

[31] Meeting Minutes. Waste Isolation Pilot Plant (WIPP) 194.24(a) Compliance Review, pp. 3-4. ICF Inc., January 30-31, 1997.

5.0 WASTE ANALYSIS REVIEW

To satisfy requirements of 40 CFR 194.24(b), the Environmental Protection Agency (EPA) required that DOE perform an analysis to identify and assess the impact on long-term performance of those waste characteristics that influence the containment of waste in the disposal system, including those waste components that affect the waste characteristics. A *waste characteristic* is defined by EPA as a property of the waste that has an impact on the containment of waste in the disposal system. A *waste component* is defined by EPA as an ingredient of the total inventory of the waste that influences a waste characteristic (40 CFR 194.2). The inclusion of select waste components and characteristics as parameters or portions of performance assessment models links Waste Isolation Pilot Plant (WIPP) waste with the overall evaluation of disposal system performance.

Waste components impact waste characteristics and are integral to disposal system performance. For example, the characteristic of gas generation is controlled, in part, by the type and amount of waste components present, such as metal waste containers and cellulosics, rubber, and plastic material in waste. The presence of these components and a sufficient amount of brine leads to microbial degradation of cellulosics, corrosion of metals, and subsequent gas generation (i.e., CO_2, H_2, CH_4). The resulting gas pressure affects repository pressure, room closure rates, fracture development in associated marker beds, as well as brine inflow and the possibility of waste entrainment in gas during a drilling event (spallings). All of these factors are important elements of disposal system performance and are modeled in performance assessment (PA). Radionuclide solubility in Salado and Castile brine partially[32] controls the quantity of radionuclides that are released in brine to ground surface through a direct brine release; radionuclides in brine also serve as the source term to the Culebra for potential long-term transport through this rock unit. Therefore, some waste characteristics and components influence aspects of disposal system performance.

5.1 SUMMARY OF EPA'S ANALYSIS

<u>EPA Rulemaking</u>: §194.24(b) required DOE to submit the results of an analysis which substantiates that all waste characteristics and associated components influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The DOE was also required to present any decision to exclude consideration of any waste characteristic or waste component because such characteristic or component is not expected to significantly influence the containment of the waste in the disposal system. EPA expected the compliance application to include: a detailed description of the analysis performed; a list of waste characteristics retained as a result of the analysis; a list of

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[32] Depending on the performance assessment model future, the volume of brine released is as or more important than solubility.

waste components influencing these characteristics that are retained as a result of the analysis; identification of all waste related inputs into computer models; and a list of all waste characteristics and components (tabular format suggested) that were considered and excluded, including the rationale for exclusion. In accordance with §194.27, a description of the scope of peer review of the waste characterization analysis is expected to be provided, along with a discussion of reviews of technical issues, evaluations and recommendations as to the adequacy of the analysis, and follow-up actions. Also, objective evidence supporting decisions (peer review process documentation, conclusions) and the location of the evidence should be cited.

194.24(b) The Department shall submit in the compliance certification application the results of an analysis which substantiates:

(1) That all waste characteristics influencing containment of waste in the disposal system have been identified and assessed for their impact on disposal system performance. The characteristics to be analyzed shall include, but shall not be limited to: solubility; formation of colloidal suspensions containing radionuclides; production of gas from the waste; shear strength; compactability; and other waste-related inputs into the computer models that are used in the performance assessment."

(2) That all waste components influencing the waste characteristics identified in paragraph (b)(1) of this section have been identified and assessed for their impact on disposal system performance. The components to be analyzed shall include, but shall not be limited to: metals; cellulosics; chelating agents; water and other liquids; and activity in curies of each isotope of the radionuclides present.

<u>EPA Final Determination:</u> EPA concluded that the Department of Energy (DOE) generally performed a thorough and well documented analysis, adequately identified all waste characteristics and components, and appropriately assessed these and included them (as appropriate) as PA input parameters. In the case of actinide solubility, EPA believes that DOE assumed the incorrect solubility controlling mineral phase of magnesium carbonate. However, the error led to the use in the Compliance Certification Application (CCA) of higher actinide solubilities than what EPA believes will be the case.

<u>Location of EPA's Review of Waste Characteristics and Components</u>: EPA's review of DOE's waste characteristic analyses is documented in multiple areas including: Response to Comments for sections 23 and 24 (A-93-02, V-C-1), CARDs 23, 24, 31 (A-93-02, V-B-2) and in Technical Support Documents for sections 194.23 and 194.24 (Technical Support Document for Section 194.23: Models and Computer Codes, A-93-02, V-B-6; Technical Support Document for Section 194.23: Parameter Justification Report, A-93-02, V-B-14; Technical Support Document for

Section 194.23: Sensitivity Analysis Report (A-93-02, V-B-13); Technical Support Document for Section 194.24: EPA's Evaluation of DOE's Actinide Source-Term, A-93-02, V-B-17). For example, Section 194.23(c)(4) in CARD 23 -- Models and Computer Codes (and the associated section in V-B-6) discusses DOE's selection of model parameter values for the physical waste characteristics of waste particle diameter, waste compressibility and shear strength. CARD 23 and Technical Support Document for Section 194.23: Models and Computer Codes, A-93-02, V-B-6 also discuss the conceptual models that were used by DOE and EPA's review of those conceptual models, such as the gas generation, chemical conditions and dissolved actinide source term conceptual models. The Technical Support Document for Section 194.24: EPA's Evaluation of DOE's Actinide Source-Term (A-93-02, V-B-17) discusses solubility and actinide oxidation states; effects of magnesium carbonates on predicted repository conditions; computer code FMT modeling results; influence of ligands and complexants; and microbial effects. CARD 31 discusses the calculation of the waste inventory. A summary of EPA's process and findings are listed below.

DOE's Major Conclusions

- DOE indicated that the components identified below and on Table 5-1 (Table WCA-2, pp. WCA-9, WCA-10) were expected to have a significant effect on disposal system performance and were used in performance assessment:
  - Ferrous metals;
  - Cellulose and other chelating agents as they pertain to enhanced actinide mobility;
  - Radioactivity in curies of each isotope;
  - %-emitting TRU radionuclides, $t_{1/2}$ > 20 years ($t_{1/2}$ is the half-life);
  - Radionuclides;
  - Solid waste components;
  - Sulfates; and
  - Nitrates.

Table 5-1
Selected Waste Components and Characteristics and Their Effect on PA

Component	Characteristic Impacted by the Component	Effect on PA
Ferrous metals	Redox potential and gas generation	Impact actinide oxidation state, actinide solubility/mobility , and gas generation/pressure via hydrogen production
Cellulosics and chelating agents (rubber/plastics)	Microbial substrate: methane generation and colloid development	Increase in gas pressure and actinide mobility
Radioactivity in curies of each isotope	Radioactivity in curies of each isotope	Used in calculating normalized releases
%-emitting TRU radionuclides, t1/2 > 20 years	TRU radioactivity at closure	Determines waste unit factor
Radionuclides	Redox state and solubility	Actinide mobility
Solid Waste Components	Compressibility, shear strength, particle diameter	Effect on creep closure, cuttings, cavings and spallings release
Sulfates	Microbial gas generation; methane production	Increase in gas pressure
Nitrates	Microbial gas generation; methane production	Increase in gas pressure

- DOE provided a list of those waste characteristics and components that were considered for PA, but were ultimately excluded for various reasons, such as negligible impact on performance assessment (Appendix WCA, Table WCA-4, presented as Table 5-2 below). These characteristics and components included the following:

Table 5-2

Characteristic	Component	Reason Excluded
cellulosic radiolysis	radionuclides	negligible effect on total CO_2
explosivity	other organic compounds	no effect
brine radiolysis	radionuclides	negligible effect on actinide valence
galvanic action	nonferrous metals	negligible effect on PA
complexation with actinides	soil/humic material	actinide mobility
buffering action	cement	negligible; reacts w/CO2 and MgCl2
heat of solution	cement	negligible effect on PA
Ca^{2+} binding-organic ligands	cement	negligible compared to other metals
buffering action	ferrous metals	would reduce actinide mobility
galvanic action	ferrous metals	negligible effect on PA
binding to organic ligands	ferrous alloy components	can reduce actinide mobility
redox reactions	nonferrous metals	negligible compared to iron
binding to organic ligands	nonferrous metals	can reduce actinide mobility
complexation with actinides	organic ligands	negligible effect on PA
gas generation	Al, other non-ferrous metals	negligible effect relative to steels
microbial nutrients, CO_2 generation	phosphates	negligible due to MgO-CO_2 reaction
microbial nutrients CH_4 generation	phosphates	negligible
heat generation	RH-TRU	negligible
electrochemical processes	sulfate, nitrate, phosphate	negligible

- DOE concluded that curie content of the waste is a very significant component for performance assessment. DOE included 10 isotopes in direct release by cuttings, cavings, and spallings, for which they also calculated curie content (Section WCA.3.2.1, Figure WCA-4):
  - ^{38}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu;
  - ^{241}Am;
  - ^{233}U, ^{234}U;
  - ^{90}Sr;
  - ^{137}Cs; and
  - ^{244}Cm.

- DOE indicated that the following components were used in performance assessment but were not expected to have a significant effect on disposal system performance (Table WCA-3, p. WCA-11):
  - Solid waste components related to waste permeability and porosity; and
  - Water in the waste.
- Figure WCA-1 (p. WCA-13) in Appendix WCA presents DOE's interpretation regarding how waste components and associated characteristics contribute to performance assessment codes. The waste components and/or characteristics identified as being important to system performance are included as parameters in performance assessment.

<u>EPA Analysis Process:</u>

- EPA performed an extensive technical analysis of DOE's submission pertaining to waste characteristics. This analysis included CCA review, additional technical document review, code analysis and parameter calculations, as well as experiment recommendation and result critique, and new PA modeling using modified waste characteristic driven parameters. CCA references were examined, both individually and in concert, to determine whether DOE presented rationale and logical arguments for all characteristic and associated component identifications. EPA considered whether all relevant waste characteristics and components were identified and evaluated. Screening procedures used to determine whether waste characteristics and components were examined for reasonableness and consistency of application. Results of DOE experimental programs as they pertain to identified characteristics and components were also examined in detail to determine whether conclusions drawn by DOE, based upon experimental program results, were sound. In addition, DOE's sensitivity analysis, as well as applicable bounding analysis, were also examined to determine whether the sensitivity analysis includes all applicable components and to review the application of sensitivity analysis results.

- EPA performed a detailed analysis of the actinide oxidation states that may be present in the repository, recognizing that actinides can exist in oxidation states ranging from +3 to +6, depending on the specific actinide under consideration and prevailing redox conditions. EPA's analysis showed that reducing conditions will be expected in the repository; thorium will be present in the +4 oxidation state; americium is expected to be present in primarily the +3 oxidation state; plutonium is expected by EPA to be present as either Pu(+3) or Pu(+4); and uranium (U) is expected by EPA to exist in both the +4 and +6 oxidation states. For the PA, uranium is designated as being present as U(+4) in 50% of the (PA) runs and as U(+6) in the other 50%. Likewise, neptunium is expected to be present as either Np(+4) and/or Np(+5), because the designation of a predominant form could not be made with complete certainty for repository conditions.

- EPA has conducted a thorough evaluation of the conceptualizations and methodology used by DOE to calculate the solubilities of actinides under equilibrium conditions (Docket A-93-02, Item V-B-17). EPA's analysis showed that DOE's sampling of oxidation distribution states is appropriate, and that the redox conditions of the repository will likely be reducing rather than oxidizing. EPA also agrees that chemical equilibrium models are appropriate for predicting the concentrations of actinides that might be reached in the brines infiltrating into the repository.

- EPA evaluated the use of MgO with respect to mineral species that will form in the WIPP and subsequent impact that these species will have on actinide solubility. EPA's detailed analysis indicates that hydromagnesite is the appropriate mineral phase to base solubility on. EPA believes that the sequence of events resulting from brine infiltration and reaction with the MgO backfill in the repository may be conceptualized by the following reactions, in order:

    1. Rapid reaction (hours to days) between the brine and MgO to produce brucite.
    2. Rapid carbonation (hours to days) of the brucite to produce nesquehonite and possibly hydromagnesite.
    3. Rapid conversion (days to weeks) of the nesquehonite to hydromagnesite.
    4. Slow conversion (hundreds to thousands of years) of the hydromagnesite to magnesite.

- EPA performed Fracture Matrix Transport (FMT) verification runs, which were initiated during a visit to Sandia National Laboratory (SNL) on January 20-23, 1997 (for details of the review see Appendix A of the Technical Support Document to Section 194.23: Models and Computer Codes (A-93-02, V-B-6)). The initial runs focused on verifying the results documented in the CCA for predicted actinide concentrations. The version of the FMT model (version 2.0) and associated database used for these CCA runs was found to calculate incorrect results for some conditions. Consequently, on April 24, 1997, an updated version of the FMT model (version 2.2) and associated databases was made available to EPA for use by Sandia National Laboratory.

- Results from EPA's runs using the CCA version 2.0 of FMT, indicated that the pH would be lowered and CO_2(g) partial pressure increased for equilibria with the hydrated magnesium carbonate phases compared to magnesite (Tables 4-6 and 4-7 of A-93-02, V-B-17). As a result, the predicted concentrations of Th(IV) increased to very high concentrations compared to the case of brucite/magnesite equilibria. Inspection of the speciation results indicate that the increase in Th(IV) is primarily the result of the formation of $Th(CO_3)_5$-6 under the higher CO_2(g) partial pressures present at equilibrium for brucite/hydromagnesite and brucite/nesquehonite.

- EPA's FMT runs using version 2.0 and assuming hydrated magnesium carbonates were repeated with the updated version 2.2 of the FMT model and associated databases in April, 1997 and thereafter because of the obvious errors in some of the predicted actinide concentrations. The results also show that Th(IV) concentrations are predicted to be highest under conditions of equilibrium with brucite and nesquehonite, as was found for the CCA version of the FMT model (Tables 4-8 and 4-9).

- EPA's results with the updated version of the FMT database also show that the form of the hydromagnesite, either $Mg_5(CO_3)_4(OH)_2.4H_2O$ or $Mg_4(CO_3)_3(OH)_2.3H_2O$, used in the equilibrium calculations has little impact on the predicted actinide concentrations for both brines (Tables 4-8 and 4-9 of A-93-02, V-B-17). Both stoichiometries for hydromagnesite have been reported in the literature. Tables 4-8 and 4-9 include the solubility values (for the Salado and Castile brines) used in the Performance Assessment Verification Test (PAVT) (also see the Technical Support Document for Section 23: Parameter Justification Report, A-93-02, V-B-14). Note that the values as calculated are in molal, whereas the values reported in the CCA are in moles per liter.

- The results of DOE's FMT model were, for the most part, verified by EPA′s independent modeling runs following the methodologies provided in support documents to the CCA. Small differences in calculated actinide concentrations were observed but are not considered significant enough to affect PA. Most importantly, errors in the FMT thermodynamic database identified by EPA but used for calculations presented in the CCA have been corrected. The corrections resulted in more realistic predictions of actinide concentrations for the range of possible conditions that might be expected for equilibria with different magnesium carbonates.

- EPA's independent model runs indicate that the actinide solubilities calculated by FMT and used in the CCA performance assessment appear to be higher than what would be expected in the repository.

- As a result of EPA's preliminary runs, the Performance Assessment Verification Test was run using values for hydromagnesite equilibria.

- EPA examined the viability of using a single concentration for representing U(VI) concentrations in the repository and calculated U(VI) concentrations that might be expected for equilibrium with potential solubility controlling solids such as schoepite, sodium uranate, and calcium uranate. As a result of it′s analysis, EPA considered the concentration of U(VI) at 8.8×10^{-6} molal a reasonable upper bound for U(VI) concentrations in the WIPP brines.

- EPA also examined the methodology developed by DOE to assign uncertainty limits to the concentrations of actinides predicted from solubility calculations. These uncertainty limits were determined by DOE to range from 1.4 log units above to 2.0 log units below the actinide concentrations calculated from solubility expressions contained in the FMT model. Because the uncertainty distribution is based on direct comparisons between predicted and observed data from actinide solubility experiments, it is expected to provide a reasonable depiction of the uncertainty in calculations of actinide solubilities made with the FMT model.

- EPA reviewed DOE's characterization and parameterization of microbial, humic, actinide intrinsic, and mineral colloids. EPA concluded that the parameterization for actinide intrinsic and mineral colloids was adequate for use in performance assessment due to the low sensitivity of colloids in EPA's sensitivity analysis (A-93-02, V-B-13). Microbial and humic colloids were examined in detail by EPA.

- EPA examined humic colloid development, including the explanations presented by DOE in the CCA. EPA concluded that the mechanisms postulated came primarily from fundamental physiochemical principles, existing literature references, and chemical equilibrium model calculations. EPA found that DOE's overall approach to understanding the impact of humic materials on the actinide source term appears to be reasonable for use in performance assessment. In addition, EPA's sensitivity analysis (Technical Support Document for Section 194.23: Sensitivity Analysis, A-93-02, V-B-13) indicates that humic materials have minimal effect on solubilities.

- EPA's evaluation of microbial issues began with a consideration of the types of microbes likely to grow in the WIPP repository and the general lack of knowledge about their properties. Evaluations of parameters for microbial gas generation and development for microbially-mediated actinide transport was also performed. EPA found that:

    1. DOE's approach to address the probability of gas generation is adequate for use in performance assessment although there are uncertainties in future microbial populations.

    2. DOE's simplified formulation of microbial actinide accumulation in the CCA is appropriate given the knowledge of expected microbial populations.

    3. The experiments used as support to estimate actinide binding parameters have uncertainties associated with them due to limited data and projection to future populations. EPA recognizes the uncertainties associated with the parameterization of PROPMIC and CAPMIC, however, EPA found that the approach used in the CCA reasonable given the data and the need to use existing populations to extrapolate to future populations.

- EPA examined experiments using the cultured strain WIPP-1A that were used by DOE to estimate the rate of WIPP organic carbon mineralization as being between 0.3 and 0.02 mol C/kg organic material/yr (6.3×10^{-10} to 9.5×10^{-9} mol C/kg organic materials per second, Table 8.2). EPA believes that CO_2 production rates estimated from these experiments are likely to be conservative overestimates of possible CO_2 production rates in the WIPP repository. With the addition of MgO backfill to the WIPP. EPA concluded that estimated rates of CO_2 production are not likely to be of significant concern to PA results.

- EPA's review of gas generation mechanisms and parameterization indicated that DOE's inundated corrosion-related gas generation rate is conservative and appropriate, based upon literature and available experimental data. Regarding the likelihood of microbial gas generation. EPA concluded that the 50% probability of microbial gas generation and subsequent 50% probability for plastic and rubber degradation is appropriate. EPA also reviewed DOE's CO_2 production rate data. EPA also concluded that the CO_2 production values (high) are likely conservative overestimates of possible CO_2 production rates in the WIPP repository.

- EPA concluded that available data would indicate, therefore, that the upper value used by DOE for gas generation could be conservatively high. Although the lower value does not include nitrate, it could be considered representative when the presence of added inoculum is taken into account. EPA also examined the iron corrosion rate, and determined that the rate should be modified so that the maximum corrosion rate was approximately twice that used in PA. EPA used 3.17E-14 m/g in its Performance Assessment Verification Test (PAVT), rather than the PA′s maximum of 1.587E-14 m/g (Appendix PAR, p. PAR-15).

- EPA conducted its own sensitivity analysis to determine the sensitivity of selected parameters, including waste-related parameters (A-93-02, V-B-13). EPA examined the sensitivity to the performance assessment of numerous waste and source term related characteristics and components. EPA's analysis indicated that four components significantly affect the results of the sensitivity analysis:

  1. Waste material combined inventory/density,

  2. Waste cellulosics density,

  3. Waste rubber density, and

  4. Waste plastic density.

- EPA performed a detailed analysis of waste components associated with waste characteristics important to WIPP performance. EPA agrees that ferrous metals are important waste components relative to gas generation, and that iron will be present in abundance in waste containers shipped to WIPP. EPA also concurs with values used in PA for density of iron; see EPA Technical Support Document for Section 194.23: Parameter Justification Report (A-93-02, V-B-14) for EPA's evaluation of parameter values, and EPA Technical Support Document for Section 194.23: Sensitivity Analysis (A-93-02, V-B-13) for EPA's sensitivity analysis. EPA also agrees that DOE appropriately found that cellulosics will contribute to gas generation and that chelating agents (organic ligands) will bind to metals other than actinides. EPA's sensitivity analysis indicates that chelating agents and colloids are not important to performance. EPA Technical Support Document for Section 194.23: Sensitivity Analysis (A-93-02, V-B-13) provides EPA's PA-related sensitivity for related parameters such as cellulosic and plastic density. EPA Technical Support Document for Section 194.23: Parameter Justification Report (A-93-02, V-B-14) includes discussion of DOE's value selection for these parameters. EPA also notes that iron (via number of containers) and cellulosic content will be determined for each container intended for disposal in the WIPP by tracking the number of waste containers and through waste content evaluation using process knowledge and radiography and/or visual examination.

- EPA found that DOE appropriately identified radioactivity in curies of each isotope, %-emitting TRU radionuclides ($t_{1/2} > 20$ years) (with respect to TRU activity at closure), and radionuclides (with respect to redox state and solubility) as important waste components.

EPA's review of the CCA indicated that DOE did not account for all waste when calculating the waste unit factor (which is based upon the total activity at closure), although the omission did not result in inventory modifications that impacted WIPP performance evaluations by EPA.

- EPA's evaluation of the waste inventory revealed that DOE had not adequately considered the entire waste inventory when determining the total curie content anticipated at closure. DOE provided supplementary information pertaining to this issue in which DOE concurred with EPA that the waste unit factor at closure (2033) was 3.59, not 3.44, as stated in Chapter 4 (p. 4-26). EPA concluded that these values did not result in a significant difference in complementary cumulative distribution function (CCDF) curves and did not affect EPA's assessment of the WIPP's compliance.

- EPA's review of specific actinide activities presented in the CCA indicates that the values selected by DOE were consistent with those presented by generator sites (and modified, in the case of cuttings values, in accordance with modifications presented in the BIR), and that values used in PA were appropriately decayed to the closure data.

- The CCA lists in Table WCA-4 those characteristics and components not considered in performance assessment, and references locations in Appendices SCR and WCA where supporting justification is contained. EPA concludes that DOE has considered the effects of each appropriately.

6.0 WASTE LIMITS

The Environmental Protection Agency's (EPA's) regulations at 40 CFR Part 194 recognized that there may be limiting values of waste components that could affect the ability of the facility to meet performance criteria. Section 194.24 requires the Department of Energy (DOE) to evaluate the wastes destined for the Waste Isolation Pilot Plant (WIPP) and determine whether maximum or minimum limits should be placed on these components. DOE imposed maximum limits on free water emplaced with waste and on cellulosics, rubber, and plastic. DOE also imposed minimum limits for ferrous and nonferrous metals. EPA evaluated the waste limits provided by DOE and determined that the appropriate components requiring limitation were identified and the waste limits applied were sufficient. EPA believes that DOE adequately addressed questions regarding uncertainties, the presentation of upper/lower limits, and plausible combinations of these limits. This section discusses how EPA arrived at that decision.

6.1 SUMMARY OF EPA'S ANALYSIS

EPA Rulemaking: Section 194.24(c)(1) requires DOE to specify numeric limits on significant waste components and demonstrate that, for those component limits, the WIPP complies with the numeric requirements of §§194.34 and 194.55. EPA expected DOE to establish either upper or lower limits were to be established for components that must be controlled to ensure that the performance assessment (PA) results comply with the containment requirements. EPA also expected DOE to describe plausible combinations of upper and lower limits and their associated uncertainties and demonstrate that the combination of these selected limits would result in the greatest estimated release.

Sections 194.24(e)(1) and (2) require DOE to ensure that the total quantity of emplaced waste in the disposal system will not exceed the upper limiting value for waste components and will not fall below the lower limiting value for waste components. EPA expected the compliance application to describe DOE's system for maintaining centralized control over waste characterization activities, maintaining chain of custody over waste and waste records, the controls currently in place for receipt of waste at the WIPP, and the record keeping/accounting system for controlling limited waste components. EPA also expected current documentation on the WIPP Waste Acceptance Criteria (WIPPWAC).

Section 194.24(g) requires DOE to demonstrate that the total inventory emplaced in the WIPP will not exceed limitations on transuranic (TRU) waste described in the WIPP Land Withdrawal Act (LWA). Specifically, the LWA defines limits for: surface dose rate for remote-handled ("RH") TRU waste, total amount (in curies) of RH-TRU waste, and total capacity (by volume) of TRU waste to be disposed. (LWA, Section (7)(a)) EPA expected the compliance application to: (1) describe the inventory of waste proposed for disposal at the WIPP in terms of the units specified in the limitations of the LWA, in addition to limits of important waste components; and (2) describe how these limitations will be assured through implementation of the required system of controls.

EPA Final Determination: EPA finds DOE in compliance with §194.24(c)(1). EPA concurred with DOE that it was not necessary to provide estimates of uncertainty for waste limits, so long as the PA demonstrated compliance at the fixed limits. EPA finds that the WIPP Waste Information System (WWIS), which will be used by DOE to track specific data related to each of the waste component limits and LWA limits, is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility; as discussed above, waste generator sites will demonstrate WWIS procedures before they can ship waste for disposal at the WIPP. Therefore, EPA finds DOE in compliance with §§194.24(e) and (g).

EPA Analysis Process: Section 194.24(c)(1) requires the implementation of a system of controls that will be used to ensure that critical waste components for which waste limits have been established are appropriately traced to confirm that the total amount of each component will not exceed these limits. DOE evaluated waste components, determined which waste components needed either minimum or maximum limits, and documented their determination in the CCA. Finally, EPA evaluated the waste limits provided by DOE and determined that the appropriate components requiring limitation were identified and the waste limits applied were sufficient. These steps included:

Limiting Value of Waste Component and Upper or Lower Limiting Value Designation

- EPA reviewed the Compliance Certification Application (CCA) and determined that DOE identified four waste component grouping limits in the CCA, Section 4.2.2 and Table 4-10, and Appendix WCL's Table WCL-1. See Section 194.24(b) of CARD 24 and EPA Technical Support Document for 194.23: Sensitivity Analysis (EPA 1998a) for a discussion of how EPA assessed waste components and their effect on PA. EPA concluded that DOE identified those waste components that must have limits imposed, and that the limits are reasonable and traceable. Limitations on cellulosic/rubber/and plastics are based upon the quantity of MgO that can be emplaced in the WIPP to ensure that the quantity of MgO can react with CO_2 generated from biodegradation of emplaced cellulosics, plastics, and rubber.

- EPA concurred that using the quantity of iron from the container itself as the minimum limiting value is an appropriate and easily traceable waste limit, and also recognizes that iron within waste will provide additional iron and other components.

- EPA believes that the Waste Acceptance Criteria (WAC) limitations will ensure that water within the waste is less than 1% by volume, and that the quantity of water in waste will likely be well below the maximum limit imposed by DOE.

- EPA concurred that limitations on radionuclides are not explicitly warranted at this time, although tracking of radionuclides within the inventory will be performed to ensure that the inventory is well defined for future recertification activities.

- EPA's sensitivity analysis indicated that PA is not particularly sensitive to humic and organic ligand parameters modeled, and limitations on these components are not warranted. EPA also noted that information gleaned through the waste characterization process will provide additional detailed information pertaining to waste inventory, and that modification of waste limits could be imposed as part of the recertification process if identified as necessary by a PA for purposes of recertification.

<u>Associated Uncertainty to the Limiting Values</u>

- EPA reviewed the CCA and initially determined that DOE did not provide the associated uncertainty for the waste component limits. In DOE's responses to an EPA completeness comment regarding the absence of associated uncertainties (Docket A-93-02, Item II-I-17, Enclosure 1), DOE stated the waste component limits are fixed values, and fixed values do not have uncertainties associated with them (A-93-02, II-I-24 and II-I-28).

- EPA examined DOE's logic surrounding the associated uncertainty issue and agreed with DOE's approach because a limiting value can be a fixed value without an associated uncertainty. That is, the limiting value itself is imposed to ensure compliance, and in fact represents the upper "end" of an uncertainty value. EPA believed that this approach captures the intent of the regulation.

<u>Plausible Combinations of Upper and Lower Limits of Waste and their Associated Uncertainties and Rationale for the Selection of the Plausible Combinations</u>

- EPA reviewed the CCA and questioned whether DOE had addressed the issues of compliance with numeric requirements, plausible combinations of upper and lower limits of waste components and associated uncertainties, the rationale for the selection of these combinations, results of modeling run of the code, results of the analysis, and the combination of the selected limits resulting in the greatest estimated release. EPA stated its concerns in a March 19, 1997 letter to DOE (Docket A-93-02, Item II-I-17). DOE responded to EPA's questions, stating that the results of the WCA, SA, CCDFs and PAs established fixed-value repository-scale WCLs, and these also addressed Section 194.24(c)(1) (Docket A-93-02, Items II-I-24 and II-I-28). Furthermore, DOE stated that the plausible combinations of upper and lower limits are equivalent to the fixed values selected and included in the CCA PA calculations. Therefore, DOE asserted the combination of selected limits that result in the greatest estimated release was used in the analysis.

- EPA examined DOE's responses in concert with a detailed examination of the PA and performance assessment verification test (PAVT) results. EPA concluded that DOE adequately addressed the issue of plausible combinations of upper and lower limits and their associated uncertainties through implementation of the PA, wherein multiple combinations of parameters are used that capture the spectrum of plausible PA results and associated uncertainties.

<u>Modeling Run of the Code, Compliance with Numeric Requirements, and Documentation that the Combination of Selected Limits Result in the Greatest Estimated Release</u>

- EPA concluded, given the quantity of ferrous iron in waste containers identified by DOE, that a number of parameters used in the PA -- including the oxidation state distribution parameter (Appendix PAR, page PAR-148) -- incorporated the effects of reducing conditions. Also, the quantity of drums (Parameter ID 3132, p. PAR-235) is input to PA, as is the fixed volume of the repository.

- Since the density of waste containers relative to ferrous and nonferrous metals was established by DOE (Table 4-4) and is input to PA (see Section 194.24(b)(2) of CARD 24 for specific values), the combination of fixed PA repository volume, drum content, and waste density captures the effect that ferrous metals would have on PA.

- A specific quantity of water was not included as a separate PA parameter, but the anticipated volume of water was incorporated in the initial brine saturation parameter (parameter SAT_BRN = 1.5%, Table PAR-38).

- EPA examined the CCA (Chapter 6, Appendix SA) and found that Figures 6-35 through 6-41 present the results of PA, including input as a result of waste-related analysis, and show that the disposal system complies with EPA's numeric requirements. EPA found that Figures 6-35 through 6-37 show the individual CCDF curves for the three replicate runs performed. EPA noted that the curves on these figures that are closest to EPA containment requirement limit are those that represent the combination of conditions -- including waste-related parameters -- that result in the maximum calculated releases. See **CARD 23 -- Models and Computer Codes** and **CARD 34 -- Results of Performance Assessments** for discussion of modeling results.

- In addition, EPA determined that DOE appropriately linked the waste components and characteristics with the waste related inputs to computer models; see Section 194.24(b) above. Figure WCA-1 in Appendix WCA shows the relationships between the waste components, their associated waste characteristics, and the PA codes. See CARD 23 -- Models and Computer Codes for a detailed discussion of waste-related parameters as input to PA.

Section 194.24 (e)(1) and (e)(2) requires that the total quantity of emplaced waste must not exceed the estimated upper-bound limits for waste components and will not fall below the estimated lower-bound limits for waste components, which is linked to §194.24(c)(4) in that the specified system of controls will ensure that the total quantity of emplaced waste will meet the limiting values. The controls established by DOE pursuant to §194.24(c)(4) are discussed in Section 9 of this document.

System for Maintaining Centralized Control Over Waste Characterization Activities and Authorization of Grants to Generator Sites to Characterize and Ship Waste

- EPA reviewed the CCA and determined that in Section 4.4 (pp. 4-44 to 4-49), DOE provided an adequate description of the system for maintaining centralized control over waste characterization activities.

- During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed DOE Carlsbad Area Office (CAO) auditors through their audit checklists and interviews, and determined that the auditors sufficiently examined the LANL waste characterization records center personnel qualifications, responsibilities, and activities, and the records themselves. During the WWIS demonstration of June 1997, EPA observed the WWIS security, data backup and archiving functions and reviewed the associated documentation.

- During the WWIS test of September 1997, which occurred simultaneously at WIPP and LANL, EPA observed the nuclide reporting, waste container data reporting, and the calculation of total cellulosics (including plastics and rubber).

- To evaluate DOE's system for maintaining centralized control over waste characterization activities, EPA inspected the waste characterization certification audits at Rocky Flats Environmental Technology Site (RFETS) (June 1997) and Los Alamos National Laboratories (LANL) (May, August, and September 1997), as well as the Performance Demonstration Programs (PDPs) at LANL (June 1997) and RFETS (November 1996). These are the only audits and PDPs that EPA inspected. EPA verified at the audits and

PDPs that DOE had an adequate DOE system for maintaining centralized control over waste characterization activities. See Section 12.0

- EPA reviewed the CCA and determined that in Chapter 4.4 (pp. 4-48 to 4-49), DOE provided an adequate description of the site certification process, which includes the authorization of grants to generator sites to characterize and ship waste.

- EPA verified DOE's site certification process, which includes the authorization of grants to generator sites to characterize and ship waste, when it inspected waste characterization certification audits at LANL (May, August and September 1997) and RFETS (June 1997), and the PDPs at LANL (June 1997) and RFETS (November 1996). These are the only audits and PDPs that EPA inspected. See Section 12.0.

- EPA reviewed the CCA and determined that in Section 4.4 (p. 4-49) DOE did not provide adequate detail on the radiological waste characterization portion of the audit process, and that the audit checklist (as presented in Appendix WAP, Appendix C11) does not include a radiological waste characterization portion. However, through EPA's inspection of the waste characterization certification audits at LANL (May, August and September 1997), EPA reviewed DOE/CAO auditors' checklists and observed the auditors during interviews, and determined that the auditors sufficiently examined LANL's waste characterization program as it relates to radiological waste characterization. See Section 12.0.

<u>Mechanism for Maintaining Chain of Custody Over Waste and Waste Records from the Point of Characterization to the Point of Disposal</u>

- EPA reviewed the records management and records storage information that DOE provided in Appendix WAP, Section C-5 (pp. C-46, 47), and found the information to be adequate. During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed that the LANL waste characterization records center exceeds the records management and storage guidelines previously noted. See Section 12.0.

- Also during the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed DOE/CAO auditors through their audit checklists and interviews, and determined that the auditors sufficiently examined the LANL waste characterization records center personnel qualifications, responsibilities, and activities, as well as the records themselves. During the WWIS demonstration of June 1997, EPA observed the WWIS security, data backup and archiving functions and reviewed the associated documentation.

Controls Currently in Place for Receipt of Waste at the WIPP, including: Provisions for Records and Shipment Surveys, Acceptance and Emplacement of Waste, and Provisions for Dealing with Non-Conforming Waste/Waste Records; and Citation of Applicable Procedures

- EPA reviewed the CCA to determine if DOE provided adequate information on controls currently in place for receipt of waste at the WIPP. In Appendix WAP, Section C-5 (pp. C-42 through C-47), DOE provided details on the Phase II - Waste Shipment Screening and Verification, although DOE did not cite applicable procedures. However, EPA believed that DOE has sufficient controls in place for waste receipt.

- DOE did not provide information on shipment surveys for CH-TRU and RH-TRU waste in the CCA. However, DOE included adequate CH-TRU and RH-TRU waste shipment survey information in the Resource Conservation and Recovery Act (RCRA) Part B Permit Application submitted to the New Mexico Environment Department (DOE 1996d). Refer to RCRA Part B Permit Application Chapter D, Section D-10a(3)(b), CH TRU Waste Handling, and Section D-10a(3)(c), RH TRU Waste Handling, respectively.

Record Keeping/Accounting System for Controlling Limited Waste Components for Verification of Emplacement of Waste

- EPA reviewed the CCA and determined that DOE provided generally adequate descriptions of the WWIS including documentation, data fields and features in Chapter 4.3.2 (pp. 4-35 to 4-39) and the WIPP Waste Information System Software Design Description (WWIS SDD) (DOE, 1996d).

- EPA submitted a request for additional WWIS information (i.e., automatic limits, range and quality assurance (QA) checks; automatic report generation) in the completeness comment letter dated December 19, 1996 (Docket A-93-02, Item II-I-01).

- EPA reviewed DOE's May 2, 1997 response to EPA's completeness comment by referencing the information already provided in the CCA (A-93-02, II-I-28). EPA determined that DOE provided no additional information on the WWIS in its response and therefore did not demonstrate that the WWIS was functional.

- In September 1997, DOE demonstrated for EPA the operation of the WWIS at Los Alamos National Laboratory (LANL). EPA observed that the WWIS provides checks that are for repository-based limits (i.e., cellulosics in kilograms, total capacity of contact-handled (CH) waste in cubic feet or cubic meters).

- During the WWIS test, which occurred simultaneously at the WIPP and LANL, EPA also observed the nuclide reporting, waste container data reporting, and calculation of total cellulosics (including plastics and rubber).

- The following WWIS documents were reviewed by EPA and found to be adequate:

  - WWIS Evaluation and Recommendation;
  - WWIS Software Quality Assurance;
  - WWIS Software Verification and Validation Plan;
  - WWIS Software Requirements;
  - WWIS Software Design Description;
  - WWIS Software Configuration Management Plan;
  - WWIS Security Plan;
  - Contingency Plan - WIPP Wide-Area Network; and
  - Risk Analysis Report - WIPP Wide-Area Network.

- EPA determined that the WWIS tracks individual waste material parameters (WMPs) (i.e., cellulosics) and the weight of individual WMPs.

- DOE has determined that there are ten radionuclides important to the long-term performance of WIPP: ^{241}Am, ^{244}Cm, ^{137}Cs, ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu, ^{90}Sr, ^{233}U, and ^{234}U. Of these ten, ^{90}Sr, ^{233}U, and ^{137}Cs are important to RH but not CH waste streams. In addition, DOE has identified four important waste components that need to be tracked because DOE identified that limits were required (Appendix WCL, Table WCL-1). The waste components with limiting values are:

  - Ferrous metals (iron): minimum of 2×10^7 kilograms;
  - Cellulosics/plastic/rubber: maximum of 2×10^7 kilograms;
  - Free water emplaced with waste: maximum of 1684 cubic meters; and
  - Nonferrous metals (metals other than iron): minimum of 2×10^3 kilograms

- When EPA conducts inspections and records reviews under 194.24(h), such as audits, to verify compliance with § 194.24, EPA will review DOE's system of controls for the following items that DOE has committed to track:

  - The total quantity of waste (volumetrically);
  - The quantity of the four important waste components for which DOE has identified limits (listed above);
  - Radionuclide activity for the ten radionuclides important to long-term performance (listed above);
  - Radionuclide activity uncertainty;
  - Radionuclide mass;
  - Radionuclide mass uncertainty;
  - TRU alpha activity;
  - TRU alpha activity uncertainty;
  - Verification data;
  - Verification method;
  - Visual examination of container;
  - WAC certification data; and
  - Waste Matrix Code (WMC).
  - General location of the waste in WIPP

- For the WIPP, EPA determined that several reports (i.e., bar code batch processing errors, nuclide, waste emplacement, headspace gas concentration) will be generated, and that the reporting schedule was provided. According to the WWIS Software Design Document (SDD), Section 2.6 (p. 26), the WWIS also has the capability to perform decay analysis using RADAC software and to do regulatory reporting (i.e., by radionuclide, biennial), but little detail beyond a mention of these features was provided in the CCA.

- EPA reviewed the CCA and determined that DOE adequately referenced and summarized WIPP WAC in the CCA. EPA concluded that Chapter 4.2.3 (pp. 4-30 to 34) and 4.4 (pp. 4-44 to 49) adequately discussed the WIPP WAC and provided the container-based limits imposed by the WAC, as well as the waste characterization requirements detailed in the WAC.

Section 194.24(g) requires that DOE demonstrate that the total WIPP waste inventory will comply with the limits in the LWA. The purpose of this section is to discuss how EPA reviewed DOE's methodology for demonstrating compliance with the LWA specific limitations.

- EPA reviewed DOE's CCA to determine if DOE adequately described the inventory of waste proposed for disposal at the WIPP in terms of the units specified in the limitations of the LWA, in addition to limits of important waste components. Specifically, EPA reviewed the Transuranic Waste Baseline Inventory Report (TWBIR) in its entirety, including TWBIR Revision 3, Tables ES-1, ES-2, ES-3, ES-4, 2-1, and 3-1. EPA also reviewed Chapter 4, Section 4.1.3.2, Table 4-3 and Section 4.2.2, Table 4-10, and Appendix WCL, Table WCL-1.

- EPA concluded that the CCA adequately described the inventory of waste proposed for disposal at the WIPP in terms of the units specified in the limitations of the LWA as they pertain to total RH activity and total volume, in addition to limits for important waste components. See Section 194.24(a) of CARD 24 for additional information regarding EPA's review of the TWBIR.

- EPA noted that the CCA does not specify the rem limitations within the LWA on Table 4-10, although the text of the CCA (p. 4-5 and 4-6) discussed the limits. This information will be gathered as part of the waste characterization process, as each container will undergo nondestructive assay and surface dose rate analysis in accordance with the WIPP WAC (Table 4-12, p. 4-33) (DOE 1996c). EPA concluded that this information will be tracked by the WWIS adequately.

- EPA reviewed information pertaining to the WWIS, including Chapter 4.3.2 (pp. 4-35 to 4-39), relative to its ability to track emplacement limits imposed by the LWA. (See Section 194.24(c)(4) of CARD 24 for additional discussion of the WWIS.) EPA also reviewed the CCA to determine if DOE described how these limitations will be ensured through implementation of the required system of controls.

- EPA found that Appendix WAP, Section C-5, provides a detailed description of DOE's Phase I and II waste stream/shipment screening and verification procedures. In general, Phase I describes waste stream screening and verification that will occur before waste is shipped to the WIPP. These data will be entered into the WIPP Waste Information System

(WWIS), which will provide DOE the ability to generate: (1) container emplacement reports; (2) shipment summary reports; (3) characterization data reports; and (4) a change log report. EPA also found that verification of these data will be carried out through the Waste Operations section and Environmental Compliance and Support staff.

- EPA determined that Phase II of the waste shipment screening and verification procedures occurs after waste is received at the WIPP. In this phase, DOE will make determinations about the wastes concerning completeness and accuracy of EPA hazardous waste manifest, waste shipment completeness, and land disposal restriction notice completeness for hazardous waste components.

- EPA noted that DOE identified a number of data fields contained in the WWIS that can store and track information relevant to demonstrating compliance with 40 CFR 194.24(g). DOE should ensure that the WWIS data fields include the following:

  - ^{239}Pu fissile gram equivalent;
  - Radionuclide activity;
  - Radionuclide activity uncertainty;
  - Radionuclide mass;
  - TRU alpha activity;
  - TRU alpha activity uncertainty;
  - WAC certification data;
  - Waste Material Parameters (WMPs); and
  - Waste Matrix Codes (WMCs).

- EPA concluded that DOE adequately described how the LWA limitations will be assured through implementation of the required system of controls.

7.0 WASTE CHARACTERIZATION METHODS

The Environmental Protection Agency (EPA) expected the Department of Energy (DOE) to identify the method(s) that will be used to quantify each waste component. Chapter 4 presents several waste characterization methodologies to identify the physical, chemical and radiological properties of the waste. Specifically, DOE proposed to use non-destructive assay (NDA), non-destructive examination (NDE) (i.e., radiography), visual examination (VE), headspace gas sampling and analysis, and solid waste sampling and analysis as the methods to quantify various waste components (see Compliance Certification Application (CCA), Section 4.4). The first three methodologies are most important to compliance with § 194.24 because they pertain to waste components for which limits have been set and can be identified through radiological and physical waste characterization. The last two methodologies pertain to chemical waste characterization for hazardous waste components. DOE determined that the hazardous waste components did not have an impact on repository performance relative to radiological standards, and so set no limits for these components. EPA concurred with the DOE determination, and thus is not setting requirements for headspace gas sampling or solid waste sampling and analysis. This discussion is therefore limited to methods for NDA, NDE, and VE.

DOE provided descriptions of various waste characterization methods used to quantify waste components. DOE presents waste characterization methods used to quantify waste components in the CCA, Section 4.4, the Transuranic (TRU) Waste Characterization Quality Assurance Program Plan (QAPP), Chapters 9 and 10, and Section 5.4.2, and the Transuranic Waste Characterization Sampling and Analysis Methods Manual (Methods Manual), Methods 310.1 and 310.2. DOE also opened their systems and procedures to EPA inspections.

EPA reviewed the waste characterization information and methods to quantify waste components as presented by DOE in the CCA, Section 4.4; QAPP, Chapters 9 and 10, and Section 5.4.2; and Methods Manual, Methods 310.1 and 310.2. In addition, EPA reviewed site-specific procedures at Los Alamos National Laboratory (LANL) and Rocky Flats Environmental Technology Site (RFETS) during waste characterization certification audits and Performance Demonstration Program (PDP) tests. The DOE characterization methods apply to contact-handled transuranic (CH-TRU) waste. DOE did not specify waste characterization methods for remote-handled transuranic (RH-TRU) waste.

7.1 SUMMARY OF EPA ANALYSIS

EPA Rulemaking: 40 CFR 194.24(c) states "For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:

(2) "Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section."

EPA expected the compliance application to specify:

- The waste characterization method (e.g., process knowledge, non-destructive assay, non-destructive examination, visual inspection, statistical sampling and analysis, etc.) that is being or will be used to determine the quantity of each waste component.

- How each method will be used to quantify the amounts of listed waste components prior to disposal;

- The procedure followed and the scale to which the method is applied (e.g., individual waste container, batch, statistical sample of drums, etc.);

- The instrumentation used and its sensitivity; and

- The parameter measured and how it is related to the waste component in question.

DOE proposed to use non-destructive assay (NDA), non-destructive examination (NDE), and visual examination (VE) as the methods used to quantify various waste components. EPA expected the compliance application to describe how the data obtained by each method meet or exceed any quality assurance indicators or data quality indicators that were assumed or derived relative to waste-related inputs to the modeling of compliance. Finally, EPA expected the CCA to demonstrate the DOE ability to quantify each of the listed waste components (for purposes of control, at the precision and accuracy adequate to assure that limiting values will not be exceeded in the inventory shipped to WIPP). DOE must show that the proposed methods can be performed, using the current technology, at the precision and accuracy necessary to quantify the waste components.

<u>EPA Final Determination:</u> The CCA described numerous NDA instrument systems and described the equipment and instrumentation found in NDE and VE facilities. DOE also provided information about performance demonstration programs intended to show that data obtained by each method could meet data quality objectives established by DOE. EPA found that these methods, when implemented appropriately, would be adequate to characterize the important waste components. Therefore, EPA finds that DOE has demonstrated compliance with §194.24(c)(2).

<u>EPA Analysis Process:</u>

- Site-specific information on LANL was collected from August 1996 to September 1997 during CAO Waste Characterization and Certification Quality Assurance Surveillance S-96-48 (August 1996) and Quality Assurance Audits A-97-01 (May 1997), A-97-07 (July 1997) and A-97-16 (September 1997). These activities provided opportunities to obtain detailed information on the LANL waste characterization program and to observe NDA practices and documentation first hand.

- Information for RFETS was collected from November 1995 to July 1997 during three CAO activities: (1) DOE CAO Waste Characterization Audit No. A-95-06 in November 1995; (2) the preparation of standard drums for the CAO NDA Cycle 2 Performance Demonstration Program in November 1996; and, (3) DOE CAO Waste Characterization and Certification Audit # A-97-03 in July 1997.

7.1.1 Non-Destructive Assay (NDA)

- EPA reviewed the CCA, Sections 4.4.2 (p. 4-55) and 4.4.2.1 (pp. 4-56, 57) for NDA as the radiological waste characterization methodology to quantify radionuclides and their activity. EPA also reviewed the Transuranic Waste Characterization Quality Assurance Program Plan (QAPP, DOE/CAO-94-1010) for QA guidelines in Chapter 9 for NDA. After performing these reviews, EPA determined that DOE adequately identified NDA as the radiological waste characterization methodology to quantify radionuclides and their activity.

- EPA reviewed the CCA and determined that DOE does not provide a discussion of instrument sensitivities for NDA within the CCA. EPA reviewed the QAPP, Section 9.1, for DOE's discussion of the minimum detectable concentration (MDC) for NDA. EPA determined the MDC requires a minimum sensitivity given the variety of NDA instruments used by DOE, and that the 60 nCi/g MDC meets the intent of EPA's request in the Compliance Application Guide (CAG) regarding instrument sensitivities. The 60 nCi/g standard provides a 95% confidence that any drum containing TRU waste at 100 nCi/g will be properly classified.

- EPA reviewed Chapter 4.4.2 (pp. 4-55 to 57) and the QAPP, Chapter 9.0. EPA determined that DOE provided sufficient information showing NDA could measure radionuclides and their activity. The LANL NDA methods have been verified as capable of characterizing radionuclide activity in the retrievably-stored legacy debris waste streams.

- EPA conducted inspections during waste characterization certification audits to verify DOE's ability to quantify radionuclides and their activity in WIPP waste components using NDA. During the LANL waste characterization certification audit (Docket # A-93-02, II-A-51) of the passive active neutron (PAN) system in May 1997, EPA identified issues regarding software quality assurance and inadequate isotopic identification prior to using the PAN system. The LANL PAN system provides quantitative results for Pu-240 in passive mode, and fissile grams equivalent in active mode. Quantitative results for other nuclides are calculated using the ratios of the measured isotope's activity to the activity of the other isotopes present in the waste container. This ratio information must be provided either by AK or by another waste characterization method. LANL is using the PC-FRAM gamma spectroscopy system to provide the isotopic ratio information to the PAN system. EPA attended the LANL follow-up audit of September 1997, at which the software quality assurance, calibration, equipment set-up, and the PC-FRAM issues previously noted were adequately addressed.

- EPA performed NDA inspections at two generator sites, RFETS and LANL. LANL conclusively demonstrated their NDA system's ability to detect individual radionuclides for the combustible debris waste stream as an example of retrievably-stored legacy debris waste streams. RFETS could not conclusively demonstrate their NDA system's ability to detect individual radionuclides. EPA therefore concluded that DOE has sufficiently demonstrated at LANL that their NDA systems can identify and quantify radionuclides and their activity for the retrievably-stored legacy debris waste streams, but not for the full variety of waste streams and waste matrices expected at LANL. In addition, EPA has concluded that DOE has not sufficiently demonstrated that NDA systems at RFETS can identify and quantify radionuclides and their activity.

- EPA reviewed site-specific NDA procedures at LANL during the waste characterization certification audit of May 1997 for the passive active neutron (PAN) system, and, during the follow-up audits of August 1997 and September 1997, for the gamma system. EPA concluded the LANL procedures adequately control NDA for the combustible debris waste stream.

- EPA reviewed the Chapter 9 of the QAPP for the NDA program, and agrees that the proposed 100% NDA of waste containers is appropriate.

- EPA reviewed Chapter 4.4.2 (pp. 4-55 to 57) and the QAPP, Chapter 9.0. EPA determined that DOE provided sufficient information showing NDA could measure radionuclides and their activity. EPA questions the ability of the generator sites to demonstrate that individual radionuclides and their activities can be measured for different waste matrices, and will verify these capabilities in specific inspections. The LANL NDA methods have been verified as capable of characterizing radionuclide activity in the combustible debris waste stream.

- EPA reviewed the PDP Cycle 1 and 2 Reports for NDA performance data. EPA determined that by providing adequate performance data, DOE sufficiently described how the data obtained by NDA could meet or exceed the required quality assurance indicators or data quality indicators. See "Performance Demonstration Program for Nondestructive Assay for the TRU Waste Characterization Program, Scoring Report - April 1996 Distribution," (DOE 1996e) and "Performance Demonstration Program for Nondestructive Assay for the TRU Waste Characterization Program, Scoring Report - November 1996 Distribution," (DOE 1997a) for details of NDA PDP procedure performance data.

7.1.2 Non-Destructive Examination (NDE)

- EPA evaluated the adequacy of NDE radiography methods to verify adherence with the compliance limits for ferrous metals, cellulosics, plastics, rubber, water, and nonferrous metals as specified in Appendix WCL of the CCA. EPA reviewed the CCA, Sections

4.4.1 (p. 4-50), 4.4.1.2 (p. 4-54), 4.4.1.3 (p. 4-55), and 4.2.2 (p. 4-29), and Appendix BIR (Section 1, pp. 17-20; Section 2, pp. 6-7; Appendix M, pp. 1-3) to evaluate the adequacy of radiography as a physical waste characterization methodology. EPA determined that DOE adequately demonstrated that the ferrous metals content would not fall below the minimum waste limit based on the ferrous metal content of the containers emplaced in the WIPP. EPA also reviewed Chapter 10 of the QAPP for QA guidelines and Method 310.1 of the Methods Manual for procedures in order to evaluate the adequacy of radiography as a method for quantifying cellulosics, plastic, and rubber waste components. After performing these reviews, EPA determined that DOE adequately identified NDE as an appropriate physical waste characterization methodology to quantify waste components (including cellulosics, plastics and rubber).

- EPA reviewed the CCA, Section 4.2.2 (p. 4-29), to determine if NDE is an adequate methodology for verifying the waste acceptance criterion that free liquids emplaced with the waste constitute one percent or less of the total waste volume. DOE demonstrated adequate procedures that would limit the free liquid by requiring that any waste container exceeding the one-percent criteria (as determined by NDE) will be rejected and/or repackaged to exclude the unacceptable characteristic. Therefore, EPA agrees with the DOE assertion that a method of quantification other than NDE is not necessary for the waste containers within the scope of NDE radiography.

- EPA reviewed CCA Sections 4.4 (p. 4-49), 4.4.1.2 (pp. 4-53, 54); Appendix WAP of the CCA; and the Section 10 of the QAPP, to evaluate the appropriateness of the scope and scale of NDE that will be employed in waste characterization activities. EPA determined that NDE would be utilized on all retrievably stored waste containers. However, visual examination (VE) will be employed for all retrievably stored waste containers that are repackaged, on all newly-generated waste containers, and on any retrievably stored waste containers that are not suitable for radiography. In addition, visual examination of a statistically selected sample of drums subject to NDE radiography will be performed (Appendix WAP, pp C6-1 to C6-3). EPA determined that DOE adequately identified the scope and scale to which NDE methodology is applied to newly-generated and retrievably stored wastes. EPA also determined that visual examination is appropriately used to confirm NDE radiography results.

- EPA reviewed the QAPP, Section 10, and the Methods Manual, Method 310.1, to evaluate the adequacy of quality assurance objectives and quality control procedures in place for NDE activities. EPA determined that DOE adequately identified and addressed quality assurance objectives for completeness, accuracy, precision, and comparability. EPA concluded that DOE has adequate training and oversight controls for NDE radiography operators.

- EPA prepared procedurally based audit requirements and checklists as part of waste characterization audits of Los Alamos National Laboratories (LANL) and Rocky Flats Environmental Technology Site (RFETS). These checklists were used to verify that generator sites NDE radiography procedures and instrumentation were adequate and reflected the requirements established by DOE for the scale and quantification of waste containers. EPA reviewed site-specific NDE procedures at LANL during the waste characterization certification audit of May 1997 and follow-up audit of August 1997. EPA concludes that LANL adequately demonstrated NDE procedures for selected waste streams. Also, EPA reviewed site-specific procedures during the RFETS audit of June. Although the RFETS radiography procedure appeared adequate, further review of RFETS will be necessary prior to approving the NDE system there.

- During the May 1997 audit at LANL and the June 1997 audit at RFETS, WIPP Waste Certification Audit Team members discovered the NDE radiography systems had difficulty detecting cellulosics in lead-lined drums. This difficulty arose because a higher energy X-ray must be used to scan through the lead lining. The higher energy X-ray scans past the cellulosics as well. This was resolved when EPA found adequate procedures in place to ensure that lead lined drums were appropriately identified and the cellulosics inside those lead-lined drums were appropriately characterized.

7.1.3 Visual Examination

- EPA evaluated the adequacy of visual examination methods in verifying adherence to the compliance limits for ferrous metals, cellulosics, plastics, rubber, water, and nonferrous metals as specified in Appendix WCL of the CCA. EPA reviewed the CCA, Sections 4.4.1 (p. 4-50), 4.4.1.2 (p. 4-54), 4.4.1.3 (p. 4-55), and 4.2.2 (p. 4-29), and Appendix BIR (Section 1, pp. 17-20; Section 2, pp. 6-7; Appendix M, pp. 1-3) to evaluate the adequacy of radiography as a physical waste characterization methodology. EPA determined that DOE adequately demonstrated that the ferrous metals content would not fall below the minimum waste limit based on the ferrous metal content of the containers emplaced in the WIPP. EPA also reviewed the Transuranic Waste Characterization Quality Assurance Program Plan for QA guidelines in Section 10 (radiography) and the Transuranic Waste Characterization Sampling and Analysis Methods Manual for procedures in Method 310.1 to evaluate the adequacy of VE as a method for quantifying cellulosic, plastic, and rubber waste components. After performing these reviews, EPA determined that DOE adequately identified visual examination as an appropriate physical waste characterization methodology to quantify waste components (including cellulosics, plastics and rubber).

- EPA reviewed the CCA, Section 4.2.2 (p. 4-29), to determine if visual examination is an adequate methodology for verifying the waste acceptance criteria that free liquids emplaced with the waste is one percent or less of the total waste volume. DOE demonstrated adequate procedures that would limit the free liquid through requirements that any waste container exceeding the one percent criteria as determined through visual examination will be rejected and/or repackaged to exclude the unacceptable characteristic. Therefore, EPA agrees with the DOE assertion that a method of quantification other than visual examination is not necessary for the waste containers within the scope of visual examination.

- EPA reviewed the CCA, Sections 4.4.1 (p. 4-50) and 4.4.1.2 (pp. 4-53, 54) for the description of how visual examination will be used to quantify the amounts of waste components (including cellulosics, plastics and rubbers). EPA also reviewed the Transuranic Waste Characterization Quality Assurance Program Plan for QA guidelines in Sections 5.3.2, 5.3.3, and 10; and the Transuranic Waste Characterization Sampling and Analysis Methods Manual for procedures in Methods 310.2 (visual examination). After performing these reviews, EPA determined that DOE adequately described how radiography would be used to quantify the amounts of waste components (including cellulosics, plastics and rubber) and free liquids in each waste container.

- EPA reviewed CCA Sections 4.4 (p. 4-49), 4.4.1.2 (pp. 4-54, 55); Appendix WAP of the CCA; and the Transuranic Waste Characterization Quality Assurance Program Plan, Sections 5.3.2, 5.3.3, and 10 to evaluate the appropriateness of the scope of visual examination that will be employed in waste characterization activities and scale. EPA determined that visual examination will be utilized on newly-generated waste containers, repackaged retrievably stored waste containers, and on any retrievably stored waste containers that are not suitable for NDE radiography. In addition, visual examination of a statistically selected sample of drums subject to NDE radiography will performed (Appendix WAP, pp C6-1 to C6-3). EPA determined that DOE adequately identified the scope and scale to which NDE methodology is applied to newly-generated and retrievably stored wastes. EPA also determined that visual examination is appropriately used to confirm NDE radiography results.

- EPA reviewed the Methods Manual for procedures in Methods 310.2 (visual examination) to evaluate if adequate quality assurance and quality control procedures are implemented to ensure the quality of visual examination results. EPA concluded that the training requirements for visual examination are adequate, and that the equipment calibration and operational checks are appropriate. EPA concluded that the frequency requirements for replicate weight measurements are adequate.

- EPA reviewed site-specific visual examination procedures at LANL during the waste characterization certification audit of May 1997 and follow-up audit of August 1997. EPA concludes that LANL adequately demonstrated visual examination procedures for selected waste streams.

7.2 WASTE CHARACTERIZATION METHOD REVIEW

7.2.1 Proposed Methodologies for Non-Destructive Assay (NDA)

Sections 4.4.2 (p. 4-55) and 4.4.2.1 (pp. 4-56, 57) of the Compliance Certification Application (CCA) present NDA as the quantitative methodology for radiological waste characterization for radionuclide inventory. EPA believes that including a basic discussion of NDA technology, the proposed systems, and the EPA review results for those systems will be helpful in understanding the EPA position in the certification rule. A more detailed discussion of the NDA methods potentially employed by the DOE is available in the Sanford Cohen & Associates report of February 19, 1998 (SCA 98).

7.2.1.1 NDA Principals and Applicability to WIPP Waste

NDA techniques are non-invasive methods allowing the radiological characteristics of a waste container to be determined without altering its physical or chemical form. By using sensitive radiation detection equipment located external to the waste container, modern NDA technologies can quantitatively describe the radiological characteristics of TRU waste to the precision and accuracy required by Quality Assurance Objectives (QAOs) in the QAPP, without the need to open the waste container. Radiation doses received by waste characterization personnel are reduced to a minimum when NDA methods are employed in place of intrusive measurement methods, making NDA the preferred choice for waste assay. Mass spectroscopy and radiochemistry also provide the precision and accuracy to meet the QAO requirements in the QAPP, but are more time consuming and have an inherently higher risk of exposure to the personnel performing the assay.

The NDA techniques approved for use on WIPP waste containers can be classified as active or passive. Passive NDA methods measure spontaneously emitted radiation produced by natural decay of the radioactive isotopes inside the waste container. Active NDA methods measure radiation produced by artificially generated reactions in the waste material. Active NDA systems utilized for assay of TRU waste generate reactions in the heavy metals within the waste using a low intensity beam of neutrons.

The radioactive materials in TRU waste naturally emit a wide variety of radiation, including alpha particles, beta particles, gamma rays, and neutrons. The alpha and beta radiation has little penetrating ability and generally is not capable of escaping from the waste container. This makes them of little use for non-destructive assay. Depending on the waste material, gamma rays and neutrons with certain amounts of energy are capable of escaping the waste material and container, and carry with them information concerning the radioactive material from which they were produced.

The neutron counting systems being used for NDA of WIPP waste containers are designed to provide quantification of the plutonium isotopes in TRU waste. Neutrons are naturally produced by only a small number of isotopes; the rate at which neutrons of certain energies are produced by the waste container provides a good measure of the quantity of these isotopes. Passive neutron counting systems detect these naturally occurring neutrons and use various computational techniques to relate their quantity to isotopic activities. Many NDA systems using neutron counting are also capable of active counting. In the active mode, a low intensity beam of neutrons is fired into the waste container. This neutron beam will produce a series of reactions in the fissionable and fissile isotopes within the waste, with the number of particles produced by the reactions being proportional to the amount of fissile and fissionable isotopes present in the waste. The external detectors then count these particles and convert the particle response to source strength. By using active NDA methods and special sensitive neutron detectors, even very small quantities of plutonium in the waste containers can be detected and quantified.

The gamma ray measurement systems being used to characterize WIPP waste containers are based on two basic principals. First, almost all radioactive materials produce gamma rays. Second, the gamma ray pattern produced by any isotope is unique to that isotope; no two isotopes produce the same number of gamma rays having the same energies. Given a detector with good enough resolution to individually count the various gamma rays and a method to figure out what the gamma ray energy patterns mean, it is possible to quantitatively determine the isotopes present in a waste sample. Modern radiation detectors coupled to sophisticated computer programs that solve the energy pattern for the presence of certain isotopes are capable of performing this task for a large number of isotopes. The gamma measurement systems approved for use in characterizing WIPP waste are capable of quantifying the presence of many of the isotopes defined by 40 CFR Parts 191 and 194, even in the presence of potential interfering isotopes and background radiation.

When the gamma and neutron NDA systems are used together, these systems provide a great deal of information about the radiological content of a waste container with precision and accuracy sufficient to meet the QAOs specified in the QAPP. The information which can be produced by the WIPP waste NDA systems includes, but is not limited to, ^{239}Pu equivalent activity, ^{239}Pu fissile gram equivalent, total alpha activity, the decay heat of waste containers, and the activity of the isotopes of interest from the performance assessment and the applicable regulations. The purpose of these data relative to long-term repository compliance with 40 CFR Parts 191 and 194 is to provide, on a container basis, corroborative data relating to the radionuclide content emplaced in the repository. This information permits keeping a running inventory of the activity of the TRU waste emplaced in the WIPP disposal system.

All assay systems using radiation detection methods must be calibrated using a variety of standards that simulate the various waste compositions, source distributions and interferences common to the waste streams originating form a particular generator site. Acceptable knowledge enhances the NDA systems by providing advance information on the radiological characteristics of a waste stream, which allows the NDA systems to be made particularly sensitive to that type of waste by developing realistic calibration standards. Calibration records and expected system performance curves are compared against the actual results of the measurements performed on the waste containers. Waste containers with results outside the expected norms for their waste stream are isolated for further analysis. This provides both a feedback check on the acceptable knowledge and an ongoing check of the system calibrations.

A variety of NDA technologies (e.g., segmented gamma scanner, tomographic gamma scanner, passive neutron coincidence counter, and gamma spectroscopy) may be effective in meeting the requirements of the QAPP. A number of such instrument systems are available or in use at various DOE and/or contractor testing facilities. Prior to any of these systems being used for NDA of TRU waste intended for the WIPP, a number of conditions must be met. The system must be shown to meet the QAOs contained in the QAPP when used to assay the type of waste streams for which the system is being proposed. Whenever applicable, the assay procedures cited in American Society for Testing and Materials (ASTM), and the Nuclear Regulatory Commission (NRC) standard practices and guidelines must be incorporated into the system calibration and operating procedures. All analysis software, system procedures, and records systems must be shown to meet the requirements of the Nuclear Quality Assurance standards defined by the applicable Quality Assurance plans. The methods and systems must also undergo inspection by the CAO and any applicable regulatory agencies in order to ensure that the various requirements are being implemented.

7.2.1.2 Neutron Detection and NDA

Because they have no charge, and are not purely an electromagnetic packet like gamma rays, neutrons have a unique set of interactions with matter. They do not interact with the electron cloud around a nucleus, but rather with the nucleus itself. Thus, when a material absorbs neutrons, the neutrons are interacting with and changing the nuclei of the atoms in the absorbing material, which can produce a number of secondary reactions. Neutron interactions with nuclei may result in the disappearance of the neutron and it's replacement by secondary radiations, or a significant change in the neutron's energy or direction. It may even result in the fragmentation of the nucleus with which it is interacting, in a process known as fission. The secondary radiations produced by neutron interactions are usually heavy charged particles; it is these charged particles produced by the conversion of the neutron energy that is seen by neutron detectors, as discussed below. Generally, the type and probability of the various neutron interactions with any given type of nucleus depend strongly on the energy of the neutron. NDA systems do not require exact measures of neutron energy. For NDA purposes, neutrons can simplistically be divided into two categories based on their energy, high energy or "fast" neutrons, and low energy or "slow" neutrons, using an arbitrary energy cutoff of approximately 0.5 electron volts (eV). The primary focus in NDA is slow neutrons, as discussed below.

Neutrons are measured indirectly by detecting secondary particles resulting from interactions of neutrons with target nuclei. These possible interactions include:

- (n,p) or (n,α)[33] reactions where a nucleus absorbs a neutron and emits a charged particle which, along with the recoil product nucleus, cause ionization in the detector;

- neutron induced fission, or (n,f) reactions, where the detector registers ionization produced by the fission fragments or the prompt or delayed neutrons and photons; and/or

- neutron scattering, where the recoil nucleus produces ionization in the detector.

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[33] The typical notation for this type of interaction presents the incoming particle and the product of the interaction in parentheses, but does not specify the target. For example, the notation (n,p) indicates a reaction of a neutron, n, with an unspecified target to produce a proton, p. The notation (n,a) indicates a neutron induced interaction that produces an alpha particle, (n,f) indicates a neutron induced reaction that causes fission, (n,n') indicates a neutron induced reaction that produced another neutron, etc.

The probability of any certain type of reaction occurring per unit of path length traveled by the neutron is called the cross section for that reaction. The concept of cross section as applied to NDA is discussed below.

The (n,p), (n,α) and (n,f) reactions are of greatest interest for neutron detection because they produce secondary radiations that are charged particles which can be detected directly. The neutron detectors most widely used in NDA systems are gas proportional detectors filled with a light isotope of helium (He-3). These detectors are commonly called helium tubes; a neutron detection system typically contains many helium tubes, maintained under applied voltage, or electric field. The neutron-helium reaction of interest is shown below:

$$\text{He-3} + n \rightarrow \text{H-3} + p + 0.764 \text{ MeV}$$

Helium is used because it has a high cross section for interaction with thermal neutrons, which provides a high detection efficiency and pulse height resolution. The charge liberated by the neutron-helium interaction produces initial ionizations of helium gas. By maintaining the appropriate electric field within the gas, the number of secondary ionizations produced is proportional to those produced initially while the number of actual ion pairs is multiplied by a factor of many thousands. The detection system collects the ion pairs as charge which, with proper calibration, is correlated with the number of neutron interactions and therefore the sample reaction rate.

Because the probability of neutrons interacting with target materials is a strong inverse function of the neutron's energy, high energy neutrons produced by spontaneous or induced fission ("fast" neutrons) must be slowed before they can be efficiently detected. This occurs through multiple collisions with atoms in the materials within the detection system, i.e., polyethylene, graphite. The probability of any neutron interactions occurring is represented by the concept of cross section, defined as the probability per unit path length of a specific interaction. For NDA purposes, cross section can be considered the likelihood of a neutron interacting with a target nuclei within the TRU waste being assayed. Neutron cross sections are interaction specific, i.e., there is a different cross section for fission, elastic scattering, inelastic scattering, (n,p) reaction, and each is strongly dependent on the neutron energy. Cross sections are also material specific. Certain elements have large cross sections for absorption meaning that they are more likely to absorb a neutron and therefore interact, and these attributes affect the choice of material for neutron detection systems.

Assays of TRU wastes by measuring the neutrons emitted by spontaneous fission are called "passive" mode assays; "passive" mode assays measure Pu-240. Neutrons are also emitted by TRU radionuclides in response to induced fission caused by bombardment with energetic neutrons supplied by the measurement system. Such assays measuring induced neutrons are called "active" mode assays. "Active" mode assays provide information for Pu-238, Pu-239 & Pu-241 as well as other fissile isotopes present in the TRU waste being assayed, e.g., U-235, that fission in response to neutrons supplied by the measurement system.

The main source of neutrons of interest to NDA result from spontaneous or induced nuclear fission, the disintegration of an atomic nucleus into two or more lighter fragments. In general, isotopes of plutonium and uranium have a low rate of spontaneous fission compared to the rate of alpha emission, particularly TRU radionuclides with odd numbers of neutrons and therefore, odd mass number. They can be made to undergo induced fission by bombardment with low energy neutrons, for example U-233, U-235 and Pu-239. Plutonium isotopes with even mass numbers (Pu-238, Pu-240 & Pu-242) undergo higher rates of spontaneous fission, and for Pu-240 the rates of spontaneous fission and alpha emission are close. This is important since Pu-240 is typically present as an impurity in weapons grade plutonium and is a component of TRU wastes.

7.2.1.3 Photon Emission and NDA

Photons in the general sense are packets of electromagnetic energy, and are the basic constituents of any electromagnetic energy including visible light. When these photons are generated by de-excitation reactions in an atomic nucleus, they are often referred to as gamma radiation or gamma rays. Gamma photons are essentially the same as x-rays, but have different origins; gamma radiation is emitted during changes in the state of nuclei, while x-rays are emitted during changes in the state of inner or more tightly bound electrons. Gamma radiation is a penetrating radiation best attenuated by dense materials like concrete and lead. Gamma emissions occur at discrete energies that are characteristic of specific radionuclide transitions, enabling their identification by spectroscopic techniques, as discussed below. Gamma photon emissions range in energy from approximately one thousand electron volts (1 KeV) to almost ten million electron volts (10 MeV). For purposes of NDA isotopic measurements of plutonium, the photon emissions of interest occur between the energies of approximately 40 to 640 KeV; for uranium, the photon emissions of interest occur between approximately 100 KeV and 1 MeV in energy.

Their electromagnetic nature causes photons to interact strongly with the charged electrons in the atoms of all matter. The photon gives up energy to an electron, which then is released from its parent atom and collides with other atoms, liberating more electrons. The total charge released is proportional to the photon energy, since the higher the photon energy the more energy is available to release electrons. The charge resulting from this cascade of released electrons is then collected, causing a signal indicating the presence of the gamma photon. The magnitude of the signal tells the energy of the photon since the electrical signal output to the detector is proportional to the energy deposited in the detector. After a large number of these gamma photons have been detected, a graph of the number of gamma photons measured versus the energy of the photons can be displayed. This graph, or spectrum, results in a "fingerprint" of specific radionuclides since the gamma photon energy release pattern is unique for each isotope. With the appropriate calibration, the spectrum allows identification and quantification of photon emitting radionuclides in various media.

There are many types of materials suitable for use in photon detectors. The NDA systems of interest primarily use modern solid state detectors constructed from germanium, in which the charge produced by the photon interactions is collected directly. Germanium is the semiconductor material of choice for modern photon detectors due to its nearly ideal electronic characteristics that allow electrons and "electron holes" to move freely. The ionization charge resulting from the photon interaction within the detector is swept to an electrode by the high electric field in the semiconductor material produced by the voltage applied to the detector with the system's high voltage power supply. The charge is converted to a voltage pulse by a preamplifier; this voltage is then amplified and sent to a multi-channel analyzer, which displays the spectrum of gamma counts detected versus energy. Spectroscopic evaluation, including radionuclide identification by energy peak pattern, background correction, pulse height determination, etc., can then be performed on the spectrum either manually or by computer. By applying calibration and correction factors appropriate to the waste matrix, container and radionuclides, the spectroscopic data can be transformed into concentrations of specific photon emitting TRU radionuclides.

7.2.1.4 Systems for NDA at WIPP Generator Sites

LANL, RFETS, and Idaho National Engineering Laboratory (INEEL) use various NDA systems. Equipment at LANL includes a Passive Gamma System, a Tomographic Gamma Scanner, a High Efficiency Neutron Counter, and a Passive-Active Neutron Counter. The Environmental Science and Waste Technology Group operate all WIPP-related assay equipment within LANL's Chemical Science and Technology Division.

NDA activities at RFETS involve personnel from three site contractors (Rocky Mountain Remedial Services, Safesites of Colorado and Dyncorp) using RFETS fixed-base assay systems. In addition, Canberra Industries recently characterized 450 drums of TRU waste for RFETS using its mobile equipment on site. To date, RFETS has limited experience assaying TRU waste in accordance with the WIPP Data Quality Objectives and the WIPP waste acceptance criteria (WAC). In 1996, responsibility for NDA was transferred from the Safeguards Management Group to the Waste Management Group at RFETS.

The NDA equipment at INEEL consists of a passive-active neutron counter and the Stored Waste Examination Pilot Plant (SWEPP) Gamma Ray Spectroscopy system, a segmented gamma scanner. INEEL has been actively involved in the development of computer software for specific NDA systems and the NUC 2 C^{++} developed by INEEL probably represents the most advanced approach currently available for TRU assays using a passive-active neutron counter.

Each of the systems in place at the generator sites relies on either neutron or gamma assay methods, or on some combination of the two. The following discussion describes the various systems.

<u>Neutron Systems</u>

There are many types of neutron based NDA systems available for assaying TRU wastes. Carlsbad Area Office (CAO) recommends the use of assay procedures published by the American Society for Testing and Materials (ASTM) and the U.S. Nuclear Regulatory Commission (NRC), when applicable (AST 89a), (AST 89b), (AST 91), (AST 92), and (NRC 84). Table 7-1 lists three categories of neutron assay methods of potential applicability to WIPP. This section focuses on the Passive-Active Neutron (PAN) system that is currently used by the three TRU waste generator sites evaluated in this report. This system is based on a second generation PAN unit developed initially at LANL in the mid-1980s that has undergone continual developmental upgrades in hardware and software at LANL and INEEL. The PAN system is based on basic detection techniques for measuring neutrons described in the previous section and combines passive and active mode assays. The system consists of an enclosed assay chamber, neutron moderating and shielding materials, and a neutron generator and detector assembly. A turntable assembly continuously rotates the drum 360 degrees during both active and passive assays. Detectors assemblies (helium tubes) surround the waste drum. Each assembly is a "detector package" consisting of a combination of shielded and unshielded detectors. The shielded detectors are surrounded by cadmium and borated rubber and are sensitive only to fast neutrons; the unshielded (bare) detectors are sensitive to thermal neutrons (INE 94). The PAN system measures either: (1) prompt neutrons emitted by spontaneous fissions in the "passive" mode; or (2) neutrons emitted in response to fissions induced by thermal neutrons generated by the measurement system in the "active" mode. The system assays waste drums in both modes sequentially, using multiple shielded and unshielded detectors. Passive mode data are time-correlated using "coincidence counting," described in section below. In practice, PAN systems perform the passive assay first, followed by the active assay, with typical measurement times of 100 to 1,200 seconds for passive mode assays, and less than 100 seconds for active mode assays (INE 94). The passive assay provides information that assay personnel refer to as the "moderator index;" the active assay provides the "absorber index." These indices are used to indicate that the waste materials in the drum being assayed are compatible with the range of conditions for which correction and/or calibration factors have been developed.

Table 7-1. NDA Methods for Potential Use for TRU Waste Assay

Types of Measurements	Methods
Passive Neutron Measurements	Shielded Neutron Assay Probe Totals Counter Passive Neutron Coincidence Counter Advanced Matrix Corrected Passive Neutron Counter (Add-A-Source)
Passive/Active Neutron Measurements	Am-Li Source Driven Coincidence Counter Californium Delayed-Neutron Counter (Shuffler) Neutron Generator Differential Die-Away Counter Combined Thermal/Epithermal Neutron Counter
Thermal Neutron Capture	Californium Delayed-Neutron Counter Neutron Generator Differential Die-Away Counter Combined Thermal/Epithermal Neutron Counter

(Source CAO 96a)

Total Neutron Counting - All plutonium isotopes emit neutrons, and the presence of specific chemicals in TRU wastes can produce enhanced neutron emission from (α,n) reactions (i.e., beryllium and fluorine compounds). Other chemicals, i.e., cadmium and boron, act as neutron "poisons" and depress the observed neutron emission rate. Neutron production from spontaneous fission depends only on the sample's isotopic composition. In contrast, neutron production from (α,n) reactions depends on the sample's chemical form <u>and</u> isotopic distribution. The considerable differences in neutron production attributable to the sample's chemical form and their importance are illustrated by comparing the neutron production rates in plutonium metal, PuO_2 and PuF_4 for three isotopic compositions. See Table 7-2 (PAS 91). For example, a dramatic increase in (α,n) neutron production follows the presence of fluorine compounds for virtually all plutonium isotopes, as well as Am-241. Total neutron counting is most applicable for samples in which: (1) the material's physical, chemical and isotopic distribution are known to be essentially homogeneous; (2) neutron emission is dominated by spontaneous fission or (α,n) reactions; and (3) induced fissions would complicate the assay. Two examples are assaying uranium or plutonium metal where spontaneous fission neutrons dominate and assaying UF_6 or PuF_4 where (α,n) produced neutrons dominate.

Table 7-2. Primary Neutron Production Rates in Plutonium Metal, Oxide (PuO_2) and Fluoride (PuF_4) For Three Plutonium Isotopic Compositions, Including Contribution from Am-241

		Neutron Production Rates per 100 g Pu in neutrons/second		
Isotope	Weight %	Pu Metal spontaneous fission	PuO_2 (α,n)	PuF_4 (α,n)
Pu-238	0.024	62	322	52,800
Pu-239	89.667	2	3,416	502,135
Pu-240	9.667	9,838	1,360	202,545
Pu-241	0.556	0	1	95
Pu-242	0.109	187	0	29
Am-241	0.327	0	880	144,417
Pu-238	0.059	153	791	129,800
Pu-239	82.077	2	3,127	458,631
Pu-240	16.297	16,623	2,298	342,237
Pu-241	1.231	0	2	209
Pu-242	0.336	578	1	91
Am-241	0.162	0	436	71,546
Pu-238	1.574	4,077	21,092	3,462,800
Pu-239	57.342	1	2,185	321,115
Pu-240	24.980	25,480	3,522	524,580
Pu-241	10.560	0	14	1,795
Pu-242	5.545	9,537	11	1,497
Am-241	1.159	1	3,118	511,863

(Source PAS91)

Because TRU wastes typically consist of materials that are more heterogeneous with respect to their physical, chemical and isotopic distribution, total neutron counting is of limited applicability to WIPP assays. NDA techniques must be sufficiently robust to identify and correct for a variety of sample conditions within a waste drum. For this reason, assay systems rely predominantly on passive and/or active mode neutron assays that are discussed in subsequent sections.

Passive Neutron Counting - Passive neutron assay is based on measuring prompt neutrons caused by the spontaneous fission of fissile material within the waste, i.e., Pu-238, Pu-240 and Pu-242. These fissions typically produce two to three neutrons per event (EDF 95a). This contrasts to other neutron-producing reactions, particularly (α,n) reactions caused by energetic alpha particles interacting with low atomic number (low Z) materials present in TRU wastes (i.e., boron and fluorine) that produce a single neutron per event.

To discriminate the multiple neutrons produced by spontaneous fission from single neutrons produced from (α,n) reactions, the technique of coincidence counting is employed. The two to three neutrons produced from a single fission event are closely time-correlated, since they occur at precisely the same time. By contrast, (α,n) events produce neutrons that occur at random. Coincidence counting involves establishing a time interval, called a "gate," during which simultaneous neutron detection events will be recorded (INE 94). When a neutron is detected, the "gate" is opened and all events occurring within the gate period are recorded. In theory, multiple fission neutrons should maintain their original time-correlation. However, the original time correlation period may be extended as a result of the neutrons slowing down (thermalizing) and being detected (INE 94).

Two “gates” are typically used: a “short gate” of 35 μseconds using the signals from only the shielded detectors; and a “long gate” of 200 μseconds using the summed output from all detectors (shielded and bare). The shielded detectors are generally less affected by random or uncorrelated neutrons. Counting data from both gates may be averaged or, more typically, are evaluated relative to instrument specific criteria, which results in the use of data from a single gate. However, for high count rates the use of gating techniques results in losses due to the coincidence gates becoming saturated (SHU 91) (PAS 91) (INE 94).

This limitation can be overcome through the use of a “shift register” correction. The mechanism for this correction can be described briefly as generating a new “gate for each input” pulse; all events within the gate are counted (EDF 95a) (PAS 91). The PAN systems at LANL and INEEL will be upgraded to include shift register-based coincidence electronics in the future; we are not aware of a schedule to upgrade the PAN system at RFETS.

Correlation of the detector's response to actual drum conditions is complex due to the variety of a waste’s physical form and its spatial distribution within a drum. This is difficult to represent mathematically and is typically modeled using Monte Carlo Neutron Photon (MCNP) calculations (EDF 92a) (PAS 91). MCNP calculations develop a three dimensional geometrical representation of the assay system which is then used to produce correction factors specific to waste matrices, drum component configuration (geometry), and densities typical of a class of wastes (content code, TRUCON Code) (EDF 94a) (EDF 94b).

Passive neutron counting is appropriate for assaying all plutonium wastes that contain Pu-240. The advantages of passive assays are their low sensitivity to the perturbing effects of waste matrices and their ability to provide good discrimination against uranium. As long as the fission-produced fast neutrons are not thermalized, passive mode assays are relatively insensitive to matrix heterogeneity. However, the passive assay has relatively poor sensitivity, does not measure a drum’s fissile content directly, and suffers from a lack of precision when (α,n) background rates are high (INE 94). Passive mode assays are also prone to positive bias for large plutonium gram loadings. This occurs due to the TRU materials spontaneous fissions-produced fast neutron causing additional fissions, e.g., multiplication effects. The probability of "false" or accidental coincidence rates increases when a waste drum's (α, n) neutron production is high and must be taken into account by the system's algorithms.

As with all assay techniques, limitations arise when the material being assayed does not match the assumptions upon which the system calibration is based. When information regarding the waste's physical nature is incomplete or inadequate, these limitations may be considerable. Additional technical limitations are discussed in Section 7.2.1.6.

Passive neutron counting was originally developed for use by DOE safeguards personnel for purposes of nuclear materials accountability, which requires tracking of plutonium and all special nuclear materials at the gram level (RFP 92) (RFP 93a). Assaying WIPP TRU waste involves essentially the same procedure as is used for safeguards determinations. However, WIPP assays require greater analytical sensitivity than is normally employed in safeguards assays, and TRU waste generator sites have typical detection limits on the order of tens of milligrams per 55-gallon drum (INE 94). For example, the Quality Assurance Objectives (QAOs) specified for TRU wastes identify four categories according to alpha Curies (CAO 96a). These values are correlated to the mass of weapons grade plutonium as indicated[34] in Table 7-3.

Table 7-3. Correlation of Weapons Grade Plutonium Alpha Activity and Mass

α Curies	Equivalent Weapons Grade Pu Mass (grams)
>0 to 0.04	0 to 0.5
0.04 to 0.4	0.5 to 5
0.4 to 4	5 to 50
>4	>50

(Source CA0 96a)

To meet the WIPP QAOs, DOE TRU generator sites' NDA systems must meet a level of analytical sensitivity such that the plutonium mass values listed in Table 7-3 are routinely achievable. Some TRU generators, i.e., LANL, have developed and implemented procedures reflecting this greater sensitivity, as well as other quality assurance requirements specific to WIPP. RFETS and INEEL have also begun to address the need for greater sensitivity by revising their technical and quality assurance procedures. By developing the TRU QAPP and QAOs for NDA (CAO 96a) and the WIPP WAC (DOE 91a), CAO has established an internal standard for NDA measurements that must be met for all wastes shipped to WIPP.

As discussed previously, passive mode neutron assays involve measuring time-correlated fast neutrons produced by the spontaneous fission of even mass number plutonium isotopes, of which Pu-240 is the major contributor. Passive mode assays of Pu-240 are the empirical basis for deriving mass values for Pu-238, Pu-239, Pu-241, and Pu-242. These data are calculated by

[34]See Table 7-5, which provides the Quality Assurance Objectives (QAOs) imposed on TRU waste generators for NDA as required by CAO (CAO 96a).

determining the ratio of plutonium isotopes in the waste sample (the isotopic distribution). This ratio is then applied to the empirically-derived Pu-240 mass to obtain mass values for Pu-238 through Pu-242. Because of the importance of the isotopic distribution, this value is best determined empirically using gamma spectroscopy.

The software used in neutron-based data reduction systems is dependent on waste matrices and the specific configuration or spatial arrangement of the waste drum contents. It is difficult to reproduce such calculations manually and data reduction and calculation rely on computer-based techniques such as radionuclide decay and ingrowth calculations and Monte Carlo Neutron Photon (MCNP) modeling. MNCP is a three dimensional Monte Carlo transport code developed at LANL (BRI 86). It obtains solutions by simulating individual particles and recording aspects of their behavior using statistical sampling of probabilistic events for neutron interaction for each drum. The MCNP data are then used to evaluate the matrix correction factors integral to the neutron assay system. The MCNP methods and models are well characterized, and have become the industry standards for statistical transport calculations.

Active Neutron Counting - Active mode assays involve the measurement of fast neutrons emitted in response to fissions of odd mass number fissile isotopes within the waste. The fissions are produced by interrogating waste drums with thermal neutrons which are typically produced by a deuterium-tritium (d,t) generator mounted to the wall of the assay chamber. The generator supplies 14 MeV neutrons in a pulsed mode (PAS 91) that are thermalized through interaction with the assay chamber walls and the waste matrix. Some systems use Cf-252 as the neutron source. Conceptually, a uniform thermal neutron flux would be created throughout the waste matrix; however, this is heavily matrix-dependent and does not actually occur (EDF 91a) (EDF 94a). These "matrix effects" are limitations of this assay method.

In theory, this technique provides a high sensitivity for Pu-239 in a relatively short counting time, i.e., 40-100 seconds for as little as 15 mg of Pu-239. However, significant interferences arise when waste drums have nonuniform matrices (i.e., heterogeneous) and fissile source distributions. Self-shielding of lumps of fissile material also poses a considerable problem; these effects can be considerable for spherical masses as small as 200 μg (INE 94). Active mode assays do not offer the means to discriminate between uranium and plutonium and are heavily matrix-dependent.

Photon Methods

There are several types of photon based measurement systems that are applicable to WIPP assays. Two main approaches are Transmission Corrected Gamma Spectroscopy, called a Segmented Gamma Scanner or SGS, and High Resolution Passive Gamma Spectroscopy. Both are discussed in this section. The only method that has been certified is the High Resolution Passive Gamma Spectroscopy at LANL.

Segmented Gamma Scanner - The photon-based assay system in use at LANL, RFETS, and INEEL to determine a waste drum's isotopic distribution is the segmented gamma scanner

(SGS). A typical system consists of a germanium photon detector, which derives a correction factor for each drum being assayed. The correction factor provides a numerical adjustment that corrects for the attenuation of the waste drum's photons caused by the sample matrix, the detector assembly, and the drum itself. This correction factor is waste drum specific and is used as part of the assay algorithm to calculate the detection system's efficiency and provide meaningful data on TRU radionuclides present in the drum. The system contains a transmission source (i.e., a radioactive source) placed close to the side wall of the waste container. The source is typically collimated or focused using lead or tungsten. The source of transmission choice for plutonium measurements is selenium 75 (Se-75), with a typical strength of 10 mCi, which provides sufficient photon emission for approximately a year based on its 120 day half life (LED 67). Ideally, the transmission source's photon energy would be in the same range as the radionuclides measured. Se-75 has strong photon lines at 136 (57%)[35], 265 (60%), and 280 (25%) KeV (LED 67). These energies correlate closely with photon energies used for isotopic plutonium determinations (PAS 91). For assays of U-235, ytterbium 169 (Yb-169) is the preferred transmission source, with photon lines at 110 (18%), 131 (11%), 177 (22%), and 198 (35%) KeV (LED 67) (PAS 91).

Directly opposite the transmission source is a solid state photon detector; the waste container is placed between the transmission source and the detector and moved in the vertical axis systematically through a predetermined series of positions called "segments," that cover the height of the drum. The transmission source "scans" the container in each "segment." Since the source's intensity is known, the effect of the waste material on the source's intensity for each segment can be observed by noting the response of the detector on the other side of the waste drum in line with the source's photon beam. This is a measure of photon attenuation by the waste matrix and the drum. Many operational details involving SGS operation are instrument and/or site specific, for example, the number of segments per scan, the counting time for each, and the degree of segment overlap. These data are then interpreted using a computer-based algorithm to develop a correction factor[36] specific to the container and the waste it contains. Next, the container is assayed with the transmission source shielded, the data are corrected using the correction factors obtained previously in the scanning mode, results are calculated, and the assay is complete. The data are used to establish the drums distribution of plutonium isotopes for

[35]Photon emissions exhibit a discrete, characteristic energy. However, a radionuclide may not emit a photon for each nuclear transformation. For example, Se-75 emits a photon at 136 KeV in 57% of its transitions, a photon at 265 KeV in 60% of its transitions. The percentage of transitions in which a photon emission occurs is referred to as the Transition Probability or Gamma Abundance and is shown in this report in parentheses following the photon energy.

[36]This correction factor is also called an attenuation factor or transmission factor.

neutron measurements. They may also be used to indicate the presence of other gamma-emitting radionuclides that are potential interferences for neutron and/or photon determinations, i.e., Am-241, U-235 or Np-237.

A recent development is the use of tomographic imaging capabilities in conjunction with SGS technology. This technique provides the ability to locate photon-emitting sources within a waste drum and to develop a computerized map of the drum's content showing areas of different levels of photon activity. It is equivalent in general terms to computer-assisted axial tomography (CAT) scans performed for diagnostic medical purposes. While it is not clear that this technology is required to ensure compliance for all waste drums, it could be helpful for extremely heterogeneous drums or instances in which established drum calibrations are questionable or problematic. For example, chunks of plutonium metal in waste drums may provide anomalous correction factors if their response is averaged over an entire segment. Tomography provides the means to identify and locate the chunk, thereby providing more accurate data.

SGS transmission correction factors are typically averaged over an entire segment of the waste container. As a result, problems associated with high-Z materials, lumps of plutonium metal, and heterogeneous matrices can cause SGS instruments to underestimate the amount of plutonium in a waste container. This is related to the more general problem of sample self-absorption (self-shielding). For example, a 0.02 centimeter (cm) diameter plutonium (Pu-239) metal sphere will absorb approximately 4% of its 414 KeV photons; similarly, a uranium (U-235) sphere of the same diameter will absorb approximately 15% of its 186 KeV photons (SHU 91). It is not currently possible for TRU generators to adequately correct for self-shielding.

Passive assay systems - The simplest type of gamma assay system for determining the distribution of plutonium is a passive assay system. This system typically uses a high resolution gamma detector appropriately positioned relative to a waste container, shielding, and data reduction software. A system of this type was observed at LANL in September 1997, and is the assay system approved by CAO for use in certifying WIPP wastes.

Photon-based NDA determinations are generally well suited for determining the distribution of plutonium isotopes in TRU waste drums. However, the limitations typical of photon detection systems used for routine isotopic analyses also apply to NDA measurements, in particular, rate-related losses such as dead time-pileup corrections. These limitations are addressed by use of an additional or reference source of the appropriate energy depending on the assay of interest, i.e., Ba-133 for Pu-239 assays and Cd-109 for U-235 (PAS 91).

Table 7-4 lists the photon emission lines typically used for NDA determinations of a waste drum's isotopic distribution (PAS 91). Because of their low transition probabilities (gamma abundance) and energy (LED 67), photon determinations of plutonium radionuclides are prone to negative bias when determining mass or gram loading for dense waste matrices such as metals, sludges, debris wastes, and cemented sludges. Additionally, SGS transmission sources are limited in their ability to penetrate dense waste materials, thereby restricting the maximum gross weight of waste drums assayed by SGS.

The energy spectrum data provided in Table 7-4 indicate the importance of Am-241 for gamma determination. Pu-241 decays predominantly by beta to Am-241 (99.998%). However, approximately 2.46 x 10^{-3}% of the Pu-241 transitions are by alpha emission to U-237 (PAS 91) which emits photons at 165 (2%), 208 (23%), 267 (0.76%), 332 (1.4%), and 370 (0.17%) KeV (LED 67) (PAS 91). Because some of these U-237 photon emissions occur at the same energies as photons from Am-241, there is a potential for interferences when using the Pu-241 and lower energy U-237 photon lines for a gamma-based plutonium isotopic determination. Their use requires correction for the effects of any Am-241 present in the waste drum.

Table 7-4. Photon Emission Lines Used for Determining Isotopic Plutonium Distribution In TRU Wastes, Including Am-241

Region (keV)	Pu-238		Pu-239		Pu-240		Pu-241		Am-241	
	KeV	γ/s-g	Kev	γ/s-g	KeV	γ/s-g	KeV	γ/s-g	KeV	γ/s-g
40 - 60	43.48	$2.49x10^8$	51.63	$6.19x10^5$	45.23	$3.80x10^6$			59.54	$4.45x10^{10}$
90 - 105	99.86	$4.59x10^7$	98.78	$2.80x10^4$	104.24	$5.86x10^5$	103.68	$3.86x10^6$	98.95 102.97	$2.57x10^7$ $2.47x10^7$
120 - 450	152.68	$6.05x10^6$	129.29 203.53 345.01 375.04 413.71	$1.44x10^4$ $1.28x10^4$ $1.28x10^4$ $3.60x10^4$ $3.24x10^4$	160.28	$3.38x10^4$	148.57 164.58 208 332.35 370.93	$7.15x10^6$ $1.73x10^6$ $2.04x10^7$	125.29 335.4	$5.16x10^6$ $6.28x10^5$
450 - 800	766.41	$1.39X10^5$	645.97 717.72	$3.42x10^2$ $6.29x10^1$	642.48	$1.05x10^3$		$1.14x10^6$ $1.04x10^5$	662.42 721.99	$4.61x10^5$ $2.48x10^5$

(Source PAS 91)

Other TRU or actinide radionuclides may be present in sufficient quantity to interfere with peak identification. For example, wastes from LANL's TA-55 Facility were originally thought to be free of interfering radionuclides, based on available acceptable knowledge. Upon closer examination, they were found to contain Np-237, Np-239, Th-232, and Am-243 in quantities that could interfere with the passive gamma assays used by LANL.

Isotopic concentrations for weapons grade plutonium are assumed to remain constant within a waste drum (EDF 94a). However, for Am-241 and U-235 this assumption is not necessarily valid, since their relative concentrations can vary within a given waste drum. Some sites, i.e., LANL, state that they are able to obtain accurate gamma assays for drums that contain isotopically heterogeneous TRU material. Most TRU generators acknowledge that significant quantities of U-235 or unsupported Am-241 can prevent an accurate determination of a drum's isotopic distribution (EDF 94c). Such drums are segregated for individualized attention.

Like neutron counting, photon assays of nuclear materials were originally developed for the purpose of accounting for special nuclear materials. Such techniques are applicable to the identification of photon-emitting TRU nuclides and determination of plutonium isotopic ratios in 55-gallon drums over a range of plutonium gram loadings. Their adaptation to certifying TRU wastes for WIPP requires consideration of technical and quality assurance related issues, particularly with respect to analytical sensitivity and achieving QAOs. LANL, INEEL and RFETS have been integrating these criteria in their NDA measurement protocols; CAO will evaluate the extent and acceptability of these protocols during quality assurance waste characterization and certification audits.

Photon measurement usually utilizes computer software for data reduction. This software typically provides the following parameters: energy versus channel calibration and determination of peak position; energy resolution measurements; determination of full-energy-peak area; corrections for rate-related losses; measurements of detector efficiency; and, following the appropriate matrix-specific calibration, relative contributions of plutonium isotopes and Am-241 (PAS 91), (AST 85), (NRC 81). Of particular importance are site specific corrections for photon attenuation within waste matrices. As discussed earlier, photon-based assays of TRU waste focus on determining the isotopic distribution within samples of weapons grade plutonium-bearing wastes. This is the determination of a ratio, rather than the absolute quantity of any one radionuclide (PAS 91), commonly expressed as the observed intensities of Pu-238/Pu-241, Pu-239/Pu-241, and Pu-240/Pu-241. This approach is not appropriate for Pu-242 due to its lack of measurable photon emission. Pu-242 cannot be determined directly, and instead, its contribution is "predicted" based on isotopic correlation techniques[37], Material Process Knowledge, or other information (GUN 80). Once the relative isotopic ratios have been determined, neutron-derived data can be used to calculate a mass value for plutonium isotopes 238 through 242, and values for FGE, PE Ci Total Alpha Activity, Total TRU Activity, and Thermal Power (PAS 91).

7.2.1.5 NDA Performance Requirements

In the TRU Waste Characterization Quality Assurance Program Plan (QAPP), DOE specifies Quality Assurance Objectives (QAOs) for NDA techniques for precision, accuracy, minimum detectable concentration (MDC), completeness and total bias (CAO 96a). CAO intends that the numerical QAOs will be used to establish minimum performance requirements for NDA measurement systems that are used to generate waste characterization data for WIPP wastes. The numerical values obtained for waste containers will be a function of the waste type, TRU content, its distribution and the characteristics of the measurement system. DOE derived QAOs for four ranges of alpha activity, based on a review of assay data for 12,205 waste drums that covered fifty Item Description Codes (IDCs), as shown in Table 7-5 below.

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[37]Because of the nature of neutron capture reactions that produce plutonium in nuclear reactors (see Section 7.1.1.1), correlations exist among the plutonium isotopes. However, the correlation for a specific material depends on the reactor type and details of the irradiation history that produced the material. See GUN 80 for a detailed discussion of Pu-242 correlation techniques.

Table 7-5. Quality Assurance Objectives for Nondestructive Assay

Range of Waste Activity in Curies[a]	Nominal Compliance Point Curies (g WG Pu)[b]	PARAMETER				
		Precision[c] (%RSD)	Accuracy[d] (%R)	Total Bias[e] (%)	Completeness[f] (%)	MDC (nCi/g)
0	0	-	-	-	-	60
>0.002 to 0.02	0.008 (0.1)	≤ 20	75-125	Low 25 High 400	100	
>0.02 to 0.2	0.08 (1.0)	≤ 15	50-150	Low 35 High 300	100	
>0.2 to 2.0	0.8 (10)	≤ 10	75-125	Low 67 High 150	100	
>2.0	12.5 (160)	≤ 5	75-125	Low 67 High 150	100	

(Source CA096a)

[a] Applicable range of TRU activity in a 208-liter drum to which the QAOs apply. Units are Curies of alpha-emitting TRU isotopes with half-lives greater than 20 years.

[b] The nominal activity for weight of Pu in the 208-liter drum used to demonstrate that QAOs can be achieved for the corresponding range in column 1, values in parentheses are the approximate equivalent weights of weapons grade plutonium (WG Pu) fifteen years after purification; for purposes of demonstrating QAOs, "nominal" means within ± 10 percent.

[c] ± one standard deviation, based on fifteen replicate measurements of a noninterfering matrix.

[d] Ratio of measured to known values based on the average of fifteen replicate measurements of a noninterfering matrix.

[e] 95 percent confidence bounds for system bias established by studies to determine contributions to total uncertainty from all significant sources. Units are confidence bound divided by true value, expressed as a percent. Requirement for the QAO for total uncertainty is to determine and document, but no system wide limiting values are established.

[f] Value radioassay data are required for all waste containers.

The vehicle for demonstrating that a facility is capable of meeting the above measurement requirements is the Performance Demonstration Program (PDP). Prior to being certified, analytical facilities that provide non-destructive assay must successfully participate in the PDP. The waste characterization manager (WCM) administers PDP tests as described in the respective program plans for each analytical facility performing TRU waste analysis activities. The WCM formally document satisfactory completion of the PDP requirements when the facility meets the requirements spelled out in the individual PDP.

The Performance Demonstration Program (PDP) is administered by the CAO and managed by the NTP Waste Characterization Manager. The PDP tests are designed to help ensure compliance with the QAOs identified in the QAPP for the WIPP. The PDP tests are intended for use by the CAO as part of the assessment and approval process for the measurement facilities supplying services for the characterization of WIPP TRU waste.

Each PDP is defined in its respective PDP Plan, which describes the detailed elements comprising the program, including the nature of the test materials and the analyses required. The PDP Plan also identifies the criteria that will be used for the evaluation of the laboratory performance, the responsibilities of the Program Coordinator, the responsibilities of the Standard Preparation Team (SPT), and the responsibilities of the participating laboratories. The CAO will ensure the implementation of the PDP Plan by designating a Program Coordinator and by providing technical oversight and coordination for the program

The Performance Demonstration Program for Nondestructive Assay consists of a series of tests conducted every six months to evaluate the capability for nondestructive assay of TRU waste by the WIPP waste measurement facilities. Each semi-annual group of tests is termed a PDP cycle. These evaluation cycles will provide an objective measure of the reliability of measurements performed with TRU waste characterization systems.

Measurement of facility performance will be demonstrated by the successful analysis of blind audit samples according to the criteria set by the PDP Plan for Nondestructive Assay. Inter-comparison between measurement facilities will be achieved by comparing the results of measurements on similar or identical blind samples reported by the different measurement facilities. Blind audit samples (also referred to as PDP samples) will be used to independently assess the performance of measurement facilities regarding compliance with the established QAOs. As defined for this program, a PDP sample consists of a 55-gallon standard drum emplaced with standards and fabricated matrix inserts. These PDP sample components, once manufactured, will be secured and stored at each participating measurement facility under secure conditions to protect them from loss, tampering, or accidental damage.

Isotopic activities in the SPT-prepared PDP samples will encompass the range of concentrations anticipated in actual waste characterization. The removable PDP sample standards will address activity ranges relative to WIPP WAC limits, QAPP QAOs, and/or NDA method detection limits. Manufactured matrices will simulate expected waste matrix conditions and provide acceptable consistency in the sample preparation process at each measurement facility. Analyses required by the WIPP to demonstrate compliance with various regulatory requirements and included in the PDP may only be performed by measurement facilities using the methods that have demonstrated acceptable performance in the PDP.

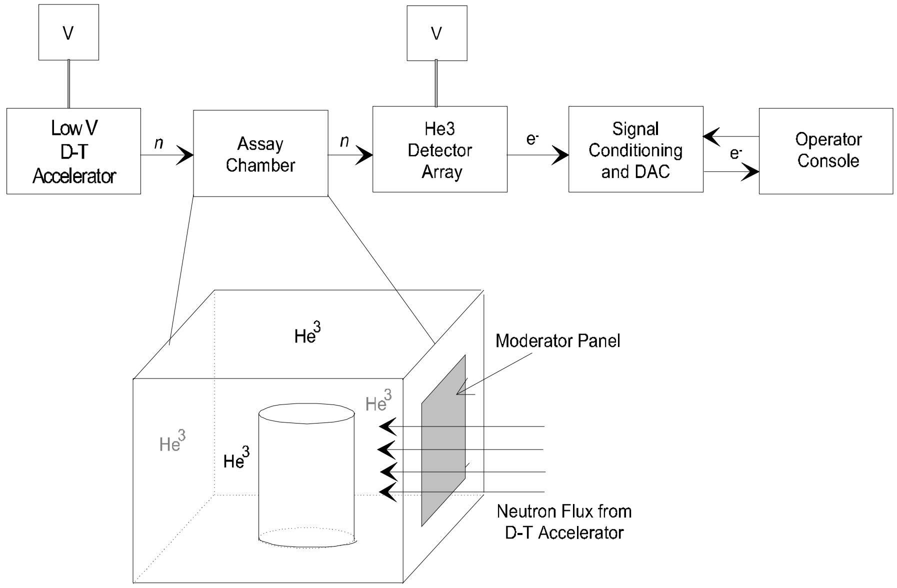
NDA instruments must meet minimum detectable concentration (MDC) requirements in addition to the QAO limits contained in Table 7-5. DOE provided a discussion of the minimum detectable concentration (MDC) for NDA, also known as the detection limit, in the QAPP, Section 9.1. The MDC corresponds to a level of activity that is practically achievable with a given instrument, analytical method and analyte/matrix combination. The MDC considers not only the instrument characteristics (background and efficiency), but all other factors and conditions which influence the measurement. The MDC required for NDA is 60 nCi/g. The 60 nCi/g standard provides a 95% confidence that any drum containing TRU waste at 100 nCi/g will be properly classified. This standard meets the requirements imposed through the WIPP performance assessment.

7.2.1.6 EPA Review

Each generator site must receive certification from the DOE prior to shipping waste to the WIPP. Part of the DOE certification process is a technical and quality assurance audit of the NDA systems and processes in place at the generator site. Additionally, EPA must approve DOE's certification. The EPA develops the information necessary to decide whether to approve certification by performing reviews of DOE documents and independent inspections of DOE NDA systems and processes. EPA inspections include technical reviews of the ability of the proposed NDA systems to meet the performance requirements when measuring specific waste streams, personnel qualification reviews for NDA staff, and procedural reviews to ensure that the NDA process is being properly controlled. Although preliminary reviews and inspections have been performed at RFETS and INEEL, the only site receiving a shipping certification at this time is LANL. This discussion will therefore describe the EPA review of the LANL NDA systems.

NDA Methods - LANL plans to use the Passive Active Neutron (PAN) system, located in Technical Area 54, to analyze WIPP waste. This system, which is based on the N2/N156 assay systems designed by Caldwell at LANL (SHU 91), assays 55-gallon drums using coincidence counting. The PAN system was developed to operate either as a passive neutron counter or to interrogate the drum with accelerator produced neutrons and count the neutrons generated by the induced fission events. The system is thus capable of active or passive neutron counting to determine the inventory of the drum being assayed. The PAN uses predetermined calibration curves for neutron absorption and moderation within the waste matrix to develop source inventory based upon count rate. Therefore, prior knowledge of the waste matrix allows (and is essential for) the assay system to be "tweaked" with specific calibration information to produce better accuracy. Although they were developed initially at LANL, these systems were used extensively at INEEL where they underwent considerable modifications prior to returning to LANL for use on the WIPP project, particularly with respect to their analysis software, NUC 2, which was installed on the LANL system two years ago. The PAN system currently reports the active assay results if they indicate less than three grams of plutonium; passive results are reported if the active assay plutonium results exceed three grams (DTP 97b). Recent work by LANL indicates a preference for using passive results, as they are less prone to bias (DTP 97b). Figure 7-1 provides a block diagram of the LANL PAN system.

Figure 7-1: Block Diagram of LANL PAN System



PAN methods are usually best used in conjunction with some means of determining the activity ratios of the various PU isotopes, because PAN assay does not identify individual radionuclides other than Pu-240. The isotopic ratio information can be supplied by Acceptable Knowledge (AK) where AK is sufficient. LANL will not rely on AK to provide isotopic ratios, but rather will use the PC-FRAM gamma spectroscopy system as the technique to proceed PAN. Note that, although LANL will not use AK directly for isotopic information, they will use AK information to help define the range of tests necessary for meeting the NDA system performance requirements. Without AK, much additional work would be required to prove the NDA systems capable of meeting the QAPP QAOs for any given waste stream.

The PC-FRAM gamma spectroscopy system is formally called the Fixed Energy Response Function Analysis with Multiple Efficiencies system. It is housed in the Radioassay and Nondestructive Testing (RANT) Facility located in Technical Area 54 (TA 54), Building 34. The PC-FRAM is essentially a portable system but uses the drum rotation mechanism of the Real Time Radiography (RTR) unit to provide continuous rotation during the assay period. The PC-FRAM system consists of a single, unshielded, EG&G ORTEC High Purity Germanium Coaxial Detector System, with a relative efficiency of 100%[38], mounted on a concrete block that rests on a round "drum dolly". The detector is shielded from external radiation by surrounding it with lead bricks. Lead walls placed between the detector area and the waste drum holding area

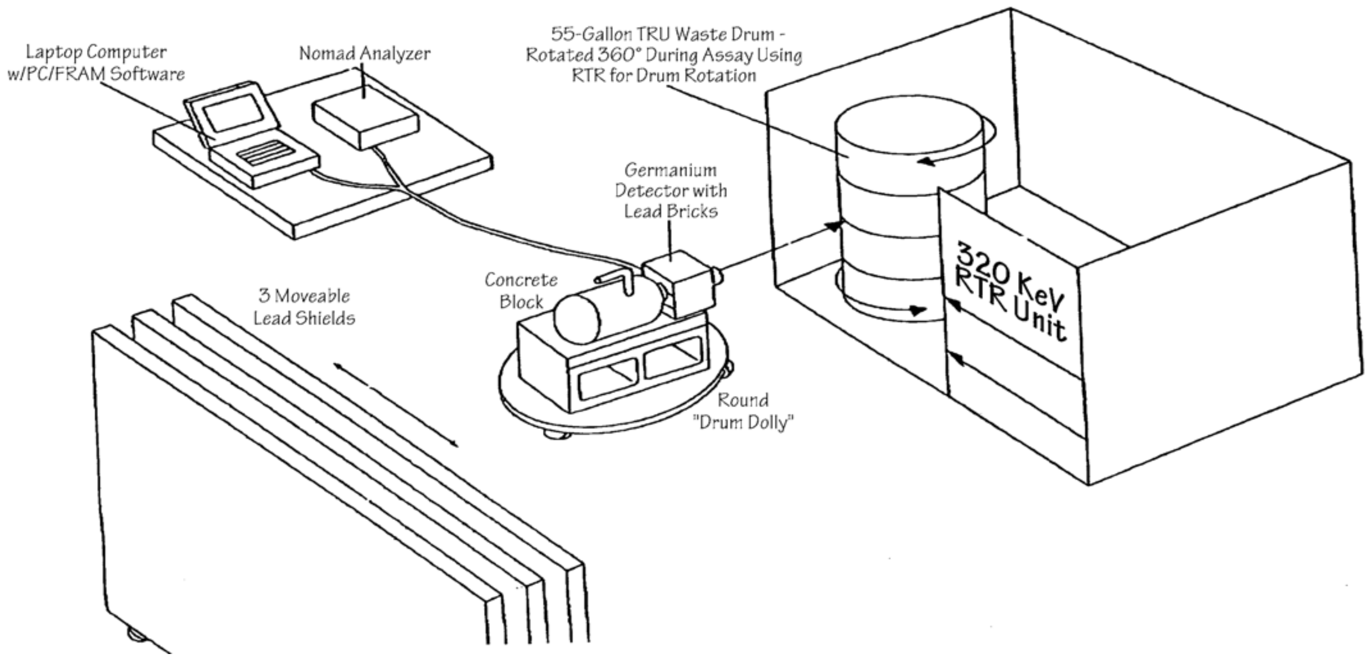
[38]Relative efficiency is a detector's ability to detect gamma radiation relative to the efficiency of a 3"×3" Sodium Iodide (3×3 NaI) crystal measuring the 1,330 KeV photon from Co-60 at a distance of 25 cm. A relative efficiency of 100% for a germanium detector means the detector is as efficient as a 3×3 NaI for the conditions described.

provide additional shielding from other waste drums. The detector is placed at an approximate height of 54", level with the middle of a 55-gallon waste drum. The assay system operates with an EG&G ORTEC Nomad Portable Spectroscopy System, Model 92X-P, attached to a laptop computer using 8192 channels calibrated for 0.125 KeV/channel. The detector is used with a cadmium filter placed directly over the detector face to remove low energy photons and x-rays (<100 KeV, e.g., the 59 KeV line from Am-241). A system check is performed using a traceable source of weapons grade plutonium[39] placed on polystyrene blocks raised to the approximately height of the detector. Upon successful completion of the check, a waste drum is moved into the RTR unit. The drum-to-detector distance is set to achieve a desired count rate and/or dead time criterion based on previous experience by the RANT assay personnel. Allowable dead time is also limited by the assay procedure. The assay begins and drum-specific data are collected, analyzed, and recorded. Each assay takes approximately 15 minutes (900 seconds) of actual counting time, with the drum undergoing continuous 360 degree rotation for the entire assay period. Please refer to Figure 7-2 for an illustration of the LANL PC-FRAM system.

The software being used for data acquisition and analysis is a combination of the FRAM code, which has been ported to the PC environment (PC-FRAM) and the MAESTRO package.

[39]The plutonium source observed in use is PuO_2-Diatomaceous Earth Standard PDP1-3.0, high purity plutonium dioxide dispersed in diatomaceous earth and double encapsulated in stainless steel, fabricated by the Los Alamos Inorganic Element Analysis Group. The plutonium and americium contents of the standard were characterized and quantified on 7-15-95 using methods that are traceable to the National Institute of Standards and Technology (NIST) or the New Brunswick Laboratory (NBL) standards (DTP 97a).

Figure 7-2.
Modified Gamma Spectroscopy System Observed at RANT Facility Used to Determine



Isotopic Plutonium Distribution of Waste Drums

LANL will use the FRAM system for several functions:

As a screening tool to determine if the PAN system can be used for a given drum;

- To provide isotopic ratios needed by the PAN system (the PAN system in passive mode effectively only measures Pu-240, so the quantities of the other plutonium isotopes relative to the Pu-240 mass must be determined for the assay to be complete);
- To provide quantification of non-Pu isotopes; and
- To develop the isotopic uncertainty term for the total measurement uncertainty determination for the PAN system.

Source: Waste Isolation Pilot Plant Audit Inspection Report: Los Alamos National Laboratory Transuranic Waste Characterization, Certification and Transportation Programs: Department of Energy, Carlsbad Area Office Quality Assurance Audit, A-97-16, p. 5., September 30 1997.

To complete these functions, the FRAM and PC/FRAM calculate isotopic mass ratios by finding a least squares solution to set of linear equations with peak areas, relative efficiency, and isotopic ratios as unknowns. The coefficients resulting from the least squares analysis are the relative activities of each isotope; these coefficients are combined with half life and atomic mass data to calculate isotopic mass values for each plutonium isotope. To eliminate any effects from radial heterogeneities in determining the isotopic ratios, the drums are rotated at a constant angular velocity during the count. If the user believes there may be significant spatial heterogeneities in the isotopic distributions, the code can develop different relative efficiency curves for different isotopes. This capability may be useful for future waste streams containing pyrochemical residues where the americium is in a salt form and the plutonium is a metal dispersed in the salt, as gamma rays having nearly identical energies from the two materials will likely see different shielding effects.

The PC-FRAM system has the ability to account for other isotopes known to be in the waste by adding them to the parameter files. The PC-FRAM User Manual lists four parameter sets appropriate for coaxial detectors. LANL employs a parameter set developed expressly for use with drums from waste stream TA-55-20A.001, *cx_np_pa-u/cst*. This parameter set incorporates photons from 120 to 451 KeV and assumes Pu-241→U-237 equilibrium and Pu/Am homogeneity (DOE 96d). This parameter set also detects the presence of interference peaks from U-235, Am-243, Np-239, and Np-237, as well as detecting non-equilibrium Pu-241-U-237 and heterogeneous Am/Pu ratios (DOE 96d).

Isotopic measurement is also performed at LANL using the MAESTRO code running on an offline system. LANL performs this analysis in two steps. First, the MAESTRO package identifies and measures the isotopic peaks. The operator on a peak-by-peak basis then confirms the computer analysis. This two step analysis provides independent confirmation of the isotopic content of the drums.

NDA Procedures - NDA operators perform the assay measurements according to established procedures and within the appropriate time frame (28 days from the date the drums are signed for). The Detailed Technical Procedure (DTP) for operating and calibrating the PAN system includes the following: *Waste Assay using the Mobile Passive-Active Neutron (PAN) Assay* (TWCP-DTP-1.2-009, R.1) and *Calibrating the Mobile Passive-Active Neutron (PAN) Assay System* (TWCP-DTP-1.2-010, R.1). The DTP for the FRAM system is the *Detailed Technical Procedure for Determining Isotopic Ratios in Waste Containers Using the RANT PC FRAM Assay System* (TWCP-DTP-1.2-029, R.2).

In the PAN system, most of the decisions related to the assay process are made by the analysis system software, including the selection of the active or passive measurement and the selection of the calibration curve to relate signal to source. The system operator's role is to ensure the system is operating properly, and that it is properly calibrated, prepared, and loaded. Source efficiency calibrations are performed annually on the PAN system and after the PAN system has been serviced, as required by the Quality Assurance Project Plan (QAPjP). Operational checks are performed at the beginning and ending of each work shift when the PAN system is in production. Replicate assays must be performed on one of every 20 waste containers or one container per operation day, whichever is more frequent. This data is used to develop system control charts.

An efficiency calibration check is performed annually on the FRAM system, as required by the Quality Assurance Project Plan using National Institute of Standards and Technology (NIST) traceable standards. When the FRAM system is in production, operational checks are performed at the beginning and end of each work shift. Background spectra are taken daily. Replicate sample counts are performed on at least every twentieth drum.

Limitations - Prior knowledge of the characteristics of the waste stream being analyzed will increase the accuracy of the PAN system. Prior knowledge of the drum matrix allows calibration curves specific to the matrix to be developed, which reduces a potential source of error. Also, selecting the appropriate isotopic distribution is important to the accuracy of the PAN system. Since the system is optimized for sources of "type 52," consisting of 93.7% Pu-239, 6% Pu-240, and 0.3% Pu-241, it may not exhibit similar performance for sources where the plutonium is in a different mix. The PAN system may have difficulty deciphering different isotopes if AK does not exist or is missing isotopic distribution information. In this case, the PAN system must be used in conjunction with some type of gamma scan, which identifies individual radionuclides. To address this limitation, LANL plans to use the FRAM system in conjunction with the PAN system to identify individual radionuclides. As DOE certifies additional instruments such as the SGS and TGS, EPA will examine them to determine their adequacy.

Another limitation arises because the LANL mission involves extensive research on weapons grade plutonium. Some of the LANL wastes contain "ingrown" or unsupported Am-241 that was chemically separated from weapons grade plutonium. The wastes from such operations will be added to drums containing weapons grade plutonium wastes, presenting the possibility of anomalies in the measurements. Additionally, drums containing both uranium and plutonium are problematic for neutron assays, and may be good candidates for photon determinations. LANL is developing protocols for identifying potentially problematic drums for further evaluation based on observed differences between a sample's active and passive counts, and single and coincidence counts. LANL has also shown that the PC-FRAM system can identify drums with unsupported Am-241 or significant amounts of fissile uranium. These drums will be set aside for further measurement.

During the WIPP Waste Certification Follow-up Audit conducted in August 1997, several limitations of the FRAM system were identified. One limitation of the FRAM system is its ability to account for non-Pu isotopes (Am-241, Np-237, Am-243, Pa-231, and U-235) when they are present in quantities large enough to degrade the precision of the measurement. Another limitation is when isotopes that are not accounted for are present, and these isotopes have gamma emissions that partly overlap the energy peaks used by FRAM for the isotopic mass calculations. LANL addressed this problem in their procedure for data analysis by using MAESTRO for peak identification in the energy region of interest for the analysis. The procedure requires two independent verifications, one by computer and one by the human analyst, that no interfering, unaccounted for isotopes are present. The FRAM system is also limited in directly quantifying the isotopic content of the drum. Without a separate method for determining the absolute quantity of at least one of the isotopes in the drum, the system will not provide absolute quantification for any of the isotopes.

A WIPP Waste Certification Follow-up Audit Team member also discovered, in August 1997, that the evaluations of PC/FRAM v2.3, PAN v1.0 and MAESTRO v3.00 did not define all requirements, test cases or acceptance criteria needed to fully validate the software for its intended use. Specifically, software requirements, test cases and/or test results did not fully demonstrate the ability of the PC/FRAM and PAN software to support measurement of total alpha activity and the activity of all individual isotopes present. LANL has since adequately addressed these concerns and demonstrated the improved testing methods during the September 1997 follow-up inspection.

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8.0 ACCEPTABLE KNOWLEDGE

Acceptable knowledge (AK) is a method that can be used in appropriate circumstances by waste generators, or treatment, storage, or disposal facilities to make preliminary physical and chemical waste determinations. AK is defined in *Waste Analysis: EPA Guidance Manual for Facilities That Generate, Treat, Store and Dispose of Hazardous Waste* (EPA 1994) to include process knowledge, waste analysis data, and facility records of analysis. Acceptable knowledge, as an alternative to sampling and analysis, is typically used to meet all or part of the waste characterization requirements under the Resource Conservation and Recovery Act (RCRA) (EPA 1994), but is also proposed as an initial characterization element to defining those waste characteristics and components important to performance assessment. Specifically, the Department of Energy (DOE) proposes to use AK to initially define the individual radionuclides in a waste stream, and to identify physical components important to performance assessment (PA). DOE discusses acceptable knowledge in section 4 of the Quality Assurance Program Plan (QAPP) and much of that chapter is reproduced here.

AK is also instrumental in identifying the origin or generation of transuranic (TRU) wastes. This information is needed to help non-destructive assay (NDA) measurement personnel in selecting the appropriate correction or calibration factors for NDA. AK also will be used to address the presence of items or conditions that are prohibited by the Waste Isolation Pilot Plant (WIPP) Certification Plan. Examples of such items are: reactives, corrosives, ignitables, pyrophorics, compressed gases, free liquids, and the maximum number of confinement layers.

AK is one of a number of techniques used to characterize TRU waste. It is used in conjunction with radiography, visual examination (VE), and NDA to define important waste components important to performance assessment, including radionuclide cellulosic, rubber, plastic, and liquid (water) content in waste. It should be noted that AK will also be used to determine some hazardous wastes that may be present and will be used in conjunction with headspace gas sampling and analysis, and solidified waste sampling and analysis to meet the requirements of the RCRA Waste Analysis Plan (WAP). To summarize, AK is used in TRU waste characterization activities in many ways:

- To delineate general waste summary category group
- To delineate TRU waste streams
- To identify physical waste components important to PA
- To identify expected radionuclides within the waste
- To determine if TRU debris wastes exhibit a toxicity characteristic (40 CFR §261.24)
- To determine if TRU wastes are listed (40 CFR §261.31)

8.1 SUMMARY OF EPA'S ANALYSIS: 194.24(c)(3)

EPA Rulemaking: §194.24(c)(3) required DOE to provide information which demonstrates that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance requirements found in §194.22. EPA expected the CCA to provide information used in connection with control of the use of process knowledge; cite objective evidence substantiating the degree of implementation of quality assurance (such as audit reports, status of corrective actions, etc.) for each generator site that is approved to use process knowledge for characterization; and provide an implementation plan for application of quality assurance requirements to process knowledge at remaining sites.

EPA Final Determination: EPA determined that DOE had adequately described the use of process knowledge for the retrievably stored (legacy) debris waste stream at LANL. EPA has confirmed establishment and execution of the required QA programs at that waste generator site through inspections. Therefore, the Agency determined that DOE has demonstrated compliance with the §194.24(c)(3) QA requirement for LANL. EPA did not find, however, that DOE has adequately described the use of process knowledge for any other waste streams at LANL (other than the retrievably-stored (legacy) debris waste streams discussed above). Furthermore, DOE has not demonstrated compliance with §194.24(c)(3) for any other waste generator site.

EPA Analysis Process:

- EPA conducted a thorough review of the waste analysis process that included DOE acceptable knowledge documentation presented in the CCA. Information reviewed included Chapter 4, Appendix WAP (and Appendix C8 of the WAP), and the QAPP included in the CCA.

- EPA found that the descriptions of AK in Chapter 4, Section 4.4.1.1 (p. 4-50), Appendix WAP, and the QAPP did not provide adequate documentation of the compilation, confirmation, and auditing of AK information and processes specifically for radioactive constituents. EPA requested additional information regarding acceptable knowledge for radioactive constituents in its December 19, 1996, letter to DOE (Docket A-93-02, Item II-I-01). DOE responded in a letter dated February 14, 1997, that the revised QAPP and the CCA contained the requested information (Docket A-92-03, Item II-I-08). EPA obtained a copy of the revised QAPP subsequent to receipt of the CCA (DOE 1996a).

- Based on this information, EPA prepared a checklist that detailed the AK requirements each site must meet, which was used on EPA audits of the generator sites to examine AK technical elements.

- EPA participated in site audits for INEEL, RFETS and LANL which included examination of the AK procedures in-house and implementation of these procedures.

EPA shadowed DOE personnel at the audit and, using the EPA checklist, examined whether individual sites had the appropriate procedures and other processes in place to adequately characterize waste using acceptable knowledge.

- EPA concluded that LANL had sufficiently demonstrated that it could characterize waste using acceptable knowledge for the retrievably stored legacy debris waste stream.

8.2 EPA'S REVIEW OF ACCEPTABLE KNOWLEDGE (194.24(c)(3))

EPA conducted a thorough review of the waste analysis process that included DOE acceptable knowledge documentation presented in the CCA. In addition, supplemental information, such as the QAPP was also reviewed. Based on this information, EPA prepared a checklist that detailed the AK requirements each site must meet, which was used on EPA audits of the generator sites to examine AK technical elements. The requirements listed below are reproduced from section 4 of the QAPP.

8.2.1 Overview of Acceptable Knowledge

DOE provided acceptable knowledge (AK) documentation in the CCA's Chapter 4 and Appendix WAP. Although not provided as part of the CCA, DOE also includes AK information in its QAPP; the QAPP is an updated version of Appendix WAP, Appendix C9, that has been modified to include specific reference to radionuclides. In section 4 of the QAPP, DOE defined the AK process for waste characterization to include three general activities:

- Compiling AK documentation into an auditable record, including mandatory and supplemental AK information, as defined by DOE in the Quality Assurance Program Plan;

- Confirming AK information with waste analysis results by comparison of AK characterization with those obtained through sampling and analyses, including discrepancy resolution; and

- Auditing of AK records. (Audit steps are also discussed in Appendix WAP: Appendix C11, the WIPP Generator Waste Audit Program).

8.2.1.1 Compilation of Acceptable Knowledge Data

It is the responsibility of each DOE TRU waste generator/storage site to develop a logical sequence of acceptable knowledge information that progresses from general facility information (TRU Waste Management Program Information) to more detailed waste-specific information (TRU Waste Stream Information).

In section 4 of the QAPP, the TRU waste management program information must clearly define waste categorization schemes and terminology, provide a breakdown of the types and quantities of TRU waste that are generated and stored at the site, and describe how waste is tracked and managed at the site, including historical and current operations. Information related to TRU waste certification procedures and the types of documentation (e.g., waste profile forms) used to summarize acceptable knowledge must also be provided. The following information must be included as part of the acceptable knowledge record:

- Map of the site with the areas and facilities involved in TRU waste generation, treatment, and storage identified

- Facility mission description as related to TRU waste generation and management (e.g., nuclear weapons research may involve metallurgy, radiochemistry, and nuclear physics operations that result in specific waste streams)

- Description of the operations that generate TRU waste at the site (e.g., plutonium recovery, weapons design, or weapons fabrication)

- Waste identification or categorization schemes used at the facility (e.g., item description codes, content codes)
-
- Types and quantities of TRU waste generated, including historical generation through future projections

- Correlation of waste streams generated from the same building and process, as appropriate (e.g., sludge, combustibles, metals, and glass)

- Waste certification procedures for retrievably stored and newly generated wastes to be sent to the WIPP facility

Required TRU Waste Stream Information. DOE may use acceptable knowledge to define site-specific waste streams. For each TRU waste stream, sites must compile all process information and data that support the acceptable knowledge used to characterize that waste stream. The type and quantity of supporting documentation will vary by waste stream, depending on the process generating the waste and site-specific requirements imposed by DOE or state agencies. At a minimum, the waste process information must include:

- Area(s) and building(s) from which the waste stream was or is generated

- Waste stream volume and time period of generation (e.g., 100 standard waste boxes of retrievable stored waste generated from June 1977 through December 1977)

- Waste generating process described for each building (e.g., batch waste stream generated during decommissioning operations of glove boxes)

- Process flow diagrams (e.g., a diagram illustrating glove boxes from a specific building to a size reduction facility to a container storage area)

- Material inputs or other information that identifies the chemical and radionuclide content of the waste stream and the physical waste form (e.g., glove box materials, chemicals and radionuclides handled during glove box operations, if applicable)

A summary must be provided that identifies all sources of information. The basis and rationale for defining each waste stream, based on the parameters of interest, must be clearly summarized and traceable to referenced documents. Assumptions made in defining each waste stream also must be identified and justified. If discrepancies exist between required information, then sites must apply all potential hazardous waste codes to the subject waste stream.

Supplemental Acceptable Knowledge Documentation. Supplemental information may also be available. Examples of additional documentation that must be used in addition to mandatory information for acceptable knowledge, if available, include, but are not limited to, the following:

- Process design documents (e.g., Title II Design)

- Standard operating procedures that may include a list of raw materials or reagents, a description of the process or experiment generating the waste, and a description of wastes generated and how the wastes are managed at the point of generation

- Preliminary and final safety analysis reports and technical safety requirements

- Waste packaging logs

- Test plans or research project reports that describe reagents and other raw materials used in experiments

- Site databases (e.g., chemical inventory database for Superfund Amendments and Reauthorization Act Title III requirements)

- Information from site personnel (e.g., documented interviews)

- Standard industry documents (e.g., vendor information)

- Previous analytical data relevant to the waste stream, including results from fingerprint analyses, spot checks, or routine verification sampling

- Material Safety Data Sheets, product labels, or other product package information

- Sampling and analysis data from comparable or surrogate waste streams (e.g., equivalent nonradioactive materials)

- Laboratory notebooks that detail the research processes and raw materials used in an experiment

All specific, relevant supplemental information must be identified and justification provided for its use (e.g., identification of a toxicity characteristic). Supplemental documentation is not required but must be used, if available, to further document the rationale for the hazardous waste designations. Similar to required information, if discrepancies exist between supplemental information and the required documentation, then sites must include all potential hazardous waste codes to the subject waste stream. For example, if personnel interviews indicate that lead (Pb) was part of the input materials, then D008 must be designated in spite of the fact that no records of the use of lead exist in the required documentation.

Sites must prioritize the sources of information used to assign hazardous waste codes in terms of accuracy of the information. Published documents and controlled databases are considered the most reliable information. Second priority will be given to unpublished data, internal procedures, and notes. Correspondence, such as memoranda, letters, telephone logs, and interviews are considered the least defensible. The pages from large documents, such as safety analysis reports, must be flagged with the relevant information noted.

DOE sites must ensure the following criteria are met in establishing acceptable knowledge records:

- Acceptable knowledge information must be compiled in an auditable record, including a road map for all applicable information

- The overview of the facility and TRU waste management operations in the context of the facility's mission must be correlated to specific waste stream information

- Correlations between waste streams, with regard to time of generation, waste generating processes, and site-specific facilities must be clearly described. For newly generated wastes, the rate and quantity of waste to be generated must be defined

- A reference list must be provided that identifies documents, databases, Quality Assurance protocols, and other sources of information that support the acceptable knowledge information

Container inventories for TRU waste currently in retrievable storage must be defined as waste streams by correlating the container identification to all of the mandatory acceptable knowledge information and any supplemental acceptable knowledge information.

8.2.1.2 Confirmation of Acceptable Knowledge

Acceptable knowledge characterization results must be confirmed for both retrievably stored and newly generated waste. All retrievably stored waste must be characterized using radiography to confirm the waste matrix code and waste stream and certify compliance with Attachment II-1, the RCRA Waste Analysis Plan. If a site must repackage its retrievably stored waste, then visual examination of the waste during repackaging must be used to confirm acceptable knowledge information rather than radiography.

For newly generated wastes, sites must have written procedures to document the confirmation of acceptable knowledge information with visual examination prior to or during waste packaging. The following minimum requirements must be addressed in site-specific procedures:

- scope (i.e., waste streams) and purpose
- responsible organization(s)
- administrative process controls
- material inputs to process
- process controls and range of operation that affect final hazardous waste determinations
- rate and quantity of the hazardous waste generated
- list of applicable operating procedures relevant to the hazardous waste determination
- nonconformance reporting
- process knowledge verification sampling (i.e., headspace-gas sampling and/or solidified waste annual sampling)
- reporting and records management

According to the QAPP, sites must establish procedures for reevaluating acceptable knowledge if radiography or visual examination results in the assignment of a different waste matrix code [e.g., Plastic/Rubber (S5310) versus Paper/Cloth (S5330)]. Site procedures must describe how the waste is reassigned, acceptable knowledge reevaluated, and appropriate hazardous waste codes assigned.

If a waste must be assigned to a different waste matrix code based on radiography or visual examination, the following minimum steps must be taken to reevaluate acceptable knowledge:

- Review existing information based on the container identification number and document all differences in hazardous waste code assignments

- If differences exist in the hazardous waste codes that were assigned, reassess and document all required acceptable knowledge information (Section II6-2) associated with the new designation

- Reassess and document all sampling and analytical data associated with the waste

- Verify and document that the reassigned waste matrix code was generated within the specified time period, area and buildings, waste generating process, and that the process material inputs are consistent with the waste material parameters identified during radiography or visual examination

- Record all changes to acceptable knowledge records

- If discrepancies exist in the acceptable knowledge information for the reassigned waste matrix code, complete a nonconformance report (Attachment II-5), document the segregation of this container, and define the corrective actions necessary to fully characterize the waste

8.2.1.3 DOE Site Audits of Acceptable Knowledge

As stated in section 4 of the QAPP, the DOE Carlsbad Area Office (CAO) will conduct an initial audit of each generator/storage site prior to certifying the site for shipment of TRU waste to the WIPP facility. This initial audit will establish an approved baseline that will be reassessed annually by the DOE/CAO. The QAPP/RCRA portion of these audits will verify compliance with the requirements specified in the Waste Analysis Plan (WAP) and QAPP. The QAPP/RCRA audits will be used to ensure the consistent compilation, application, and interpretation of acceptable knowledge information throughout the DOE complex and to evaluate the completeness and defensibility of site-specific acceptable knowledge documentation related to hazardous waste determinations. The following information was derived from the QAPP.

Audit plans will be prepared by DOE to identify the scope of the audit, requirements to be assessed, participating personnel, activities to be audited, organizations to be notified, applicable documents, and schedule. Audits will be performed in accordance with written procedures and checklists that will be developed by DOE prior to the audit. The audit checklists will include specific items associated with the compilation and evaluation of the required acceptable knowledge information.

Audit checklists must include all of the following elements for review during the audit:

- Documentation of the process used to compile, evaluate, and record acceptable knowledge is available and implemented

- Personnel qualifications and training are documented

- All of the required acceptable knowledge documentation specified in Section C9-3 of Appendix WAP (A-93-02, II-G-1) has been compiled in an auditable record

- All of the required procedures specified in the WAP have been developed and implemented, including but not limited to:

  - A procedure exists for assigning hazardous waste codes to waste streams

  - A procedure exists for resolving discrepancies in acceptable knowledge documentation

  - A procedure exists for confirming acceptable knowledge information through: a) radiography or visual examination, b)headspace gas sampling and analysis, and c) solidified waste sampling and analysis

- Results of other audits of the TRU waste characterization programs at the site are available in site records.

Members of the audit team will be knowledgeable regarding the required acceptable knowledge information, RCRA regulations, and EPA guidance regarding the use of acceptable knowledge for waste characterization, RCRA hazardous waste determinations, and the WAP and QAPP requirements. Audit team members will be independent of all TRU waste management operations at the site being audited.

Auditors will evaluate all documents associated with the evaluation of the acceptable knowledge documentation for at least one debris waste stream and one solidified waste stream during the audit. For these waste streams, auditors will review all procedures and associated processes developed by the site for documenting the process of compiling acceptable knowledge documentation; correlating information to specific waste inventories; assigning hazardous waste codes; and identifying, resolving, and documenting discrepancies in acceptable knowledge records. The adequacy of acceptable knowledge procedures and processes will be assessed and any deficiencies in procedures documented in the audit report.

Auditors will review the acceptable knowledge documentation for selected waste streams for logic, completeness, and defensibility. The criteria that will be used by auditors to evaluate the logic and defensibility of the acceptable knowledge documentation include completeness and traceability of the information, consistency of application of information, clarity of presentation, degree of compliance with Appendix WAP with regard to acceptable knowledge confirmation data, nonconformance procedures, and oversight procedures. Auditors will evaluate compliance with written site procedures for developing the acceptable knowledge record. A completeness review will evaluate the availability of the minimum required TRU waste management and TRU waste stream information. Records will be reviewed for correlation to specific waste streams and the basis for making hazardous waste determinations. Auditors will verify that sites include all required information and conservatively include all potential hazardous waste codes indicated by the acceptable knowledge records. All deficiencies in the acceptable knowledge documentation will be included in the audit report.

Auditors will verify and document that sites use administrative controls and follow written procedures to make hazardous waste determinations for newly-generated and retrievably stored wastes. Auditors will review procedures used by the sites to confirm acceptable knowledge information using radiography or visual examination, headspace gas sampling and analysis, and solidified waste sampling and analysis. Procedures to document changes in acceptable knowledge documentation and additions to hazardous waste code assignments to specific waste streams also will be evaluated for compliance with the WAP.

After the audit is complete, the DOE/CAO will provide the site with preliminary results at a close-out meeting. The DOE/CAO will prepare a final audit report that includes all observations and findings identified during the audit. Sites must respond to all audit findings and identify corrective actions. Audit results will be available at DOE/CAO for review by EPA, NMED and other regulatory agencies, and copies will be provided upon request. If acceptable knowledge procedures do not exist, the minimum required information is not available, or findings of noncompliance are identified associated with acceptable knowledge compilation, acceptable knowledge confirmation and/or hazardous waste determinations, the DOE/CAO will not grant the site waste characterization and certification authority for the subject waste summary category. Waste stream summary category characterization and certification authority will be revoked or suspended if findings during subsequent annual audits indicate a lack of compliance with approved acceptable knowledge procedures. Waste characterization and certification authority will not be reinstated until the site demonstrates all corrective actions have been implemented and the program is reassessed by the DOE/CAO.

The National TRU Program disseminates information regarding TRU waste characterization requirements and program status through the TRU Waste Characterization Interface Working Group. Sites use the CAO electronic bulletin board to disseminate information to other generator sites regarding TRU waste streams, RCRA compliance, and operational and programmatic issues, methods development, and waste characterization information, including the application of acceptable knowledge. WIPP personnel are provided the required waste characterization information prior to waste acceptance at WIPP and also will conduct audits at least annually. WIPP will maintain an operating record for review during regulatory agency audits. Regulatory agencies may also review information during generator site audits. The regulatory agencies will be notified regarding any site's failure to implement corrective actions associated with hazardous waste determinations.

8.2.1.4 Acceptable Knowledge Training Requirements and Mandatory Procedures that Must be Implemented

Site personnel responsible for compiling acceptable knowledge, assessing acceptable knowledge, and resolving discrepancies associated with acceptable knowledge must have the following minimum qualifications and training. Sites must also develop and implement acceptable knowledge procedures to ensure consistent application of the acceptable knowledge process and requirements. Site-specific acceptable knowledge procedures must address the following:

- Sites must prepare and implement a written procedure outlining the specific methodology used to assemble acceptable knowledge records, including the origin of the documentation, how it will be used, and any limitations associated with the information (e.g., identify the purpose and scope of a study that included limited sampling and analysis data)

- Sites must develop and implement a written procedure to compile the required acceptable knowledge record. The procedure must describe that sites must assemble and evaluate available documentation in the following priority: a) relevant information from published documents and controlled databases, b) unpublished data, internal procedures and notes, such as log books, and c) correspondence, such as memoranda, letters, telephone logs, and interviews

- Sites must develop and implement a written procedure that describes the waste certification program and ensures unacceptable wastes (e.g., reactive, ignitable, corrosive) are identified and segregated from certifiable TRU waste populations

- Sites must prepare and implement a written procedure to evaluate acceptable knowledge and resolve discrepancies. If different sources of information indicate different hazardous wastes are present, then sites must include all sources of information in its records and conservatively assign all potential hazardous waste codes. Discrepancies in acceptable knowledge documentation must be resolved by including all available information in the auditable records and assigning all hazardous waste codes indicated by all of these records to the subject waste. For example, if one record indicates that solvents were not part of a process, while another record indicates that 1,1,1-trichloroethane was used for cleaning parts, then the F001 hazardous waste code must be applied to the waste. No judgements may be made regarding the quality of the required documentation, and the assignment of hazardous waste codes must be tracked to all required documentation

- Sites must prepare and implement a written procedure in compliance with Section II6-3(d) to identify hazardous wastes and assign the appropriate hazardous waste codes to each waste stream. For newly generated wastes, procedures must be developed and implemented to make hazardous waste determinations using acceptable knowledge prior to packaging the waste

- Sites must develop and implement a written procedure for the confirmation of acceptable knowledge

- Sites must prepare and implement a written procedure that provides a cross reference to the applicable waste summary category group (i.e., S3000, S4000, and S5000) to verify all of the required confirmation data has been evaluated and the proper hazardous waste codes have been assigned

- Sites must develop and implement written procedures to compile adequate documentation to demonstrate consistency in assigning hazardous waste codes and to defend and justify the use of acceptable knowledge in making hazardous waste determinations to independent auditors. The following are minimum baseline requirements/standards that site-specific procedures must include to ensure comparable and consistent identification of hazardous waste:

  - Compile all of the required information in an auditable record

  - Review the required information to determine if the waste is listed under 40 CFR Part 261, Subpart D. Assign all listed hazardous waste codes

  - Review the required information to determine if the waste may contain hazardous constituents included in the toxicity characteristics specified in 40 CFR Part 261, Subpart C. If a toxicity characteristic contaminant is identified and is not included as a listed waste, assign the toxicity characteristic code. Unless data is available from the sampling and analysis of a representative sample of the waste stream that demonstrates that the concentration of the constituent in the waste is less than the toxicity characteristic regulatory level, no judgement may be made regarding the concentration of the constituent. When analytical data is not available, the toxicity characteristic hazardous waste code for the identified hazardous constituent must be applied to the waste stream

  - In the case of discrepancies in information, no judgement may be made regarding the quality of the information. Sites must ensure that all potential hazardous waste codes are assigned to the waste stream

Furthermore, the waste certification procedure(s) must describe the administrative controls used by the site to ensure that nonconforming items are documented and managed in accordance with site-specific certification plans. The following minimum elements must be addressed in site-specific documentation associated with administrative controls:

- Identify the organization(s) responsible for compliance with administrative controls

- Identify the oversight procedures and frequency of actions to verify compliance with administrative controls

- Develop on-the-job training specific to administrative control procedures

- Ensure that personnel may stop work if noncompliance with administrative controls is identified

- Develop a nonconformance process that complies with the requirements in Section C8-13 of the WAP to document and establish corrective actions

- As part of the corrective action process, assess the potential time frame of the noncompliance, the potentially affected waste population(s), and the reassessment and recertification of those wastes

8.2.1.5 Implementation of AK at Generator Sites and Quality Assurance

The QAPP presents the system of controls DOE proposes to implement for AK characterization. DOE has prepared a training program for site personnel responsible for assessing AK information and resolving discrepancies. DOE required each generator site to follow the requirements of the QAPP, and DOE asserted that this three-step process leads to consistent characterization of waste among DOE generators sites using AK.

To ensure that the acceptable knowledge process is consistently applied, sites must comply with the following data quality requirements for acceptable knowledge documentation:

- Precision - Precision is the agreement among a set of replicate measurements without assumption of the knowledge of a true value. The qualitative determinations, such as compiling and assessing acceptable knowledge documentation, do not lend themselves to statistical evaluations of precision. Therefore, precision requirements are not established for acceptable knowledge

- Accuracy - Accuracy is the degree of agreement between an observed sample result and the true value. The percentage of waste containers that require reassignment to a new waste matrix code and/or designation of different hazardous waste codes based an the reevaluation of acceptable knowledge and sampling and analysis data will be reported as a measure of acceptable knowledge accuracy

- Completeness - Completeness is an assessment of the number of waste streams or number of samples collected to the number of samples determined to be useable through the data validation process. The acceptable knowledge record must contain 100 percent of the required information. The useability of the acceptable knowledge information will be assessed for completeness during audits

- Comparability - Data are considered comparable when one set of data can be compared to another set of data. Comparability is ensured through sites meeting the training requirements and complying with the minimum standards outlined for procedures that are used to implement the acceptable knowledge process. All sites must assign hazardous waste codes and provide this information regarding its waste to other sites who store or generate a similar waste stream

- Representativeness - Representativeness expresses the degree to which sample data accurately and precisely represent characteristics of a population. Representativeness is a qualitative parameter that will be satisfied by ensuring that the process of obtaining, evaluating, and documenting acceptable knowledge information is performed in accordance with the minimum standards established in Appendix WAP. Sites also must assess and document the limitations of the acceptable knowledge information used to assign hazardous waste codes (e.g., purpose and scope of information, date of publication, type and extent to which waste parameters are addressed and limitations of information in identifying hazardous wastes)

Each site must address quality control by tracking its performance with regard to the use of acceptable knowledge by: 1) assessing the frequency of inconsistencies among information, and 2) documenting the results of acceptable knowledge confirmation through radiography or visual examination, headspace-gas analyses, and solidified waste analyses. In addition, the acceptable knowledge process and waste stream documentation must be evaluated through internal assessments by quality assurance organizations and assessments by auditors or observers external to the organization (i.e., DOE/Carlsbad Area Office (CAO), NMED, EPA).

DOE indicated that generator site AK programs must be approved and certified through the audit process prior to any waste shipment to WIPP. When the CCA was submitted in October of 1996, no generator or storage sites had yet received certification of their AK process. As of September, 1997, DOE has certified certain waste characterization activities at Los Alamos National Laboratory (LANL), including approval of their AK process. Rocky Flats Environmental Technology Site (RFETS) and Idaho National Engineering Laboratory (INEL) have undergone precertification audits and were certified for AK by DOE in early 1998.

8.2.2 EPA's Analysis of Acceptable Knowledge

EPA's initial review of AK documentation in the CCA led to the conclusion that the general AK processes described in the QAPP and Appendix WAP, Appendix C9, constitute a comprehensive methodology for characterizing waste via AK. The process includes mandatory steps that will be followed to compile and confirm AK information and to audit sites' AK processes. By requiring each generator site to prepare procedures for compilation and confirmation in accordance with the QAPP, DOE can ensure relative consistency between generator sites. In addition, the confirmation process presents detailed yet flexible procedures for generator sites, allowing sites to explain minor discrepancies without changing waste designations, if appropriate.

However, EPA found that the descriptions of AK in Chapter 4, Section 4.4.1.1 (p. 4-50), Appendix WAP, and the QAPP did not provide adequate documentation of the compilation, confirmation, and auditing of AK information and processes specifically for radioactive constituents. EPA requested additional information regarding acceptable knowledge for radioactive constituents in its December 19, 1996, letter to DOE (Docket A-93-02, Item II-I-01). DOE responded in a letter dated February 14, 1997, that the revised QAPP and the CCA contained the requested information (Docket A-92-03, Item II-I-08). EPA obtained a copy of the revised QAPP subsequent to receipt of the CCA (DOE 1996a).

Although the QAPP purportedly was revised to include information on AK for radionuclides, its discussion of AK still emphasized characterization of nonradioactive (RCRA) waste and did not adequately address radioactive waste. The revised QAPP contained the general details of the three-step AK process but did not describe the process specifically in relation to radiological waste characterization. Also, Appendix WAP, Appendix C9, provided general audit information but did not address auditing specifically in relation to radionuclide characterization. EPA concluded that DOE did not sufficiently revise the QAPP to address the compilation, confirmation, and auditing of AK information and processes for radionuclides.

AK is a component of waste characterization. As discussed above, DOE uses AK in conjunction with nondestructive assay for proper characterization of waste. Because non-destructive assay techniques rely heavily on AK to provide the initial basis of analysis, EPA must have sufficient information to demonstrate that AK for radionuclides is adequate.

EPA concluded that the CCA does not provide a description of the status of the AK program, but EPA ascertained this status by observing DOE's site AK certification audits (EPA 1998f). To facilitate it's inspections of DOE generator facilities with respect to AK, EPA developed a checklist that was followed to thoroughly assess DOE's AK process. The checklist is presented, below, as Table A.

Table A

INSPECTION CHECKLIST - ACCEPTABLE KNOWLEDGE (AK)

Acceptable knowledge refers to applying knowledge of hazardous characteristic of the waste in light of the materials or processes used to generated the waste. This may include accompanying records; administrative, procurement, and quality controls associated with the processes generating the waste; past sampling and analytical data; material inputs to the waste generating process; and the time period during which was generated.

The Technical Evaluation Items listed below are based on the Quality Assurance Program Plan as well as general auditing activities. All of the Technical Evaluation Items below can and should be asked at various personnel levels (i.e., upper management, middle management, laboratory analyst) to determine technical adequacy. The following should be incorporated in every certification audit:

- Inquire about the waste process information. The information must include: area(s) and building(s) form which the waste stream was or is generated; waste stream volume and time period of generation; waste generating process described for each building; process flow diagrams; material inputs other information that identifies the chemical and radionuclide content of the waste stream and the physical waste form; and a summary identify all sources of information.

- Inquire about any supplemental acceptable knowledge documentation used for acceptable knowledge (e.g. process design documents; SOPs that may include a list of raw materials or reagents, a description of the process or experiment generating the waste, and a description of wastes generated and how the wastes are managed at the point of generation; and waste packaging logs, etc.).

- Inquire about the qualifications of the site personnel responsible for assessing information and resolving discrepancies. Do they meet the requirements outlined in Section 4.4.1 of the QAPP?

- Inquire about the information used for characterizing the waste, which should include: physical form of the waste, the matrix parameter of the waste stream, waste material parameters and radionuclides present in each waste stream, identify hazardous wastes and assign the appropriate matrix EPA hazardous waste numbers and documented changes to the process and/or material inputs.

- Inquire about the way acceptable knowledge is used. It can be used in three ways: to delineate waste streams; to make all hazardous waste determinations for debris and special waste; and to determine if homogenous solids and soil/gravel are RCRA-listed wastes.

- Inquire if the site maintain the required information in an auditable record . This information include TRU waste management program information (e.g., site maps, facility mission description, description of operations) and TRU waste stream information (e.g. waste stream volume and time period of generation, waste generating processes, process flow diagrams). DOE sites must ensure the following four criteria are met in establishing acceptable knowledge records: an auditable record with a road map; overview of the facility and TRU waste management operations; correlations between waste streams; and a reference list.

- Inquire about the written procedures that describe the compilation, use and confirmation of acceptable knowledge. The site must have a written procedure outlining the specific methodology used to assemble acceptable knowledge records, including the origin of the documentation, how it will be used, and any limitations associated with the information (e.g. identify the purpose and scope of a study that included limited sampling and analysis data).

- Inquire about the written procedures that describe how the required acceptable knowledge records are compiled. Sites must assemble and evaluate available documentation in the following priority: relevant information from published documents and controlled databases; unpublished data; internal procedures and notes, such as log books; and correspondence such as memoranda, letters, telephone logs, and interviews.

- Inquire about the procedures that are used to ensure unacceptable wastes are identified and segregated and waste is certified for shipment to the WIPP facility.

- Inquire about the management controls used to ensure nonconforming items are documented and managed. Sites must ensure radiography and visual examination procedures include a list of nonconforming items that the operator must verify are not present in each container of waste (i.e., corrosives, ignitables, reactives, incompatible wastes).

- Inquire about the procedure(s) for the confirmation of acceptable knowledge prepared in accordance with Section 4.4.3 of the QAPP (e.g. logical sequence of acceptable knowledge information that progresses from general facility information to more detailed waste-specific information)

- Inquire about the cross reference for applicable matrix parameter summary category to verify all of the required confirmation data has been evaluated and the proper EPA hazardous waste numbers have been assigned.

- Inquire how acceptable knowledge information is evaluated and any discrepancies in documentation are resolved.

- Inquire how changes to matrix parameter categories, waste stream assignment, and any associated EPA hazardous waste numbers based on material composition are documented for debris waste streams.

- Inquire about the non-destructive techniques (i.e., radioassay, radiography, headspace gas sampling and analysis) which is used to confirm acceptable knowledge information.

- Inquire about the visual examination of retrievably stored waste which is repackaged. Visual examination during repackaging is used to confirm acceptable knowledge rather than radiography.

- Inquire about the written procedures to document the confirmation of acceptable knowledge prior to or during waste packaging of newly generated wastes. (Section 4.2.1 of the QAPP)

- Inquire the procedures used to demonstrate through compliance with written procedures that discrepancies in information will be documented and that hazardous waste codes will be conservatively applied.

In May 1997, EPA inspected DOE/CAO's waste characterization certification audit at LANL which included the examination of the AK process, procedures and output. LANL prepared a AK report that was reviewed by EPA during the audit. DOE/CAO auditors' checklists and interviews included AK for radiological waste characterization. The AK information included the identification of radioisotopes, but LANL had not conducted the confirmation step at the time of the audit. LANL's follow-up audit was performed the week of August 18, 1997. During this audit, EPA observed that the development and subsequent use of AK is conducted in accordance with Quality Procedure (QP), TWCP-QP-1.1-021, *R.2-Acceptable Knowledge*. This procedure was developed at LANL for detailing how the required information on AK should be documented to satisfy the AK requirements included in the *Quality Assurance Program Plan (QAPP)*. The AK procedure is used to provide for a systematic examination of information necessary to develop an understanding of a particular waste stream.

EPA auditors noted that AK reconciliation with VE data is accomplished at LANL in accordance with TWCP-QP.1.1-028, R.1- *Reconciliation of Waste Stream Information*. The reconciliation process was revised after the May 1997 audit to include other analytical data such as headspace gas sampling as demonstrated during the August 1997 follow-up audit, and non-destructive assay as demonstrated during the September 1997 follow-up audit.

Limitations to AK at LANL were identified during a WIPP certification audit conducted May 12-16, 1997 and the follow-up audit conducted August 18-22, 1997:

- Although the AK procedure can be used to determine if reactives, corrosives, ignitables, and pyrophorics are likely to be present, it cannot be used to determine whether free liquids or compressed gases are present. To counter this limitation, LANL will use radiography and/or visual examination to determine whether free liquids and/or compressed gases are present

- AK is unable to develop a distribution of radionuclides, which is critical for conducting a proper PAN assay of the waste stream. Although AK is able to identify which radionuclides are definitely not present, it cannot identify every radionuclide present. To address this limitation, LANL will use the Fixed Energy Response Function Analysis with Multiple Efficiencies (FRAM) assay system (discussed below in Section 3.2.3) to identify the radionuclide distribution to support the PAN assay. LANL demonstrated the FRAM assay system capabilities during WIPP certification follow-up audits conducted in August and September 1997

- AK cannot be used for determining the concentration (or mass) of specific materials, RCRA constituents, or radioisotopes. To counter this limitation, LANL will use waste characterization methods such as radiography and/or visual examination, headspace gas sampling and analysis, and non-destructive assay to determine concentration (or mass)

- AK procedure did not specifically list screening for the presence of containers larger than four liters. To address this limitation, LANL revised the AK procedure and checklists to include a step to ensure AK personnel check the AK documentation for the possible presence of this prohibited item. The revised AK procedure and checklist were observed during the follow-up audit in August 1997

- AK documentation listed Np as a potential radionuclide. However, this radionuclide was never presented in the AK Summary Report. To address this limitation, LANL revised the AK Summary Report to include Np. The revised AK Summary Report was observed to include Np during the September 1997 follow-up audit

Audit results indicated that LANL must address additional issues (including conduct of the confirmation step for AK radionuclide information and NDA data) before certification relative to AK could be obtained. LANL addressed these issues during the follow-up audit that took place September 10-12, 1997. As of October 1997, DOE has certified certain waste characterization activities at LANL, including approval of the AK process.

9.0 SYSTEM OF CONTROLS REVIEW

To ensure that the generator sites ship only waste that conforms with the waste component limits, a system of controls must be implemented that tracks and measures the waste components destined for the Waste Isolation Pilot Plant (WIPP). This system of controls must also comply with the quality assurance (QA) requirements of §194.22.

The fundamental objective of the Environmental Protection Agency's (EPA's) review of the Department of Energy's (DOE's) waste characterization at waste generator sites is to assure that the proposed system of controls can quantify and track both the important radionuclides and the four waste component limits important for the repository performance. Because DOE's defense missions varied at the sites, the waste generated and the methods to characterize waste vary accordingly.

All waste sent to WIPP will be appropriately and thoroughly characterized. First, the acceptable knowledge provides essential waste content information that later determines the waste categories. The measurement techniques (non-destructive assay (NDA), non-destructive examination (NDE), visual examination (VE)) confirm data, and further define the content and limits of the waste. This information is tracked from a site to the WIPP. The waste characterization process, if implemented accordingly, provides complete and thorough characterization of the waste. DOE has committed to implementing this process. No generator site will be allowed to ship waste to the WIPP until the waste characterization process is met at every generator site for every waste stream(s) proposed.

When EPA conducts inspections and records reviews under 194.24(h), such as audits, to verify compliance with § 194.24, EPA will review DOE's system of controls for the following items that DOE has committed to track:

- The total quantity of waste (volumetrically);
- The quantity of the four important waste components for which DOE has identified limits (listed below);
- Radionuclide activity for the ten radionuclides important to long-term performance (listed below);
- Radionuclide activity uncertainty;
- Radionuclide mass;
- Radionuclide mass uncertainty;
- TRU alpha activity;

- TRU alpha activity uncertainty;
- Verification data;
- Verification method;
- Visual examination of container;
- WAC certification data;
- Waste Matrix Code (WMC); and
- General location of the waste in WIPP.

DOE has determined that there are ten radionuclides important to the long-term performance of WIPP: ^{241}Am, ^{244}Cm, ^{137}Cs, ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu, ^{90}Sr, ^{233}U, and ^{234}U. Of these ten, ^{90}Sr, ^{233}U, and ^{137}Cs are important to RH but not CH waste streams. In addition, DOE has identified four important waste components that need to be tracked because DOE identified that limits were required (Appendix WCL, Table WCL-1). The waste components with limiting values are:

- Ferrous metals (iron): minimum of $2x10^7$ kilograms;
- Cellulosics/plastic/rubber: maximum of $2x10^7$ kilograms;
- Free water emplaced with waste: maximum of 1684 cubic meters; and
- Nonferrous metals (metals other than iron): minimum of $2x10^3$ kilograms

DOE stated that the WIPP Waste Information System (WWIS) will be used to track specific data related to each of the limits; by generating routine WWIS reports, DOE will be able to determine compliance with the imposed limits. The WWIS will also be used to track information on each of the important waste components for which limits were established. EPA finds that the WWIS is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility; as discussed above, waste generator sites will demonstrate WWIS procedures before they can ship waste for disposal at the WIPP.

This section provides an overview of EPA's analysis of DOE's system of controls for measuring and reviewing waste data (i.e., confirming its accuracy). This section also describes EPA's evaluation of DOE's ability to track these data once they are confirmed to ensure compliance with repository limits.

9.1 SUMMARY OF EPA'S ANALYSIS: 194.24(c)(4),(5)

EPA Rulemaking: Sections 194.24(c)(4) and (5) require the implementation of a system of controls that will be used to ensure that critical waste components for which waste limits have been established (§194.24(c)(1)) are appropriately traced to confirm that the total amount of each component will not exceed these limits. Sections 194.24 (e)(1) and (e)(2) require that the total quantity of emplaced waste must not exceed the estimated upper-bound limits for waste components and will not fall below the estimated lower-bound limits for waste components, which is linked to §194.24(c)(4) in that the specified system of controls will ensure that the total quantity of emplaced waste will meet the limiting values. Section 194.24(g) requires DOE to demonstrate that the total inventory emplaced in the WIPP will not exceed limitations on TRU waste described in the LWA. Specifically, the LWA defines limits for: surface dose rate for remote-handled ("RH") TRU waste, total amount (in curies) of RH-TRU waste, and total capacity (by volume) of TRU waste to be disposed.

EPA Final Determination: The system of controls must also conform to the QA requirements specified in §194.22. With respect to the requirements in §§194.24(c)(4) and (5) DOE described a system of controls over waste characterization activities, such as the requirements of the TRU QA Program Plan ("TRU QAPP") and the Waste Acceptance Criteria ("WAC"). EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: (1) waste stream screening/verification (pre-shipment from waste generator site); and (2) waste shipment screening/verification (pre-receipt of waste at the WIPP). The tracking system for waste components against their upper and/or lower limits is found in the WIPP Waste Information System ("WWIS"). EPA believes that the TRU QAPP, WAC, and WWIS are adequate to control important components of waste emplaced in the WIPP. EPA audited DOE's QA programs at Carlsbad Area Office, Sandia National Laboratory and Westinghouse Waste Isolation Division and determined that DOE properly adhered to QA programs that implement the applicable Nuclear Quality Assurance standards and requirements. However, in the CCA, DOE did not demonstrate that the WWIS is fully functional and did not provide information regarding the specific system of controls to be used at individual waste generator sites.

After submission of the CCA, EPA subsequently received information regarding the system of controls (including measurement techniques) to be used at LANL. The Agency confirmed through inspections that the system of controls -- and in particular, the measurement techniques -- are adequate to characterize waste and ensure compliance with the limits on waste components and also confirmed that a QA program had been established and executed at LANL in conformance with Nuclear Quality Assurance requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. At the same time, DOE demonstrated that the WWIS is functional with respect to the WIPP facility -- i.e., that information incorporated into the central database can be retrieved at the WIPP and compiled to produce reports for tracking compliance with the waste limits. Therefore, EPA finds DOE in compliance with §§194.24(c)(4) and (5) for retrievably-stored legacy debris waste at LANL. (Docket A-93-02, Item V-B-15 and CARD 24.) EPA's decision is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[40] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

<u>EPA Analysis Process:</u>

- EPA conducted inspections during waste characterization certification audits to verify DOE's ability to quantify waste components using VE, radiography, and NDA (including cellulosics, plastics and rubbers, and radionuclides and their activity). EPA determined that DOE demonstrated the ability to quantify waste components (including cellulosics, plastics and rubber) by VE and radiography during the LANL audits of May 1997 and August 1997, and by radiography during the RFETS audit of July 1997. During the LANL waste characterization certification audit of the passive active neutron (PAN) system in May 1997, EPA identified issues regarding software quality assurance, and inadequate isotopic identification prior to using the PAN system. The LANL PAN system cannot identify individual radionuclides, but can quantify radionuclide activity after the radionuclide is identified by another waste characterization method. Therefore, inadequate isotopic identification prior to using the PAN directly impacts the PAN system's ability to quantify radionuclide activity.

- EPA attended the LANL follow-up audit of September 1997, at which the software quality assurance, calibration, equipment set-up, and FRAM issues previously noted were adequately addressed. During the RFETS audit of July 1997 of the mobile Canberra NDA unit, issues were identified by EPA regarding software quality assurance.

- EPA inspected audits that included NDA at only two generator sites, RFETS and LANL. LANL conclusively demonstrated their NDA system's ability to detect individual radionuclides for a legacy debris waste stream. RFETS could not conclusively demonstrate their NDA system's ability to detect individual radionuclides.

- After reviewing the CCA, EPA determined that DOE did not provide any waste characterization methods for RH-TRU waste, nor was there discussion specific to how DOE will quantify the RH-TRU waste. All of the waste characterization discussions in the CCA's Chapter 4 are geared toward contact-handled transuranic (CH-TRU) waste, except for Chapter 4, Table 4-13 (p. 4-49), which is entitled "Applicable CH- and RH-

[40] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

TRU Waste Component Characterization Methods." Furthermore, there was no discussion provided regarding the applicability of traditional CH-TRU waste characterization methods to RH-TRU waste. Therefore, EPA is not able to certify that DOE has demonstrated that the WIPP will comply with the radioactive waste disposal regulations for any RH-TRU wastes.

- EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: (1) waste stream screening/verification (pre-shipment from waste generator site); and (2) waste shipment screening/verification (pre-receipt of waste at the WIPP).

- EPA reviewed the CCA and determined that in Section 4.4 (pp. 4-44 to 4-49), DOE provided an adequate description of the system for maintaining centralized control over waste characterization activities. During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed DOE/CAO auditors through their audit checklists and interviews, and determined that the auditors sufficiently examined the LANL waste characterization records center personnel qualifications, responsibilities, and activities, and the records themselves.

- EPA also inspected the waste characterization certification audits at Rocky Flats Environmental Technology Site (RFETS) (June 1997) and Los Alamos National Laboratories (LANL) (May, August, and September 1997), as well as the Performance Demonstration Programs (PDPs) at LANL (June 1997) and RFETS (November 1996). These are the only audits and PDPs that EPA inspected. EPA verified at the audits and PDPs that DOE had an adequate DOE's system for maintaining centralized control over waste characterization activities.

- EPA reviewed the CCA and determined that in Section 4.4 (p. 4-49) DOE did not provide adequate detail on the radiological waste characterization portion of the audit process, and that the audit checklist (as presented in Appendix WAP, Appendix C11) does not include a radiological waste characterization portion. However, through EPA's inspection of the waste characterization certification audits at LANL (May, August and September 1997), EPA reviewed DOE/CAO auditors' checklists and observed the auditors during interviews, and determined that the auditors sufficiently examined LANL's waste characterization program as it relates to radiological waste characterization. See EPA Technical Support Document for Section 194.24: Waste Characterization Status of INEL, LANL and RFETS (Docket A-93-02, Item V-B-15) for further discussion of the LANL inspection.

- EPA reviewed the records management and records storage information that DOE provided in Appendix WAP, Section C-5 (pp. C-46, 47), and found the information to be adequate. During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed that the LANL waste characterization records center exceeds the records management and storage guidelines previously noted. EPA also observed DOE/CAO auditors through their audit checklists and interviews, and determined that the auditors sufficiently examined the LANL waste characterization records center personnel qualifications, responsibilities, and activities, as well as the records themselves.

- EPA reviewed the CCA and determined that DOE provided generally adequate descriptions of the WWIS including documentation, data fields and features in Chapter 4.3.2 (pp. 4-35 to 4-39) and the WIPP Waste Information System Software Design Description (WWIS SDD) (DOE, 1996d). EPA submitted a request for additional WWIS information (i.e., automatic limits, range and QA checks; automatic report generation) in the completeness comment letter dated December 19, 1996 (Docket A-93-02, Item II-I-01). DOE responded on May 2, 1997 to EPA's completeness comment by referencing the information already provided in the CCA (A-93-02, II-I-28). EPA determined that DOE provided no additional information on the WWIS in its response and therefore did not demonstrate that the WWIS was functional.

- In September 1997, DOE demonstrated for EPA the operation of the WWIS at Los Alamos National Laboratory (LANL). EPA observed that LANL site operators were knowledgeable about the WWIS system and had procedures in place to ensure accurate entry of waste information into the system. EPA observed that the WWIS provides checks that are for repository-based limits (i.e., cellulosics in kilograms, total capacity of contact-handled (CH) waste in cubic feet or cubic meters). During the WWIS test, which occurred simultaneously at the WIPP and LANL, EPA also observed the nuclide reporting, waste container data reporting, and calculation of total cellulosics (including plastics and rubber).
- EPA determined that the WWIS tracks individual waste material parameters (WMPs) (i.e., cellulosics) and the weight of individual WMPs.

- EPA finds that the WWIS is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility; as discussed above, waste generator sites will demonstrate WWIS procedures before they can ship waste for disposal at the WIPP.

9.2 EPA'S SYSTEM OF CONTROLS REVIEW

194.24(c) "For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) for each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:

(4) Provide information which demonstrates that a system of controls has been and will continue to be implemented to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value described in the introductory text paragraph (c) of this section. The system of controls shall include, but shall not be limited to: Measurement; sampling; chain of custody records; record keeping systems; waste loading schemes used; and other documentation."

(5) Identify and describe such controls delineated in paragraph (c)(4) of this section and confirm that they are applied in accordance with the quality assurance requirements found in §194.22."

(e) "Waste may be emplaced in the disposal system only if the emplaced components of such waste will not cause:

(1) The total quantity of waste in the disposal system to exceed the upper limiting value, including the associated uncertainty, described in the introductory text to paragraph © of this section; or

(2) The total quantity of waste that will have been emplaced in the disposal system, prior to closure, to fall below the lower limiting value, including the associated uncertainty, described in the introductory text to paragraph © of this section."

(g) "The Department shall demonstrate in any compliance application that the total inventory of waste emplaced in the disposal system complies with the limitations on transuranic waste disposal described in the WIPP LWA."

9.2.1 EPA's Review of System of Controls for Waste Characterization Activities

To ensure that the generator sites ship only waste that conforms with the waste component limits, a system of controls must be implemented that measures the waste components destined for the WIPP. This system of controls must also comply with the QA requirements of §194.22. (See Section 7 for details on EPA's analysis of DOE's measurement methods, and Section 10 for details on EPA's analysis of DOE's quality assurance requirements.)

Waste identification, quantification, and control are critical elements of DOE's waste characterization program. Activities performed by DOE to demonstrate compliance with 194.24(c) describe the progression from characterization of the WIPP waste at the generator site through waste control, and WIPP inventory identification and management.

DOE described a system of controls over waste characterization activities, such as the requirements of the TRU QAPP and the WAC. The TRU waste characterization program is conducted by the generator sites and is implemented in accordance with the requirements of the QAPP and WAC. DOE stated that implementation of the TRU waste characterization program at DOE sites requires that all waste characterization activities be conducted in accordance with approved documentation that describes the management, operations and QA aspects of the program. DOE also indicated that conformance with applicable regulatory (i.e., EPA, NMED), programmatic and operational requirements is monitored by DOE/Carlsbad Area Office (CAO) audit and surveillance program. EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans.

9.2.1.1 System of Controls for Quantification of Radionuclides and Waste Components

EPA reviewed the CCA, Section 4.4 (pp. 4-48 to 4- 49), which discusses the waste stream profile form (WSPF). However, the WSPF (as provided in Appendix WAP, Figure C-4, P. C-130) does not include radiological waste characterization information beyond "material inputs or other information identifying radionuclide content" which is required waste stream information for acceptable knowledge. The WSPF provides a location for sampling and analysis data, but does not provide a location for NDA data. NDA data are a critical part of the waste characterization program, and a location must be provided for it on the WSPF.

EPA further reviewed the CCA and determined that in Section 4.4 (p. 4-49) DOE did not provide adequate detail on the radiological waste characterization portion of the audit process, and that the audit checklist (as presented in Appendix WAP, Appendix C11) does not include a radiological waste characterization portion. However, through EPA's inspection of the waste characterization certification audits at LANL (May, August and September 1997), EPA reviewed DOE/CAO auditors' checklists and observed the auditors during interviews, and determined that the auditors sufficiently examined LANL's waste characterization program as it relates to radiological waste characterization. See Attachment 1 and 3 of this document for further discussion of the LANL inspection.

EPA inspected the waste characterization certification audits at Rocky Flats Environmental Technology Site (RFETS) (June 1997) and Los Alamos National Laboratories (LANL) (May, August, and September 1997), as well as the Performance Demonstration Programs (PDPs) at LANL (June 1997) and RFETS (November 1996). These are the only audits and PDPs that EPA inspected. EPA verified at the audits and PDPs that DOE had an adequate system for maintaining centralized control over waste characterization activities.

<u>Acceptable Knowledge</u>

EPA conducted inspections during waste characterization certification audits at LANL to verify the adequacy of acceptable knowledge (AK) to provide a systematic examination of information necessary to develop an understanding of a particular waste stream, including procedures to reconcile waste characterization data. LANL plans to use AK to assign matrix parameter categories and EPA hazardous waste numbers to waste streams and to determine the waste material parameters and radionuclides present in waste streams. LANL has developed a procedure for detailing how the required information on AK should be documented to satisfy the AK requirements included in the *Quality Assurance Program Plan (QAPP)*. AK also will be used to address the presence of items that are prohibited by the WIPP Certification Plan such as reactives, corrosives, ignitables, pyrophorics, compressed gases, free liquids, and the maximum number of confinement layers.

During the LANL audit conducted in May 1997, EPA observed that LANL's procedure appears technically adequate for assigning matrix parameter categories and EPA hazardous waste numbers to waste streams. The procedure also appears technically adequate for assigning waste material parameters and determining if reactives, corrosives, ignitables, and pyrophorics are likely to be present. However, the technical adequacy of AK appears to fall off when used (1) to determine whether free liquids or compressed gases are present, or (2) to develop a distribution of radionuclides. In addition, AK cannot be used for determining the concentration (or mass) of specific materials, RCRA constituents, or radioisotopes. EPA found that AK cannot be used to develop a radionuclide distribution. This information is critical for conducting a proper PAN assay of the waste stream. While AK can be used to determine what radionuclides definitely are not present, it can not identify every radionuclide that is present. Further, LANL's AK procedure did not specifically list containers larger than 4 liters as an item that's presence should be screened. It was further noted during this audit that LANL's procurement records only go back for a period of four years. The AK expert, therefore, will be unable to rely on procurement records as a potential source of information for any waste stream generated prior to 1992. However, AK will not be used alone. AK will be used in conjunction with other methods such as radiography and visual examination.

During the August 1997 follow-up audit at LANL, EPA observed that AK pertaining to radionuclide distribution was still lacking despite the addition of the gamma assay using the FRAM. For example, AK documentation listed Np as a potential radionuclide. This radionuclide was never present in the AK summary report, and the FRAM did not identify the Np. During the September 1997 follow-up audit, EPA observed that Ak pertaining to radionuclide distribution was properly presented in the summary report and that the FRAM identified the Np.

Visual Examination and Real-Time Radiography

LANL

EPA conducted inspections during waste characterization certification audits to verify DOE's ability to quantify waste components using VE and radiography (including cellulosics, plastics and rubbers). EPA determined that DOE demonstrated the ability to quantify waste components (including cellulosics, plastics and rubber) by VE and radiography during the LANL audits of May 1997 and August 1997.

Specifically, EPA evaluated the equipment used by LANL to conduct VE, which included the use of a video camera to record the examination. EPA observed that the operators followed detailed technical procedures for *WCRRF Visual Examination and Drum Packaging Process Procedure for the TWCP* (DTP-1.2-001, R.1), which appeared to be technically adequate. EPA noted two concerns during the May 1997 audit with LANL's procedures for determining the drum miscertification rate. First, EPA noted that a miscertification rate based on an annual drum population can not be truly representative of each waste stream. Second, EPA expressed concern over the application of the number of drums requiring VE using random selection to the entire annual waste population not each waste stream. EPA determined that both the determination of the miscertification rate and the application of the numbers of drums requiring VE should be waste stream specific. During the audit, EPA observed that CAO provided guidance to LANL stating that only those drums physically available should be placed on the random number generator list. If a drum is not available, it should not be put on the list. Once a drum changes status from unavailable to available, the drum will be placed on the random number generator list. EPA also reviewed the detailed technical procedure for *Random Selection of Containers and Sampling Locations for TRU Waste Characterization Activities* (DTP-1.2-014, R.3) and found it to be technically adequate.

EPA observed the use of the RTR equipment at LANL during the May 1997 audit. EPA found the equipment used to perform RTR to be technically adequate. The equipment scans at a complete rotation and then scans down. This enables the entire drum to be analyzed. Further, the operator can control drum rotation and elevation using distinctive drum characteristics as a guide. During the audit, limitations of the RTR system were revealed. The system has difficulties detecting cellulosics which may be found in a lead-lined drum. The higher beam must be used to scan through the lead lining and it scans past the cellulosics as well. In order to compensate for this limitation, the operator must examine the waste container data sheet. This data sheet contains acceptable knowledge information as to what types of wastes are expected to be in the container. If the items listed on the sheet are not observed when performing the RTR analysis of a lead-lined drum, the operator will tag the drum for visual examination. During the May 1997 audit, it was found that the RTR data form did not list sealed containers greater than four liters as a prohibited item, nor did the RTR operator look for this prohibited item. In response to this issue, EPA observed, during the August 1997 follow-up audit that LANL had revised its procedure to include this prohibited item on the form and the RTR operator also looks for this prohibited item, and objective evidence that the new form was used after the effective date of the revised procedure.

RFETS
EPA observed the use of the RTR equipment at RFETS during the July 1997 waste certification audit. EPA found the equipment used to perform RTR to be technically adequate. The equipment scans at a complete rotation and then scans down. This enables the entire drum to be analyzed. During the audit, limitations of the RTR system were revealed, similar to those identified during the LANL audit. The system has difficulties detecting cellulosics which may be found in a lead-lined drum. The higher beam must be used to scan through the lead lining and it scans past the cellulosics as well.

<u>Non-Destructive Assay</u>

EPA conducted inspections during waste characterization certification audits to verify DOE's ability to quantify waste components using NDA (radionuclides and their activity). EPA reviewed the technical adequacy of the PAN system, and found that, overall, the detailed operating procedures for *Waste Assay Using the Mobile Passive-Active Neutron (PAN) Assay* (TWCP-DTP-1.2-009, R.1) and *Calibrating the Mobile Passive-Active Neutron (PAN) Assay System* (TWCP-DTP-1.2-010, R.1) appear to be technically adequate. During the audit conducted in May 1997, EPA identified issues regarding software quality assurance, and inadequate isotopic identification prior to using the PAN system. The LANL PAN system cannot identify individual radionuclides, but can quantify radionuclide activity after the radionuclide is identified by another waste characterization method. Therefore, inadequate isotopic identification prior to using the PAN directly impacts the PAN system's ability to quantify radionuclide activity. During the LANL follow-up audit of the gamma system (commonly referred to as FRAM, the Norwegian name for the system software) in August 1997, issues were identified with software quality assurance, calibration, equipment set-up, and the inability of the FRAM system to identify the radionuclide Neptunium (Np). Since the FRAM did not identify Np and the PAN system relies upon the isotopics provided by the FRAM, the PAN system did not quantify Np.

EPA attended the LANL follow-up audit of September 1997, at which the software quality assurance, calibration, equipment set-up, and FRAM issues previously noted were adequately addressed. During this audit, EPA observed that LANL demonstrated that the FRAM system is capable of developing isotopic mass ratios for the debris waste stream; in combination with the PAN system it should be capable of developing isotopic quantities as well. Further, EPA found that LANL's new procedure for using the FRAM system, TWCP-DTP-1.2-029, R.2, will minimize the effect of spatial heterogeneities by rotating the drums at a constant angular velocity during the count, which should remove any effects from radial heterogeneities.

EPA also observed the LANL Performance Demonstration Program Cycle 3 performance in June 1997. The PDP as observed was performed in two distinct stages, the first being the preparation of the sample drums and the second the assaying of these sample drums in the Pajarito Scientific Corporation (PSC) Imaging Passive Active Neutron system contained in the PSC mobile assay system. Overall, EPA observed that the PDP provided a reasonable test of the NDA system, and that the methods used for controlling the sample information provided reasonable assurance that the assaying personnel did not have sufficient information to bias their results. This conclusion takes into account the fact that the PDP is an evolving series of tests, with each test being more rigorous.

LANL conclusively demonstrated their NDA system's ability to detect individual radionuclides for a debris waste stream. However, LANL's NDA systems have not yet demonstrated the ability to detect individual radionuclides for the variety of waste streams and waste matrices expected to be encountered at LANL. Furthermore, RFETS could not conclusively demonstrate their NDA system's ability to detect individual radionuclides. EPA therefore concluded that DOE has sufficiently demonstrated at LANL that their NDA systems can identify and quantify radionuclides and their activity for a debris waste stream, and that DOE has not demonstrated the same for the variety of waste streams and waste matrices expected to be encountered at LANL.

In addition, EPA has concluded that DOE has not sufficiently demonstrated that NDA systems at RFETS can identify and quantify radionuclides and their activity.

RH-TRU Waste

After reviewing the CCA, EPA determined that DOE did not provide any waste characterization methods for RH-TRU waste, nor was there discussion specific to how DOE will quantify the RH-TRU waste. All of the waste characterization discussions in the CCA's Chapter 4 are geared toward contact-handled transuranic (CH-TRU) waste, except for Chapter 4, Table 4-13 (p. 4-49), which is entitled "Applicable CH- and RH-TRU Waste Component Characterization Methods." Furthermore, there was no discussion provided regarding the applicability of traditional CH-TRU waste characterization methods to RH-TRU waste. Therefore, EPA is not able to certify that DOE has demonstrated that the WIPP will comply with the radioactive waste disposal regulations for any RH-TRU wastes.

Training

DOE's waste characterization program includes a significant training component for both waste measurement and tracking. EPA observed LANL's training records during the May 1997 audit. EPA observed that although specific training requirements for running the Training Section were neither identified in LANL's *TWCP Training Procedure* (TWCP-QP-1.1-003, R.1) nor available for review in any other LANL TWCP-QP document, it was evident that training specialist is capable of implementing and maintaining the training program. EPA observed, however, that training records were often incomplete and difficult to understand, and that LANL had failed to keep accurate and detailed records. EPA observed that, although LANL staff are obtaining the proper training and certifications, it was impossible to verify because the training records were inadequate and thus unacceptable. During the LANL follow-up audit in August 1997, EPA observed that training records appeared to be complete for and acceptable all systems audited, including the FRAM, RTR, and AK.

9.2.1.2 System of Controls for Tracking Radionuclides and Waste Component Data

To ensure that the generator sites ship only waste that conforms with the waste component limits, a system of controls must be implemented that tracks the waste components destined for the WIPP. This system of controls must also comply with the QA requirements of §194.22. DOE's main tracking system for waste components against their upper and/or lower limits is found in the WIPP Waste Information System ("WWIS"). To verify compliance with this requirement, EPA reviewed the CCA (Section 4) and participated in audits and demonstrations of DOE's system of controls for tracking wastes and important waste components, including the WWIS, procedures for tracking waste containers and conducting reconciliation of waste characterization data.

WIPP Waste Information System Overview

In Section 4.3.2 (pp. 4-35 to 39) and the WIPP Waste Information System Software Design Description (WWIS SDD) (DOE 1997n), DOE provided descriptions of the WWIS, including documentation, data fields and features. The WWIS is the recordkeeping and accounting system for controlling limited waste components for verification of waste emplacement. The WWIS is a computerized data management system used by the WIPP to gather, store, and process information pertaining to TRU waste destined for or disposed at the WIPP. The WWIS supports those organizations who have the responsibility for managing TRU waste by collecting information into one source and providing data in a uniform format that has been verified or certified as being accurate. The WWIS is used to store all information pertaining to characterization, certification, and emplacement of waste at the WIPP. The WWIS will be available at all times except for periodic maintenance. The WWIS has features such as automatic limit, range and QA checks, automatic report generation, and the ability to determine compliance with QA requirements.

DOE indicated in the CCA (Chapter 4.3.2) that the WWIS tracks waste components and associated uncertainties against their upper and lower limits and provides notification before the waste component limits are exceeded, in accordance with §§194.24(e)(1) and (2) and (g). The WWIS is used for the storage and processing of information pertaining to characterization, certification, receipt and emplacement of WIPP waste. Information for the system is supplied by the TRU waste generator sites and the WIPP facility.

DOE indicated (CCA, Chapter 4.3.2, p. 4-35), that the WWIS has features such as automatic limit, range and QA checks and automatic report generation. WIPP personnel review data packages submitted by generator sites for completeness and adequacy before notifying the shipping site of acceptance.

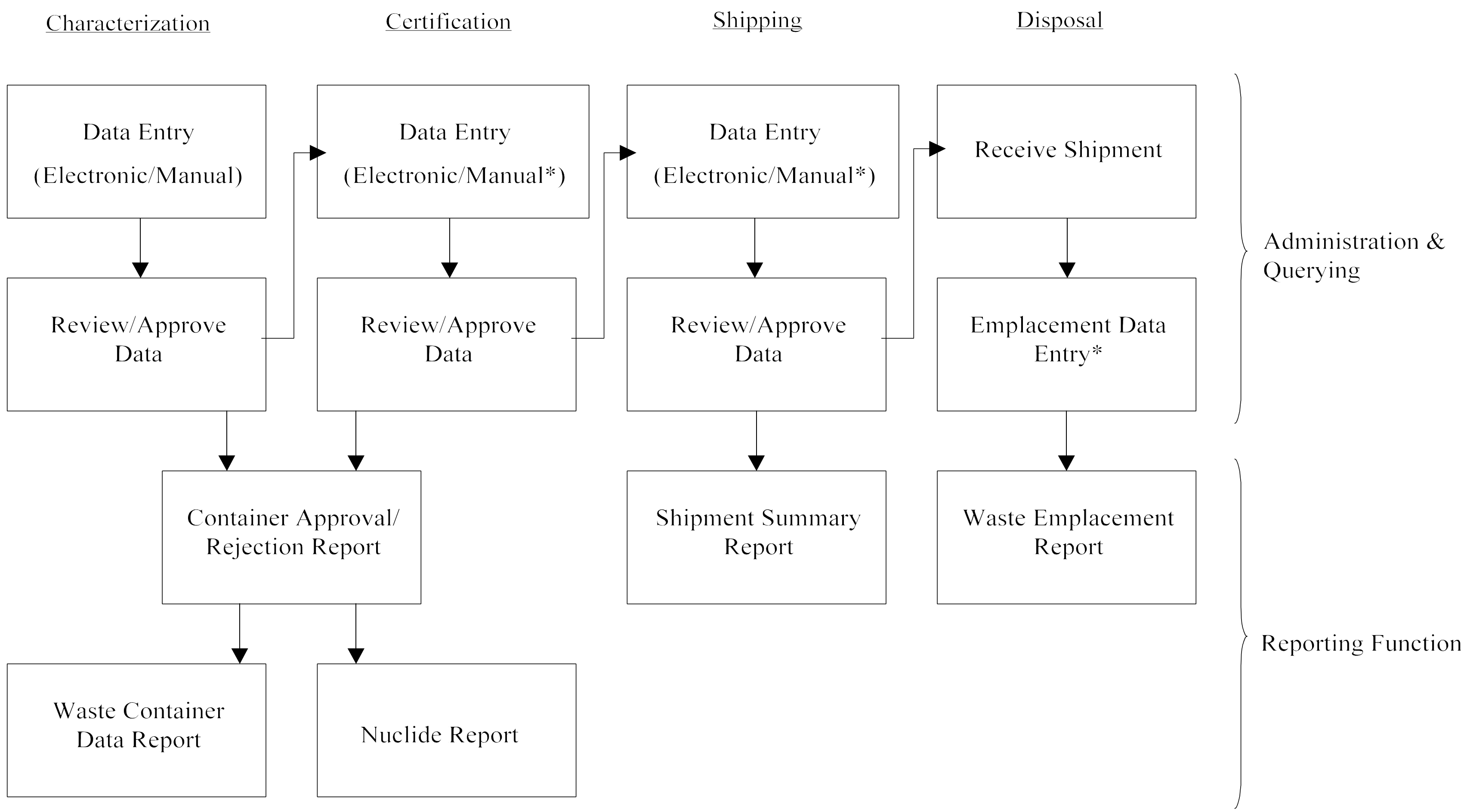
In CCA Chapter 4.3.2 (pp. 4-36 and 4-39), DOE stated that there are 130 data fields associated with the WWIS and referenced Appendix WAP, Appendix C13, for this information. Appendix WAP, Appendix C13, provides a description of the data fields associated with the WWIS.

DOE referred to the WWIS SDD (DOE 1997n) in Chapter 4.3.2. The WWIS SDD communicates software design information about the system's application software by translating requirements into a description of software structure, components, interfaces and data necessary for implementation. Section 2 of the WWIS SDD describes how the system has been structured and the purpose and function of each entity. The five design entities are: characterization, certification, shipment, disposal, and administration. (See Figure 1 for an overview of the relationship of each the modules.)   For the characterization, certification and shipment entities, there is a function to "perform edit/range checks on data." DOE has the capability to generate reports that contain waste-related information. DOE demonstrated during the WWIS Test of September 1997 that current fields include checks for components such as weight of cellulosics in kilograms, and the total capacity of CH waste in cubic feet or cubic meters. For the certification entity, there is a WAC exception function. For the disposal entity, several reports (i.e., bar code batch processing errors, nuclide, waste emplacement, headspace gas concentration) will be generated. DOE has provided the reporting schedule. For the administration entity, there are numerous reference tables (i.e., material parameters, nuclide, assay method, etc.) and several reports (i.e., reference tables, change log short, and change log long). Section 5 of the WWIS SDD contains the internal details of each design entity, including a description of the data elements associated with each entity.

EPA reviewed the CCA and determined that DOE provided generally adequate descriptions of the WWIS including documentation, data fields and features in Chapter 4.3.2 (pp. 4-35 to 4-39) and the WIPP Waste Information System Software Design Description (WWIS SDD) (DOE, 1996d). EPA submitted a request for additional WWIS information (i.e., automatic limits, range and QA checks; automatic report generation) in the completeness comment letter dated December 19, 1996 (Docket A-93-02, Item II-I-01). DOE responded on May 2, 1997 to EPA's completeness comment by referencing the information already provided in the CCA (A-93-02, II-I-28). EPA determined that DOE provided no additional information on the WWIS in its response and therefore did not demonstrate that the WWIS was functional.

Figure 1

WWIS Module Relationships



* New data may be added; previously approved data cannot be changed.

WWIS Implementation Review

EPA actively inquired about the WWIS during a demonstration at the WIPP site and the certification and follow-up certification audits at LANL.

During the WWIS Demonstration conducted in June 1997 at the WIPP site, DOE presented an overview of responsibilities, explaining the roles of key DOE personnel. The main objectives are to ensure CCA compliance, RCRA compliance, conduct safety analysis, and develop information systems. At the time of the site visit, independent integrated testing of the system was in progress. (See Handout 1) During this overview, EPA questioned how data are entered into the WWIS by the sites and at what level of aggregation the data would be received by the WIPP site. DOE noted that data entry would be conducted either electronically through batch files, or via manual data entry and that the WWIS system could support both of these types of data entry. DOE further noted that the data entered into WWIS would be on a payload container basis (i.e., individual waste container for waste characterization and certification and a payload basis for shipment and emplacement).

DOE indicated that detailed module testing was conducted for the WWIS. Test case performance has included edit, limit, upper and lower range values, and null data entries checks. DOE also has conducted electronic data transfer tests using terminals located at the WIPP site. Additional test cases were conducted on the functional data flow between the various system modules. Test cases were conducted for various container types, waste types and handling types for both manual and electronic data entry. In all cases, the tests were successful. During the demonstration, EPA reviewed the test case data and observed that the tests appeared adequate to ensure the viability of the system for tracking waste data.

DOE also discussed software quality assurance for the WWIS (Handout 3). Software quality assurance (SQA) is based on the requirements of NQA-2, Subpart 2.7 (1989 addition with 1990 addenda), as required by 40 CFR 194.23. Original WWIS documentation and current development of the WWIS has been prepared in accordance with these requirements. EPA reviewed the following documents pertaining to the requirements of NQA-2.7 and the WWIS SQA program:

- Software development and life cycle;
- Software verification and validation;
- Configuration control;
- Documentation;
- Verification reviews;
- Problem reporting and corrective action;

- Access control;
- Software procurement; and
- Records Management.

Copies of the documents that describe DOE's compliance with the NQA requirements are contained in the attachments to Technical Background Document 104.24: EPA's Analysis of DOE's WIPP Waste Information System (WWIS).

DOE also demonstrated its configuration management process. Configuration management is folded into existing Engineering Management Process (See Docket A-93-02, Item V-B-16, Attachment 11). System modifications are submitted on the WWIS Software Modification Request form to the Software Configuration Control Board. The Control Board reviews the request and either concurs or denies the request. The WWIS Cognizant Engineer (a member of the Control Board) then evaluates the proposal and initiates the Engineering Change Proposal process if necessary. Typically, only system design changes require an engineering change proposal. The Cognizant Engineer then initiates an Engineering Change Order and attaches the modification request form. The change order is then routed for approval. Modifications are then implemented by the WWIS programmers. Each change is then independently tested (including regression testing as necessary). Once testing is completed, the Cognizant Engineer places the completed modification in the WWIS Software Configuration Management Control Log. EPA observed the personnel qualifications of the Cognizant Engineer and believes him to be capable of evaluating proposed changes to the system. EPA also reviewed data packages for several proposed system modifications and found all documentation to be appropriate.

DOE also discussed WWIS system security and WIPP network (WIPPnet) management relative to the WWIS. Functions of the WIPP network that support the WWIS include providing connectivity to WWIS from the generator sites, providing network and server management, implementing data backup and recovery, and maintaining computer security. Internally, the WIPPnet uses T1 lines to connect with the CAO. The CAO is then connected to the Records Center, CTAC, and the Carlsbad DOE Office. Externally, WIPP is currently using the DOE Business Network to connect the sites to WWIS. The only exception is the Los Alamos National Laboratory (LANL), which does not have access to the DOE Business Network. Connectivity to the WWIS for LANL is via modem. The actual connection to the Business Network links the sites to the CAO, which is then transferred to the WWIS via the WIPPnet. DOE indicated that their intent is that the WWIS will be accessible via the Internet.

System security is ensured externally in several ways. The CAO has firewalls to protect from unauthorized access via the DOE Business Network. Similar firewalls also exist for the WIPPnet. Access to the system for LANL is controlled by the use of keycard dial-in and passwords. Access to the system server at the WIPP site is by password and user ID. System privileges are controlled based on the individual user. Access to the WWIS system is also based on password and user ID. Privileges and module access are based on specific user needs. (See Handout 4)

A number of planned connectivity enhancements were also described by DOE. WIPP is evaluating a new Internet firewall that can be programmed to selectively allow WIPPnet access from external sites and also IP tunneling capabilities which would provide additional security through encryption. DOE also discussed the WWIS server which is a dedicated DEC Alpha 2100 server operating on a UNIX platform. The system is backed up fully each weekend, with incremental backups Monday through Thursday. Backup tapes are stored in a different building than the one that houses the system. The entire system is protected by an uninterruptable power source. DOE conducted a risk analysis and prepared a Risk Analysis Report which is a systematic, quantitative examination of computer system resources, assets, applications, vulnerabilities, and threats. The purpose of the risk analysis was to establish an expected loss from certain events based upon the magnitude of the loss and the frequency of occurrence of the events causing that loss. In conjunction with the risk analysis, WIPP developed a Contingency Plan that documents actions needed for emergency response, extended backup operations, and post-disaster actions should the WIPP wide-area network experience partial or total loss of use. EPA observed the documentation associated with system security and connectivity and found them to be technically adequate.

The next part of the site visit included a demonstration of the capabilities of each of the discrete modules that make up the WWIS system.

Characterization Module Demonstration

This module contains waste characterization data for each container proposed for disposal in WIPP. Personnel from generator sites enter these data on various screens. EPA requested copies of each of the screens related to the characterization module. These are included in Docket A-93-02, Item V-B-16. The demonstration conducted by DOE focused on manual data entry of waste characterization data. Eventually, DOE hopes that generator sites will be able to enter data via batch reports, which will require each generator site to develop its own data management system for TRU waste data. EPA observed DOE successfully enter data into the characterization module and submit it for approval.

Certification Module Demonstration

The certification module contains the data in the characterization module required for Waste Acceptance Criteria (WAC) certification. The module provides the capability for transmittal and verification of generator/shipper site waste certification data at WIPP. This module can not be accessed for a waste container until characterization has been approved by the WWIS Data Administrator. EPA observed DOE successfully enter data into the certification module and submit it for approval.

Shipment Module Demonstration

The shipment module contains information related to the transmittal and verification of *certified* TRU waste container shipment data. Data can not be entered into this module for a waste container unless certification approval has been given by the WWIS Data Administrator. EPA observed DOE successfully enter data into the shipment module and submit it for approval.

Disposal Inventory Module Demonstration

The disposal inventory module tracks input and retention of container locations in the WWIS. Actual container identification is conducted using a barcoder. As a backup, each container is also labeled with the written container information to allow for easy identification. Discussion of this module focused on the ability of WIPP personnel to track data related to emplacement limits, including total amounts of cellulosics and radionuclides.

Data Administration Module Demonstration

The data administration module contains the reference tables that provide approved data used to perform the edit and limit checks on data input into the system. The data contained in the reference tables were input by the Data Administrator using approved documents. The reference tables contain data used by the WWIS to verify edits and limits for:

- Data entry fields;
- Identification of approved user sites and personnel;
- Characterization methods approved by DOE/CAO for use by the generator/shipper sites;
- Aspiration methods;
- Allowable container types;
- Allowable filter types;
- Hazardous codes allowed by a site;
- Liner types;
- Packaging reference data;
- Nuclide reference data;
- Analyte data;
- Assay methods;

- WIPP location data;
- Material parameter data;
- TRUPACT-II content code (TRUCON) data;
- Approved sampling methods;
- Shipment category reference data;
- Approved transporters;
- WAC exception data; and
- Waste stream profile reference data.

During discussions, EPA requested copies of each of the reference tables in order to ensure that the tables contain appropriate data. EPA observed that these tables were in draft form. The tables will need to be updated as generator sites become certified in order to accurately depict the types of characterization, assay, and sampling methods allowed for use by the sites. Further, the WAC exception table will need to be updated each time a WAC exception is approved. DOE does not anticipate many requests for WAC exceptions. EPA has reviewed these tables and concluded that they are currently appropriate.

Query Module Demonstration

The query module allows the user to obtain quick access to waste container and shipment data contained in the WWIS, including the approval status of the container and shipment records.

Reporting Function Demonstration

WWIS has several pre-programmed reports that can be run at any time. These reports are used to track the status of waste containers and to ensure that disposal limits are met. Four main reports are currently available in WWIS. These include (1) Nuclide Report (See Attachment 9), (2) Waste Container Data Report (See Attachment 7), (3) Shipment Summary Report (See Attachment 8), and (4) Waste Emplacement Report (See Attachment 10). EPA observed the WWIS system generate each of the reports using test data contained in the WWIS system. The reports appeared to be technically adequate to track waste and waste component data to ensure compliance with disposal limits. However, EPA suggested that additional reports may be desirous to track certain data related to compliance. DOE noted that the WWIS is designed to allow for development of any type of report based on individual needs. DOE fully expects that additional reports will be developed during the life of the WIPP.

In August and September 1997, DOE demonstrated for EPA the operation of the WWIS at LANL during the site certification audit and EPA observed the WWIS interface between the WIPP site and LANL. The purpose of the demonstration was to verify LANL's ability to transfer waste data to WIPP for purposes of waste characterization, certification, and shipment of TRU waste to WIPP for disposal.

EPA observed the LANL operator enter waste characterization data for a waste stream that had been approved by WIPP. EPA observed that the data entered were read from a spreadsheet containing verified data for the specified waste containers. When attempting to enter analyte data, EPA observed that when a mistake was made, the system would sum deleted data, which had the effect of making the container exceed the limits established by WIPP. DOE could not proceed with the test of entering waste container data. EPA observed another problem when the LANL operator attempted to enter sample data for analytes. Apparently, the internal flags in WWIS did not recognize certain analytes as being flammable. Therefore, data could not be entered into the system. LANL attempted to demonstrate the shipping function using test data provided by WIPP. EPA observed that this function worked as designed with no problems identified.

After consultation with the WIPP site, the LANL operator was able to demonstrate its ability to enter and send waste container data to WWIS. EPA observed that all functions appeared to work as designed, and the problems encountered the previous day had been resolved. EPA requested copies of LANL's procedures for entering data into WWIS, which consisted of the WWIS User's Guide for Generators and Shippers. This document did not appear to be adequate in outlining all the procedures necessary to ensure that data submitted to WIPP and received by WIPP are accurate. EPA suggested that procedures needed to be developed to ensure that personnel were reviewing data received by WWIS and comparing these data to the data inputs from the spreadsheets. LANL personnel noted that the procedure was the site's initial attempt and that it would be updated in the near future.

Based on the performance of interface between LANL and WWIS, it was determined that a follow-up audit would be necessary to ensure that the site could submit data to WWIS in a manner consistent with the requirements of 40 CFR Part 194.24(c)(4).

EPA participated in the follow-up waste characterization audit of LANL in September 1997. For purposes of WWIS demonstration, EPA was present at both the LANL site and at the WIPP site to ensure that data sent by LANL were received by the WIPP site.

At the LANL site, EPA reviewed LANL's new procedure, TWCP-QP-1.1-034, R.1 which establishes procedures for submitting data to the WIPP via the WWIS. This procedure requires independent verification for each module of the data as it is entered. LANL reviews an echo report generated by the WWIS server to verify that the data received by the WWIS were the same as the data submitted. EPA concludes that the results of the demonstration at the LANL site indicated that LANL was able to successfully transmit data to the WWIS and receive information related to TRU waste data back from the WWIS Data Administrator.

EPA's observations of the WWIS demonstration at the WIPP site focused on five major issues: (1) the security of the WWIS; (2) how waste material parameter data would be tracked; (3) the validity of data transmission verification activities; (4) adequacy of data reporting schedules; and (5) the functionality of the characterization, certification, shipping, and disposal modules with the administration module.

Data for a test shipment of waste drums was transmitted from LANL to the WIPP site via the WWIS interface. EPA observed the receipt of data from LANL and verified that the WIPP inventory increased. The total amount of each waste component as specified was then calculated separately by the WWIS software. Shipment totals of cellulosics, plastics and rubbers were calculated manually by the WWIS Data Administrator and maintained on worksheets. It was observed that the WWIS software can calculate and generate a nuclide report for each radionuclide emplaced at the WIPP.

Transmission verification, (i.e., how to verify that the data sent is the same data received) was demonstrated in several ways. The WWIS Data Administrator calculates the composition of the shipment to ensure that the data represent weapons grade transuranic waste. A waste container report is completed by the transporters for each shipment. The waste container report is sent to the WWIS Data Administrator at the WIPP, who verifies that the data in the WWIS is correct. If a drum is rejected by the Data Administrator, all of the data for that drum are deleted from the system, and the shipper is required to reenter all of the data for that drum once corrections have been made. To ensure that all test data have been removed from the system prior to shipment of any real waste to the WIPP, the Data Administrator will delete all data from the system and a new baseline will be established. At this point, only certified shippers will have access to the WWIS system.

The WWIS Data Administrator will generate a waste emplacement report weekly while waste is being accepted by the WIPP. As recommended by EPA, DOE will generate a Biennial Information Report. Generation of all reports will be handled in accordance with the requirements established by document control procedures.

EPA observed that control of the WWIS system is performed adequately by the WIPP site software QA organization, the information management staff, and the WWIS Cognizant Engineer. The level of control will ensure that the system is recoverable, and that all changes are documented and traceable. Inadvertent changes should be minimal both in number and severity, and the data will be adequately protected.

EPA further observed that LANL site operators were knowledgeable about the WWIS system and had procedures in place to ensure accurate entry of waste information into the system. EPA observed that the WWIS provides checks that are for repository-based limits (i.e., cellulosics in kilograms, total capacity of contact-handled (CH) waste in cubic feet or cubic meters). During the WWIS test, which occurred simultaneously at the WIPP and LANL, EPA also observed the nuclide reporting, waste container data reporting, and calculation of total cellulosics (including plastics and rubber).

The following WWIS documents were reviewed by EPA during this audit and found to be adequate:

- WWIS Evaluation and Recommendation;
- WWIS Software Quality Assurance;
- WWIS Software Verification and Validation Plan;
- WWIS Software Requirements;
- WWIS Software Design Description;
- WWIS Software Configuration Management Plan;
- WWIS Security Plan;
- Contingency Plan - WIPP Wide-Area Network; and
- Risk Analysis Report - WIPP Wide-Area Network.

Waste Container Tracking

EPA observed LANL's internal waste container tracking procedures during the certification audit conducted in May 1997 and the follow-up audit in September 1997. During the May 1997 audit the waste container tracking procedure was found to be inadequate because once the supervisor/operators received tracking forms via e-mail there was no procedure for the latest tracking form to be automatically renamed. Also, it was observed that the form content (i.e., codes, dates) was confusing. There was no version number to be updated after each revision of the tracking form, and there was no consistent page numbering of the tracking form. The Waste Container Tracking Procedure (TWCP-Qp-1.1-032, R.1) was revised in July 1997. During the August follow-up audit, EPA observed that the form was updated to include consistent page numbering and an automatic system for tagging each revision so that each individual on the distribution list knows which is the latest version of the form. Each time a revision is made hard copies of forms are filed. EPA concludes that LANL's waste container tracking procedure appears adequate.

Reconciliation of Waste Characterization Data

During the May 1997 LANL waste characterization audit, EPA observed LANL's process for reconciling waste stream information obtained from VE and AK. EPA determined that the process for conducting the reconciliation is technically adequate, but could be improved by incorporating within the procedure the use of other analytical data, including headspace gas sampling, NDA, and sludge coring and sampling. EPA observed that data reconciliation was conducted in accordance with procedure *Reconciliation of Waste Stream Information* (TWCP-QP.1.1-028, R.0).

9.3 CONCLUSIONS: EPA'S SYSTEM OF CONTROLS REVIEW

Sections 194.24(c)(4) and (5) require DOE to demonstrate that a system of controls has been and will continue to be implemented to confirm that the waste components emplaced in the WIPP will not exceed the upper limit or fall below the lower limit calculated in accordance with §194.24(c)(1). The system of controls must also conform to the QA requirements specified in §194.22. With respect to the requirements in §§194.24(c)(4) and (5) DOE described a system of controls over waste characterization activities, such as the requirements of the TRU QA Program Plan ("TRU QAPP") and the Waste Acceptance Criteria ("WAC"). EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: (1) waste stream screening/verification (pre-shipment from waste generator site); and (2) waste shipment screening/verification (pre-receipt of waste at the WIPP). The tracking system for waste components against their upper and/or lower limits is found in the WIPP Waste Information System ("WWIS"). EPA believes that the TRU QAPP, WAC, and WWIS are adequate to control important components of waste emplaced in the WIPP. EPA audited DOE's QA programs at Carlsbad Area Office, Sandia National Laboratory and

Westinghouse Waste Isolation Division and determined that DOE properly adhered to QA programs that implement the applicable Nuclear Quality Assurance standards and requirements. (See the preamble discussion of §194.22, Quality Assurance, for further information). However, in the CCA, DOE did not demonstrate that the WWIS is fully functional and did not provide information regarding the specific system of controls to be used at individual waste generator sites.

EPA also reviewed the records management and records storage information that DOE provided in Appendix WAP, Section C-5 (pp. C-46, 47), and found the information to be adequate. During the May 1997 waste characterization certification audit at Los Alamos National Laboratory (LANL), EPA observed that the LANL waste characterization records center exceeds the records management and storage guidelines previously noted. See EPA Technical Support Document for Section 194.24: Waste Characterization Status of INEL, LANL and RFETS (Docket A-93-02, Item V-B-18) for further discussion of records management and storage.

After submission of the CCA, EPA subsequently received information regarding the system of controls (including measurement techniques) to be used at LANL. The Agency confirmed through inspections that the system of controls -- and in particular, the measurement techniques -- is adequate to characterize waste and ensure compliance with the limits on waste components for some waste streams, and also confirmed that a QA program had been established and executed at LANL in conformance with Nuclear Quality Assurance requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. At the same time, DOE demonstrated that the WWIS is functional with respect to the WIPP facility -- i.e., that information incorporated into the central database can be retrieved at the WIPP and compiled to produce reports for tracking compliance with the waste limits.

In order to meet the §§194.24(e) and (g) limits, DOE intends to rely on the TRU QAPP, WAC, and two-phase waste characterization (pre-shipment at generator sites and pre-receipt at the WIPP). The DOE stated that the WWIS will be used to track specific data related to each of the LWA limits; by generating routine WWIS reports, DOE will be able to determine compliance with the imposed limits. The WWIS will also be used to track information on each of the important waste components for which limits were established. EPA finds that the WWIS is adequate to track adherence to the limits, and that the WWIS has been demonstrated to be fully functional at the WIPP facility; as discussed above, waste generator sites will demonstrate WWIS procedures before they can ship waste for disposal at the WIPP.

10.0 QUALITY ASSURANCE REQUIREMENTS

Quality assurance (QA) is a very broad topic; elements of a QA program are found in all activities associated with approving Waste Isolation Pilot Plan (WIPP) waste certification activities. In the area of waste characterization alone, the Environmental Protection Agency (EPA) has imposed quality assurance requirements on every step of the process. This discussion of QA does not address all QA activities associated with waste characterization, but rather is specific to the requirement for quality assurance stated in 40 CFR 194.24(c)(5). Further information describing the Department of Energy (DOE) QA program for WIPP activities, and the EPA audits and reviews of that program, is available in CARD 22, Quality Assurance Program Audits. In addition, a more detailed discussion of the Performance Demonstration Program (PDP), including the associated performance standards, is included in section 7-2 of this document.

10.1 SUMMARY OF EPA ANALYSIS

<u>EPA Rulemaking:</u>

Sections 194.24(c)(4) and (5) require DOE to demonstrate that a system of controls has been and will continue to be implemented to confirm that the waste components emplaced in the WIPP will not exceed the upper limit or fall below the lower limit calculated in accordance with §194.24(c)(1). EPA expected DOE to provide a description of all Performance Demonstration Program (PDP) tests used to certify the capability and comparability of measurements at waste generation sites, and to provide standardized waste characterization methodologies, if not provided under §194.24(c)(2). EPA also expected DOE to cite objective evidence of the status of current implementation methods or procedures. Finally, EPA expected that the Compliance Certification Application (CCA) would include documentation of QA for waste characterization activities from the point of generation (for to-be-generated waste) to the point of emplacement and disposal at the WIPP.

<u>EPA Final Determination:</u>

> Sections 194.24(c) "For each waste component identified and assessed pursuant to paragraph (b) of this section, the Department shall specify the limiting value (expressed as an upper or lower limit of mass, volume, curies, concentration, etc.), and the associated uncertainty (i.e., margin of error) of each limiting value, of the total inventory of such waste proposed for disposal in the disposal system. Any compliance application shall:
>
> (5) Identify and describe such controls delineated in paragraph (c)(4) of this section and confirm that they are applied in accordance with the quality assurance requirements found in §194.22."

After submission of the CCA, EPA subsequently received information regarding the system of controls to be used at the Los Alamos National Laboratory (LANL). The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with Nuclear Quality Assurance (NQA) requirements. Moreover, DOE demonstrated that the WIPP Waste Information System (WWIS) is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits.

EPA determines DOE to have demonstrated compliance with §§194.24(c)(4) and (5) for waste streams in the category of retrievably stored legacy debris waste streams at LANL. EPA's determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[41] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

EPA Analysis Process:

- EPA reviewed the Performance Demonstration Program (PDP) for non-destructive assay described in Chapter 4.3.3.1 (p. 4-40) and 4.4 (p. 4-44) of the CCA. The CCA in Chapter 4.3.3.1 describes the detailed elements that comprise the program, including test materials and analysis required.

- DOE did not include the PDP Plan for NDA in the CCA. However, DOE later provided the PDP Plan for NDA (DOE 1995). DOE has since updated the PDP Plan for NDA (DOE 1997b). DOE has provided results of Cycle 1 and Cycle 2 PDPs (DOE 1996e and DOE 1997a).

- NDA PDP Cycle 1 was completed in April 1996; Cycle 2 was completed in December 1996; and Cycle 3 was completed in June 1997. DOE presented the results of Cycle 1 at the September 1996 Technical Exchange meeting held in Washington, D.C., and the results of Cycle 2 at the January 1997 NDA/NDE Waste Characterization conference held in Salt Lake City, Utah (DOE 1996e and DOE 1997a). EPA reviewed DOE documentation pertaining to these activities, including the PDP plan and results reports, and participated in the Cycle 2 PDP at RFETS and the Cycle 3 PDP at LANL.

- The EPA inspections of Los Alamos consisted of one preliminary inspection of a CAO audit in May 12, 1997 and two full inspections of CAO audits during demonstrations of

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[41] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

waste characterization in August 18-22 and September 10-12, 1997 (Docket Number A-93-02, Item II-A-51). EPA's inspections determined that the Los Alamos site had appropriately established and executed a QA program for WCA.

- After performing inspections of waste characterization activities, EPA is satisfied that DOE has controls in place to control the quality of data related to both waste characterization and monitoring. In the case of waste characterization, the TRU Waste Quality Assurance Program Plan (QAPP) (CAO-94-1010) describes controls that will enable generator sites to demonstrate an acceptable level of assurance in the quality of their data. Specifically, the QAPP identifies data quality objectives for each type of measurement data.

- EPA found that the TRU QAPP established appropriate technical quality control and performance standards.

10.2 PERFORMANCE DEMONSTRATION PROGRAM (PDP) DESCRIPTIONS

DOE described the Performance Demonstration Program (PDP) for non-destructive assay (NDA) in Chapter 4.3.3.1 (p. 4-40) and 4.4 (p. 4-44). The PDP for non-destructive assay (NDA) is designed to ensure compliance with the Quality Assurance Objectives (QAOs) identified in the Quality Assurance Program Plan (QAPP) by providing a test program that each generator site must pass prior to waste shipment. The PDP is a multiple cycle program that tests a site's NDA abilities to detect radionuclides from various source standards in different waste matrices. The Carlsbad Area Office (CAO) is the reviewing and approving authority for the PDP. All DOE facilities intending to dispose of their waste at the WIPP must participate in the PDP and pass all individual tests within each PDP cycle. The CAO uses the PDP to assess, evaluate, and approve DOE facilities for waste measurement and characterization before the waste is shipped to the WIPP.

As indicated in Chapter 4.3.3.1, the PDP describes the detailed elements that comprise the program, including test materials and analysis required. The PDP also identifies the criteria used for the evaluation of laboratory performance and the responsibilities of the personnel involved in the PDP. DOE indicated that PDP radioactive source standards used in the PDP tests encompass the range of activities (masses) anticipated in waste characterization. The PDP standards address activity ranges relative to waste acceptance criteria (WAC) limits, QAPP Quality Assurance Objectives (QAOs), and NDA method detection limits. The isotopes analyzed under this program include, but are not limited to, ^{238}Pu, ^{239}Pu, ^{240}Pu and ^{241}Am. Fifty-five gallon drums used in the PDP contain matrix inserts which simulate waste conditions as well as contain no matrix material or a benign material (see CCA Chapter 4.4.3.3.1, pp. 4- 42 and 4-43).

DOE indicated in Section 4.3.3.1, that measurement performance must be demonstrated by the successful analysis of samples by all participating facilities on a semiannual basis. PDP samples are analyzed using methods that the facility will use for the analysis of the WIPP waste and that meet the QAPP specifications. PDP scoring is pass/fail. To pass the PDP, the facility must pass all individual tests. Only measurement facilities and instruments that have demonstrated acceptable performance in the PDP (Section 4.3.3.1, p. 4-43) will perform waste analyses.

10.2.1 PDP Documents

DOE provided the updated the PDP Plan for NDA (DOE 1997b) after the submission of the CCA. DOE has provided results of Cycle 1 and Cycle 2 PDPs (DOE 1996e and DOE 1997a).

10.2.2 Objective Evidence of the Status of Current Implementation of the PDP

NDA PDP Cycle 1 was completed in April 1996; Cycle 2 was completed in December 1996; and Cycle 3 was completed in June 1997. DOE presented the results of Cycle 1 at the September 1996 Technical Exchange meeting held in Washington, D.C., and the results of Cycle 2 at the January 1997 NDA/NDE Waste Characterization conference held in Salt Lake City, Utah (DOE 1996e and DOE 1997a). DOE will provide the Cycle 3 report upon completion of the report. These reports indicate that LANL for the passive-active neutron system (PAN) system and the Idaho National Engineering Laboratory (INEL) for the Stored Waste Examination Pilot Plant (SWEPP)/PAN system passed both Cycles 1 and 2, and the Rocky Flats Environmental Technology Site (RFETS) passed on its PAN measurement system, but not its segmented gamma scan system. EPA attended the cycle 3 PDP test of the Pajarito Scientific Corporation (PSC) Imaging PAN (IPAN) system in Tech Area 55 of LANL. The report of this inspection is included in Attachment 2 of this document.

12.0 WASTE CERTIFICATION INSPECTION

The Environmental Protection Agency (EPA) will use inspections to verify that the Department of Energy's (DOE's) waste certification and quality assurance (QA) programs comply with all applicable requirements and that the programs are implemented as described in the Compliance Certification Application (CCA).

Prior to EPA allowing DOE to ship wastes to the WIPP, DOE must demonstrate that the sites shipping the waste have established and executed the requisite QA programs described in §§194.22(a)(2)(i) and 194.24(c)(3) and (5). In addition, due to the site specific nature of operations at each of the generator sites, DOE is required to establish and implement site-specific plans for waste characterization at each of the individual sites.

EPA also required DOE to implement a system of controls at each of the sites, in accordance with §194.24(c)(4), to confirm that the total amount of each waste component that will be emplaced in the disposal system will not exceed the upper limiting value or fall below the lower limiting value. DOE's implementation of such a system of controls includes a demonstration that the site has procedures in place for adding data to the WIPP Waste Information System (WWIS), and that such information can be transmitted from that site to the WWIS database; and a demonstration that measurement techniques and control methods can be implemented in accordance with §194.24(c)(4) for the waste stream(s) proposed for disposal at the WIPP.

Only sites that have waste characterization and QA programs that comply with the applicable requirements will be certified to ship wastes to the Waste Isolation Pilot Plant (WIPP).

12.1 SUMMARY OF EPA ANALYSIS

EPA Rulemaking

Section 194.24(h) gives the Administrator of the EPA the authority to use inspections and record reviews, such as audits, to verify compliance with the requirements of § 194.24. EPA also has authority under § 194.22(e) to verify execution of the QA programs through inspections, record reviews, and recordkeeping requirements. Section 194.21 requires that DOE provide EPA access to any sites, records, or information needed to verify the compliance application. These requirements establish the basis for EPA's waste certification inspections.

EPA Final Determination

EPA confirmed through inspections that the system of controls at the Los Alamos National Laboratory (LANL) is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements.

Through inspections and audits, EPA found that DOE is in compliance with §194.24, and that LANL has demonstrated compliance with §§194.24(c)(3) through (5) for certain retrievably stored legacy debris waste streams inspected by EPA and may therefore ship TRU waste for disposal at the WIPP.

EPA Analysis Process

- EPA reviewed DOE's description of the QA and waste characterization (including process knowledge) programs presented in the CCA and associated reference documents. EPA then performed audits and inspections at the WIPP site, as well as WIPP-related facilities, to verify DOE's (1) compliance with both the QA requirements and site-specific waste characterization plans, and (2) implementation of a system of controls. For example, EPA conducted audits to verify the proper execution of the QA and/or waste certification program(s) at DOE's Carlsbad Area Office ("CAO"), Sandia National Laboratories ("SNL"), Los Alamos National Laboratory (LANL), and Westinghouse's Waste Isolation Division ("WID") at the WIPP facility. In this way, EPA was able to both (1) review voluminous records required by the NQA standards, but not required to be submitted as part of the CCA, and (2) assess the suitability and implementation of site specific waste characterization programs.

- EPA subsequently received information regarding the system of controls to be used at LANL. The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. Therefore, EPA determined DOE to have demonstrated compliance with §§194.24(c)(4) and (5) for several waste streams in the category of retrievably stored legacy debris waste at LANL. EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[42] EPA does

[42] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies/relevant procedures, such as that used for entering data into theWWIS database.

not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

- In summary, EPA finds that DOE is in compliance with §194.24, and that LANL has demonstrated compliance with §§194.24(c)(3) through (5) for certain retrievably stored legacy debris waste streams and may therefore ship TRU waste for disposal at the WIPP (as such shipments relate solely to compliance with EPA's disposal regulations; other applicable requirements or regulations still may need to be fulfilled before disposal may commence). EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.

- To certify LANL's legacy debris waste stream, EPA reviewed all of LANL's quality procedures (QPs) and detailed technical procedures (DTPs) related to the characterization and quality assurance activities associated with LANL's Transuranic Waste Characterization and Certification Program, which included LANL's acceptable knowledge (AK) procedure - TWCP-QP-1.1-021, R.2.

- As part of this review process, EPA also attended three waste certification audits conducted by the Carlsbad Area Office (CAO). EPA documented its observations made at the three audits in the following documents: "Technical Support for Evaluating DOE's WIPP Waste Characterization Program: Inspection Report, Los Alamos National Laboratory, Waste Characterization Certification Audit," May 12-16, 1997; Attachment 1 to this section), "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," August 18-22, 1997; and "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," September 10-12, 1997 Attachment 3 to this section). During the first waste certification audit conducted on May 12 through 16, 1997, EPA observed CAO's auditing of the following quality assurance project description (QAPD) elements:

  - Organization
  - QA Program Implementation
  - Personnel Qualification and Training
  - Quality Improvement
  - Documents and Records
  - Work Processes
  - Procurement
  - Inspection and Testing
  - Measuring and Test Equipment
  - Assessments
  - Sample Control
  - Data Documentation, Control, and Validation
  - Software Requirements.

- EPA also observed CAO's auditing of the following Waste Characterization (QAPP) technical elements:

  - Acceptable Knowledge
  - Sampling Process Design
  - Sampling-Headspace Gas
  - Testing - non-destructive assay (NDA) and real-time radiography (RTR)
  - Visual Examination
  - Analysis - Headspace Gas
  - Data Validation, Usability, and Reporting
  - Performance Demonstration Program (PDP).

For a complete description of EPA's audit observations, see "Technical Support for Evaluating DOE's WIPP Waste Characterization Program: Inspection Report, Los Alamos National Laboratory, Waste Characterization Certification Audit," May 12-16, 1997 (Docket A-93-02, Item).

- EPA attended two LANL follow-up audits conducted by CAO on August 18-22, and September 10-12, 1997, respectively. The two follow-up audits were much more limited in scope than the initial waste characterization certification audit of May 1997. The August 1997 follow-up audit focused on the waste characterization issues identified during the May 1997 audit (i.e., NDA, acceptable knowledge, waste container tracking, software quality assurance, miscertification rates, and random selection) as well as the waste stream profile data and the manual data entry and transmission of LANL waste characterization data to the WIPP site via the WIPP Waste Information System (WWIS). Docket A-93-02, Item V-B-16.) The September 1997 follow-up audit focused on three waste characterization issues identified during the August 1997 follow-up audit (i.e., NDA, acceptable knowledge, and the WWIS). (Attachment 3 to this section.)

12.2 DATA QUALITY OBJECTIVES

The waste characterization data obtained through the Waste Analysis Plan implementation will be used to ensure that the WIPP facility meets regulatory requirements with regard to both regulatory compliance and to ensure that all wastes are properly managed during the Disposal Phase. The Data Quality Objectives (DQOs) established for the plan are implemented by the Quality Assurance Project Plan (QAPP). They are designed to address the specific waste characterization parameters that will be evaluated and will be augmented at the site level under the Quality Assurance Project Site Plan (QAPjP). To satisfy the regulatory compliance requirements, the following DQOs are established in the WAP and have been incorporated into the QAPP/QAPjPs:

- Radiography
    - To verify the TRU waste streams by Waste Matrix Code for purposes of physical waste form identification and determination of sampling and analytical requirements.
- Visual Examination
    - To verify the TRU waste streams by Waste Matrix Code for purposes of physical waste form identification and determination of sampling and analytical requirements.
    - To provide a process check on a sample basis by verifying the information determined by radiography.

12.2.1 Quality Assurance Objectives (QAOs)

Each characterization method described in the QAPP has a corresponding set of QAOs that are intended to provide assurance that the data generated by that method is of known quality. The generator sites must demonstrate compliance with each QAO associated with the various characterization methods as described in the QAPP. Site Project Managers are further required to perform a reconciliation at the project level of the data sets submitted by the various organizations at the site with the DQOs established in this WAP and implemented in the QAPP. The Site Project Manager must determine that all of the DQOs have been met for the characterization of the waste stream prior to submitting a Waste Stream Profile Form to WIPP for approval). The following QAO elements must be considered for each technique, as a minimum:

- <u>Precision</u>
    - Precision is a measure of the mutual agreement among multiple measurements.

- <u>Accuracy</u>

  - Accuracy is the degree of agreement between a measurement result and the true or known value.

- <u>Completeness</u>

  - Completeness is a measure of the amount of valid data obtained from a method compared to the total amount of data obtained that is expressed as a percentage.

- <u>Comparability</u>

  - Comparability is the degree to which one data set can be compared to another.

12.2.2 Sample Control

The sites will implement a sample handling and control program that will include the maintenance of field documentation records, proper labeling, and a chain of custody (COC) record. The site QAPjP will document this program and include COC forms to control the sample from the point of origin to the final analysis result reporting. WIPP will review and approve the QAPjP, including the determination that the sample control program is adequate. Details of this sample control program are summarized below to include:

- Field Documentation of samples including: point of origin, date of sample, container ID, sample type, analysis requested, and COC number.

- Proper Labeling and/or tagging including: proper sample numbering, sample ID, sample date, sampling conditions, and analysis requested.

- Chain-of-Custody control including: name of sample relinquisher, sample receiver, and the date and time of the sample transfer.

- Proper sample handling and preservation.

12.2.3 Data Generation

The DOE's waste characterization program implements the programmatic QA requirements in Chapter 1.0 of SW-846 (EPA, 1986), and the DOE/CAO verifies these requirements through QAPjP review and approval. The generator site QAPjPs are controlled by the QAPP. The QAPP identifies the specific requirements for all QAPjPs including:

- DQOs
- QAOs
- sampling procedures
- sample custody procedures
- calibration procedures and frequencies
- analytical procedures
- data reduction, validation, and reporting requirements
- internal QC checks and frequencies
- performance and system audits and frequencies
- preventive maintenance
- procedures for assessing data quality
- procedures for corrective actions.

A pre-approved format will be used by each generator site for reporting waste characterization data. This form will be defined by the generator site QAPjP. The data reporting format will include all of the elements required by this WAP and implemented through the QAPP for data reports). The generator site must prepare data packages to meet the requirements of QAPjPs. All generator site QAPjPs are reviewed and approved by the DOE/CAO.

The DOE/CAO will perform audits of the generator site waste characterization programs to verify that site sampling, data collection, data validation, and reporting practices, as implemented by the site QAPjPs, will meet DQOs in the WAP (Generator/Storage Site Waste Screening and Acceptance Audit Program). The primary functions of these audits are to review data packages prepared by the generator sites that demonstrate adherence to the requirements of the WAP and assure adherence to the written, approved characterization program (as required by their QAPjPs). These audits ensure that implementation of the QAPjPs are consistent with the intent of the requirements of the WAP as implemented by the QAPP.

The DOE/CAO further requires all analytical laboratories analyzing WIPP waste characterization samples for the generator sites to have established, documented QA/QC programs. The DOE/CAO annually evaluates these laboratories and their QA/QC programs as part of their participation in the laboratory performance program. The audits cover the requirements of the lab's QA/QC program as well as compliance with the method parameters specified in the Methods Manual, the WAP, and the QAPP. Continued compliance with these parameters will be verified by ongoing CAO audits. The laboratory's QA/QC program must include the following:

- Facility organization
- Lists of equipment/instrumentation
- Operating Procedures
- Laboratory QA/QC Procedures
- Quality Assurance Review
- Laboratory Records Management

EPA will observe these audits and inspections conducted by CAO to verify each of the DOE site's (1) compliance with both the QA requirements and site-specific waste characterization plans, and (2) implementation of a system of controls. In this way, EPA will be able to both (1) review voluminous records required by the NQA standards, but not required to be submitted as part of the CCA, and (2) assess the suitability and implementation of site specific waste characterization programs. The Agency will also confirm both the execution of these programs and the continued compliance with the requirements of §§194.24(c)(3) through (5) at each of the waste generator sites through inspections and audits under its authority at §§194.21, 194.22(e) and 194.24(h).

12.3 CRITERIA OF EVALUATION

EPA's Site Certification Inspection focused on Los Alamos National Laboratory's (LANL) ability to meet the waste characterization and data tracking/reporting requirements of 40 CFR §194.

12.3.1 Overview

12.3.1.1 Inspection Acceptance Criteria

Inspection Acceptance criteria, included the following:

- Examination to determine whether the personnel running the system or operating the equipment are technically competent,

- Examination to determine whether the equipment is technically adequate,

- Examination to determine whether the procedures used are technically adequate,

- Examination to determine whether the wastes are being analyzed for all the Waste Acceptance Criteria (WAC) Requirements,

- Examination to determine whether waste characterization information is effectively tracked and integrated into data reporting systems to produce required reports, and

- Examination to determine the certification status of the site's waste characterization program (QAPjPs, TRAMPAC, QA Plan, resources, etc.).

12.3.1.2 Inspection Method

EPA's inspection method employed observation of the technical elements associated with the waste characterization and data reporting requirements of 40 CFR §194. EPA examined the following processes: radioassay instrumentation used for non-destructive assays (passive active drum counters), physical and chemical characterization instrumentation (RTR, visual examination facilities, analytical laboratories), waste profile forms, and data reporting and integration systems. Although EPA observed DOE/CAO's conductance of the overall audit, EPA actively participated in the audits and questioned various personnel levels (i.e., upper management, middle management, laboratory analyst) to determine technical adequacy of the following technical evaluation items:

1) Current analytical methods the measurement facility uses (and will use) to characterize the nuclear, chemical, physical, and gas generation properties of WIPP wastes. Inquire if these methods have been developed and approved within the specifications of the QAPP. Inquire which methods were demonstrated during any applicable PDPs.

2) Personnel positions and their associated responsibilities, authority and accountability.

3) Analytical instrumentation being used for the characterization of the nuclear, chemical, physical, and gas generation properties and anticipated to be used for the analysis of WIPP wastes. Inquire about: calibration and frequency; data reduction and validation; internal audits; and preventive maintenance.

4) Quality assurance objectives (QAOs) (i.e., precision, accuracy, bias) associated with the QAPjP.

5) How they determine the nuclear properties of the CH-TRU and RH-TRU wastes (including, nuclear criticality, PU-239 content, contact dose rate, thermal power, TRU alpha activity).

6) Isotopes of interest (including Americium 241 and 243, Carbon 14, Cesium 135 and 137), Iodine 129, Neptunium 237, Plutonium 237-240 and 242, Radium 226, Thorium 230 and 232, Strontium 90, Technetium 99, Tin 126, and Uranium 233-236 and 238).

7) How they determine the chemical properties of the wastes (including, the presence of phyrophoric materials, explosives, corrosives, compressed gases, PCBs, phosphates, nitrates, organic ligands, methane, hydrogen gas, metals, volatile organic constituents, and semi-volatile organic constituents).

8) How they assess the potential for gas generation (including, flammable volatile organic constituents, aspiration techniques, shipping provisions, layers of confinement).

9) How they determine the physical properties of the wastes (including, waste form/content codes; presence of cement/soils, free liquids, vitrified materials, other inorganic materials, solidified organic and inorganics; and the mass/volume of metals, cellulosics, rubber, plastic, and chelating agents present in the waste).

10) Procedures for data transmittal (including, reporting methods, site databases, data integration, current tracking systems, future tracking systems-WWIS) and specific reports that will be generated to track required parameters for meeting emplacement limits.

11) Site's current certification status (does the site have the requisite certifications to ship waste to the WIPP - QAPjP, site-specific TRAMPAC and QA Plan, TRU Waste Certification Plan, Packaging QA Plan).

12) Results of past audits and status of any CARs or observations made concerning the site's waste characterization and data reporting/tracking systems.

13) Analysis completion and reporting time period, and whether sufficient resources are (will be) available to characterize all the wastes at LANL.

EPA also conducted spot-reviews of the field logbook and copies of the forms utilized by LANL to ensure that the documentation procedures and administrative requirements were met. EPA prepared inspection reports on each of the processes observed during the audit. These inspection reports provide, at a minimum, the following information:

1) Item inspected,
2) Date(s) of inspection,
3) Inspector,
4) Type of observation to include results of your evaluation relative to technical adequacy of personnel running the program, adequacy of equipment, adequacy of procedures, and a specific comment as to whether the inspector(s) had adequate access to the inspected areas,
5) Results or acceptability, and
6) Reference to information on actions taken in conjunction with nonconformances.

12.3.2 Processes and Items Examined During LANL Observations

12.3.2.1 Overview of Inspection Activities

To certify LANL's combustible debris waste stream, EPA reviewed all of LANL's quality procedures (QPs) and detailed technical procedures (DTPs) related to the characterization and quality assurance activities associated with LANL's Transuranic Waste Characterization and Certification Program, which included LANL's acceptable knowledge (AK) procedure - TWCP-QP-1.1-021, R.2. As part of this review process, EPA also attended three waste certification audits conducted by the Carlsbad Area Office (CAO). EPA documented its observations made at the three audits in the following documents: "Technical Support for Evaluating DOE's WIPP Waste Characterization Program: Inspection Report, Los Alamos National Laboratory, Waste Characterization Certification Audit," May 12-16, 1997; (Attachment 1 to this section), "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," August 18-22, 1997 ; and "Inspection Report for Los Alamos National

Laboratory, Waste Characterization Certification Follow-up Audit," September 10-12, 1997 (Attachment 3 to this section).

12.3.2.2 May 12-16, 1997 Waste Characterization Certification Audit - LANL

During the first waste certification audit conducted on May 12 through 16, 1997, EPA observed CAO's auditing of the following quality assurance project description (QAPD) elements:

- Organization
- QA Program Implementation
- Personnel Qualification and Training
- Quality Improvement
- Documents and Records
- Work Processes
- Procurement
- Inspection and Testing
- Measuring and Test Equipment
- Assessments
- Sample Control
- Data Documentation, Control, and Validation
- Software Requirements.

EPA also observed CAO's auditing of the following Waste Characterization (QAPP) technical elements:

- Acceptable Knowledge
- Sampling Process Design
- Sampling-Headspace Gas
- Testing - non-destructive assay (NDA) and real-time radiography (RTR)
- Visual Examination
- Analysis - Headspace Gas
- Data Validation, Usability, and Reporting
- Performance Demonstration Program (PDP).

In particular, the scope of the first audit focussed on personnel qualifications and NDE/NDA technical adequacy. The scope of the audit also included additional waste characterization related issues. These issues are acceptable knowledge, software, waste container tracking, miscertification rates, random selection, training records as well as other issues as presented in this Inspection Report.

From the late morning of May 12, 1997 through the early morning of May 16, 1997, the CAO auditors broke into four separate audit teams consisting of lead auditors and technical specialists. Even then, most of the teams were further divided into two subteams of at least one lead auditor and one technical specialist. At any given time, there were four to eight different audits occurring. At the direction of EPA, CAO audit team and subteam assignments were given to the EPA staff and the team members. Some CAO audits were covered by one EPA staff member or one team member, while other audits had two or more EPA staff members or team members present. The audits which were less relevant (i.e., procurement, grading) to waste characterization were not attended by EPA or its' contractors.

For a complete description of EPA's audit observations, see "Technical Support for Evaluating DOE's WIPP Waste Characterization Program: Inspection Report, Los Alamos National Laboratory, Waste Characterization Certification Audit," May 12-16, 1997. (Attachment 1 to this section).

12.3.2.3 August 18-22, 1997 Follow--Up Waste Characterization Certification Audit - LANL

EPA then attended a follow-up audit conducted at LANL by CAO on August 18-22. The follow-up audit was much more limited in scope than the initial waste characterization certification audit of May 1997. The August 1997 follow-up audit focused on the waste characterization issues identified during the May 1997 audit (i.e., NDA, acceptable knowledge, waste container tracking, software quality assurance, miscertification rates, and random selection) as well as the waste stream profile data and the manual data entry and transmission of LANL waste characterization data to the WIPP site via the WIPP Waste Information System (WWIS).

The first follow-up audit began with a kick-off meeting on the morning of August 18, 1997. The meeting was attended by EPA WAM - Kyle Rogers, the first set of WIPP Waste Characterization team members as previously mentioned, the CAO audit group, and the LANL waste characterization staff. EPA and the WIPP Waste Characterization team members conducted their own meetings at the end of each day to discuss waste characterization issues. Each morning there were management meetings between CAO and LANL which were attended by EPA. On August 22, 1997, there was a CAO auditor close-out meeting which was attended by LANL staff, EPA and the WIPP Waste Characterization team members.

From the morning of August 18, 1997 through the evening of August 22, 1997, the CAO auditors broke into four separate audit teams consisting of lead auditors and technical specialists. At the direction of the EPA WAM, CAO audit team assignments were given to the WIPP Waste Characterization team members. The CAO audits were covered by at least one EPA staff member and/or one WIPP Waste Characterization team member. One technical area, manual waste characterization data entry and transmittal from LANL to the WIPP site via the WWIS, was added to the August 1997 follow-up audit that was not covered during the May 1997 audit. The audits which were not relevant (i.e., transportation) to waste characterization were not attended by EPA or its' contractors.

12.3.2.4 September 10-12, 1997 Follow--Up Waste Characterization Certification Audit - LANL

The September 1997 follow-up audit focused on three waste characterization issues identified during the August 1997 follow-up audit (i.e., NDA, acceptable knowledge, and the WWIS). ((Attachment 3 to this section.) The second follow-up audit began with a kick-off meeting on the morning of September 10, 1997. The meeting was attended by EPA WAM - Kyle Rogers, the second set of WIPP Waste Characterization team members as previously mentioned, the CAO audit group, and the LANL waste characterization staff. EPA and the WIPP Waste Characterization team members conducted their own meetings at the end of each day to discuss waste characterization issues. Each morning there were management meetings between CAO and LANL which were attended by EPA. On September 12, 1997, there was a CAO auditor close-out meeting which was attended by LANL staff, EPA and the WIPP Waste Characterization team members.

From the morning of September 10, 1997 through the evening of September 11, 1997, the CAO auditors broke into three separate audit teams consisting of lead auditors and technical specialists. At the direction of the EPA WAM, CAO audit team assignments were given to the WIPP Waste Characterization team members. The CAO audits were covered by at least one EPA staff member and/or one WIPP Waste Characterization team member. Angela Jones of A.T. Kearney was not present at LANL, but was present at the WIPP site in Carlsbad, New Mexico to witness the receipt and processing of waste characterization data transmitted from LANL to WIPP via the WWIS.

12.3.2.5 Specific Processes and Items Observed

As discussed earlier, EPA's inspection method was primarily based on the observation of the technical elements associated with the waste characterization and data reporting requirements of 40 CFR §194. EPA examined the following processes:

- radioassay instrumentation used for non-destructive assays (passive active drum counters)
- physical and chemical characterization instrumentation (RTR, visual examination facilities, analytical laboratories)
- waste profile forms
- data reporting and integration systems.

Although EPA observed DOE/CAO's conductance of the overall audit, EPA actively participated in the week-long audits and used the check lists provided below to question various personnel levels (i.e., upper management, middle management, laboratory analyst) to determine technical adequacy of the waste characterization systems used at LANL.

Visual Examination (VE)

1. As a QC check on radiography, does the site open and visually examine a statistical portion of the certified waste containers?

2. Does the site use the data from visual examination to check the matrix parameter category and waste material parameter weight estimates as determined by radiography?

3. Does the site use the data obtained from the visual examination to determine, with acceptable confidence, the percentage of miscertified waste containers?

4. For the first year of operation, did the site use INEL's historical miscertification rate of 2% to calculate the number of waste containers that must be visually examined during the first year of program activities?

5. Has the site established a site-specific miscertification rate? Is the site's revised miscertification rate based on the last 12 (or more) months of certification activities?

6. Table 5-1, page 19 of 27 presents the number of waste containers requiring visual examination by miscertification rate and annual number of waste containers undergoing characterization. Is the annual number of waste containers undergoing characterization within the range used in the table (50 to 500)? Is the miscertification rate within the range presented in the table (1% to 6%)?

7. Were waste containers randomly selected and examined?

8. Were only waste containers certified for compliance with WIPP-WAC and TRAMPAC selected?

9. Is there a definable finite population of waste containers for which the proportion miscertification rate was based on (e.g., 200 drums)?

10. What period of time was the miscertification rate based on? If less than 12 months of operating data were available, was the historical miscertification rate of 2% used?

11. Does the facility have a procedure for randomly selecting waste containers?

12. Does the facility have a replacement strategy for selecting waste containers?

13. Was the replacement visual examination performed on the sampled containers?

14. Was the replacement strategy restricted to a waste stream or waste stream lot that, through the random selection process, happened to have container(s) identified for visual examination.

15. If fewer containers were visually examined than were sampled, were the replacements selected randomly from the population of sampled containers? Were the replacement containers from a different lot?

16. Once containers have been visually examined, was the UCL_{90} for the proportion miscertified calculated?

17. Did the site take precautions to ensure that corrective actions taken after the containers were visually examined to improve certification accuracy were not used to adjust the visual examination results and the UCL_{90}?

18. Did the facility use the hypergeometric distribution for the UCL_{90} calculation? The normal distribution is not allowed.

19. If the binomial distribution was used, was *N* larger than 500 waste containers?

20. Are the results of the visual examination forwarded to the radiography facility?

21. Was the visual examination based on a semi-quantitative and/or qualitative evaluation of the waste container contents? Was the examination recorded on audio/videotape?

22. Is there a standardized training program for visual inspection examiners? Does it include both formal classroom and OJT? Is it specific to the site and include the various waste configurations generated/stored at the site?

23. Do the visual inspectors receive training on the specific waste generating processes, typical packaging configurations, and waste material parameters expected to be found in each matrix parameter category at the site?

24. Was the OJT and apprenticeship conducted by a qualified, experienced operator?

25. Are the visual inspectors requalified once every two years?

26. Does the site specific training program contain the following required elements based on ASME NQA-1:

    <u>Formal Training</u>
    - Project Requirements
    - State and Federal Regulations
    - Application Techniques
    - Site-Specific Instruction

    <u>On-the-Job Training</u>
    - Identification of Packaging Configurations
    - Identification of Waste Material Parameters
    - Weight and Volume Estimation
    - Identification of Prohibited Items

27. Has the site designated a visual examination expert? Has the visual examination expert completed all of the required training? Is the visual examination expert familiar with the

waste generating processes that have taken place at the site? Is the visual examination expert familiar with all of the types of waste being characterized at that site?

28. Is the visual examination expert responsible for the overall management and implementation of the visual examination aspects of the program? Does the site's QAPjP specify the selection, qualification, and training requirements of the visual examination expert?

29. Has the visual examination expert decided the extent of waste segregation necessary to achieve program objectives?

30. Does the site's QAPjP specify decision-making criteria for the visual examination expert to follow when determining the appropriate degrees of segregation? Does the site have SOPs to support the visual examination process? How does the visual examination expert document the basis for his/her decision?

31. Does the visual inspector record the description of the waste container contents on any form? Does the description clearly identify the appropriate matrix parameter categories listed in the BIR? Is the information sufficient to estimate weights of waste material parameters?

32. If the bags are not opened, is a brief written description of the contents of the bags prepared to document the estimated amounts of each waste type in the bags?

33. Are the written records of visual examination supplemented with the audio/video recording?

34. Does the site have a site-specific SOP for conducting visual examinations?

35. How does the site define testing batch? Does the testing batch have less than 20 waste containers? If so, is it possible for the site to examine the number of waste containers in one day?

36. If the site visually examines a waste container that has not undergone radiography, were the results of the visual examination placed in a separate visual examination report?

37. Does the site have a SOP for handling instances when the inspector is unable to see through the inner plastic bags/packages of waste because of discoloration, grease and dust adhering to the interior surface of the bags/packages or because of sealed and taped containers within the bags/packages? Does the facility use documented acceptable knowledge to identify the matrix parameter category and estimate waste material parameter weights?

38. Does the visual examination expert have decision-making criteria for assessing the need to open the bags/packages in order to identify all of their contents?

39. Was the weight estimates based on the best possible values?

40. Are visual examinations conducted in areas that have adequate radiation containment facilities? Does the visual examination area have the following equipment:

    - Drum, waste bag, and waste handling equipment?
    - Video cameras and audio equipment?
    - Mass balances and calibration standards?
    - Bag opening unit?
    - Data input station?
    - Safety equipment?

41. Does the site follow all the waste container handling and chain-of-custody procedures described in Section 6.0 of the QAPP?

42. Prior to starting the visual examination, did the visual examination expert review all documented data related to the waste container and its contents? If the visual examination expert determined in advance to open all bags/packages in a waste container of a particular TRUCON code, matrix parameter category, and/or IDC, was this decision based on documented acceptable knowledge or data from previous examinations of the waste? Did the visual examination expert document the basis for these decisions?

43. In cases when visual examination is done as a QC check to the RTR results, are precautions taken to ensure that the visual examination team does not review the RTR results prior to the visual examination?

44. Are there SOPs for ensuring that headspace gas sampling is conducted prior to the visual examination team's opening of the waste container?

45. Once the lid of the waste container is removed, does the visual examination expert estimate the waste container volume utilization percentage?

46. Are the number of liners and types of liners present in the waste container documented? Are the individual inner bags/packages, if present, removed from the poly liner(s)? Are all of the inner bag/packages labeled and weighed using a properly calibrated mass balance?

47. Is the video camera properly focused prior to the start of the visual examination of an unopened inner bag/package? Is the operator's verbal description of the inner bag/package's inventory recorded?

48. Does the inventory include a description of all waste items, residual materials, packaging materials, and/or waste material parameters contained in the inner bag/package?

49. Are the estimates of the weights of the waste items, residual materials, packaging materials and/or waste material parameters recorded on both audiotape and the visual examination data form?

50. Has the site developed reference tables to assist the operators in making weight estimates and for assigning waste to a particular wast material parameter? Does the site have a procedure for updating these reference tables as the site gains experience in conducting visual examinations?

51. Does the visual examination expert assess the accuracy of the TRUCON code, matrix parameter category, and/or IDC? Does the visual examination expert recommend changes? If so, are they documented?

52. If it is determined that the inner bag/package needs to be opened, are all of their contents sorted, weighed, and recorded? Is an inventory of loose waste items, residual materials, packaging materials, and/or waste material parameters not contained in inner bags/packages also recorded, sorted, and weighed?

53. If liquids are found, is a description of their location, container, and estimated volume recorded?

54. Is the weight of the empty container and its rigid poly liner, if present, recorded and documented? Is the gross weight of the waste container (container plus contents) recorded on the visual examination data form? Is the total number of bags/packages also recorded on the data form?

55. Has the site established standard nomenclature, based on current site practice, to assure that all operators recognize waste by the same descriptors?

56. Are visual examination operators trained on all types of waste that are generated, stored, and/or characterized at the particular site?

57. Has Sandia National Laboratories developed standard error calculations for use by the site? If so, is the site using them?

58. Does the site make replicate weight measurements? Are one in twenty, or at least one waste item, residual and packaging material, or waste from a single waste material parameter from each drum reweighed after all other drum contents are weighed? Are these replicate measurements used as a measure of the precision of the weighing process?

59. Does the site have mass balances spanning a range of weights from 10 g to 450 kg (1,000 lbs). Are the mass balances checked prior to use and calibrated annually? Is the weighing system calibrated using standards traceable to the National Institute of Standards and Technology (NIST)?

60. Did the visual examination operators conduct checks of the audio/visual recording equipment prior to each day's use to ensure that the video picture and record meet minimum quality requirements? Are observations of test patterns made?

61. Did two operators concur on the results of the visual examination by signing the data form? If the operators were unable to concur, did the visual examination expert resolve the discrepancies?

62. Did the visual examination expert determine the relative percent difference (RPD) between the reported weights for cellulosics and aluminum using the weight estimates determined by radiography?

63. Did the visual examination program conform to the following assumptions to determine the number of containers to examine:

    - Waste containers selected randomly
    - Only containers certified for compliance with WIPP-WAC and TRAMPAC selected
    - Population of containers has been established and is finite
    - 98% of containers properly certified if no experience available
    - Certification process is uniform and unbiased regardless of waste stream
    - Radiography system is functioning properly.

64. Can the site provide objective evidence of the status of the current implementation of PDPs (schedule of past and planned tests, reports on test rounds conducted, etc.)?

65. Are the standardized Methods Manuals, Sampling and Analysis Procedures, manuals, etc., which are used to standardize waste characterization methodologies present in the visual examination facility?

66. Can the site provide objective evidence (e.g., audit reports, certification reports, etc.,) of the status of the current implementation of methods/procedures?

<u>Acceptable Knowledge (AK)</u>

Acceptable knowledge refers to applying knowledge of hazardous characteristic of the waste in light of the materials or processes used to generated the waste. This may include accompanying records; administrative, procurement, and quality controls associated with the processes generating the waste; past sampling and analytical data; material inputs to the waste generating process; and the time period during which was generated.

The Technical Evaluation Items listed below are based on the Quality Assurance Program Plan as well as general auditing activities. All of the Technical Evaluation Items below can and should be asked at various personnel levels (i.e., upper management, middle management, laboratory analyst) to determine technical adequacy. The following should be incorporated in every Certification Audit:

1. Inquire about the waste process information. The information must include: area(s) and building(s) form which the waste stream was or is generated; waste stream volume and time period of generation; waste generating process described for each building; process flow diagrams; material inputs other information that identifies the chemical and radionuclide content of the waste stream and the physical waste form; and a summary identify all sources of information.

2. Inquire about any supplemental acceptable knowledge documentation used for acceptable knowledge (e.g. process design documents; SOPs that may include a list of raw materials or reagents, a description of the process or experiment generating the waste, and a description of wastes generated and how the wastes are managed at the point of generation; and waste packaging logs, etc.).

3. Inquire about the qualifications of the site personnel responsible for assessing information and resolving discrepancies. Do they meet the requirements outlined in Section 4.4.1 of the QAPP.

4. Inquire about the information used for characterizing the waste, which should include: physical form of the waste, the matrix parameter of the waste stream, waste material parameters and radionuclides present in each waste stream, identify hazardous wastes and assign the appropriate matrix EPA hazardous waste numbers and documented changes to the process and/or material inputs.

5. Inquire about the way acceptable knowledge is used. It can be used in three ways: to delineate waste streams; to make all hazardous waste determinations for combustible debris and special waste; and to determine if homogenous solids and soil/gravel are RCRA-listed wastes.

6. Inquire if the site maintain the required information in an auditable record . This information include TRU waste management program information (e.g., site maps, facility mission description, description of operations) and TRU waste stream information (e.g. waste stream volume and time period of generation, waste generating processes, process flow diagrams). DOE sites must ensure the following four criteria are met in establishing acceptable knowledge records: an auditable record with a road map; overview of the facility and TRU waste management operations; correlations between waste streams; and a reference list.

7. Inquire about the written procedures that describe the compilation, use and confirmation of acceptable knowledge. The site must have a written procedure outlining the specific methodology used to assemble acceptable knowledge records, including the origin of the documentation, how it will be used, and any limitations associated with the information (e.g. identify the purpose and scope of a study that included limited sampling and analysis data).

8. Inquire about the written procedures that describe how the required acceptable knowledge records are compiled. Sites must assemble and evaluate available documentation in the following priority: relevant information from published documents and controlled databases; unpublished data; internal procedures and notes, such as log books; and correspondence such as memoranda, letters, telephone logs, and interviews.

9. Inquire about the procedures that are used to ensure unacceptable wastes are identified and segregated and waste is certified for shipment to the WIPP facility.

10. Inquire about the management controls used to ensure nonconforming items are documented and managed. Sites must ensure radiography and visual examination procedures include a list of nonconforming items that the operator must verify are not present in each container of waste (i.e., corrosives, ignitables, reactives, incompatible wastes).

11. Inquire about the procedure(s) for the confirmation of acceptable knowledge prepared in accordance with Section 4.4.3 of the QAPP (e.g. logical sequence of acceptable knowledge information that progresses from general facility information to more detailed waste-specific information

12. Inquire about the cross reference for applicable matrix parameter summary category to verify all of the required confirmation data has been evaluated and the proper EPA hazardous waste numbers have been assigned.

13. Inquire how acceptable knowledge information is evaluated and any discrepancies in documentation are resolved.

14. Inquire how changes to matrix parameter categories, waste stream assignment, and any associated EPA hazardous waste numbers based on material composition are documented for combustible debris waste streams.

15. Inquire about the non-destructive techniques (i.e., radiography, headspace gas sampling and analysis) which is used to confirm acceptable knowledge information.

16. Inquire about the visual examination of retrievably stored waste which is repackaged. Visual examination during repackaging is used to confirm acceptable knowledge rather than radiography.

17. Inquire about the written procedures to document the confirmation of acceptable knowledge prior to or during waste packaging of newly generated wastes. (Section 4.2.1 of the QAPP)

18. Inquire the procedures used to demonstrate through compliance with written procedures that discrepancies in information will be documented and that hazardous waste codes will be conservatively applied.

Non-Destructive Assay (NDA)

1. How is acceptable knowledge (AK) being used to support NDA?

2. If waste stream is contaminated with radioactive materials of variable or unknown isotopic composition, the method used to determine isotopic ratios must be:
   - independent of AK (but does not preclude AK)
   - documented and supportable basis/bases for isotopic ratios

3. How is destructive assay being used to support NDA?

4. The NDA techniques being used must be appropriate for the wastes? Take into consideration:
   - physical form
   - radionuclide content
   - waste generating process

5. Total uncertainty must be calculated using terms derived for compliance with QAO for total uncertainty and be reported with the data. See pages 17 and 18 of the QAPP for details.

6. Refer to Table 9-1 of the QAPP for QAOs for NDA.

7. Precision - Compliance with QAO for precision should be demonstrated by replicate processing of a waste container containing the quantities of TRU isotopes for each range in Table 9-1 for which the measurement system is to be qualified. Activity should be distributed in a well characterized, noninterfering matrix and should not be one of the calibration standards. Fifteen replicate counts are needed with removal and reinsertion of container from measurement system between measurements. Precision should be computed as %RSD of the distribution of these replicates. See Table 9-1 of the QAPP.

8. Accuracy - Compliance with QAO for accuracy should be demonstrated by replicate processing of a waste container containing the quantities of TRU isotopes for each range in Table 9-1 of the QAPP for which the measurement system is to be qualified. Activity should be in the form of a verification standard, but should not be one of the calibration standards nor should it be derived from a calibration standard. Activity should be

distributed in a well characterized, noninterfering matrix. Fifteen replicate counts are needed with removal and reinsertion of container from measurement system between measurements. Accuracy should be computed as %R of the distribution of these replicates. Evidence of standard traceability and certificates for individual standards should be available for inspection. See Table 9-1 of the QAPP.

9. Sensitivity Limits - The ability to achieve the required detection limit in Table 9-1 must be demonstrated for each specific waste type/method combination planned for use in the Program.

10. Minimum Detectable Concentration (MDC) - The ability to establish that some minimum overall measurement conditions can be met must be demonstrated. The MDC is the level of activity that is practically achievable under a set of typical measurement conditions (i.e., with a given instrument, method, analyte, matrix). The MDC is only applicable to systems discriminating TRU from LLW. See Table 9-1 of the QAPP. MDC = 60 nCi/g

    Compliance with QAO for precision should be demonstrated by replicate processing of a waste container containing only a well characterized, noninterfering matrix with no added activity. However, radioactive materials may be included in the background drum if this is required to simulate a confounding background activity. Fifteen replicate counts are needed with removal and reinsertion of container from measurement system between measurements. Alternate methods may be proposed, but have to be fully justified and demonstrated to be more appropriate to the system and conditions. MDC should be computed using the variance of the background count. See Table 9-1 of the QAPP.

11. The QAOs for total bias are expected to be achievable in the presence of backgrounds, absorbing materials and moderating materials. See Table 9-1 of the QAPP.

12. Completeness - Acceptable NDA data should be obtained for 100% of the waste containers characterized for disposal. Acceptable data consists of data obtained from measurement systems that have demonstrated to meet all relevant QAOs for NDA.

13. Comparability - When multiple systems are planned for use in determining the same or comparable parameters, the participating sites should perform multiple, independent radioassays of a sample of waste containers. Resulting data should be reported to CAO in semi-annual QA reports.

14. Performance of software controlling the measurement process and analyzing data should be demonstrated and documented in accordance with ASME NQA-1 and NQA-2. Performance may be demonstrated by the use of test problems and/or QC samples. Software testing must cover the full range of expected applications of the system.

15. Any type of NDA technology may be used as long as the QAOs are met.

16. Whenever applicable, the assay procedures cited in ASTM (1989a or b, 1991b, 1992) and NRC standard practices and guidelines (NRC 1984) are recommended for use. These procedures require the use of proper calibration standards, proper equipment and equipment setup, avoidance of practices known to result in inaccurate assays (i.e., misalignment of waste packages), attention to proper recordkeeping and equipment maintenance, and safe operation of equipment.

17. NDA SOPs must instruct operators to perform all necessary background and performance checks prior to performing waste assay. The performance check data must be checked against predetermined acceptance criteria. If any criterion is not met, corrective action (i.e., repetition of background and/or standards measurements) must be taken. There must be a method for determining and recording acceptance criteria. The disposition of any waste assay data obtained during a period ending in a suspect performance check, any resulting investigation or any corrective action must be documented and justified.

18. NDA SOPs must contain all necessary instructions for the operation of computerized data acquisition systems. Software instruction should include explanations of required input, options, and prohibitions for operators when exercising interactive portions of the software.

19. Procedures must be codified as SOPs which have been written, approved and controlled under the QAPjP.

20. Procedures must have internally demonstrated and documented performance characteristics which meet the QAOs.

21. There must be an implemented and documented facility QA program which should include qualitative and quantitative acceptance criteria for the QC checks of the Program and corrective action to be taken when criteria are not satisfied.

22. The QA officer is responsible to monitor and document procedure performance (including analysis of QC samples). Nonconformance report must be generated and resolved if the final, reported QC measurements do not meet acceptable criteria. QA officer and technical supervisor should have the responsibility to implement corrective actions when acceptable performance is not met.

23. NDA systems must be checked through the use of calibration check and background waste containers as well as replicate determinations.

24. All NDA systems should be operated in statistical control as determined by the control limits in the SOP.

25. All required instrument performance parameters for each instrument used to perform measurements intended for use in the Program must be performed and reported in the semi-annual reports to CAO.

26. If any QC measurement fails to meet Program criteria, the analytical measurement may not be continued prior to taking corrective action.

27. Instrument Performance Check sources do not have to be NIST traceable. Requirements for these sources are that they be long-lived, simple to reposition, sufficiently high activity, and relatively insensitive to handling.

28. Performance check control charts should be used to track trends in the parameters measured. Data should be logged, plotted on control charts and compared to preset limits. Data should be delivered with analytical data, covering the same time period over which the analyses were performed.

29. Performance checks should include efficiency and background. Performance checks for spectrometric instruments should also include energy calibration and energy resolution checks. Performance checks (except for backgrounds) should be performed and documented at least twice per shift. These checks should be performed prior to waste assay for that shift and after completion of all waste assay for that shift. When shifts overlap, the final check of one shift can also be considered the initial check of the next shift. Site SOPs should indicate the frequency of background checks.

30. Replicate Counts - Duplicate measurements must be performed on 1 of every 20 waste containers, or 1 container per day whichever is more frequent.

31. Facility must participate in site intercomparison programs such as the NDA PDP.

32. Only trained personnel will be allowed to operate NDA systems. Standardized training requirements of ASME (1989) NQA-1 (Element 2 with the exception of Supplement 2S-2). Requalification of operators must be based upon evidence of continued satisfactory performance and must be done every 2 years. Unsatisfactory performance will result in disqualification of operator. Retraining and demonstration of satisfactory performance are required before operator is again allowed to operate an NDA system.

33. NDA systems must be calibrated and maintained according to controls established and implemented in facility QAPjPs and SOPs, respectively. SOPs must cover routine system calibration, performance checks and system operation. For systems addressed b ANSI, ASTM or other consensus standards, SOPs must be consistent with all relevant provisions of these standards.

34. All NDA systems must be calibrated for the analysis of interest. This includes the determination of the counting efficiency or some other response factor. Each NDA system must be subjected to a complete calibration appropriate to its planned usage and based on applicable consensus standards (i.e., ASTM). Each calibration must be fully supported by records which can be tracked to standards obtained form NIST or suppliers with NDA systems traceable to NIST. Once established, the calibration is valid until a preset time

limit has been exceeded or the instrument fails other performance checks. Complete calibration verification of the NDA system for at least 1 counting geometry/sample matrix combination must be repeated at least annually.

35. Primary calibration standards should be obtained from NIST or other supplier as previously noted, whenever such standards are available. Whenever such standards are not available, the actual standards used should be calibrated against primary standards obtained from NIST or other supplier as noted above. Documentation of this cross-calibration should be retained in the QA record.

36. Working calibration standards should be prepared using isotopes, geometries and matrices like those of the actual waste without compromising the quantitative integrity or homogeneity of the standard.

37. Range of applicability of the calibration must be specified in the SOP. If assay measurements fall out of that range, assay measurements must be repeated on other measurement systems covering the required range or corrective actions must be taken and be documented.

38. Commonly accepted techniques of transmission and live-time corrections (to compensate for matrix effects) are acceptable. Calibration of NDA systems using correction factors should include the determination of calibration factors and functional relationships to other waste parameters. The range of waste types applicable to a given calibration and set of correction factors must be determined and documented.

39. All computer programs and revisions must be documented, verified and validated per the QAPD before initial production of analytical data. Verification includes both verification of the algorithm used and test runs of the program comparing the program output to true values. Test runs should exercise all default and boundary values of parameters. Programs should be documented per ANSI standards.

40. Individuals responsible for (1) system operation and maintenance including documentation and training, (2) database integrity including data entry, data updating and QC, and (3) data and system security, backup and archiving must be identified.

41. NDA data reduction software and/or other data reduction procedures must be specified in QAPjPs and SOPs. The exact algorithms used must be contained in site-specific technical documentation.

42. All data must be reviewed and approved prior to being reported. See Section 3.0 of the QAPP for details on the data validation process which includes verification that the QAOs have been met. The values for all parameters critical to the demonstration that QAOs have been met must be maintained the same for actual waste measurements as were used for the QAO demonstration.

43. Data Reporting - The results of the NDA must be documented and available to the users. Raw data must be retained in sufficient detail with adequate support documentation to repeat all calculations. If activities of isotopes other than the isotopes of interest are detected, the activity of these isotopes must be reported. Data must be reported to the site project office on a testing batch basis, and on approved standard forms (or electronic version). Reports should include data review checklists, and testing report sheets for each sample. All associated uncertainties should be reported at the 95% confidence level. Total uncertainty must be calculated using the terms derived for compliance with the total uncertainty QAO. Testing facilities should maintain in their files, documented and retrievable by testing batch number the following: (1) original waste container COC forms, (2) all raw data including instrument readouts, calculation records, and QC results, and (3) all applicable instrument calibration reports. These items should be forwarded to the site project office for storage in their files, and may be submitted in electronic format.

Radiography (RTR)

1. Does the site use RTR to determine the matrix parameter category and estimate waste material parameter weights of retrievably stored waste?

2. Precision - Did the site project QA Officer calculate and report the relative percent difference (RPD) between the estimated waste material parameter (WMP) weights as determined by radiography, and these same parameters as determined by visual examination (VE)?

3. Accuracy - Was the accuracy with which the matrix parameter category and WMP weights can be determined documented through VE of a randomly selected statistical portion of waste containers?

4. Accuracy - Was the percentage of waste containers which requires a new matrix parameter category after VE calculated and reported by the site project QA officer as a measure of radiography accuracy?

5. Completeness - Was an audio/videotape of the radiography examination and a radiography data form validated according to the requirements in Section 3.0 of the QAPP?

6. Completeness - Was an audio/videotape of the radiography examination and a radiography data form obtained for 100% of the retrievably stored waste containers?

7. Comparability - How is the comparability of radiography data from different sites performed? The QAPP says comparability shall be enhanced by using standardized radiography procedures and operator qualifications (and training are described in Section 10.3) in accordance with the QAPP.

8. Was the objective of radiography to verify the matrix parameter category and estimate the WMP weights met?

9. Was the data to meet this objective obtained from an audio/videotaped scan provided by trained radiography operators?

10. Were results recorded on a radiography data form?

11. Were all activities required to achieve the radiography objective described in site Quality Assurance Project Plans (QAPjPs) and Standard Operating Procedures (SOPs)?

12. Did the radiography system consist of the following:

    - a shielded room that is properly ventilated and lighted?
    - an X-ray producing device? (See #13 below.)
    - an imaging system? (See #14 below.)
    - an enclosure for radiation protection?
    - a waste container handling system (including a turntable dolly assembly)?
    - an audio/video recording system?
    - safety interlocks?
    - an operator control and data acquisition station?

13. Did the X-ray producing device have controls which allow the operator to vary voltage, thereby controlling image quality? Was it possible to vary the voltage, typically between 150-400 kV, to provide an optimum degree of penetration through the waste? Was high-density material examined with the X-ray device set on the maximum voltage? Was low-density material examined at lower voltage settings to improve contrast and image definition?

14. Did the imaging system typically utilize a fluorescent screen and a low light television camera?

15. To perform radiography, was the waste container scanned while the operator viewed the television screen?

16. Was an audio/videotape made of the waste container scan and maintained as a nonpermanent record?

17. Was a radiography data form used to document the matrix parameter category and estimated WMP weights of the waste?

18. Were the estimated WMP weights determined by compiling an inventory of waste items, residual materials and packaging materials? Were the items on the inventory sorted by

WMP and combined with a standard weight look-up table to provide an estimate of WMP weights?

19. Did radiography indicate that the waste does not match the waste stream description? If so, was a nonconformance report completed? Was the inconsistency resolved by obtaining an Operational Variance? If so, was a Record of Variance prepared and subsequently approved by the site project QA officer?

(a) Did the Record of Variance provide the following information (Section 2.1.2.2, p. 5 of 7):

- Title or heading, "Record of Variance"
- Waste container or sample identification number
- Reason for the deviation from the requirements contained in the QAPjP or SOP
- A description of the variation from the accepted sampling, testing, or analytical procedure
- A description of special equipment or personnel required
- Initiator's signature and date
- Site project manager's signature and date
- Site project QA officer's signature and date.

20. Was the proper waste stream assignment determined, the correct hazardous waste codes assigned, and the resolution documented?

21. Were only trained personnel allowed to operate radiography equipment?

22. Were training requirements for radiography operators based upon existing industry standard training requirements?

23. Did training requirements comply with the training and qualification requirements of ASME NQA-1, Element 2, except for Supplement 2S-2?

24. Was a training program developed to provide radiography operators with both formal and on-the-job training (OJT)?

25. Were the radiography operators instructed in the specific waste generating practices and typical packaging configurations expected to be found in each matrix parameter category at the site?

26. Was the OJT and apprenticeship conducted by an experienced, qualified radiography operator prior to qualification of the candidate?

27. Did the training program contain the following required elements based on ASME NQA-1 requirements:

Formal Training

- Project Requirements
- State and Federal Regulations
- Basic Principles of Radiography
- Radiographic Image Quality
- Radiographic Scanning Techniques
- Application Techniques
- Radiography of Waste Forms
- Standards, Codes, and Procedures for Radiography
- Site-Specific Instruction

On-the-Job Training

- System Operation
- Identification of Packaging Configurations
- Identification of WMPs
- Weight and Volume Estimation
- Identification of Prohibited Items

28. Did the radiography test drum include items common to the waste streams generated/stored at the site?

29. Was the test drum divided into layers with varying packing densities or were different drums used to represent different situations that may occur during radiography examination at the site?

30. Did the radiography test drum include the following required elements:

    - Aerosol can with puncture?
    - Horsetail bag?
    - Pair of coveralls?
    - Empty bottle?
    - Irregular shaped pieces of wood?
    - Empty one gallon paint can?
    - Full container?
    - Aerosol can with fluid?
    - One gallon bottle with three tablespoons of fluid?
    - One gallon bottle with one cup of fluid (upside down)?
    - Leaded glove or leaded apron?
    - Wrench?

31. Were the required elements of the test drum successfully identified by the operator as part of the qualification process?

32. Did the qualification of the radiography operators, at a minimum, encompass the following requirements:

- Successfully pass a comprehensive exam based upon training enabling objectives?
- Perform practical capability demonstration in the presence of appointed site radiography subject matter expert (SME)? A radiography SME is an experienced radiography operator who is qualified as an OJT trainer?

33. Was requalification of operators performed every two years?

34. Was requalification of operators based upon evidence of continued satisfactory performance (primary audio/videotape reviews)?

35. Was performance determined to be unsatisfactory (the misidentification of a prohibited item or a score of <80% on the comprehensive exam)? If so, did unsatisfactory performance result in disqualification? Did the operator go through retraining and was satisfactory performance demonstrated before an operator was again allowed to operate the radiography system?

36. Was a training drum with various container sizes periodically scanned by each operator? Was the videotape reviewed by a supervisor to ensure that operators' interpretations remain consistent and accurate?

37. Were the imaging system characteristics verified on a routine basis?

38. Were independent replicate scans and replicate observations of the video output of the radiography process performed under uniform conditions and procedures? Were independent replicate scans performed on one waste container per day per testing , which ever is less frequent? Were independent observations of one scan (not the replicate scan) performed once per day per testing , which ever is less frequent, by a qualified radiography operator (other than the individual who performed the first examination)?

39. Were oversight functions including periodic audio/videotape reviews of accepted waste containers performed by qualified radiography personnel (other than the operator who dispositioned the waste container)?

40. Is the site project QA officer responsible for monitoring the quality of the radiography data and calling for corrective action, when necessary?

41. As an additional QC check, were the radiography results verified directly by visual examination of the waste container contents of a statistically determined portion of waste containers?

42. Were the matrix parameter category and waste material parameter weights verified through a comparison of radiography and visual examination results?

43. Did the RTR operator have access to the visual examination results?

44. Were all equipment used during radiography procured in accordance with Section 1.8 of the QAPP?

45. Were all equipment tested and maintained in accordance with manufacturer instructions?

46. Did the site QAPjP and SOPs document the specific manufacturer's requirements for testing and inspection?

47. Is the RTR equipment calibrated and maintained in accordance with controls established and implemented in the site's QAPjP and SOPs, respectively? Do these procedures address performance criteria?

48. When the RTR equipment is in use, are operational checks conducted at the beginning of each work shift? Do these checks include observation of a test pattern to ensure that the RTR system has adequate video quality?

49. Does the site submit testing data reports for each testing ? Do these forms go to the site project office? Do they use approved standard forms?

50. At the data generation level, are all electronic and video data stored appropriately to ensure that waste container, sample, and associated QA data are readily retrievable? Are radiography tapes reviewed, at a minimum of every tenth waste container against the data reported on the radiography form?

51. At the project level, did the site QA officer certify that the radiography data are complete and acceptable based on the videotape review of at least one waste container per testing ?

52. Does the RTR testing data reports provide the following information:

- RTR facility name
- testing number
- waste container numbers included in that testing
- appropriate signatures (operator, independent reviewers, technical supervisor, site project manager, site project QA officer)
- table of contents
- data review checklists for each test verifying that the data generation level review, validation, and verification has taken place?

53. Does the site prepare separate testing report sheets for each waste container in the testing? If so, does the report provide the following information:

- Title “Radiography Data Sheet”
- Date of the RTR exam
- Waste container number
- TRUCON code, Item Description Code, and Matrix Parameter Category, as applicable
- Any changes made to the matrix parameter category
- Estimate of each applicable waste material parameter weight
- Presence/absence of waste container liner (yes/no)
- Description of contents packaging materials, including the number of layers of packaging
- QC replicate scan (yes/no); if yes, is a brief description of comparison results provided
- Audio/videotape identification number
- Operator signature/date
- Reviewer signature/date
- Nonconformance reports (as applicable)

54. For waste containers undergoing visual examination, does the testing report sheet for each waste container also identify the matrix parameter category and waste material parameter weights as determined by visual examination?

55. Does the on-site RTR facility (if present) maintain in their files or does the contract RTR facility provide a report that is sent to the site project office for storage in the site project files, the following information documented and retrievable by testing number:

- Audio/videotapes
- Original waste container COC forms
- All raw data, including instrument readouts, calculation records, and RTR QC results
- All instrument calibration reports, as applicable.

56. How does the site define testing? Does the testing have less than 20 waste containers? If so, is it possible for the site to examine the number of waste containers in one day?

57. Does the site have a SOP for handling waste containers that can not be examined due to the presence of a lead liner? Are lead-lined waste containers visually examined to determine the matrix parameter category and waste material parameter weights?

58. During the RTR examination, does the operator describe the height and shape of the waste in the container so that the volume of the container and the volume utilization percentage can be determined?

59. Upon identification of liquids, does the operator describe the location, container, and estimated volume (as a percent of the container volume and depth of liquid within the container) of any liquids detected?

60. Does the operator estimate the utilized waste container volume percentage using the highest point and shape of waste in a waste container? Did the site qualify when these percent values will not hold due to the presence of certain packaging materials (e.g., presence of fiber packs)?

61. Is the RTR equipment tuned precisely enough to allow an operator to resolve a 2-2T hole in a steel block?

62. Are independent replicate scans performed? If so, how often? At least one out of every 20 drums?

63. Can the site provide objective evidence of the status of the current implementation of PDPs (schedule of past and planned tests, reports on test rounds conducted, etc.)?

64. Are the standardized Methods Manuals, Sampling and Analysis Procedures, manuals, etc., which are used to standardize waste characterization methodologies present in the RTR examination facility?

65. Can the site provide objective evidence (e.g., audit reports, certification reports, etc.,) of the status of the current implementation of methods/procedures?

EPA used the above checklists to serve as benchmarks for evaluating both the depth of DOE/CAO's auditing activities and LANL's waste characterization process. EPA documented its observations made at the three audits in the following documents: "Technical Support for Evaluating DOE's WIPP Waste Characterization Program: Inspection Report, Los Alamos National Laboratory, Waste Characterization Certification Audit," May 12-16, 1997; (Attachment 3 to this section), "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," August 18-22, 1997 ; and "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," September 10-12, 1997 (Attachment 3 to this section).

12.4 INSPECTIONS

The Compliance Criteria require that QA programs be established and executed specifically with respect to the use of process knowledge and a system of controls for waste characterization. (§§194.22(a)(2)(i) and 194.24(c)(3) through (5).) To accomplish this, waste generator site-specific QA programs and plans must be individually examined and approved by EPA to ensure adequate waste characterization programs are in place before EPA allows individual waste generator sites to transport waste for disposal at the WIPP. Since waste characterization activities have not begun for most TRU waste generator sites and storage facilities, EPA has not yet evaluated the compliance of many site-specific QA plans (QAPPs and, where applicable, QAPjPs) and programs.

12.4.1 LANL Inspection Findings

To date, only one WIPP waste generator site, Los Alamos National Laboratory ("LANL"), has been approved by EPA to have established adequate QA programs (encompassed in a QAPP and QAPjP) and to have properly executed QA procedures in accordance with the applicable NQA requirements. Prior to approval of LANL's site-specific QA program, EPA conducted an audit of DOE's overall WIPP QA program and approved its capability to perform audits in accordance with the requirements of NQA-1. EPA then inspected three DOE audits of LANL's QA program. Based on the results of the inspections, the EPA inspectors determined that the QA program had been properly executed at LANL. Therefore, EPA proposes to find that the requirements of §194.22(a)(2)(I) have been met for the WID QAPD, the WWIS, and waste characterization activities at LANL.

EPA also determined DOE to have adequately described the use of process knowledge for retrievably stored legacy debris waste streams at LANL. EPA has confirmed establishment and execution of the required QA programs at that waste generator site through inspections. Therefore, the Agency determines that DOE has demonstrated compliance with the §194.24(c)(3) QA requirement for LANL.

After submission of the CCA, EPA subsequently received information regarding the system of controls to be used at LANL. The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. Therefore, EPA determined DOE to have demonstrated compliance with §§194.24(c)(4) and (5) for several waste streams in the category of retrievably stored legacy debris waste at LANL. EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[43] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

In summary, EPA finds that DOE is in compliance with §194.24, and that LANL has demonstrated compliance with §§194.24(c)(3) through (5) for certain retrievably stored legacy

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[43] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

debris waste streams and may therefore ship TRU waste for disposal at the WIPP (as such shipments relate solely to compliance with EPA's disposal regulations; other applicable requirements or regulations still may need to be fulfilled before disposal may commence). EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.

Attachments 1 through 3 present the inspection reports prepared by EPA to summarize the activities observed during the three separate inspections and audits at the LANL site. Complete inspection reports can be found in the following documents: "Technical Support for Evaluating DOE's WIPP Waste Characterization Program: Inspection Report, Los Alamos National Laboratory, Waste Characterization Certification Audit," May 12-16, 1997;(Attachment 1 to this section), "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," August 18-22, 1997 ; and "Inspection Report for Los Alamos National Laboratory, Waste Characterization Certification Follow-up Audit," September 10-12, 1997 (Attachment 3 to this section).

12.4.2 Future Waste Certification Requirements and Procedures

Section 194.24(c)(3) requires DOE to demonstrate that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance ("QA") requirements found in §194.22. EPA expected DOE to submit specific information on the process knowledge to be used at waste generator sites as part of DOE's certification application. EPA requires such information to conduct proper regulatory review of whether use of the process knowledge is appropriate and reliable. DOE provided some information on its overall plans for using process knowledge in the CCA. DOE did not, however, provide specific information on the use of process knowledge at any waste generator site in the CCA, nor did it provide information demonstrating establishment of the required QA programs.

After submission of the CCA, EPA subsequently received information regarding process knowledge to be used at the Los Alamos National Laboratory ("LANL"). EPA determines DOE to have adequately described the use of process knowledge for retrievably stored legacy debris waste streams at LANL. EPA has confirmed establishment and execution of the required QA programs at that waste generator site through inspections. Therefore, the Agency determines that DOE has demonstrated compliance with the §194.24(c)(3) QA requirement for LANL. EPA does not find, however, that DOE has adequately described the use of process knowledge for any other waste streams at LANL (other than the retrievably-stored legacy debris waste streams discussed above). Furthermore, DOE has not demonstrated compliance with §194.24(c)(3) for any other waste generator site.

Sections 194.24(c)(4) and (5) require DOE to demonstrate that a system of controls has been and will continue to be implemented to confirm that the waste components emplaced in the WIPP will not exceed the upper limit or fall below the lower limit calculated in accordance with §194.24(c)(1). The system of controls must conform to the QA requirements specified in §194.22. DOE described a system of controls over waste characterization activities, such as the requirements of the TRU QA Program Plan ("TRU QAPP") and the Waste Acceptance Criteria ("WAC"). EPA found that the TRU QAPP established appropriate technical quality control and performance standards for sites to use in developing site-specific sampling plans. Further, DOE outlined two phases in waste characterization controls: waste stream screening/verification (pre-shipment) and waste shipment screening/verification (pre-receipt of waste at the WIPP). The tracking system for waste components against their upper and/or lower limits is found in the WIPP Waste Information System ("WWIS"). If implemented as proposed, EPA believes that the TRU QAPP, WAC, and WWIS are adequate to control important components of waste emplaced in the WIPP.

EPA audited DOE's QA programs at CAO, SNL and WID and determined that DOE properly adhered to QA programs that implement the applicable NQA standards and requirements. (See the preamble discussion of §194.22 for further information.) However, in the CCA, DOE did not demonstrate that the WWIS is fully functional and did not provide information regarding the specific system of controls to be used at individual waste generator sites.

After submission of the CCA, EPA subsequently received information regarding the system of controls to be used at LANL. The Agency confirmed through inspections that the system of controls is adequate to characterize waste and ensure compliance with the limits on waste components, and also confirmed that a QA program had been established and executed at LANL in conformance with NQA requirements. Moreover, DOE demonstrated that the WWIS is functional with respect to LANL -- i.e., that procedures are in place at LANL for adding information to the WWIS system, that information can be transmitted from LANL and incorporated into the central database, and that data in the WWIS database can be compiled to produce the types of reports described in the CCA for tracking compliance with the waste limits. Therefore, EPA determines DOE to have demonstrated compliance with §§194.24(c)(4) and (5) for several waste streams in the category of retrievably stored legacy debris waste at LANL. EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.[44] EPA does not find, however, that DOE has demonstrated compliance with §194.24(c)(4) for any other waste stream at LANL, or with §§194.24(c)(4) and (5) at any other waste generator site.

In summary, EPA proposes to find that DOE is in compliance with §194.24, and that LANL has demonstrated compliance with §§194.24(c)(3) through (5) for certain retrievably stored legacy debris waste streams and may therefore ship TRU waste for disposal at the WIPP (as such

[44] See Docket A-93-02, Item II-I-70 for a list of these systems and processes. They include characterization methodologies and relevant procedures, such as that used for entering data into the WWIS database.

shipments relate solely to compliance with EPA's disposal regulations; other applicable requirements or regulations still may need to be fulfilled before disposal may commence). EPA's proposed determination of compliance is limited to those retrievably stored legacy debris waste streams that can be characterized using the systems and processes audited by DOE, inspected by EPA, and found to be adequately implemented at LANL.

The Agency also proposes to certify compliance subject to the condition that DOE may not ship other waste streams for emplacement at the WIPP until EPA determines that (1) DOE has provided adequate information on how process knowledge will be incorporated into waste characterization activities for a particular waste stream at a generator site, and (2) DOE has demonstrated that the system of controls described in §194.24(c)(4) has been established for the site. In particular, DOE must demonstrate that the WWIS system is functional for any waste generator site before waste may be shipped, and that the system of controls can be implemented for each waste stream which DOE plans to dispose in the WIPP.

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Technical Support for Evaluating
DOE's WIPP Waste Characterization Program

Inspection Report
Los Alamos National Laboratory
Waste Characterization Certification Audit
May 12 - 16, 1997

Prepared for

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August 7, 1997

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INTRODUCTION

A.T. Kearney Waste Isolation Pilot Plant (WIPP) Waste Characterization team members attended the Los Alamos National Laboratory (LANL) Audit of May 12 through 16, 1997. The team consisted of Ms. Hugo and Ms. Shanahan, both of A.T. Kearney, as well as Mr. Finkel of ICF. Per the technical direction from The Environmental Protection Agency (EPA) dated May 9, 1997, the team members evaluated the personnel qualifications and the technical adequacy of non-destructive examination/non-destructive assay (NDE/NDA) instruments and procedures.

The scope of the audit focussed on personnel qualifications and NDE/NDA technical adequacy. The scope of the audit also included additional waste characterization related issues. These issues are acceptable knowledge, software, waste container tracking, miscertification rates, random selection, training records as well as other issues as presented in this Inspection Report.

The morning of May 12, 1997 began with a series of three kick-off meetings. The first meeting was between EPA representatives, Mr. Rogers and Mr. Oliver, and the three team members previously mentioned. The second meeting was between the Carlsbad Area Office (CAO) audit group, EPA staff and EPA's contractors including the team members. The third meeting expanded to include the LANL waste characterization staff. Each evening there were CAO auditor meetings which EPA and its' contractors attended. After that, EPA and its' contractors conducted their own meetings. Each morning there were management meetings between CAO and LANL which were attended by EPA. On May 16, 1997, there was a CAO auditor close-out meeting which was attended by LANL staff, EPA and EPA's contractors.

From the late morning of May 12, 1997 through the early morning of May 16, 1997, the CAO auditors broke into four separate audit teams consisting of lead auditors and technical specialists. Even then, most of the teams were further divided into two subteams of at least one lead auditor and one technical specialist. At any given time, there were four to eight different audits occurring. At the direction of EPA, CAO audit team and subteam assignments were given to the EPA staff and the team members. Some CAO audits were covered by one EPA staff member or one team member, while other audits had two or more EPA staff members or team members present. The audits which were less relevant (i.e., procurement, grading) to waste characterization were not attended by EPA or its' contractors.

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Conditions Adverse to Quality (CARs)

As a result of the week-long audit, CAO identified a total of 10 CARs, 10 observations, 14 recommendations, and 13 items closed during the audit. CAO rated the adequacy of LANL's program as indeterminate; however, CAO stated that it anticipates that the adequacy will become satisfactory within 30 days. CAO rated LANL's implementation of its program as marginal; however, CAO did not identify any "show stoppers" and believed that LANL could resolve all outstanding items by the end of August (the expected date of CAO's next audit). Lastly, CAO graded the effectiveness of LANL's program as satisfactory.

A summary of the 10 CARs raised by CAO during Audit A-97-01 is presented below:

- CAR No. 1: On three separate occasions (March 4, 6, and 7, 1997), the continuing calibration checks (CCC) for the headspace gas chromatography/mass spectrometry (GC/MS) were out of compliance with the procedure. The samples were rerun, but remained out of compliance. Since certain analytes were not detected in the samples being run, the decision was made to continue the analysis. No non-conformance report (NCR) was prepared, nor was a new 5-point calibration performed.

  Requirement: TWCP-DTP-1.2-018, R.0, paragraph 8.3.4 and Methods Manual 430.1, Section 8.4.1.1 states that "if the %D criterion is not met, the initial calibration must be re-analyzed. If no source of the problem can be determined and re-analysis of the continuing calibration fails to meet the required performance criteria, a new 5-point calibration must be generated before quantitative sample analysis begins."

- **CAR No. 2:** The acceptable knowledge (AK) for radionuclide distribution is not adequate to support passive-active neutron (PAN) assay.

  Requirement: QAPP, Section 1.5 states "...not adequate to confirm the radionuclide inventory on which the 40 CFR Part 191 Certification Application is based..." and "...to obtain the total activity in TRU waste to support revisions of the thermal power restrictions for shipment of waste in the TRUPACT-II." Table 1-3 requires characterization of "individual radioisotopes" and "thermal power."

- **CAR No. 3:** Technical Supervisory review for data package batch number LA97-331-001 was not documented on the headspace gas (HGAS) data review checklist. The completed second level (project) review did not note the absence of this review.

  Requirement: TWCP-QP-1.1-011, paragraph 6.5 states: "The operations leader conducts a second technical supervisory review of the data..." TWCP-QP-1.1-010, paragraph 6.2 states: "...the site project Quality Assurance Officer reviews the data batch reports, the independent review checklist, and the Data Generation Level QA Validation checklist..."

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- **CAR No. 4:** Software code "EnviroQuant" used in HGAS, was not installed in accordance with the installation and checkout (I/C) form. In addition, the software was "qualified" prior to the I/C form being completed, and the software was not properly classified. Commercial software used in lab notebooks were not adequately identified and documented. Spreadsheets used in the HGAS and PAN analyses were not identified by name and version number, and did not have fully documented verification in accordance with quality procedure.

  Requirement: TWCP-QP-1.1-006, paragraph 4.3.5.1 states that personnel "shall perform the installation/checkout to the instructions on the I/C." TWCP-1.1-006, paragraph 4.3.5.4 states that the "software control manager shall review the I/C for completeness and return it to the code sponsor or approve the software for release as production software." TWCP-QP-1.1-006, paragraph 4.3.5.1 and 4.1.5 state that personnel shall perform the installation/checkout to the instruction on the I/C" and "shall classify the software listed in Appendix A, Table A.1." TWCP-QP-1.1-012, R.2, paragraph 6.1.13 states that Transuranic Waste Certification Program (TWCP) personnel document the following (for commercial software):
  - Name and version number
  - Document formulas or verification documentation.

- **CAR No. 5:** The following deficiencies in training documentation were noted:

  - Required reading forms do not always include the revision of the procedure read by the TWCP personnel
  - Training attendance sheets do not include procedure identification numbers or revision numbers
  - Training procedure does not provide adequate guidance on retraining for procedure revisions
  - Work is being performed to revisions of procedures, but there is no documentation of training to these revisions

  (Note: LANL's recent internal quality assurance (QA) audit identified some of the same issues. Corrective action taken as a result of the internal audit was not adequate to correct the deficiencies.)

  Requirement: TWCP-QP-1.1-003.R.1, Section 6.2 states "Initial training is any training for an individual to...perform unsupervised work assignments." Section 6.3 states: "...continuing training is also referred to as retraining, or refresher training."

- **CAR No. 6:** Documents are not prepared in accordance with quality procedures:

  - There was no evidence of <u>specific</u> criteria used for review
  - Six of the seven documents sampled were reviewed by the preparer (operations leader)

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- There was not evidence that comments to revisions made after the 4/7/97 effective date were resolved per QP-1.1-017 (Peer Review)
- QA staff approved one of the sampled technical procedures as the Operations Leader (DTP-1.2-014, R.3)

Requirement: TWCP-QP-1.1-001, R.2, paragraphs 5.2, 6.71, 6.73, and 6.75 state that: "revisions to the approved documents must receive the same level of approval as the original document", "...the requesting organization shall identify the applicable criteria for review", "...review is performed by individuals other than the originator", and "...review comment documentation shall be resolved in accordance with Peer Review..."

- **CAR No. 7:** The management assessment which LANL conducted April 7-11, 1997 was not performed in accordance with the requirements of the Quality Procedure (QP).

  Requirement: TWCP-QP-1.1-013.R.1 and R.2, Assessments and Assessment Resolution.

- **CAR No. 8:** Six NCRs of 15 sampled and reviewed did not contain information on the cause of the NCRs (incomplete on the form). Root cause analysis was not performed for these NCRs as required. Four root cause analysis checklists sampled were signed off; however, three of the checklists did not include a documented root cause. Two instances were identified where a Record of Variance (ROV) was issued to correct a problem that should have been documented as NCRs.

  Requirement: TWCP-QP-1.1-007, R.2, Sections 6.22 and 6.35 require root cause determinations in accordance with TWCP-QP-1.1-020. TWCP-QP-1.1-007, R.2 definitions section defines non-conformances. TWCP-QP-1.1-020, R.2, Section 6.2 states that the "site project QA officer along with the operations leader shall take the attached checklist and...determine the root cause."

- CAR No. 9: Procurement requirements are not implemented in accordance with the QP:

  - Three of the four purchase requests had no Quality Assurance Supplement, as required

  - The TWCP project office has not maintained procurement records required by the procedure

  - Buyers are not fully aware of the procurement procedure requirements

  Requirement: TWCP-QP-1.1-005, R.2 paragraphs 6.2, 6.3.1, and 7.0 require that the Site Project Officer prepare a Quality Assurance Supplement Form (QAS), requires the buyer to ensure the vendor is on the qualified vendor list, and delineates that the records that are to be maintained by the TWCP Project Office.

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- **CAR No. 10:** Sealed containers larger than four liters are prohibited waste items in accordance with the QAPP. The LANL Certification Plan states that Real-Time Radiography (RTR) and/or acceptable knowledge will be used to ensure compliance with this requirement. The existing radiography data form does not list sealed containers over 4 liters as a prohibited item, nor do RTR and acceptable knowledge personnel check for this prohibited item.

  Requirement: LANL Certification Plan, R.0, Section 3.5.6 states that "sealed containers >4 liters are prohibited....for retrievable stored waste..."

Format of Inspection Report

The Inspection Report begins with this introduction about the audit, and contains a separate chapter for each inspection item. A chapter includes the following chapters: (1) items inspected, (2) date of inspection, (3) inspector, (4) type of observation, (5) results, and (6) recommendations regarding nonconformance issues. Chapter (4) is broken down into the following subchapters: (A) Personnel qualifications (including training), (B) Technical adequacy, © Procedures, and (D) Other (including related issues). There are twelve chapters, labeled Chapters A through L.

<u>**Chapter A**</u>

1) Item inspected

Passive-Active Neutron Assay System

2) Date(s) of inspection

May 14, 1997

3) Inspector(s)

Mr. Rogers, Mr. Oliver, Ms. Hugo

4) Type of observation

The Carlsbad Area Office (CAO) auditor, Mr. Paedon, and technical specialist, Mr. Bresson, reviewed the Passive-Active Neutron (PAN) assay system data packages. They also interviewed Mr. Taggart of Los Alamos National Laboratory (LANL). During the interview, the PAN assay system and procedures were discussed.

<u>A) Personnel qualifications</u>

Mr. Taggart (PAN supervisor) is a seasoned professional who is well qualified and experienced to technically and managerially support the PAN assay system. Mr. Taggart is a PhD. nuclear physicist by training including education and numerous years of professional experience.

B) Technical adequacy

The non-destructive assay (NDA) technique, PAN, appears to be adequate as long as LANL has accurate acceptable knowledge (AK) regarding the relative radionuclide isotopes. If AK does not exist or is missing isotopic distribution information, then PAN may not be the appropriate NDA technique to be used solely or initially because PAN will have difficulty deciphering different isotopes. PAN determines the total activity from which individual activities are calculated for radionuclides and isotopic ratios as identified by AK. In these instances of deficient AK, PAN is recommended to be used in conjunction with some type of gamma scan, either segmented gamma spectroscopy (SGS) or tomographic gamma spectroscopy (TGS), which identifies individual radionuclides.

See the following audit write-ups for other issues associated with PAN. The deficient AK issue with respect to radionuclides is presented in the AK write-up. The PAN uncertainty calculation issue and unacceptable PAN efficiency check results issue are discussed in Chapter K, the CARs, NCRs, ROVs and Root Cause write-up.

C) Procedures

Overall, the Detailed Operating Procedure (DOP) for *Waste Assay Using the Mobile Passive-Active Neutron (PAN) Assay* (TWCP-DTP-1.2-009, R.1) and Detailed Operating Procedure for *Calibrating the Mobile Passive-Active Neutron (PAN) Assay System* (TWCP-DTP-1.2-010, R.1) appear to be adequate.

D) Other

There are no other issues regarding the PAN assay system.

5) Results or acceptability

Based on the observations made during the audit, the PAN assay system, its personnel and procedures seemed to be adequate except as noted above in Chapter 4.B, Technical adequacy.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

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Based on the observation of the inspector, there are no recommendations concerning nonconformance issues at this time - assuming that LANL successfully addresses the PAN system and associated issues as noted above in Chapter 4.B, Technical adequacy.

Chapter B

1) Item inspected

Visual Examination

2) Date(s) of inspection

May 14 and 15, 1997

3) Inspector(s)

Mr. Rogers, Mr. Oliver, Ms. Hugo, Mr. Finkel, and Ms. Shanahan

4) Type of observation

A) Personnel qualifications

On Wednesday, May 14, 1997, the inspectors observed visual examination (VE) expert, Mr. Yeamans, performing VE on a waste drum. There were also three VE operators present: Mr. Rios, Mr. Salazan, and Mr. Cvaros. Mr. Yeamans has over three years experience performing VE. The other operators have an average of nine years experience with VE.

The VE expert appeared technically qualified to perform the required tasks. He was able to operate the video camera and moved from different angles of the glove box in order to capture footage of the waste. Mr. Yeamans also kept records of observations during the visual examination in the logbook and completed the Transuranic Waste Certification Program (TWCP) Visual Examination Record form. He was able to answer all questions about the VE operation.

The VE operators also appeared technically qualified. They all attended training on how to fill 2 ft^3 boxes with waste. This training helps them to estimate the amount of specific waste matrix present. The operators seem to meet the specifications outlined in DTP-1.2-004, R.1 - *Qualifications of Visual Examination Personnel*.

B) Technical adequacy

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The equipment used to perform the VE appeared technically adequate. The inspector viewed a waste container undergoing VE. The container was opened inside a glove box and its contents were noted and weighed.

C) Procedures

The operators followed Detailed Technical Procedures (DTP) for *WCRRF Visual Examination and Drum Packaging Process Procedure for the TWCP* (DTP-1.2-001, R.1). This procedure appeared technically adequate.

D) Other

The first issue identified involves the miscertification rate. For 1997, the miscertification rate of 2% is based on an Idaho National Engineering Laboratory (INEL) drum miscertification rate study. After one year of certification activities, the site will be able to determine the site-specific miscertification rate to be applied to the next waste characterization year. The miscertification rate is based on the drums radiography indicates meet the WIPP Waste Acceptance Criteria (WAC) radiography-determined requirements, but VE indicates do not meet these requirements. On the hypergeometric probability distribution table, the miscertification percentage is paired with the annual number of drums undergoing characterization to obtain the actual number of drums requiring VE. That number of drums requiring VE is applied to the annual waste drum population using random selection.

There are two concerns with this approach. The first concern is the inability of a miscertification rate based on an annual drum population to be truly representative of each waste stream. For example, during the first certification year, one homogenous waste stream maybe characterized. This homogeneity lends itself to a low miscertification rate. That rate is applied to the next waste characterization year which consists of a more heterogeneous waste stream. However, that low miscertification rate was representative of a homogeneous waste stream not a heterogeneous one. The heterogeneous waste stream miscertification rate would probably be higher. This misapplication of a miscertification rate may weaken the integrity of the waste characterization program by not characterizing each waste stream in a truly representative manner.

The second concern involves the application of the number of drums requiring VE using random selection to the entire annual waste population not each waste stream. To illustrate, if one waste stream has over 100 drums and the other only five drums, it is likely that none of the drums in the smaller waste stream would be randomly selected to undergo visual examination. Therefore, the verification of the radiography data using the VE results would not be performed for the small waste stream. The inability of this approach to include all waste streams, again, could compromise the integrity of the waste characterization program by leaving a waste characterization data gap.

In order to alleviate these concerns, both the determination of the miscertification rate, and the application of the number of drums requiring VE should be waste stream specific.

While conducting interviews, concern with the actual randomness of drum selection was identified. The drums to be characterized by visual examination are randomly selected from the waste population which happens to be one waste stream. However, if one of the drums chosen is inaccessible (i.e., due to placement in earthen cover) or non-compliant (i.e., no vent), the next drum on the randomly selected list will be chosen. Other drum rejection scenarios are: drum exceeds size limitation for radiography instrument (i.e., 85-gallon drum overpack, standard waste box); drum exceeds weight limitation for VE (i.e., cemented wastewater treatment sludge drum weighing 900 pounds); and as low as reasonably achievable (ALARA) concern due to the drum's radiation level.

This approach reduces the actual randomness of the selection by decreasing the number of drums which are available for visual examination. The site representative did state that they would seek guidance from CAO if these rejections occurred frequently, and that they would perform VE on a drum if initial reason for rejection was removed (i.e., drum had vent inserted). These rejections may weaken the integrity of the random selection process by being biased toward dominant waste streams.

5) Results or acceptability

Overall, the visual examination operation appeared to be technically adequate. There is concern with the random selection process and the miscertification rate as discussed above.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

In order to alleviate the above concerns, both the determination of the miscertification rate and the application of the numbers of drums requiring VE should be waste stream specific. Regarding the rejections of drums from random selection, CAO needs to provide guidance to sites to minimize and standardize drum rejection.

<u>Chapter C</u>

1) Item inspected

Real-Time Radiography

2) Date(s) of inspection

May 12 and 13, 1997

3) Inspector(s)

ATTACHMENT 1

Mr. Oliver, Ms. Shanahan

4) Type of observation

A) Personnel qualifications

On Monday, May 12, 1997, the inspector observed Real-Time Radiography (RTR) operator Mr. Vigil examining a waste drum using the RTR system. Mr. Vigil stated that he is a Level 2 operator. There are also two other operators: Mr. Rael (Level 1) and Mr. Martinez (Level 2). Mr. Vigil has been performing RTR analysis for the last nine years. Mr. Vigil and the other operators performed the quarterly analysis of the test drum. This analysis was recorded on video tape and Mr. Vigil reviewed both Mr. Rael and Mr. Martinez's video tape for any inconsistencies in their analysis. There was no review of Mr. Vigil's tape. The RTR operators also perform analysis on a test drum every two years which is video taped and reviewed by a Level 3 operator.

The operator seemed technically qualified to perform the real-time radiography examination. He was able to run the RTR system and was also able to operate the video camera. The operator was able to answer all questions about the system and its operation well. The operators seem to meet the specifications outlined in DTP-1.2-003 - *Qualifications of Radiography Operators*.

B) Technical adequacy

The equipment used to perform the real-time radiography analysis appeared technically adequate. The inspector viewed a waste container undergoing real-time radiography examination. The equipment scans at a complete rotation and then scans down. This enables the entire drum to be analyzed. The operator can control drum rotation and elevation using distinctive drum characteristics as a guide.

When viewing the analysis the inspector saw various types of waste in the drum. Some of these include: plastic bags, boxes, plastic containers, glass vials, and zippers. It was evident as to what these materials were.

Limitations of the RTR system were revealed while conducting an interview with the RTR operator. The system has difficulties detecting cellulosics which may be found in a lead-lined drum. The higher beam must be used to scan through the lead lining and it scans past the cellulosics as well. In order to compensate for this limitation, the operator must examine the waste container data sheet. This data sheet contains acceptable knowledge information as to what types of wastes are expected to be in the container. If the items listed on the sheet are not observed when performing the RTR analysis of a lead-lined drum, the operator will tag the drum for visual examination.

C) Procedures

The operators followed the Detailed Technical Procedure (DTP) for *Performing Nondestructive Testing using the Mobile Real-Time Radiography System* (DTP-1.2-008, R.2). This procedure appeared technically adequate except for the following issue. However, the RTR data form does not list sealed containers greater than four liters as a prohibited item, nor does the RTR operator look for this prohibited item. This procedural issue regarding four liter containers was reflected in CAR No. 10.

D) Other

There are no other issues are identified at this time.

5) Results or acceptability

Overall, the RTR system and procedures appeared to be technically adequate. As previously stated, there is the issue of the four liter containers, and there is concern with its ability to detect cellulosics in lead-lined drums.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations of the inspector, there are no recommendations concerning nonconformance issues at this time - assuming that LANL successfully responds to CAR No. 10.

Chapter D

1) Item inspected

Acceptable Knowledge (AK) Process for Waste Stream TA55-19 (Combustible Materials)

2) Date(s) of inspection

May 15, 1997

3) Inspector(s)

Mr. Oliver, Mr. Rogers, Ms. Hugo, Ms. Shanahan, and Mr. Finkel

4) Type of observation

A) Personnel qualifications

On Thursday, May 15, 1997, the inspectors participated in an interview of Ms. Dziewinska and Ms. Rogers (other LANL managers and staff were there but the majority of interview focused on Ms. Dziewinska and Ms. Rogers) that was conducted by Mr. Brown and Mr. Bynum (representing CAO). Ms. Dziewinska is the technical contact responsible for LANL's AK program. Ms. Dziewinska reports to Ms. Stupka and Ms. Rogers, the Transuranic Waste Certification Program (TWCP) Site Project Manager and TRU Waste Certification Official, respectively. Ms. Dziewinska was the author of LANL's TWCP procedure for acceptable knowledge. She is a nuclear engineer and appeared (on the basis of the interview) to be well qualified to work on developing and implementing LANL's AK program/process.

B) Technical adequacy

LANL plans to use AK to assign matrix parameter categories and EPA hazardous waste numbers to waste streams and to determine the waste material parameters and radionuclides present in waste streams. LANL has developed a procedure for detailing how the required information on AK should be documented to satisfy the AK requirements included in the *Quality Assurance Program Plan (QAPP)*. AK also will be used to address the presence of items that are prohibited by the WIPP Certification Plan such as reactives, corrosives, ignitables, pyrophorics, compressed gases, free liquids, and the maximum number of confinement layers.

The AK procedure provides for a systematic examination of information necessary to develop an understanding of a particular waste stream. The procedure appears technically adequate for assigning matrix parameter categories and EPA hazardous waste numbers to waste streams. The procedure also appears technically adequate for assigning waste material parameters and determining if reactives, corrosives, ignitables, and pyrophorics are likely to be present. However, the technical adequacy of AK appears to fall off when used (1) to determine whether free liquids or compressed gases are present, or (2) to develop a distribution of radionuclides. In addition, AK cannot be used for determining the concentration (or mass) of specific materials, RCRA constituents, or radioisotopes. (Ms. Rogers stated that AK cannot tell you the concentration or activity of wastes such as evaporator bottoms containing Am).

CAO issued CAR No. 2 because AK cannot be used to develop a radionuclide distribution. This information is critical for conducting a proper PAN assay of the waste stream. The group noted that AK can be used to tell you what radionuclides definitely were not present, but that it could not tell you every radionuclide present. In addition, CAO issued CAR No. 10 because the AK procedure did not specifically list containers larger than 4 liters as an item that's presence should be screened.

The AK procedure/process is technically adequate for most uses, but as discussed above, it does have inherent limitations.

C) Procedures

AK is conducted in accordance with Quality Procedure (QP), TWCP-QP-1.1-021, R.0 - *Acceptable Knowledge*. The AK procedure provides for a systematic examination of information necessary to develop an understanding of a particular waste stream. This procedure is technically adequate; however, CAO did make one observation (Observation No. 9). Specifically, CAO found that the procedure did not address the responsibility of the preparer of the AK report, nor were the duties of the newly generated waste generators clearly addressed. In addition, CAO stated that throughout the procedure, it was not evident who performs the specific steps, resulting in key activities not being performed or properly documented.

D) Other

LANL's procurement records only go back for a period of four years. The AK expert, therefore, will be unable to rely on procurement records as a potential source of information for any waste stream generated prior to 1992.

5) Results or acceptability

In light of the specific limitations noted above and CAO's issuance of CAR Nos. 2 and 10, and Observation No. 9, LANL's AK program/process is unacceptable. However, once LANL institutes the necessary changes to correct the deficiencies noted in CAR Nos. 2 and 10, LANL's AK program/process will be acceptable. The inspector notes that LANL's AK program/process is brand new and that it will take some time to work out all of the implementation "bugs."

6) Reference to information on action taken in conjunction with nonconformances/recommendations

Based on the observations of the inspector, there are no recommendations concerning nonconformances issues at this time - assuming that LANL successfully responds to CAR Nos. 2 and 10, Observation No. 9, and recognizes the limitations of the AK procedure (discussed above).

Chapter E

1) Item inspected

Training Records

2) Date(s) of inspection

May 13 and 14, 1997

3) Inspector(s)

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Mr. Finkel

4) Type of observation

A) Personnel qualifications

On Tuesday, May 13, 1997, the inspector participated in an interview of Ms. Stanhope and Ms. Gavett that was conducted by Mr. Vega and Mr. Brown (representing CAO). Ms. Stanhope is the training specialist responsible for LANL's Training program. Ms. Stanhope reports to Ms. Gavett, the Transuranic Waste Certification Program (TWCP) Site Project Quality Assurance Officer. No other staff are assigned to training.

Although the specific training requirements for running the Training Chapter were neither identified in LANL's *TWCP Training Procedure* (TWCP-QP-1.1-003, R.1) nor available for review in any other LANL TWCP-QP document, it was evident that Ms. Stanhope understands both the importance and the mechanics of maintaining the Training Chapter. She was fully aware of the components of LANL's TWCP Training Procedure and understood her role in working with the TWCP Site Project Manager (SPM) and Operations leaders to establish qualification and training requirements for TWCP personnel.

The specific responsibilities of the Training Coordinator were spelled out in Chapter 5.3 of TWCP-QP-1.1-003, R1, are as follows:

- Maintain training files that denote the required training, the date taken, and the type of training (i.e., formal classroom, on-the-job-training (OJT), other off-site, or self-paced reading).
- Maintain individual files for each trainee (i.e., attendance records for each training session attended, reading assignments completed, date, version, title, etc.).
- Maintain training records documentation.
- Schedule training.

Ms. Stanhope's qualification to perform as the Training Coordinator was supported by her understanding of her responsibilities.

B) Technical adequacy

Although CAO stated that the TWCP records group had made excellent progress towards a more fully documented and effectively implemented program since CAO's pre-audit visit

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made eight months ago (August 1996), significant improvement in the maintenance of the training program records is still needed.

The following training records were reviewed::

- Mr. Rael
- Mr. Vigel
- Mr. Rios
- Mr. Martinez
- Mr. Baros
- Ms. Dziewinska

It became apparent that the training records were often incomplete and sometimes extremely difficult to decipher as to what training occurred when. The inadequacy of the training records was first documented by CAO last August, and again by an internal audit conducted by LANL last April. As a result of the outstanding items first identified by CAO last August and later identified by LANL, CAO issued the following CAR (CAR No. 5):

"The following deficiencies in training documentation were noted:

- required reading form do not always include the revision of the procedure read
- training attendance sheets do not include procedure identification numbers or revision numbers
- training procedures do not provide adequate guidance on retraining for procedure revisions
- work is being performed to revised procedures, but there is no documentation of training to these revised procedures."

CAO also noted that LANL's internal QA audit identified some of these issues; however, CAO believes that the corrective action taken by LANL has been inadequate. CAO also raised several observations, including:

- The "Training Requirements by Position" form is used to identify training, qualification, and certification requirements, but training requirements found in the *QAPP* and the *Methods Manual* are not always clearly addressed or included on the form. (Observation No. 3.)

- Job positions are analyzed and documented on "Training Requirements by Position" forms, but the process associated with using the form is not in any procedure. (Observation No. 4.)

LANL's training program has failed to keep accurate and detailed records of training. This issue has been identified by CAO's audit process.

C) Procedures

Training is conducted in accordance with LANL's Quality Procedure (QP), *TWCP Training Procedure* (TWCP-QP-1.1-003, R.1). Record keeping is conducted in accordance with LANL's *TWCP Document Control and Records Management Procedures* (TWCP-QP-1.1-002, R.1 and TWCP-QP-1.1-004, R.1, respectively). These procedures appear technically adequate but need to be revised to address the findings/observations noted above.

D) Other

In light of the specific exceptions noted above and CAO's issuance of CAR No. 5 and Observations Nos. 3 & 4, LANL's training program/process is inadequate. However, once LANL institutes the necessary changes to correct the exceptions noted by both CAO and LANL's internal audit assessment group, LANL's training program/process should become technically adequate.

5) Results or acceptability

Although it appears as though TWCP staff are obtaining the proper training and certifications, it is impossible to verify because the training records are inadequate (and thus, unacceptable).

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations of the inspector, there are no recommendations concerning nonconformances issues at this time - assuming that LANL successfully responds to CAR No. 5 and the other observations (made by both CAO and LANL).

Chapter F

1) Item inspected

LANL Internal Waste Container Tracking

2) Date(s) of inspection

May 15 and 16, 1997

3) Inspector(s)

Ms. Hugo, Mr. Finkel, and Ms. Shanahan

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4) Type of observation

A) Personnel qualifications

Several interviews were conducted with Ms. Rogers and Mr. Yeamans concerning this issue. Ms. Rogers was able to answer all questions and appeared to know the system well.

B) Technical adequacy

The LANL Internal Waste Container Tracking System is technically adequate with a few exceptions. The supervisors and operators on the distribution list receive the drum tracking forms via electronic mail. These individuals are responsible for updating the forms, but are unable to delete any information from the forms. In turn, the individual sends the updated forms to the other people on the distribution list. This form is not renamed automatically, and it is up to the individual to remember to rename the file. Therefore, it may become confusing when trying to locate the latest version of the drum tracking form. In addition, the codes and dates on the forms are confusing. This may lead to a misunderstanding of the drum shipment, receipt and characterization status. Also, some of the page numbers were missing from the forms which can also cause confusion. Likewise, some of the forms did not have the version file name, date and time printed on them which, again, can lead to confusion.

C) Procedures

The appropriate personnel follow the Detailed Technical Procedure (DTP) for *Waste Container Tracking* (DTP-1.2-020, R.0). This procedure appeared technically adequate.

D) Other

As stated in the Technical adequacy chapter, there is possibility for confusion due to manual not automatic renaming of file; form content (i.e., codes, dates); inconsistent page numbering; and inconsistent printing of version file name, date, and time on the forms.

5) Results or acceptability

Overall, the LANL Internal Waste Containing Tracking System appeared to be technically adequate. There are a few concerns as noted in Chapter 4.B, Technical adequacy.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

LANL Internal Waste Containing Tracking System is not a mature system and has had minimal implementation. This issue will be followed up in future audits.

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Chapter G

1) Item inspected

Software Quality Assurance

2) Date(s) of inspection

May 12, 1997

3) Inspector(s)

Mr. Rogers and Mr. Finkel

4) Type of observation

A) Personnel qualifications

On Monday, May 12, 1997, the inspector participated in an interview of Mr. Janecky that was conducted by Mr. Pelletier (representing CAO). Mr. Janecky is the technical contact responsible for LANL's Software Quality Assurance (SQA) program. Mr. Janecky reports to Ms. Rogers, the Transuranic Waste Certification Program (TWCP) Site Project Manager. Other staff include Mr. Zoltai and Mr. Longley -- neither of which participated in the audit.

Although specific training requirements were neither identified in LANL's TWCP Training Procedure (TWCP-QP-1.1-003, R.1) nor available for review in any other LANL TWCP-QP document, it was evident that Mr. Janecky understands both the importance and various components of SQA. Mr. Janecky was able to describe LANL's SQA program and process for:

- procuring commercial software
- verifying the adequacy of pre-existing software documentation
- developing new software (including development and validation documentation)
- developing, reviewing, and approving implementation documents and user manuals
- maintaining installation and checkout (I/C) and change control logs
- code retirement
- access control
- problem reporting

In addition, Mr. Janecky appeared to have a good grasp of all the software being used in the various waste characterization systems (e.g., Passive-Active Neutron - PAN, High Efficiency Neutron Counter - HENC, Tomographic Gamma Scan - TGS, headspace gas sampling - HGS, and non-destructive examination - NDE) and waste tracking and staging systems (e.g., TWCP staging, TWCP Records Image Manager (RIMs), and WIPP Waste Information System - WWIS).

B) Technical adequacy

LANL's overall program and procedures, as described by Mr. Janecky, are likely to provide the adequate structure for successful SQA. LANL also has developed and implemented a checklist to track the development, sponsor, version, type, and level of QA for all software associated with running waste characterization equipment. Sufficient resources appear to be available for the continued development and implementation of LANL's SQA program (i.e., Mr. Janecky indicated that (1) management had "bought into" the importance of SQA and (2) he had both the time and a plan for a sustained SQA effort).

Several specific limitations of LANL's SQA program/process were identified during the audit. Specifically, the following exceptions were noted during the audit and provide the basis for CAO's CAR No. 4:

- the software code (EnviroQuant) used in HGS was not installed in accordance with the installation and checkout (I/C) form;
- the software code (EnviroQuant) was "qualified" prior to the I/C form being completed and the software was not properly classified;
- commercial software used to support calculations made in laboratory notebooks were not adequately identified and documented;
- spreadsheets used in the HGS and PAN analysis processes were not identified by name and version number, and did not have fully documented verification in accordance with the quality procedure.

The audit team also documented the following concerns, observations, and recommendations:

- LANL's baseline list of software was both inaccurate and incomplete (concern);
- Excel spreadsheet macros and formulae were neither documented or identified by version (observation);
- LANL should remove from the "controlled list" an outdated procedure that is five years old and no longer implements any QPs (recommendation).

C) Procedures

SQA is conducted in accordance with TWCP-QP-1.1-006, R.4 - "*Procedure for Software Management*" and TWCP-DTP-1.2-023, R.0 - "*Software Validation and Operation Verification for Assay of U-235 in Rashing Rings Using the Tomographic Gamma Scanning System*." Neither of these documents were made available to the inspector for review.

D) Other

There is a need to follow up on the sites' interface software development with CAO's WWIS.

5) Results or acceptability

In light of the specific exceptions noted above and CAO's issuance of CAR No. 4, LANL's SQA program/process is unacceptable. However, once LANL institutes the necessary changes to correct the exceptions noted in CAR No. 4, LANL's SQA program/process will be technically adequate. The inspector notes that LANL's SQA program/process appeared to be relatively new and that it will take some time to work out all of the implementation "bugs."

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations of the inspector, there are no recommendations concerning nonconformances issues at this time - assuming that LANL successfully responds to CAR No. 4.

Chapter H

1) Item inspected

Reconciliation of Waste Characterization Data (VE and AK)

2) Date(s) of inspection

May 16, 1997

3) Inspector(s)

Mr. Rogers, Mr. Oliver, Ms. Hugo, Ms. Shanahan, and Mr. Finkel

4) Type of observation

A) Personnel qualifications

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On Friday, May 16, 1997, the inspectors participated in an interview of Ms. Rogers that was conducted by Ms. Weston (representing CAO). Ms. Rogers is the Transuranic Waste Certification Program (TWCP) Site Project Manager and technical contact responsible for reconciliation of waste characterization data (visual examination - VE & acceptable knowledge - AK). Ms. Rogers reports to Ms. Triay, the LANL Project Leader/TRU Waste Type Manager.

Ms. Rogers wrote LANL's procedure for reconciling waste stream information and has completed the training requirements specified in the Quality Procedure (QP), TWCP-QP.1.1-028, R.0. Ms. Rogers is clearly qualified to conduct the reconciliation of waste stream information.

B) Technical adequacy

The process for conducting the reconciliation of waste stream information appears to be technically adequate, but can be improved upon by incorporating within the procedure the use of other analytical data (e.g., headspace gas sampling - HGS, non-destructive assay - NDA, sludge coring and sampling) -- see Chapter 9.0, page 10 of 11, of TWCP-QP-1.1-028, R.0.

C) Procedures

Data reconciliation is conducted in accordance with TWCP-QP.1.1-028, R.0 - *Reconciliation of Waste Stream Information*. The procedure is technically adequate but can be improved upon by incorporating the use of all available data, including HGS sampling results, NDA results, and coring and sampling results to further assist in data reconciliation.

D) Other

Ms. Rogers has noticed that there always is a discrepancy between the waste volume reported by the Real-Time Radiography (RTR) and VE operators (the RTR waste volume estimates were generally higher than the VE waste volume estimates). Ms. Rogers stated that she believed that it has something to do with the waste being compacted in the drum *vs*. uncompacted in the VE glove box. She has developed a spreadsheet to help reconcile (or "normalize") waste volumes.

5) Results or acceptability

The waste stream reconciliation process appears to be acceptable for VE and AK.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

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The inspectors recommend that the procedure be modified to incorporate the use of all available data (e.g., the results of headspace gas sampling - HGS, non-destructive assay - NDA, and sludge coring and sampling) when attempting to reconcile data.

Chapter I

1) Item inspected

Data Generation Level Review

2) Date(s) of inspection

May 13, 1997

3) Inspector(s)

Ms. Hugo

4) Type of observation

The Carlsbad Area Office (CAO) auditor, Mr. Hicks, and technical specialist, Mr. Weston, reviewed the visual examination (VE) and Real-Time Radiography (RTR) data packages. They also interviewed Chris Leibman of Los Alamos National Laboratory (LANL). During the interview, the RTR data generation level review process was discussed.

A) Personnel qualifications

Mr. Leibman (RTR support) is a seasoned professional who is well qualified and experienced to technically support the RTR data generation level review process.

B) Technical adequacy

There are three data generation level reviews. First, the technical supervisor and/or analyst reviews the results according to the Technical Review checklist specific to each analytical method. Second, the operations leader ensures that an independent technical review of 100% of the data is performed. The independent technical reviewer ensures that the data generation personnel have performed the required functions specific to each analytical method, and completes the Independent Technical Review checklist to document the review. Third, the quality assurance (QA) reviewer evaluates the data to see if the two previous reviews were performed, the QA documentation is complete, the quality control (QC) checks were performed, and the quality assurance objectives (QAOs) were met. The QA reviewer also performs data validation (i.e., calculates relative percent differences, relative standard deviations), and documents the validation effort on the Data Generation

Level QA Validation Checklist. The procedure allows the technical supervisor or operations leader to act as the QA reviewer as well.

C) Procedures

Overall, the *Data Generation Level Review* procedure (TWCP-QP-1.1-011, R.2) appears to be adequate. However, the procedure fell short in one area during implementation. Although the procedure allows the technical supervisor or operations leader to act as the QA reviewer as well, LANL interpreted that to mean the technical review and the QA review can be performed together by the same person. However, the CAO auditors discovered that the technical review elements were being evaluated while the QA review elements were overlooked. The CAO auditors recommended that all QA review elements be included.

D) Other

There are no other issues regarding data generation level review.

5) Results or acceptability

Although there has been one implementation issue, the CAO auditor stated as such and identified the next steps for LANL to follow in order to resolve the issue.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observation of the inspector, there are no recommendations concerning nonconformance issues at this time - assuming that LANL successfully addresses the issue as noted above in Chapter 4.B, Technical adequacy.

Chapter J

1) Item inspected

Project Level Validation and Verification

2) Date(s) of inspection

May 13, 1997

3) Inspector(s)

Ms. Hugo

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4) Type of observation

The Carlsbad Area Office (CAO) auditor, Mr. Hicks, and technical specialist, Mr. Weston, reviewed the VE and RTR data packages. They also interviewed Ms. Rogers of Los Alamos National Laboratory (LANL) about project level validation and verification.

A) Personnel qualifications (including training)

Ms. Rogers (Site Project Manager - SPM) is a seasoned professional who is well qualified and experienced to managerially and technically support the project level validation and verification process.

B) Technical adequacy

There are two reviews associated with the project level validation and verification process. First, Ms. Gavett (the Site Project QA Officer) reviews the batch data reports, the Independent Review checklist, and Data Generation Level QA Validation checklist. She also completes the Site Project Officer QA Summary. Second, Ms. Rogers reviews the documentation for testing or sampling and analytical batch. She completes the Data Validation Summary/Batch Data Report. The SPM submits the completed report to the records center for storage.

C) Procedures

Overall, the *Project Level Data Validation and Verification* procedure (TWCP-QP-1.1-010, R.1) appears to be adequate.

D) Other

There are no other issues regarding project level data validation and verification.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

Chapter K

ATTACHMENT 1

1) Item inspected

CARs, NCRs, ROVs and Root Cause

2) Date(s) of inspection

May 12, 1997

3) Inspector(s)

Ms. Hugo

4) Type of observation

The Carlsbad Area Office (CAO) auditor, Mr. Ptacek, interviewed Ms. Sowers of Los Alamos National Laboratory (LANL). Topics of the interview were the resolution of corrective action reports (CARs) from the August 1996 CAO surveillance; CARs, nonconformance reports (NCRs) and record of variances (ROVs) LANL has issued itself; root cause analysis and results; the process; and the procedure. CARs pertain to activities and conditions, NCRs apply to items, and ROVs relate to procedures. There are two types of CARs. Those having a significant effect on health, radiation and safety, and those having an insignificant effect.

A) Personnel qualifications

Mr. Sowers (Deputy Site Project Quality Assurance Officer) is a seasoned professional who is well qualified and experienced to administratively support the CAR, NCR, ROV and root cause process.

B) Technical adequacy

The 1996 CAR process was found to be inadequate because LANL identified issues as NCRs when CAO identified the same issues as CARs. Therefore, the CAR process was totally revamped and was re-instituted in January 1997. The new CAR process is still young and immature in its implementation.

The two CARs from the August 1996 CAO surveillance have been closed. The first CAR was issued due to inadequate procedures, and the second CAR was given for incomplete records. Now, procedures are in place and records are being maintained.

The relevant CARs LANL issued itself pertain to visual examination (VE) and the Passive-Active Neutron (PAN) system. First, the most recent VE results were not used for waste characterization. This issue was researched, and was found to be a one-time incident. Second, there were repetitive NCRs for unacceptable PAN efficiency check results at shift's end which were combined into a single CAR. LANL's PAN team did not research the problem. They just re-ran the assays and the end of shift efficiency checks were acceptable for the re-runs. The CAO auditor pointed out that a root cause analysis must be performed to determine the nature of a repetitive problem and its proper resolution. LANL staff agreed with this approach. Third, PAN data packages do not include uncertainty calculations. This issue is outside of LANL's authority. CAO has to approve site uncertainty calculation steps. However, CAO has not convened an expert review panel to perform this activity.

The relevant NCRs LANL issued itself pertain to Real-Time Radiography (RTR), PAN, and drum vents. RTR NCRs pertained to not performing the replicate drum RTR scan for a batch, and not measuring the RTR equipment for radioactivity at shift's end. The nonperformance of the replicate drum RTR scan was researched, and was found to be a one-time incident. The measurement of the RTR equipment for radioactivity was researched, was found to be a potentially reoccurring problem and operational changes were implemented to prevent this from happening again. As stated above there were several NCRs for the unacceptable PAN results which were rolled-up into a CAR. Three drums removed from storage for waste characterization did not have drum vents. These drums were returned to storage for vent addition before being allowed to come back for waste characterization. The relevant ROV LANL issued itself pertain to modifications to CAO methods. See the "Other" chapter below.

The new CAR issued by CAO is discussed in the "Procedures" chapter below.

C) Procedures

Overall, LANL's *CAR* (TWCP-QP-1.1-008, R.2), *NCR* (TWCP-QP-1.1-007, R.2), *ROV* (TWCP-QP-1.1-019, R.2) and *Root Cause* (TWCP-QP-1.1-020, R.1) procedures appear to be adequate except as noted by the CAO audit CAR (CAR No. 8) as presented below. CAR No. 8 pertains to six NCRs of 15 that were sampled and reviewed did not contain information on the cause of the NCRs (incomplete on the form). Root cause analysis was not performed for these NCRs as required. Four root cause analysis checklists sampled were signed off; however, three of the checklists did not include a documented root cause. Two instances were identified where an ROV was issued to correct a problem that should have been documented as an NCR. CAR No. 8 is based on TWCP-QP-1.1-007, R.2, Chapters 6.22 and 6.35 which require root cause determinations in accordance with TWCP-QP-1.1-020. TWCP-QP-1.1-007, R.2 definitions chapter defines non-conformances. TWCP-QP-1.1-020, R.2, Chapter 6.2 states that the "site project QA officer along with the operations leader shall take the attached checklist and...determine the root cause."

D) Other

There is one other issue which pertains to method modifications. According to LANL's ROV procedure as required by CAO, CAO method modifications are to be requested by

LANL; reviewed and approved by CAO; and method modifications can only be implemented by LANL after CAO approval and not before. However, this has not been the practice at LANL. For example, LANL made a modification to a CAO headspace gas method. This ROV was requested by LANL, was never approved by CAO, but LANL was implementing the method modification. The CAO auditor told the LANL representative that this was incorrect application of their own procedure as well as CAO's requirements; to stop this immediately; and to follow their own procedure as well as CAO's requirements regarding method modifications.

5) Results or acceptability

Although there have been some CARs, NCRs and ROVs, LANL has either corrected the problems or is currently in the process of correcting the problems. When LANL has not handled the problem properly, the CAO auditor stated as such and identified the next steps for LANL to follow in order to resolve the CAR and method modification issue.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations of the inspector, there are no recommendations concerning non-conformance issues at this time - assuming that LANL successfully responds to the above CAR and method modification issue.

Chapter L

1) Item inspected

Headspace Gas Sampling

2) Date(s) of inspection

May 13, 1997

3) Inspector(s)

Mr. Finkel

4) Type of observation

A) Personnel qualifications

On May 13, 1997, the inspector participated in an interview of Mr. Moroz and Mr. Leibman that was conducted by Mr. Ptacek and Mr. Bynum (representing CAO). Mr. Moroz is the Headspace Gas Sampling (HGS) Operations Leader and Mr. Leibman is the

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HGS Analytical Supervisor. The HGS operations reports to Ms. Triay, LANL's Project Leader/TRU Waste Type Manager. Both Mr. Moroz and Mr. Leibman are Ph.Ds with 18 and 15 years of gas chromatography/mass spectrometry (GC/MS) experience, respectively. HGS staff include:

- Mr. Martinez (HGS Analyst) - M.S. with 10 years of GC/MS experience
- Mr. Baros (HGS Technician) - OJT in HGS sample collection
- Ms. Kelly (Independent Technical Review) - M.S. with 15 years of GC/MS experience

Although the Transuranic Waste Certification Program (TWCP) detailed technical procedures for HGS (which includes HGS training requirements) was not available for review during the audit, the TWCP Training Requirements Document did list the initial training requirements for HGS analysts. Based upon the inspector's review of training records, the HGS team appears to be well qualified to conduct HGS activities.

During the course of the interview, it was apparent that both Mr. Moroz and Mr. Leibman were experts in GC/MS analyses and HGS procedures. They discussed the importance of:

- drum equilibration for a minimum of 72 hours prior to sampling
- standards preparation
- field blanks, equipment blanks, leak checks, equipment calibration, and control checks
- accurate record keeping and proper logbook maintenance
- UCL90 calculation record packages
- proper construction and maintenance of the sampling equipment and GC/MS

In addition, during the observation of the HGS and analysis process on TRU waste drums, the inspector was able to question Mr. Martinez about the operation of the GC/MS. Mr. Martinez was able to explain the proper sequencing of events and operation of the GC/MS. Mr. Martinez has undergone computer training and was able to work the software to match constituents with spectra. Mr. Martinez also was able to explain the types of things that can go wrong during the analysis and how he would know that a problem had occurred. The inspector also observed Mr. Baros decontaminate the gas syringe, pull the HGS, and pass the syringe to Mr. Martinez for direct injection into the GC. Mr. Martinez and Mr. Baros both appeared to be very methodical and followed the HGS procedure outlined by Mr. Moroz and Mr. Leibman.

B) Technical adequacy

The HGS process relies on the collection and subsequent direct injection of the headspace gas sample using a calibrated, Hamilton gas collection syringe. The HGS is injected into a HP-6890 series GC system that is equipped with a HP-5973 MS detector. LANL's HGS procedure, which uses a gas syringe to collect and directly inject into the GC without using a summa canister, is a modified procedure. LANL issued a record of variance (ROV) regarding the method modification. LANL successfully participated in, and passed, the HGS Performance Demonstration Program (PDP) using this procedure.

Although the HGS process is believed to be technically adequate, several important observations were noted during the audit process, including several that could adversely affect quality. Specifically, the following exceptions were noted during the audit and provide the basis for several of CAO's CARs, observations, concerns, and recommendations::

- On three separate occasions (March 4, 6, and 7, 1997), the continuing calibration checks (CCC) for the headspace gas GC/MS were out of compliance with the procedure. The samples were rerun, but remained out of compliance. Since certain analytes were not detected in the samples being run, the decision was made to continue the analysis. No NCR was prepared, nor was a new 5-point calibration performed. (CAR No. 1.)

- Technical Supervisory review for data package batch number LA97-331-001 was not documented on the HGAS data review checklist. The completed second level (project) review did not note the absence of this review. (CAR No. 3.)

- The HGS analysis data checklist is ambiguous as to the reviewer's response due to the use of check marks instead of a "yes" or "no" entry. (Observation No. 1.)

- The HGS laboratory notebook did not always contain sufficient information to allow understanding/interpretation without input from the TWCP personnel. (Observation No. 6.)

- Documentation of the traceability to national standards of the chemicals used for preparing calibration standards does not exist. The requirement for traceability to National Institute of Standards and Technology (NIST), Standard Reference Material (SRM), or NIST/EPA approved Certified Reference Material (CRM) cannot be met because no such material exists. Note, that CAO will work to change procedure and requirements document. (Observation No. 10.)

- Pressure instrumentation appeared to be out of calibration (expired date) according to the label on the instrument; however, a calibration label (with a valid date) was attached to the transducer. (Concern.)

- The HGS procedure incorrectly defines field blank. (Concern.)

- HGS operators and analysts did not appear to be using the same terminology in the laboratory log books as that was used in the procedures. (Recommendation.)

ATTACHMENT 1

C) Procedures

The operators followed Detailed Technical Procedure (DTP) for *Headspace Gas Sampling Using the Direct Sampling Method* - TWCP-DTP-1.2-017, R.0; Detailed Technical Procedure for *Determination of Volatile Organic Compounds in Waste Container Headspace Gas by the Gas Chromatography/Mass Spectrometry Method* - TWCP-DTP-1.2-018, R.0; Detailed Technical Procedure for *Gas Chromatography Determination of Hydrogen and Methane in Waste Container Headspace* - TWCP-DTP-1.2-019, R.0; and Detailed Technical Procedure for *Headspace Gas Analysis Batch Data Report Preparation* - TWCP-DTP-1.2-025, R.0. These procedures appeared technically adequate.

D) Other

The HGS team does not record the hour in which the TRU waste drums are delivered to the sampling facility for equilibration. Currently, this does not appear to be a problem because the drums are allowed to sit for five days; however, once LANL begins characterization activities in earnest, they will need to record the time so that they can optimize the number of drums for characterization (i.e., sample drums after 72 hours, rather than waiting four or more days). In addition, LANL did not follow the WIPP Waste Analysis Plan's Appendix C7 (Submittal and Approval of Alternative TRU Waste Characterization Analytical Methods) to demonstrate to CAO that a particular analytical procedure was equivalent to the approved method listed in the *Methods Manual*. CAO needs to ensure that all sites follow Appendix C7 in order to determine and approve method equivalency of alternative procedures and method modifications to the methods/procedures in the *Methods Manual*.

5) Results or acceptability

In light of the specific exceptions noted above and CAO's issuance of CAR Nos. 1 and 3, LANL's HGS program/process is inadequate. However, once LANL institutes the necessary changes to correct the exceptions noted above, LANL's HGS program/process will be technically adequate. The inspector notes that LANL's HGS program/process appeared to be relatively new and that it will take some time to work out all of the implementation "bugs."

6) Reference to information on actions taken in conjunction with nonconformances/ recommendations

Based on the observations of the inspector, there are no recommendations concerning nonconformance issues at this time - assuming that LANL successfully responds to the above CARs, observations, concerns, and recommendations.

ATTACHMENT 2

PDP NDA Inspection Report -
Los Alamos National Laboratory

Inspection Date: June 16, 1997 through June 19, 1997

Location: Los Alamos National Laboratory (LANL)
Los Alamos, New Mexico
Technical Area (TA) - 55

Inspectors/Observers: Julie Shanahan, A.T. Kearney
Ray Wood, Trinity Engineering

Site Representatives: Mark Doherty, Carlsbad Area Office (CAO)
Rudy Maez, Los Alamos National Laboratories
Jay Armstrong, Facility Safeguards and Security
Bill Woody, Facility Safeguards and Security
Mitch Frank, Facility Safeguards and Security
Matt Newell, Pajarito Scientific Corporation

Note: This report has an adjunct report attached (Attachment 1A) as written by Mr. Raymond Wood, Trinity Engineering Associates.

Observations:

The following observations were made during the PDP Cycle 3 performance at LANL. Observations were made in accordance with the *Inspection Planning Memo* (ATK97a) issued to the EPA WAM on June 15, 1997.

1) *Inquire about the analytical methods the measurement facility uses for the PDP and anticipates using for the analysis of WIPP wastes. Inquire if these methods have been developed and approved within specifications of the QAPP. Inquire if only the methods actually used in the NDA PDP will be considered acceptable to support the analysis of WIPP wastes.*

Analytical methods used for the PDP and anticipated for use to analyze WIPP waste include nondestructive assay using an Imaging Passive Active Neutron (IPAN) system, waste content confirmation using Real Time Radiography (RTR) and GC/MS for head space gas analysis to quantify total VOCs. The nondestructive assay analysis was performed following the *Performance Demonstration Program Plan for Nondestructive Assay for the TRU Waste Characterization Program, CAO-94-1045, April 1997 (DOE97a).* The IPAN system was developed by Pajarito Scientific Corporation. The system interrogates the drum with neutron induced fission events. **However, it was unclear if the computer software used in conjunction with the analysis met the WIPP WAC or the QAPP.** Parajito intends to write procedures for calculations conducted by the computer software in order to meet the WAC and QAPP.

2) *Inquire about the isotopes of interest in the PDP standard.*

The isotopes of interest within the PDP standards were ^{239}Pu, ^{240}Pu, and ^{241}Pu. Matrices tested included combustibles and borosilicate glass for Cycle 3.

All items observed are considered acceptable.

3) *Inquire about the personnel positions and their associated responsibilities, authority and accountability, such as the Assay Coordinator and the Standard Preparation Team (SPT), which includes the PDP Standards Custodian and the PDP Standards Configuration Attestant.*

Through questioning of individuals involved in the PDP, their reported responsibilities were as follows:

Assay Coordinator: Rudy Maez

Mr. Maez is responsible for signing for drums which begins the NDA assay clock. He also ensures that the NDA operators perform the assay measurements according to established procedures and within the appropriate time frame (28 days from date drums signed for). Mr. Maez is also responsible for returning the drums intact to the PDP Standards Custodian.

PDP Standards Custodian: Jay Armstrong, Facility Safeguards and Security

Mr. Armstrong receives the letter of instruction for loading the PDP drums from the Program Assay Coordinator, Steve Betts (LANL). He secures the letter of instruction until ready to assemble the drums and stores the standards in a secure area. He also verifies that the samples received correspond to those listed on the chain-of-custody form by serial number and physical description and verifies that the samples are not damaged. Mr. Armstrong is responsible for the physical assembly and disassembly of the PDP drums. He also verifies that the tamper indicating devices (TIDs) are intact once the drums are returned.

Assistant PDP Standards Custodian: Mitch Frank, Facility Safeguards and Security

Mr. Frank assists Mr. Armstrong with the assembly and disassembly of the PDP drums.

PDP Standards Configuration Attestant: Bill Woody, Facility Safeguards and Security

Mr. Woody is responsible for overseeing the assembly and disassembly of the drums to verify the proper placement of standards according to PDP Sample Configuration Form. He also completes the paperwork (PDP Information Form and the PDP Sample Custody Form). He also seals the Information Form and attaches it to the top of the drums.

Site Program Coordinator: Steve Betts, LANL

Mr. Betts coordinates with Facility Safeguards and Security and Carlsbad Area Office (CAO). He sends the drum loading information form and the standards to Jay Armstrong.

Sample Preparation Team: Jay Armstrong, Mitch Frank, Bill Woody

Additional personnel present at the PDP drum preparation (other than observers) included a Radiation Control Technologist (RCT) who was responsible for ensuring that no detectable removable contamination was present on either the samples or drum configurations.

All items observed were considered acceptable.

4) *Inquire about the analytical instrumentation being used for the NDA PDP and anticipated to be used for the analysis of WIPP wastes. Inquire about: calibration and frequency; data validation; internal audits; and preventive maintenance.*

Instruments used

Instruments to be used in the NDA PDP include an Imaging Passive-Active Neutron (IPAN) drum system located in a mobile unit in Technical Area 55. The drums had also been analyzed using a Passive/Active Drum Counter (PADC) the week prior. The drums were then disassembled and reassembled and shipped to the Pajarito mobile unit for analysis using the IPAN system.

IPAN Calibration and Frequency

Verification runs are analyzed daily before all other runs occur. Five different standards were used in these verification runs.
The standards are placed in different locations within the drum. The verification run was observed prior to the analysis of the PDP drums.

Internal Audits

Currently, there are no internal audit plans for the Pajarito system.

Data Reduction and Validation

No observations were made during this PDP cycle. The analytical data will undergo reduction, validation and verification.

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<u>Preventive Maintenance</u>

No preventive maintenance plans are currently in place for the Pajarito system.

5) *Inquire about the quality of assurance objectives (QAOs) (i.e., precision, accuracy, bias) associated with the NDA PDP.*

This information was not provided during PDP Cycle 3.

6) *Inquire about the storage area for the NDA PDP standards and standard matrix drums. Is the storage area secure? Does the storage area have a tamper indicating device (TID)? Has the SPT coordinated with the safeguards staff to enforce the security requirements?*

The NDA PDP standards are stored in a file cabinet with a combination lock which is located in Technical Area 55. Jay Armstrong (Standards Custodian) stated that the cabinet did not meet the requirements for a safeguards safe. Rudy Maez (Assay Coordinator) and two other employees (who are not part of the SPT) have the combination to the lock on this cabinet. **Jay Armstrong does not have the combination to the lock**. However, he keeps the PDP Sample Configuration Form locked in a file cabinet in his office. **No TID is used on the file cabinet draw. The file cabinet is not used exclusively for PDP standard storage.**

7) *Inquire if the SPT has been able to inspect, inventory, and secure the standards, as well as to inspect matrices and drums for defects or damage during shipping. Inquire if problems were found, if so, what was done.*

Jay Armstrong (Standards Custodian) inspected, inventoried and secured standards upon their receipt on May 27, 1997. No defects or damages were noted in either the matrices, standards or drums.

All items observed were considered acceptable.

8) *Inquire if the SPT:*

- *Located the shipping manifest immediately upon receipt of the NDA PDP standards and matrix drums;*
- *Verified that NDA PDP standards and matrix drums received matched those listed on the shipping manifest by both serial number and physical description;*
- *Were discrepancies found, and if so, the SPT response; and*
- *Where the SPT returns the shipping manifest once it is signed.*

Jay Armstrong located the shipping manifest once the PDP standards and drums arrived. He then verified that the standards and drums matched those listed on the manifest. The shipping manifest is returned to Steve Betts (Program Assay Coordinator, LANL).

All items observed were considered acceptable.

ATTACHMENT 2

9) *Inquire about the qualification and experience of the SPT. Do they meet those qualifications and experiences listed in Section 6.1 of the NDA PDP Plan?*

All SPT members have participated in the 2 hour training course given by Charlie Marcinkiewicz, CONTACH. Jay Armstrong also attended a full day training course which was given prior to the installation of the 2 hour course. All SPT members are qualified radiation workers. Both Jay Armstrong and Bill Woody participated in the drum loadings of the last two PDP cycles. Mitch Frank was present for the drum loading at the last PDP cycle. All members of the SPT meet the requirements of Section 6.1 of the *PDP Plan for NDA (DOE97a)*.

10) *Inquire about the NDA PDP forms used:*

- *Were they completed correctly?*
- *Were they signed by the correct personnel?*
- *Were they routed properly?*
- *Were they stored properly?*

PDP Sample Custody Form for NDA

Mr. Armstrong maintains a copy of the Sample Custody Form. A copy is sent to the Assay Coordinator upon receipt of the matrix drums. Another copy is sent to the Site Program Coordinator for status reporting of the PDP NDA cycle.

PDP Sample Information Form

Mr. Armstrong maintains a copy of the Sample Information Form within a locked area in his office. This area was not observed. The original is attached to the top of the matrix drum in accordance with PDP requirements.

PDP Report Form for NDA

Completion of this form was not observed. However, Mr. Matt Newell of Pajarito stated that the completed PDP report and electronic copy would be forwarded to Charlie Marcinkiewicz.

PDP Sample Configuration Form

Mr. Armstrong maintains control of the Sample Configuration Form in a locked area in his office. This area was not observed.

PDP Sample Disassembly Form

Completion of this form was not observed. Once completed this form is sent to Steve Betts, Site Program Coordinator.

ATTACHMENT 2

All forms observed were noted to be complete and correct. All items observed were considered acceptable.

11) *Inquire if the PDP Standards Custodian:*

- *Identified the correct standards;*
- *Verified that the proper standards were used;*
- *Selected the proper serial numbered 55-gallon matrix drum for insertion of the PDP standards;*
- *Examined all required NDA PDP sample components;*
- *If problems were noted, what would the Custodian do;*
- *Inserted each NDA PDP standard into the identified position of the source insert fixture, and the PDP Standards Configuration Attestant verified this;*
- *Inquire about the site-specific sample preparation procedures and forms associated with these activities.*

During the observation, it was noted that the PDP Standards Custodian did confirm the standards identification using serial numbers against those listed to be used in the PDP cycle. Bill Woody the PDP Standards Configuration Attestant and Mitch Frank the Assistant PDP Standards Custodian reconfirmed the standards identification. It was also confirmed that the correct matrix drums were used and that the PDP standards were placed into the positions specified on the PDP Sample Configuration Form.

If a problem was noted, the Standards Custodian would report it directly to Steve Betts, Site Program Coordinator.

All items observed were considered acceptable.

12) *Inquire if:*

- *The NDA PDP Standards Configuration Attestant sealed the PDP sample with the appropriate serialized TID;*
- *If the PDP Standards Custodian security sealed the PDP Sample Information Form and affixed it to the top of the drum;*
- *If the security seal for the form and TID for the NDA PDP sample were in tact before NDA PDP sample disassembly; and,*
- *If the seal and TID were not intact and, if so, the response of the SPT to this discovery.*

During the observation, it was noted that the NDA PDP Standards Configuration Attestant did seal the PDP samples with the correct serialized TID. The PDP Sample Information Form was security sealed and placed on top of the drum.

No disassembly observations were made during the review of the Cycle 3 of the PDP.

All items observed were considered acceptable.

ATTACHMENT 2

13) *Inquire if:*

- *PDP Standards Custodian transferred the NDA PDP samples and PDP Sample Custody Form for NDA to the Assay Coordinator;*
- If the Assay Coordinator inspected the condition of the TIDs on each NDA PDP sample;
- If there were problems and, if so, the response of the Assay Coordinator;
- *If the Assay Coordinator confirmed the accuracy of the PDP Sample Custody Form; and*
- *Where the Assay Coordinator returns the form once it is signed.*

During the observation, it was noted that the PDP Standards Custodian transferred the NDA PDP samples and PDP Sample Custody Form for NDA to the Assay Coordinator. The Assay Coordinator inspected the condition of the TIDs on the PDP drums. The Assay Coordinator noted no problems. The PDP Sample Custody Form was inspected and once the assay is complete will be returned to Mr. Armstrong, Standards Custodian.

All items observed were considered acceptable.

14) *Inquire how many times the contents of each sample was analyzed and if the sample was completely removed and replaced between sequential measurements.*

During the observation, it was noted that each drum was analyzed six times. After each run the drum was removed from the system, left the system trailer, was lifted off the conveyor, replaced, and then entered back into the system for the next run of analysis. Analytical time for each drum is approximately 17 minutes.

All items observed were considered acceptable.

15) *Inquire about:*

- *The analysis completion and reporting time period*
- *If a time period extension was requested and, if so, granted; and,*
- *Inquire about any NDA PDP analytical results (if available).*

Once the Assay Coordinator signs the PDP Sample Custody Form there is 28 days to complete the analysis and report and submit it to Charlie Marcinkowitz. Mr. Matt Newell of Pajarito requested an extension and was granted an additional two-weeks. None of the completed NDA PDP analytical results were observed.

All items observed were considered acceptable.

16) *Inquire about:*

- *The information included in a report.*
- *Who signs the report;*

- *Where the report is forwarded;*
- *Corrections to the data; and*
- *The electronic version of the data.*

The data forms produced contain the information presented in the sample forms of the *PDP Plan for NDA (DOE97a)*. Matt Newell reviews and signs the hard copies and reviews the electronic copies of the data. Once it is validated both the hard and electronic copies are forwarded to Charlie Marcinkowitz.

17) *Inquire about:*
- *What happens to the NDA PDP samples after analysis but before authorization to disassemble has been received;*
- *What happens to the NDA PDP sample after authorization to disassemble has been received;*
- *Were the TIDs intact?*
- Was the seal of the PDP Sample Information Form in tact?
- *If there were problems with the TIDs and seal inquire what was done and if the problems were recorded on the Sample Disassembly Form;*
- *Did the PDP Sample Custodian removed each standard from its position and each SPT independently verify that the source positioning was correct against the Sample Configuration Form; and*
- Were these forms returned?

Mr. Armstrong stated that the drums are returned to him (TA 55) once assay has been completed. They remain intact and under his control until notified by letter that they may disassemble the drums. Once authorization is received, the drums are disassembled and the standards are stored in a locked cabinet in TA-55. The drums had not been returned at the time of the observation, therefore, it was not observed if the TIDs and the seal of the PDP Sample Information Form were intact.

All items observed were considered acceptable.

18) *Inquire if the PDP Standard Configuration Attestant coordinated the placement of the NDA PDP matrix drums and NDA PDP sample standards in the secured storage area.*

This was not observed during this PDP cycle.

References

Inspection Planning Memo for the PDP NDA Inspection of the Los Alamos National Laboratory, A.T. Kearney, Inc., June, 1997.

ATTACHMENT 2

Performance Demonstration Program Plan for Nondestructive Assay for the TRU Waste Characterization Program, CAO-94-1045, U.S. Department of Energy, Carlsbad Area Office, April, 1997.

ATTACHMENT 2-1

FROM: Dr. Raymond Wood, Trinity Engineering Associates

TO: Ms. Connie Walker, A.T. Kearney

SUBJECT: Report of Performance Demonstration Program (PDP) Observation
Los Alamos National Laboratory
Cycle 3 of the PDP, 6/15-6/19/97

NOTE: This report is written as an adjunct to the report written by Ms. Julie Shanahan of A.T. Kearney, who was also observing the PDP at Los Alamos. The guidance document for the observation team was the Inspection Planning Memo issued to the EPA Work Assignment Manager dated 6/12/97.

The PDP as observed was performed in two distinct stages, the first being the preparation of the sample drums and the second being the assaying of these sample drums in the Parajito Scientific Corporation (PSC) Imaging Passive Active Neutron (IPAN) system contained in the PSC mobile assay system. The PDP work for this cycle was performed under the requirements of the Performance Demonstration Program Plan for Nondestructive Assay for the TRU Waste Characterization Program CAO-94-1045, April 1997.

Preparation of the Sample Drums

Preparation of the sample drums was performed by the sample preparation team (SPT) in accordance with the 'procedure' contained in the PDP plan. We observed the process of preparing the sample drums with three goals in mind:

1. Gather sufficient information to adequately answer the questions contained in the Inspection Planning Memo
2. Determine whether the SPT followed the instructions for PDP sample preparation contained in Section 6.2 of CAO-94-1045
3. Observe if the sample preparation and control processes, as performed, provide for an independent and fair assessment of the non-destructive assay system being tested

Item 1: Answers to questions contained in the inspection planning memo, is addressed in Julie Shanahan's report on an item-by item basis.

Item 2: We also determined that the SPT was using the PDP Program Plan for Nondestructive Assay for the TRU Waste Characterization Program, Section 6.2, as a procedural guide for preparing the sample drums. The SPT was using the April, 1997 revision of the plan, of which the observers had only a draft version, but this was not a problem for observing that the SPT was following the plan's guidance. In all, the preparation of the sample drums was performed in an efficient and professional manner, with all steps being independently verified and attested.

ATTACHMENT 2-1

Item 3: The third goal of observing the independence and fairness of the test was an observation of the 'blindness' of the testing process as a whole (i.e,. determining if any weaknesses in the testing process could affect the outcome of the test). In particular, for this test, the information which must be controlled is the sample drum source contents. The fairness of the test could be biased if the assaying personnel had prior knowledge of the isotopic makeup of the sources in the samples, the activity of the sources, or the makeup of the test matrix containing the sources. Knowledge of the source geometry by the assaying personnel could also bias the test, but likely not to the degree which knowing the actual source activities could.

Information about the contents of the sample drums could be obtained either advertently or inadvertently in a variety of ways by the assaying personnel, including:

- Physical intrusion into the sample drums in order to check their contents
- Obtaining information from available procedures or records
- Conversations, notes, etc. from personnel who may have been present at both the loading and assaying of the sample drums
- Inferring the contents from the fact that limited combinations of the contents are possible (also known as educated guessing)
- Use of other available test methods in conjunction with the method being tested, such as gamma spectroscopy prior to neutron assaying
- Negative testing; for example, checking the dummy drums to see which sources were not used

Combinations of the above could also be done to obtain information.

From observation of this cycle of the PDP, it was determined in general that the information describing the actual contents of the sample drums was well controlled. Physical intrusion into the drums by the assaying personnel would be essentially impossible without the concurrence of the SPT and the Assay Coordinator, since breaking the TID seals would immediately void the test. The SPT personnel and the Assay Coordinator have no incentive for assisting any testing organization, so physical intrusion is not a concern. There was minimal crossover of personnel from the drum loading to the assaying (indeed, the largest crossover was the observers), so there was minimal chance of drum content information coming over via personal notes or inadvertent conversations.

Some information on the source activity of the sample drums could be obtained from records which are available to the assaying personnel, but this information could not be used to specifically determine the contents of any one drum. The total activity of the sources used in this round of the PDP could be available to the assay personnel through the Nuclear Material Accountability System, but the distribution of that total source activity within the sample drums is controlled by the Assay Coordinator and the SPT. In this PDP cycle, three test drums were developed. Two of the test drums (colored blue) were to be assayed, and the third test drum (colored white) contained the sources not used in the two test drums. This third "drum" was not assayed, and indeed could not be assayed by the PSC mobile system, as this third "drum" was actually two 55 gallon drums joined by a TID. The inability to assay the third "drum" essentially eliminates the possibility of negative testing. Each sample drum could contain up to three sources placed in any of the nine locations within the drum. Thus, the odds of guessing the source activity in any given drum are small, and the odds of guessing the physical location of the sources within a drum are very small.

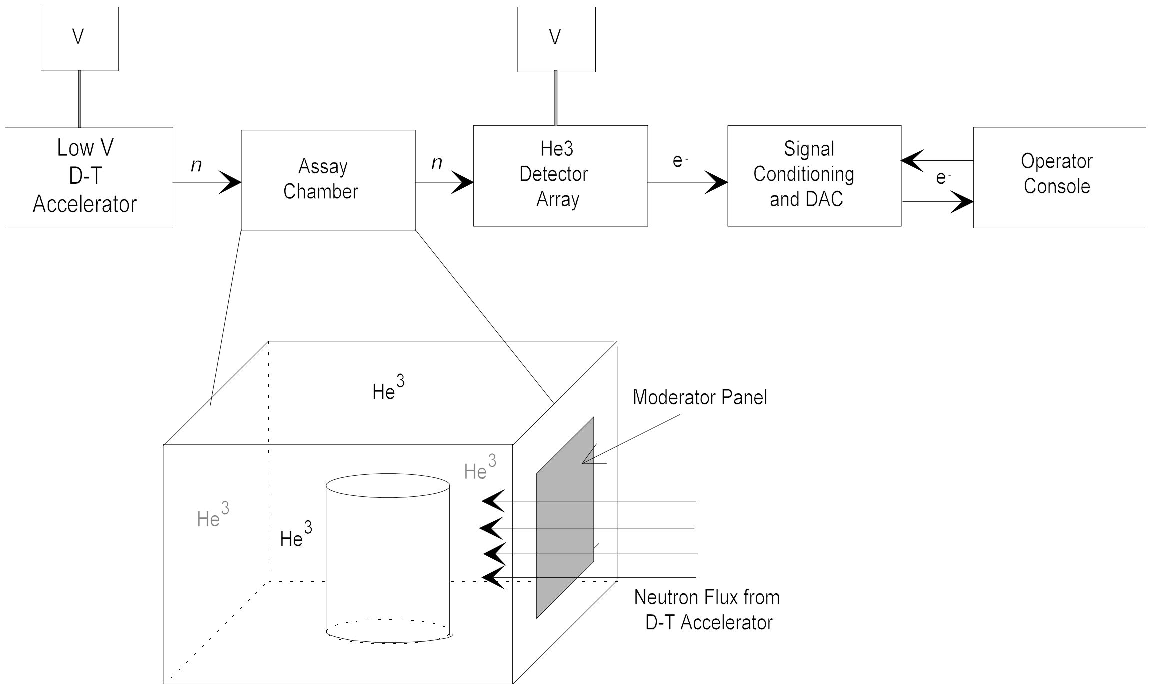
Although the assay personnel are not likely to be able to infer the inventory of the sample drums with any reasonable accuracy, they would have a reasonable chance of inferring the test matrix within the drums. For this cycle of the PDP, the only matrices being tested were known to be borosilicate glass and combustibles. The assay system uses predetermined calibration curves for neutron absorption and moderation within the waste matrix to develop source inventory based upon count rate, so prior knowledge of the waste matrix could allow the assay system to be 'tweaked' with specific calibration information in order to produce better accuracy. Additionally, although the source activities within each drum were not known to the assay personnel, the isotopic makeup of the source was. The sources used in this cycle of the PDP were known to be type 52, consisting of 93.7% Pu239, 6% Pu240, and 0.3% Pu241. Again, the nature of the system being tested could allow it to be optimized for measuring these isotopics. Finally, the sources themselves are all known to be fine grained materials contained in diatomaceous earth. The PSC system is optimized for sources of this type, and may not have similar performance for sources where the plutonium is more heterogeneous (this limitation is likely to be true for all the NDA systems currently being tested as part of the PDP).

The PSC system has the capability to perform high resolution gamma spectroscopy, so the capability does exist within this system to use other methods to assist the neutron counting system in order to improve the overall system results. There was no evidence that the gamma spectroscopy system was used during this test.

Overall, the observers felt confident that the PDP provided a reasonably fair test of the NDA system, and that the methods used for controlling the sample information provided reasonable assurance that the assaying personnel did not have sufficient information to bias their results. This conclusion takes into account the fact that the Performance Demonstration Program is an evolving series of tests, with each testing cycle becoming more rigorous. Future test cycles are intended to expand the number of test matrices and source types, leading to less likelihood that the systems being tested can be optimized in advance for the isotopes and matrices contained in the drums. These future tests should be more indicative of the actual performance of the systems in a production environment than were the Cycle 3 tests. The Cycle 3 tests would appear to be more indicative of a situation where acceptable prior knowledge of the waste stream being tested provided good information on isotopic makeup, matrix materials, and source heterogeneity.

<u>Observation of Drum Assay</u>

We observed the drum assay process on 6/19/97. The drum assay was being performed by PSC using their Imaging Passive Active Neutron (IPAN) system, which uses a pulsed D-T neutron source and differential dieaway analysis to 'image' the drum for sources. The following figure provides a summary block diagram of the PSC system as it was tested for Cycle 3 of the PDP at LANL:



The PSC IPAN system is capable of active or passive neutron counting in order to determine the inventory of the drum being assayed. As mentioned earlier, the system also has the capability to perform gamma spectroscopy, but this was not used during the PDP test. In general, the first step in the analysis is interrogation of the drum with the active system. The high energy neutrons developed by the D-T accelerator are moderated into a defined energy spectrum by the moderator panel. The drum is interrogated by this energy spectrum, and the resulting flux at the detectors is used to determine a moderator and absorber index for the drum matrix. The system then searches a library of predefined calibration curves for the best match, and uses the matrix correction factors generated from these calibration curves to calculate the drum source contents based on the detector signals. The system will select either passive or active counting depending on the count rate, which is generally a function of the source activity and the matrix characteristics. Note that in these systems, a dense drum matrix can produce higher overall detection efficiencies than a low density matrix, since the dense matrix may also have higher moderating power. This is contrary to the general behavior for gamma measuring systems.

Prior knowledge of the characteristics of the waste stream being analyzed will increase the accuracy of the IPAN system. Prior knowledge of the drum matrix would allow calibration curves specific to the matrix to be developed, which would reduce a potential source of error. In addition, the system software assumes an isotopic mix for the source within the drum in order to perform the source calculations. For the Cycle 3 PDP tests, the assumed isotopic distribution was weapons grade plutonium. This isotopic mix can be changed in the software, but changing this assumption requires some knowledge of the waste stream characteristics. Selecting an isotopic assumption different from the drum contents could lead to significant error. The system as observed also contained an implicit assumption that the plutonium was not present in lumped sources, but rather exists in particle sizes which can be fully penetrated by the neutron flux and have minimal self shielding effects. No calibration curves exist for waste containing lumped sources.

In the IPAN system, most of the decisions related to the assay process are made by the analysis system software, including the selection of the active or passive measurement and the selection of the calibration curve to relate signal to source. The system operator's role is to ensure the system is operating properly, and that it is properly calibrated, prepared, and loaded. Updates to the IPAN system software are not performed in the field, and since the code in the system is primarily executable and run-time modules, the system does not lend itself to field modifications or changes. The data files used by the system, such as the calibration curves, can be field modified but are usually changed at the main office. In general, any modifications to the system software or data is developed by PSC's physicists, and the new files distributed to the systems as an update to be loaded under instructions developed by the physicists.

Since the system software is to a large degree performing the assay, the IPAN software would fall under the requirements of NQA if it were used to develop waste information for the WIPP. This is probably true for most of the other NDA systems which are being used at the various generator sites. PSC currently does not operate under NQA for their software development, although after discussing it with Matt Newell, Engineering VP of PSC, it appears they may have a software development system which is similar. Matt noted the comments concerning QA of software, and mentioned that PSC would see what complying with NQA would require.

The overall accuracy and precision of the IPAN system can not be determined from this observation. The system passive neutron count rate efficiency is provided by PSC as approximately 12%, but this appears to be primarily a geometric detector efficiency and does not tell much about the overall system uncertainty. The system does provide results in a format of XX +/- YY, but this +/- uncertainty is apparently primarily the counting uncertainty, which would be one component of the overall system precision. The results of the two drum tests provide a better indication of the overall system precision:

First Drum Test - Combustibles Matrix

Count #	Total Pu (g)	+/- (g)	Assay Method	Mod Index	Abs Index
1	53.1	1.3	Passive	7.1	*
2	55.0	1.4	Passive	7.1	*
3	59.6	1.4	Passive	8.0	*
4	55.6	1.3	Passive	7.3	*
5	55.3	1.3	Passive	7.1	*

6	55.4	1.3	Passive	7.0	*

* - not recorded

Second Drum Test - Glass Matrix

Count #	Total Pu (g)	+/- (g)	Assay Method	Mod Index	Abs Index
1	107.0	2.1	Passive	6.7	420
2	112.6	2.2	Passive	6.6	379
3	106.4	2.1	Passive	6.5	391
4	114.2	2.2	Passive	6.5	432
5	108.2	2.1	Passive	6.6	407
6	110.4	2.1	Passive	6.6	401

Assuming normal statistics for the measurement results, the mean for the first drum results is 55.7 g, and the sample standard deviation is 2.1 g, with an s/x_m= 0.038. For the second drum, the mean is 109.8 g, and the sample standard deviation is 3.13 g, with an s/x_m=0.029. Please note that these are not official results, but are taken from the observers field notes. The official results will be distributed as described in the Performance Demonstration Program Plan, and will contain comparisons on accuracy as well as precision. These results do indicate that, with reasonable knowledge of the waste stream characteristics, the PSC system is capable of consistently characterizing the drum contents. More rigorous tests, as provided for in future cycles of the PDP, are needed to make a definitive judgment as to whether this system can meet the requirements for NDA systems used to characterize WIPP waste.

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Technical Support for Evaluating
DOE's WIPP Waste Characterization Program

Inspection Report
Los Alamos National Laboratory
Waste Characterization Certification Follow-up Audits
August 18-22, and September 10-12, 1997

Prepared for

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October 10, 1997

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INTRODUCTION

The A.T. Kearney WIPP Waste Characterization team members attended two LANL Follow-up Audits of August 18-22, and September 10-12, 1997. The first follow-up team consisted of Paula Hugo and Julie Shanahan, both of A.T. Kearney, Don Hammer of ICF, and Dr. Raymond Wood of Trinity Engineering Associates. The second follow-up team consisted of Angela Jones of A.T. Kearney, and Dr. Raymond Wood of Trinity Engineering Associates. The two follow-up audits were much more limited in scope than the waste characterization certification audit of May 1997. The August 1997 follow-up audit scope focussed on the waste characterization issues identified during the May 1997 audit (i.e., NDA, acceptable knowledge, waste container tracking, software quality assurance, miscertification rates, random selection) as well as the manual data entry and transmission of LANL waste characterization data to the WIPP site via the WIPP Waste Information System (WWIS). The September 1997 follow-up audit scope focussed on three waste characterization issues identified during the August 1997 follow-up audit (i.e., NDA, acceptable knowledge, WWIS).

The first follow-up audit began with a kick-off meeting on the morning of August 18, 1997. The meeting was attended by EPA WAM - Kyle Rogers, the first set of WIPP Waste Characterization team members as previously mentioned, the CAO audit group, and the LANL waste characterization staff. EPA and the WIPP Waste Characterization team members conducted their own meetings at the end of each day to discuss waste characterization issues. Each morning there were management meetings between CAO and LANL which were attended by EPA. On August 22, 1997, there was a CAO auditor close-out meeting which was attended by LANL staff, EPA and the WIPP Waste Characterization team members.

From the morning of August 18, 1997 through the evening of August 22, 1997, the CAO auditors broke into four separate audit teams consisting of lead auditors and technical specialists. At the direction of the EPA WAM, CAO audit team assignments were given to the WIPP Waste Characterization team members. The CAO audits were covered by at least one EPA staff member and/or one WIPP Waste Characterization team member. One technical area, manual waste characterization data entry and transmittal from LANL to the WIPP site via the WWIS, was added to the August 1997 follow-up audit that was not covered during the May 1997 audit. The audits which were not relevant (i.e., transportation) to waste characterization were not attended by EPA or its' contractors.

The second follow-up audit began with a kick-off meeting on the morning of September 12, 1997. The meeting was attended by EPA WAM - Kyle Rogers, the second set of WIPP Waste Characterization team members as previously mentioned, the CAO audit group, and the LANL waste characterization staff. EPA and the WIPP Waste Characterization team members conducted their own meetings at the end of each day to discuss waste characterization issues. Each morning there were management meetings between CAO and LANL which were attended by EPA. On September 12, 1997, there was a CAO auditor close-out meeting which was attended by LANL staff, EPA and the WIPP Waste Characterization team members.

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From the morning of September 10, 1997 through the evening of September 11, 1997, the CAO auditors broke into three separate audit teams consisting of lead auditors and technical specialists. At the direction of the EPA WAM, CAO audit team assignments were given to the WIPP Waste Characterization team members. The CAO audits were covered by at least one EPA staff member and/or one WIPP Waste Characterization team member. Angela Jones of A.T. Kearney was not present at LANL, but was present at the WIPP site in Carlsbad, New Mexico to witness the receipt and processing of waste characterization data transmitted from LANL to WIPP via the WWIS.

Conditions Adverse to Quality (CARs)

After the August 1997 follow-up audit, the status of the May 1997 audit CARs and observations was nine of ten CARS were closed (one CAR pertaining to NDA remained open), and all observations were verified as corrected. As a result of the August 1997 follow-up audit, CAO identified a total of five CARs, three observations, two recommendations, and 13 items closed during the audit. A summary of the five CARs raised by CAO during the August 1997 follow-up audit is presented below:

- CAR No. 1: The evaluations of PC/FRAM v2.3, PAN v1.0 and MAESTRO v3.00 did not define sufficient requirements, test cases or acceptance criteria to fully validate the software for its intended use. Software requirements, test cases and/or test results did not fully demonstrate the ability of the PC/FRAM and PAN software to support measurement of total alpha activity and the activity of all individual isotopes present.

  Requirement: TWCP-QP-1.1-006, Section 4.2 requires that software developed under other QA program requirements to be evaluated and the activities necessary to validate and accept the software for its intended use defined.

- **CAR No. 2:** EPA Hazardous Waste Codes are not being assigned consistently with the requirements of the QAPP.

  Requirement: QAPP, Section 4, Paragraph 4.2.1 state "...If a toxic characteristic contaminant is identified and is not included as a listed waste, assign the toxicity characteristic EPA hazardous waste number...When analytical data is not available, the toxicity characteristic EPA hazardous waste number for the identified hazardous constituent must be applied to the waste stream...In the case of discrepancies in information, no judgement may be made regarding the quality of the information. Sites must ensure that all potential EPA hazardous waste numbers are assigned to the waste stream."

- **CAR No. 3:** Two individuals report functionally to the Site Project Manager and to the Site QA Officer.

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The Operations Leader for NDA is performing the Level 1 QA review of FRAM data. The same individual is performing data reduction activities for the FRAM system.

Requirement: CAO QAPD, Rev. 1, Section 1.1.1.5.B.2.b states that "participant QA management shall be sufficiently independent from cost and schedule considerations."

- **CAR No. 4:** Procedures TWCP-DTP-1.1-029 and TWCP-DTP-1.2-006 were not performed exactly as written or the procedures did not include the necessary activities. In performance of the FRAM procedure, alternate methods from those in the procedure were used for calibration, and the procedure did not provide instructions for the set up of the FRAM equipment.

  Requirement: Effected sections of the DTP are TWCP-DTP-1.2-029, R.0, Isotopic Ratios Using FRAM Section 8.0, 8.2, 9.0 and 12.0.

- **CAR No. 5:** Checks of radioassay data to distinguish between TRU and low-level radioactive waste were not performed as required. Sampling and analysis data were in the package reviewed, but the results of the review was not documented and the check was not listed in the DQO checklist. Comparisons of NDA characterization data with acceptable knowledge information is also not addressed in the current procedure (TWCP-QP-1.1-028, R. 1, Section 7.0).

  Requirement: TWCP-QP-1.1-028, Section 8.8.1 requires that radioassay data be reviewed to ensure that the value of the TRU activity reported demonstrates that the waste is TRU waste and not low-level radioactive waste. The review requires a check to see that the average mass and activity of each radionuclide is listed for each waste container.

  TWCP-QP-1.1-028, Section 8.9 requires that gas sampling and analysis data be reviewed to ensure that concentrations of hydrogen, methane and flammable VOCs meet the flammability and waste acceptance criteria.

After the September 1997 follow-up audit, all CARs and observations remaining from May 1997 and/or new in August 1997 were verified as closed and corrected, respectively. CAO rated the adequacy of LANL's program as satisfactory, implementation of its program as satisfactory, and the effectiveness of LANL's program as satisfactory.

Format of Inspection Report

The Inspection Report begins with this introduction about the follow-up audits, and contains a separate chapter for each inspection item. A chapter includes the following sections: (1) items inspected, (2) date of inspection, (3) inspector, (4) type of observation, (5) results, and (6) recommendations regarding nonconformance issues. Section (4) is broken down into the following subsections: (A) Personnel qualifications (including training), (B) Technical adequacy,

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© Procedures, and (D) Other (including related issues). There are 10 chapters in all. They are labeled Chapters A through J.

CHAPTER A

1) Item Inspected

Fixed Energy Response Function Analysis with Multiple Efficiencies (FRAM) Assay System/Follow-up of the Passive-Active Neutron (PAN) Assay System CAR

2) Date(s) of inspection

August 18-20, 1997

3) Inspector(s)

Kyle Rogers, Julie Shanahan, Don Hammer, Dr. Raymond Wood

4) Type of observation

A) Personnel Qualifications

The DOE Carlsbad Area Office (CAO) auditor, Robert Paedon and technical specialist, Jim Bresson reviewed the FRAM gamma system. The auditor and technical specialist also reviewed the FRAM data packages along with the corresponding passive-active neutron (PAN) data. They interviewed Dan Taggart and Mr. Poths of Los Alamos National Laboratory (LANL). During the interview, the FRAM system operators were viewed and the system and procedures were discussed.

Dan Taggart, the FRAM Technical Supervisor, is a seasoned professional who is well qualified and experienced to technically and managerially support the FRAM system. Dan Taggart is a PhD. nuclear physicist by training including education and numerous years of professional experience.

Mr. Poths, the FRAM system operator, has operated the EG&G FRAM system for approximately 2 months. Prior to the operation of this system, Mr. Poths was a mass spectrometrist at LANL.

B) Technical Adequacy

Based on the results of the May 1997 audit, the non-destructive assay (NDA) technique, Passive-Active Neutron (PAN) assay system, appears to be adequate as long as LANL has completely accurate acceptable knowledge (AK) regarding the radionuclides associated with the waste and their isotopic ratios. If AK does not exist or is not completely accurate, then PAN is not the appropriate NDA technique to be used solely or initially because PAN does not identify individual radionuclides. PAN determines the total activity from which individual activities are calculated for radionuclides and isotopic ratios as identified by AK. In these instances of deficient AK, PAN should only be used after some type of gamma scan which identifies individual radionuclides. LANL has selected the FRAM as the gamma technique to follow AK and to proceed PAN.

During the August and September 1997 follow-up audits, the FRAM assay system was observed. The system which LANL is proposing for gamma spectroscopy uses a high purity germanium detector providing input via an EG&G ORTEC Nomad Portable Spectroscopy System Model 92X-P to a PC based data acquisition and analysis package. Voltage to the detection system is provided by the Nomad system. The detectors currently being used are either an EG&G ORTEC Solid State Photon Detector, GEM Series, High Purity Germanium (HPGe) Coaxial Detector System, or a GMX Series Gamma-X HPGe Coaxial Detector System. The data acquisition system typically is located near the spectroscopy system, and operates on a laptop computer utilizing an Intel microprocessor.

The software being used for data acquisition and analysis is a combination of the FRAM code which has been ported to the PC environment (PC/FRAM) and the MAESTRO package. Both PC/FRAM V2.3 and MAESTRO for Windows V3.04 were obtained from EG&G ORTEC, even though the original FRAM code was developed by LANL for Pu isotopic assaying.

The above system is referred to by LANL as the FRAM/gamma system; this report generally refers to it as the FRAM system, with specific reference to PC/FRAM meaning the software package and not the entire system. The FRAM system in it's LANL configuration uses 8192 energy channels, with an energy resolution of 125 eV per channel. Measurement time is determined by the first of either obtaining 8000 counts in the region of interest peak or 3600 seconds. Dead time is limited by procedure to less than 30%, and can be controlled by positioning the detector either closer or farther away from the waste drum until an acceptable count rate is achieved. An annual system efficiency calibration check is performed as required by the Quality Assurance Project Plan using NIST traceable standards; operational checks of the system are performed at the beginning and end of each work shift when the system is in production. Background spectra are taken daily. Replicate sample counts are performed on at least every 20th drum.

LANL intends to use the FRAM system for three purposes[1]:

1. As a decision tool for determining which assay system should be used on which drums

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2. Provide isotopic ratios needed by the PAN system

3. Provide quantification of non-Pu isotopes

In addition, although not listed as a purpose in the LANL procedure, the FRAM system will also be used in developing the isotopic uncertainty term for the total measurement uncertainty determination for the PAN system. The first purpose listed above is not completely applicable at this time. The only assay system ready for use is the PAN, so the FRAM will essentially act as a screening tool to determine if the PAN system can be used for a given drum. The decision to use other methods may have to wait until those methods are approved for use.

The FRAM system should be capable of determining the isotopic ratios needed by the PAN system. The PAN system in passive mode effectively only measures Pu-240, so the quantities of the other plutonium isotopes relative to the Pu-240 mass must be determined for the assay to be complete. The original FRAM code was designed to provide isotopic compositions of arbitrary plutonium-bearing samples in cases where the Am/Pu distributions could be heterogeneous, and the PC version being used at the RANT retains this capability. FRAM and PC/FRAM calculate isotopic mass ratios by finding a least squares solution to set of linear equations with peak areas, relative efficiency, and isotopic ratios as unknowns[2,3]. The peaks used were in the energy range of 120-450 keV; PC/FRAM has the capability to extend this by adding data in the 300-700 keV range in order to improve precision (particularly for Am-241). Using the more efficient coaxial detectors rather than the planar germanium detectors common to single detector systems when FRAM was originally written helps in extending this data range.

Peak fits are performed using a linear least squares fit response function method, where the response function is Gaussian with a short term tail[2,3]. The tail function is an adder function determined by empirical fit to data from selected tailing calibration peaks. This method of peak fitting should adequately determine the peak areas for the WIPP drum data. Relative efficiency curves are calculated by fitting a polynomial in ln(E) to the peak data for the isotopes of interest over the energy range of interest. The code does have the capability to develop different relative efficiency curves for different isotopes if the user believes that there may be significant spatial heterogeneities in the isotopic distributions for the isotopes. This capability may be useful for future waste streams containing pyrochemical residues where the americium is in a salt form and the plutonium is a metal dispersed in the salt, as gamma rays having nearly identical energies from the two materials will likely see different shielding effects.

The system should be capable of generating the Pu isotopic fractions and an associated uncertainty as long as two conditions are met. First, the effect of the presence of other radionuclides on the Pu concentration calculations must be understood. Second, the response of the system to heterogenous source isotopics in the drum must be determined.

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Unfortunately, during the August 1997 audit, the system had not been tested completely and these two conditions had not been met. This was largely because the FRAM testing to that point had only been done with Pu standards fabricated from weapons grade plutonium. Since FRAM was originally designed to work with weapons grade Pu, the results from the measurements on the standards were good. The demonstration was a good example of why systems should be tested to the range of the requirements they are intended to handle; since the system tests had not included sources with isotopes other than weapons grade Pu, the effect of the presence of other radionuclides in the drum (and potentially heterogeneously distributed sources) had not been considered. Thus, the results of the demonstration during the August 1997 audit were unsatisfactory when an actual drum was measured.

LANL recognized the shortcomings of their original FRAM method when applied to WIPP waste drums, and they developed some techniques which will address the problems. These techniques include:

1. Modifying the parameter files in PC/FRAM to account for the presence of other radionuclides in the PC/FRAM isotopic and background calculations.

2. Developing analytical techniques, such as checking the relative efficiency curve generated by PC/FRAM, to determine if a drum can be adequately tested using the PC/FRAM system.

3. Rotating the drum during measurements to minimize the effect on the measurement of isotopic heterogeneities in the source.

If these techniques prove viable during the September 1997 follow-up audit, then the combination of FRAM and the PAN should provide a good assay method for a wide variety of drums, as well as providing positive indication for drums which should not be assayed using this method.

During the September 1997 follow-up audit, LANL demonstrated the applicability of the improved FRAM system, and documented the tests LANL performed to demonstrate this. Again, the only potential problems with using the FRAM system for determining the isotopic ratios identified during the August 1997 audit were accounting for spatial inhomogeneities in the isotopic source within the drum (i.e. different isotope ratios at different locations), and accounting for other isotopes which could produce gamma rays which interfere with the Pu or Am peaks. Both of these potential problems were addressed during the September 1997 audit in the most recent LANL procedure for using the FRAM system, TWCP-DTP-1.2-029, R.2. The effect of spatial heterogeneities is minimized by rotating the drums at a constant angular velocity during the count, which should remove any effects from radial heterogeneities. Currently no axial variations in the measurements are planned, but the tests which were observed at LANL indicate that axial variations are not a concern for the debris waste stream.

The FRAM system has the ability to account for isotopes which are known to be in the waste by adding them to the parameter files. The isotopes which are currently accounted for are Am-241, Np-237, Am-243, Pa-231, and U-235. The presence of these isotopes should not invalidate the analysis unless they are present in large enough quantities to degrade the precision of the measurement. The problem arises when isotopes which are not accounted for are present, and when these isotopes have gamma emissions which partly overlap the peaks used by FRAM for the isotopic mass calculations. LANL is addressing this problem very thoroughly in their procedure for data analysis by using MAESTRO to identify all peaks in the analysis energy region of interest. The procedure requires two independent verifications that no interfering, unaccounted for isotopes are present. The first is a visual check of each energy region by the operator, and the second is a repeat check of each of these regions by the MAESTRO code. Only if the two methods agree that no unaccounted for interferences are present is the FRAM analysis considered valid. This is a very rigorous check, and will function in a general sense in that it doesn't matter what isotopes are present; as long as their emissions do not interfere with the peaks being analyzed, then the results should be valid. If unaccounted for interferences are present, then a non-conformance report will be written for that drum.

The FRAM system at this time will not directly quantify the isotopic content of the drum. The system provides knowledge of the ratios of isotopic masses, but without a separate method for determining the absolute quantity of at least one of the isotopes in the drum, then the system will not provide absolute quantitation for any of the isotopes. This is reflected in the PC/FRAM procedure, which requires in step 14.21.7 to record the mass fractions and uncertainties for only Pu-238, Pu-239, Pu-240, Pu-241, Pu-242, and Am-241 on the radioassay data sheet (note that Pu-242 mass fraction cannot be directly measured by the gamma assay; LANL is calculating the Pu-242 fraction by using a predefined correlation between Pu-242 and the other plutonium isotopes). For plutonium and americium the quantitation will occur after the PAN assay, but for the other isotopes which may be present in the waste there appears to be no absolute quantification since their relative isotopic fractions are not required to be recorded. In practice, these isotopic fractions for the other isotopes will be entered on the radioassay data sheets, as the space for them is present on the sheet and the procedure refers to them indirectly. However, LANL should make recording these a specific requirement along with the Pu and Am isotopes in order to ensure they are not overlooked.

During the September 1997 audit, LANL demonstrated that the FRAM system is capable of developing isotopic mass ratios for the debris waste stream; in combination with the PAN system it should be capable of developing isotopic quantities as well. To summarize, the CARs and concerns raised during the May and August 1997 audits were addressed during the September 1997 audit.

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References

1. LANL Procedure for FRAM Gamma Assay, TWCP-DTP-1.2-029, R.2, 9/7/97

2. Sampson, T.E., Nelson, G.W., Kelley, T.A., FRAM: A Versatile Code for Analyzing the Isotopic Composition of Plutonium from Gamma Ray Pulse Height Spectra", LA-11720-MS, Dec. 1989

3. PC/FRAM V2.1, User Manual Rev. 2, Appendix A, Los Alamos National Lab, Oct. 1996

C) Procedures

The *Detailed Technical Procedure for Determining Isotopic Ratios in Waste Containers Using the RANT PC FRAM Assay System* (TWCP-DTP-1.2-029, R.2) appeared technically adequate.

D) Other

There are no other issues regarding FRAM.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER B

1) Item inspected

Follow-up of Visual Examination's (VE's) Miscertification Rate and Random Drum Selection Issues

2) Date(s) of inspection

August 21, 1997

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3) Inspector(s)

Paula Hugo, and Julie Shanahan

4) Type of observation

A) Personnel qualifications

The CAO auditor, Steve Calvert, interviewed Pam Rogers (TWCP Site Project Manager). Pam has been trained in the associated procedure.

B) Technical adequacy

The first issue identified during the May 1997 audit involves the miscertification rate. For 1997, the miscertification rate of 2% is based on an INEL drum miscertification rate study. After one year of certification activities, the site will be able to determine the site-specific miscertification rate to be applied to the next waste characterization year. The miscertification rate is based on the drums radiography indicates meet the WIPP WAC radiography-determined requirements, but visual examination (VE) indicates do not meet these requirements. On the hypergeometric probability distribution table, the miscertification percentage is paired with the annual number of drums undergoing characterization to obtain the actual number of drums requiring VE. That number of drums requiring VE is applied to the annual waste drum population using random selection.

There are two concerns with this approach. The first concern is the inability of a miscertification rate based on an annual drum population to be truly representative of each waste stream. For example, during the first certification year, one homogenous waste stream is characterized. This homogeneity lends itself to a low miscertification rate. That rate is applied to the next waste characterization year which consists of one, heterogeneous waste stream. However, that low miscertification rate was representative of a homogeneous waste stream not a heterogeneous one. The heterogeneous waste stream miscertification rate would probably be higher. This misapplication of a miscertification rate could compromise the integrity of the waste characterization program by not characterizing each waste stream in a truly representative manner.

The second concern involves the application of the number of drums requiring VE using random selection to the entire annual waste population not each waste stream. To illustrate, if one waste stream has over 100 drums and the other only five drums, it is likely that none of the drums in the smaller waste stream would be randomly selected to undergo visual examination. Therefore, the verification of the radiography data using the VE results would not be performed for the small waste stream. The inability of this approach to include all waste streams, again, could compromise the integrity of the waste characterization program by leaving a waste characterization data gap. In order to alleviate these concerns, both the determination of the miscertification rate, and the application of the number of drums requiring VE should be waste stream specific.

The miscertification rate issue and concerns have not changed during the August and September 1997 follow-up audits because LANL is properly following the current version QAPP. The QAPP needs to be revised before LANL can change their own procedure.

While conducting interviews during the May 1997 audit, a concern with the actual randomness of drum selection was identified. The drums to be characterized by visual examination are randomly selected from the waste population which happens to be one waste stream. However, if one of the drums chosen is inaccessible (i.e., due to placement in earthen cover) or non-compliant (i.e., no vent), the next drum on the randomly selected list will be chosen. Other drum rejection scenarios are: drum exceeds size limitation for radiography instrument (i.e., 85-gallon drum overpak, standard waste box); drum exceeds weight limitation for VE (i.e., cemented wastewater treatment sludge drum weighing 900 pounds); and ALARA concern due to the drum's radiation level.

During the August 1997 follow-up audit, it was noted that CAO provided guidance to LANL stating only those drums physically available should be placed on the random number generator list. If a drum is not available, it should not be put on the list. Once a drum changes status from unavailable to available, the drum will be placed on the random number generator list.

C) Procedures

Detailed Technical Procedure for *Random Selection of Containers and Sampling Locations for TRU Waste Characterization Activities* (DTP-1.2-014, R.3) appears technically adequate.

D) Other

There are no other issues regarding VE's Miscertification Rate and Random Drum Selection.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

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Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER C

1) Item inspected

Follow-up of Real-Time Radiography (RTR) CAR

2) Date(s) of inspection

August 20, 1997

3) Inspector(s)

Paula Hugo

4) Type of observation

A) Personnel qualifications

Robert Paedon, CAO auditor, reviewed the training records of RTR operators Jack Vigil, Carlos Rael, and Flavio Martinez for revised procedure training. The CAO auditor found objective evidence of their revised procedure training in the training files.

B) Technical adequacy

During the May 1997 audit, the CAO auditor noted that the RTR data form did not list sealed containers greater than four liters as a prohibited item, nor did the RTR operator look for this prohibited item. In response to this RTR issue, LANL revised the procedure to include this prohibited item on the form and the RTR operator also looks for this prohibited item.

During the August 1997 follow-up audit, the CAO auditor reviewed the revised procedure and the new form for inclusion of the sealed containers greater than four liters as a prohibited item. Also, the CAO auditor observed objective evidence of the use of this new form after the effective date of the revised procedure.

C) Procedures

Detailed Technical Procedure For *Performing Nondestructive Testing using the Mobile Real-Time Radiography System* (DTP-1.2-008, R.3) appears technically adequate.

D) Other

There are no other issues regarding RTR.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER D

1) Item inspected

Follow-up audits of Acceptable Knowledge (AK) Process CARs

2) Date(s) of inspection

August 19-20 and September 10-11, 1997

3) Inspector(s)

Kyle Rogers, and Paula Hugo

4) Type of observation

A) Personnel qualifications

During the August and September 1997 follow-up audits, CAO auditor, Denny Brown, and technical specialist, Vann Bynum, interviewed Pam Rogers (TWCP Site Project Manager). Charles "Jim" Foxx was present to provide historical knowledge of the process. Pam and Jim have been trained in the AK procedure.

B) Technical adequacy

During the May 1997 audit, the CAO auditors found that LANL's acceptable knowledge (AK) for radionuclide distribution is not adequate to support passive-active neutron (PAN) assay. In response to this issue, LANL selected the gamma technique, FRAM, to identify the radionuclide distribution to support the PAN assay. In addition, the CAO auditors found although sealed containers larger than four liters are prohibited waste items (in accordance with the QAPP and LANL's Certification Plan), acceptable knowledge personnel check do not for this prohibited item. LANL has revised the AK procedure and checklists to include a step to ensure that AK personnel check for this prohibited item.

During the August 1997 follow-up audit, the CAO auditors found that AK pertaining to radionuclide distribution was still lacking despite the addition of the gamma assay using the FRAM. For example, AK documentation listed Np as a potential radionuclide. This radionuclide was never presented in the AK summary report, and the FRAM did not identify the Np. Also, the CAO auditors reviewed the revised procedure including the checklist and AK summary report. Both the procedure and checklist were found to include a provision for the AK personnel to check for sealed containers larger that four liters, and the AK summary report provided objective evidence that the procedure and checklist were being implemented properly.

During the September 1997 follow-up audit, the CAO auditors found that AK pertaining to radionuclide distribution was properly presented in the AK summary report, and the FRAM identified the Np.

C) Procedures

During the August and September 1997 follow-up audits, the AK process was conducted in accordance to TWCP-QP-1.1-021, R.2 - *Acceptable Knowledge*.

D) Other

There are no other issues regarding AK.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER E

ATTACHMENT 3

1) Item inspected

Follow-up audits of WWIS

2) Date(s) of inspection

August 18-22 and September 10-11, 1997

3) Inspector(s)

Don Hammer

4) Type of observation

EPA participated in an audit/demonstration of the WWIS interface between WIPP and LANL during the certification audit conducted August 18-22, 1997 at the Los Alamos National Laboratory, Los Alamos, New Mexico. LANL was represented by Dave Janecky, Sandy Wander, and Pam Rogers. The purpose of the audit/demonstration was to verify the site's ability to transfer waste data to WIPP for purposes of waste characterization, certification, and shipment of TRU waste to WIPP for disposal.

Mr. Janecky first explained how he accesses WWIS via modem. Mr Janecky was issued a key card, user ID, and password from WIPP to enable him to access the system. LANL is currently entering data into WWIS manually, but is also working on developing a database to allow for electronic entry of data to WWIS.

The first step in the demonstration was to enter waste characterization data for a waste stream that had been approved by WIPP. Mr. Janecky entered the data which were read from a spreadsheet for the specified waste containers. When attempting to enter analyte data, it was noted that when a mistake was made, the system would sum deleted data, which had the effect of making the container exceed the limits established by WIPP. Mr. Janecky could not proceed with the test of entering waste container data. A call was placed to WIPP and the issue was tabled while WIPP personnel attempted to solve the problem. This portion of the test was postponed.

Another problem occurred when LANL attempted to enter sample data for analytes. Apparently, the internal flags in WWIS did not recognize certain analytes as being flammable. Therefore, data could not be entered into the system. Again, this portion of the demonstration was tabled until the problem could be solved by WIPP personnel.

Mr. Janecky attempted to demonstrate the shipping function using test data provided by WIPP. This function worked as designed with no problems identified. It was agreed that LANL and the audit team would meet the following day to continue the demonstration.

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On the second day of the demonstration, LANL was able to demonstrate its ability to enter and send waste container data to WWIS. All functions appeared to work as designed, and the problems encountered the previous day had been resolved. EPA requested copies of LANL's procedures for entering data into WWIS. To date, this procedure consisted of the WWIS User's Guide for Generators and Shippers. This document does not appear to be adequate in outlining all the procedures necessary to ensure that data submitted to WIPP and received by WIPP are accurate. EPA suggested that procedures needed to be developed to ensure that personnel were reviewing data received by WWIS and comparing these data to the data inputs from the spreadsheets. Ms. Wander noted that the procedure was the site's initial attempt and that it would be updated in the near future.

Based on the performance of interface between LANL and WWIS, it was determined that a follow-up audit would be necessary to ensure that the site could submit data to WWIS in a manner consistent with the requirements of 40 CFR Part 194.24(c)(4).

<u>Los Alamos National Laboratory Follow-up Audit/WIPP Site Demonstration, September, 1997</u>

EPA observed the WWIS demonstration for LANL held in Carlsbad, New Mexico. Results of the demonstration indicated that LANL was able to successfully transmit data to Carlsbad via the WWIS.

<u>Conclusions</u>

EPA concluded that for LANL, the WWIS appears to adequately transfer entered data. EPA also concluded that DOE has the capability to track those waste parameters with waste limits, including required summations of these parameters. Additionally, EPA concluded that DOE has the capability to track, on a container basis, the nuclides identified in **CARD 24 (Section 194.24(c)(1)) within the WWIS.** EPA will be examining the WWIS for these capabilities in future site observations. EPA concluded that it is not necessary for the WWIS to track individual container location, although EPA recognizes that the WWIS is capable of tracking to the room level.

<u>CHAPTER F</u>

1) Item inspected

Follow-up of Waste Container Tracking Issue

2) Date(s) of inspection

August 21, 1997

3) Inspector(s)

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Paula Hugo, Don Hammer and Julie Shanahan

4) Type of observation

A) Personnel qualifications

The Carlsbad Area Office (CAO) auditors Ava Holland and Clint Kelley, interviewed Sandy Wander and Pam Rogers of Los Alamos National Laboratory (LANL). Sandy Wander (Operations Manager) is a seasoned professional who is well qualified and experienced to support the Waste Container Tracking System. Pam Rogers (Site Project Manager) is responsible for the drum selection. Ms. Rogers also has many years of related experience and is well qualified and experienced to support the waste container tracking system. The only training required is to read the procedure and pass a quiz on the procedure.

B) Technical adequacy

During the May, 1997 certification audit the Waste Container Tracking procedure was found to be inadequate because once supervisor/operators received tracking forms via e-mail there was no procedure for the latest tracking form to be automatically renamed. Also, the form content (i.e., codes, dates) was confusing. There was no version number to be updated after each revision of the tracking form, and there was no consistent page numbering of the tracking form.

The Waste Container Tracking Procedure (TWCP-QP-1.1-032, R.1) was revised on July 15, 1997. The form was updated to include consistent page numbering and an automatic system for tagging each revision so that each individual on the distribution list knows which is the latest version of the form. Each time a revision is made hard copies of forms are kept on file. The Waste Container Tracking System now appears adequate.

C) Procedures

LANL's Waste Container Tracking Procedure (TWCP-QP-1.1-032, R.1) now appears adequate. The procedure was revised to try and eliminate any confusion between updated tracking forms and old tracking forms. The new procedure includes a tagging system which labels each revision of a form differentially. This procedure also includes a consistent page numbering scheme.

D) Other

There are no other issues regarding Waste Container Tracking.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER G

1) Item inspected

Follow-up of Software Quality Assurance CAR

2) Date(s) of inspection

August 18-21, and September 10-11, 1997

3) Inspector(s)

Dr. Raymond Wood

4) Type of observation

A) Personnel qualifications

During the August and September, 1997 follow-up audits, CAO auditor, Sid Ailes, interviewed Dave Janecky. Dave Janecky is the technical contact responsible for LANL's SQA program.

B) Technical adequacy

During the May 1997 audit, several specific limitations of LANL's SQA program/process were identified. Specifically, the following exceptions were noted during the May 1997 audit and provided the basis for the SQA CAR:

- the software code (EnviroQuant) used in HGS was not installed in accordance with the installation and checkout (I/C) form;
- the software code (EnviroQuant) was "qualified" prior to the I/C form being completed and the software was not properly classified;

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- commercial software used to support calculations made in laboratory notebooks were not adequately identified and documented;

- spreadsheets used in the HGS and PAN analysis processes were not identified by name and version number, and did not have fully documented verification in accordance with the quality procedure.

The May 1997 audit team also documented the following concerns, observations, and recommendations:

- LANL's baseline list of software was both inaccurate and incomplete (concern);

- Excel spreadsheet macros and formulae were neither documented or identified by version (observation);

- LANL should remove from the "controlled list" an outdated procedure that is five years old and no longer implements any QPs (recommendation).

During the August and September 1997 follow-up audits, it was noted that LANL controls software used by the TWCP via quality assurance procedure TWCP-QP-1.1-006. This procedure specifies six categories of software, with each category being subject to a specific set of documentation requirements. The six categories and their associated documentation requirements are:

Software Category	Documentation Requirements
Firmware Data Acquisition Software	NONE
Purchased Data Acquisition Software	RD, UM, VD, IC
Developed Data Acquisition Software	RD, VVP, DD, ID, UM, VD, IC
Commercial Software	RD, UM, IC
Vendor Software	RD, VVP, ID, UM, VD, IC
Developed Software	RD, VVP, DD, ID, UM, VD, IC

RD=Requirements Document; UM=Users Manual, VVP=Verification and Validation Plan, DD=Design Document, ID=Implementation Document, VD=Validation Document, IC=Installation and Checkout

These documentation requirements are in line with the NQA 2.7 requirements. As is implied by the table, control of software developed under other QA programs is also provided by the procedure.

TWCP-QP-1.1-006 also identifies the requirements for each phase of the software life cycle as specified under NQA 2.7. These phases include requirements, design, implementation, validation, and installation/checkout. Each phase has specific requirements, which the LANL procedure specifies. In addition to the documentation, these requirements include:

a.) developing test cases, acceptance criteria, and VVP as part of the requirements phase
b.) developing the theoretical basis during the design phase
c.) documenting source code and executable generation as part of the implementation phase
d.) performing tests listed in the VVP during the validation phase
e.) installing production modules during the installation/checkout phase

Each of these requirements is adequately addressed in section 4.3 of the procedure.

LANL is performing configuration management of software by tracking version number, installed platform, operating system, software type (see the table), and code status (i.e. retired, production, etc.) in an Excel spreadsheet. At first this system seemed deficient, since it did not track the status of any changes to production software nor did it have any listing of approved users or the status of codes in development. Those requirements, however, are tracked by the software requirements checklist form which is filed for every package which is under the QA program. This mixed method of spreadsheet and paper would be cumbersome for a large organization with many codes, but since LANL only has a few it is adequate.

Computer security is well managed for the systems operating the QA software. All require at least username and password for access, and most also have limited access by being in user controlled areas. The WWIS interface is controlled by use of login ID and password coupled to a system of smartcards, which is more than adequate to meet the NQA requirements for access control.

The major software finding during the August 1997 follow-up audit was the fact that, for PC/FRAM, the validation testing was not developed in accordance with the Requirements Document. This led to a general concern that, for vendor supplied software, validation testing was being considered as complete upon the completion of the installation testing. In response to the August 1997 follow-up audit finding, LANL redeveloped and performed a series of validation tests for PC/FRAM. During the September 1997 follow-up audit, it was noted that these tests were comprehensive and objective, and indeed showed a few weaknesses in the PC/FRAM code which had been a concern to us technically. The concern on testing, however, has been adequately addressed. To summarize, the SQA CARs and concerns raised during the May and August 1997 audits were addressed during the September 1997 audit.

<u>C) Procedures</u>

SQA is conducted in accordance to TWCP-QP-1.1-006, R.5 - "*Procedure for Software Management.*" This procedure appears to be technically adequate.

D) Other

There are no other issues regarding SQA.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER H

1) Item inspected

Follow-up of Reconciliation of Waste Characterization Data

2) Date(s) of inspection

August 20, and September 10-11, 1997

3) Inspector(s)s

Kyle Rogers, and Paula Hugo

4) Type of observation

A) Personnel qualifications

During the August 1997 follow-up audit, Pam Rogers (TWCP Site Project Manager) was interviewed by CAO auditor, Sam Vega, and technical specialist, Vann Bynum. Pam Rogers wrote LANL's procedure for reconciling waste stream information and has completed the training requirements specified in the procedure TWCP-QP.1.1-028, R.0 (the only training requirement is that the procedure be read). During the September 1997 follow-up audit, CAO auditor, Denny Brown, and technical specialist, Vann Bynum, interviewed Pam Rogers.

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B) Technical adequacy

During the May 1997 audit and August 1997 follow-up audit, it was noted that the process for conducting the reconciliation of waste stream information appears to be technically adequate, but can be improved upon by incorporating within the procedure the reconciliation of AK and NDA data. During the September 1997 follow-up audit, it was noted that the process now incorporated the reconciliation of AK and NDA data.

C) Procedures

During the May and August 1997 audits, data reconciliation was conducted in accordance to TWCP-QP.1.1-028, R.0 - *Reconciliation of Waste Stream Information*. The procedure was technically adequate but can be improved upon by incorporating the use of NDA results in data reconciliation. During the September 1997 audit, data reconciliation was conducted in accordance to TWCP-QP.1.1-028, R.1 - *Reconciliation of Waste Stream Information*. The procedure is technically adequate, and was revised to incorporate the reconciliation of AK and NDA data.

D) Other

There are no other issues regarding reconciliation of waste characterization data.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER I

1) Item inspected

Follow-up of Data Generation Level Review/Project Level Data Validation and Verification CAR

2) Date(s) of inspection

August 18, 1997

ATTACHMENT 3

3) Inspector(s)

Paula Hugo

4) Type of observation

A) Personnel qualifications

The Carlsbad Area Office (CAO) auditor, Peter Rodriguez, reviewed batch data reports for RTR, VE and PAN. He also interviewed Marjorie Gavett (Site Project QA Officer) of Los Alamos National Laboratory (LANL). Marjorie Gavett (Site Project QA Officer) is a seasoned professional who is well qualified and experienced to oversee and support as necessary the data generation level review/project level data validation and verification process. The only training required is to read the procedure.

B) Technical adequacy

During the May 1997 audit, the CAO auditor identified that the technical supervisory review for a data package was not documented on the data review checklist. The completed second level (project) review did not note the absence of this review. In the August 1997 follow-up audit, the CAO auditors found that the procedure had been revised to address these issues. Also, the auditors reviewed the data package which was identified as problematic during the May 1997 audit, and data packages generated after the new procedure was effective. All data packages reviewed provided objective evidence that the procedure was being implemented accordingly.

C) Procedures

The *Data Generation Level Review* procedure (TWCP-QP-1.1-011, R.2) has been deactivated. The *Project Level Data Validation and Verification* procedure (TWCP-QP-1.1-010, R.3) has been revised to address the previously noted issues, and appears to be adequate.

D) Other

There are no other issues regarding data generation level review/project level data validation and verification.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.

CHAPTER J

1) Item inspected

Follow-up audit of NCRs CAR

2) Date(s) of inspection

August 18, 1997

3) Inspector(s)

Paula Hugo

4) Type of observation

A) Personnel qualifications

The Carlsbad Area Office (CAO) auditor, Steve Calvert, interviewed Marjorie Gavett of Los Alamos National Laboratory (LANL). Marjorie Gavett (Site Project QA Officer) is a seasoned professional who is well qualified and experienced to oversee and support as necessary the NCR process. The only training required is to read the procedure.

B) Technical adequacy

The NCR CAR from the May 1997 audit pertained to several NCRs that were sampled, reviewed and found not to contain information on the cause of the NCRs (incomplete on the form). Root cause analysis was not performed for these NCRs as required. Root cause analysis checklists sampled were signed off; however, some of the checklists did not include a documented root cause. Instances were identified where an ROV was issued to correct a problem that should have been documented as an NCR. In the August 1997 follow-up audit, the CAO auditors found that the procedure had been revised to address these issues. Also, the auditors reviewed the NCRs which were identified as problematic during the May 1997 audit, and NCRs issued after the new procedure was effective. All NCRs reviewed provided objective evidence that the procedure was being implemented accordingly.

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C) Procedures

LANL's *NCR* (TWCP-QP-1.1-007, R.3) procedure appears to be adequate.

D) Other

During the May 1997 audit, there was one issue identified which pertained to method modifications. According to LANL's ROV procedure as required by CAO, CAO method modifications are to be requested by LANL; reviewed and approved by CAO; and method modifications can only be implemented by LANL after CAO approval and not before. However, this has not been the practice at LANL. For example, LANL made a modification to a CAO headspace gas method. This ROV was requested by LANL, was never approved by CAO, but LANL was implementing the method modification. The CAO auditor told the LANL representative that this was incorrect application of their own procedure as well as CAO's requirements; to stop this immediately; and to follow their own procedure as well as CAO's requirements regarding method modifications. LANL complied with CAO's request to follow the LANL procedure as well as the CAO requirement. In response to this method modification issue, CAO issued a memo to the sites stating that the sites must e-mail CAO to ask for CAO's determination if what the site is proposing is a method modification or not.

5) Results or acceptability

Based on the observations made during the audit, the personnel and procedure seemed to be adequate.

6) Reference to information on actions taken in conjunction with nonconformances/recommendations

Based on the observations made during the audit, there did not appear to be any nonconformances. Therefore, there are no recommendations at this time.