UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

ENTERED

MAR 26 2004

OFFICE OF
AIR AND RADIATION

R. Paul Detwiler, Acting Manager
Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, NM 88221-3090

Dear Dr. Detwiler:

This letter announces the U.S. Environmental Protection Agency's (EPA's) final decision to approve the Department of Energy's (DOE's) remote handled (RH) transuranic (TRU) Waste Characterization Program Implementation Plan (WCPIP), Revision 0D, and the RH TRU Waste Characterization Plan for the Waste Isolation Pilot Plant (WIPP). We have determined that these documents provide an adequate general framework for the characterization of RH waste for disposal at WIPP, while allowing flexibility for DOE to develop characterization programs tailored to specific RH waste streams at various sites. Our review emphasized the WCPIP since this is the primary document that will guide development of site-specific plans which must demonstrate compliance with both EPA and DOE requirements.

This decision does not authorize any site to begin RH waste characterization or shipment to WIPP. Several additional approval steps are necessary for site-specific authorization of RH waste characterization and WIPP disposal. Specifically, DOE must obtain EPA approval of site-specific RH waste characterization plans (including the selection of specific waste characterization procedures and equipment for use at a given site) prior to their implementation. Note that this is more stringent than the process followed for contact-handled waste characterization; we believe that the additional review is warranted because of the greater flexibility in development of site-specific RH programs (see EPA's letter of December 19, 2003, for further discussion). After approval of RH characterization program plans, but before allowing RH waste from any site to be shipped for disposal at WIPP, EPA also will conduct an on-site inspection to confirm adequate implementation of approved site-specific RH programs. The steps necessary for site-specific authorization are described in more detail in Enclosure 1.

On December 19, 2003, EPA notified DOE and the public of our preliminary decision to approve DOE's framework for RH waste characterization. At that time, EPA opened a public comment period (through January 30, 2004) to receive comments on our proposed decision. We received five sets of comments on our proposed RH decision. EPA carefully evaluated all comments. Many of the comments addressed technical aspects of the RH waste characterization program. None of these technical comments would substantially alter the approach or content of

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the RH waste characterization framework. The comments discussed technical issues that we believe are appropriately addressed during the site-specific approval process and we will do so through our evaluation and approval of detailed waste characterization plans. Enclosure 2 highlights information that must be included with site-specific documents when provided to EPA for evaluation. We suggest that DOE make conforming changes to the WCPIP to encourage consistency across sites in the DOE complex and provide additional context and guidance to waste generator sites in developing their site-specific plans.

Several of the comments received by EPA on the preliminary decision stated that EPA should consider the RH proposal as a significant change from our 1998 Certification Decision and therefore evaluate it through a rulemaking process. EPA does not consider the approval of the RH waste characterization plan to be a significant change from the 1998 Certification Decision. During the certification, EPA determined that the DOE met the EPA's requirements to describe the expected inventory of RH waste intended for disposal at WIPP. The impact of the emplacement of RH waste on the long-term safety and performance of WIPP was fully assessed in 1998 performance assessment and the performance assessment verification test. EPA stated that the certification applied to RH waste as long as the wastes are within the waste envelope limits determined by the performance assessment, and as long as Conditions 2 and 3 of the WIPP Certification Decision – relating to site-specific approval of quality assurance and waste characterization programs – are met (see 63 FR 27359). Enclosure 3 contains a summary of EPA's evaluation of the RH proposal and contains EPA's responses to public comment on our preliminary decision.

We expect that periodic changes to the RH WCPIP may be necessary based on information and experience from program-wide and site-specific conditions (similar to the evolution of the contact-handled Waste Acceptance Criteria). Note that any significant changes to the RH WCPIP must be approved by EPA prior to implementation.

If you have questions regarding this decision, please contact Rajani Joglekar at (202) 343-9462.

Sincerely,

Frank Marcinowski, Director
Radiation Protection Division

cc:

Lynne Smith, DOE HQ
Matthew Silva, EEG
Steve Zappe, NMED
EPA Docket

Enclosure 1

Process for Site-Specific RH Waste Characterization Programs

The approval of the Remote Handled TRU Waste Characterization Plan and Waste Characterization Program Implementation Plan (WCPIP), Revision 0D, establish an acceptable framework for the development of site-specific RH waste characterization programs. In order to dispose of RH waste at the WIPP, DOE must first obtain approvals for each site that characterizes the waste:

- Approval of Site-Specific RH Characterization Plans Prior to Implementation

  In order to obtain authorization to begin RH waste characterization at a generator site, DOE must submit site-specific plans to show the requirements of the Waste Characterization Plan and WCPIP have been fully met. EPA will review the site-specific plans and must approve these plans *before* RH waste characterization can begin at the site. We will evaluate the plans to ensure that they conform to the WCPIP and fully satisfy EPA requirements for waste characterization and quality assurance measures. Approval of site-specific plans by EPA would allow implementation of RH waste characterization measures, but would not authorize the site to ship RH waste for disposal. Implementation of RH characterization activities prior to EPA approval – such as pilot or demonstration programs – are allowable but would be conducted at DOE's risk, with full understanding that the programs ultimately may not earn EPA approval or may be approved only with modifications, and that data collected under a program that ultimately is not approved may not be accepted by EPA.

- On-Site Inspection and Approval of Site-Specific Waste Characterization Programs

  Before allowing RH waste from any DOE site to be disposed at WIPP, EPA also will conduct an on-site inspection of waste characterization activities to evaluate the adequate implementation of approved site-specific RH waste characterization programs. The inspections will be conducted under our authority at section 194.8 or 194.24, as appropriate. We will verify, through inspection, that site-specific RH programs are implemented in a technically adequate manner and generate appropriate data to demonstrate compliance with the waste characterization requirements of 40 CFR 194.24.

  Following the inspection, EPA will issue a site-specific determination on RH waste characterization just as we do for contact-handled waste programs. The decision will notify DOE of the waste streams and processes that are approved for characterizing RH waste for disposal at WIPP, and will disclose any limitations on EPA's approval. EPA will make site-specific RH waste characterization plans and inspection reports available in EPA's WIPP dockets and on our website.

Only after receiving written EPA approval under both steps described above is a site authorized to characterize and ship for disposal any RH waste for the WIPP.

Enclosure 2

Additional Documentation for RH Site Approval

Information that RH Sites Must Provide in Site-Specific Plans:

DOE waste generator sites with RH waste are expected to fully implement the approved version of the WCPIP through site-specific plans. In addition, these site-specific plans should:

- Ensure that site-specific Certification Plans document the full RH waste characterization process, including modeling and measurement activities and combinations thereof, as well as any measurement data collection activities performed to acquire data prior to, as part of, or in lieu of AK qualification. RH sites must prepare related documentation (such as Confirmatory Testing Plans, Sampling Plans, or other site-specific documents) when characterization data are obtained using procedures less comprehensive (i.e., nondestructive assay and nondestructive evaluation by radiography and/or visual examination of all TRU waste containers) than those required for CH waste. Waste generator sites should follow the procedures contained in the CH-required waste characterization program if the approved WCPIP does not address them. These documents must be provided and approved by EPA prior to their implementation at a site. Implementation of RH characterization activities prior to EPA approval – such as pilot or demonstration programs – may lead to collection of characterization data that ultimately cannot be accepted by EPA.
- Develop and justify quality assurance objectives (QAOs) that are not specified in the WCPIP: dose to curie (DTC) modeling and destructive analysis. When developing and documenting outstanding QAOs, RH sites should follow EPA QA/G-5M for guidance. EPA will assess the appropriateness of these QAOs during the pre-audit process of site-specific document review and approval or during audits.
- Specify the lower limits of detection (LLD) for destructive assay (DA) comparable to those for nondestructive assay (NDA). EPA will evaluate the technical appropriateness of DA LLD on a site-specific basis.
- Ensure that the samples are obtained using approved techniques, and second, ensure that the sample sizes and types, adequately represent AK for confirmation. Failure to take these steps may result in the disqualification of data.
- Include when needed, procedure(s) for overpacking and averaging of radiological contents of waste containers for load management purposes. EPA addressed the issue of overpacking CH waste containers in ten drum overpacks (meeting the definition of a payload container for WIPP disposal) for load management in a letter dated August 8, 2003, available in the EPA Air Docket.
- Ensure discussion of quality assurance objectives conforms to the language of 40 CFR 194.24(c) (re: Section 2.2 of the WCPIP).
- Include tolerable errors for qualitative data quality objectives (DQOs) as part of the acceptable knowledge (AK) record for RH waste
- Define quantitative DQOs associated with destructive assay sampling and analysis.
- Reflect a definition of the term "waste stream" as follows: Waste stream is a waste material generated from a single process or from an activity which is similar in material,

physical form, and radiological constituents.

- Ensure that corrective action will be required in response to adverse conditions affecting compliance with QA and quality control requirements of the WCPIP as well as EPA-approved site implementing documents (re: Section 3-3 of the WCPIP).
- Use the NQA-1 Supplement S-1 definition of nonconformance.
- Quantify and propagate uncertainties in the ratios of radionuclides whether estimated by nondestructive assay (NDA), destructive assay (DA), or modeling.
- Specify when modeling should be used to acquire radiological data and sampling and analysis to confirm isotopic ratios derived from modeling.
- Include precise language defining "similar radiological properties" (re: Section 4.1.2.1 of the WCPIP).

Enclosure 3

TECHNICAL AND REGULATORY SUPPORT DOCUMENT EPA'S REMOTE HANDLED WASTE CHARACTERIZATION DETERMINATION

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Under

Contract 68-D-00-210
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Prepared for:

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RH WASTE CHARACTERIZATION TECHNICAL SUPPORT DOCUMENT

I. BACKGROUND

The Waste Isolation Plant (**WIPP**) Land Withdrawal Act (**LWA**), Pub. L. No. 102-579, signed by the President on October 30, 1992, enables a regulatory basis for disposal of defense-related transuranic (**TRU**) waste in WIPP. TRU is defined in the LWA as waste containing, per gram of waste, at least 100 nanoCuries (**nCi**) of isotopes with atomic number greater than 92 and half-life greater than 20 years. The LWA further defines two categories of TRU waste, contact-handled (**CH**) waste, and remote-handled (**RH**) waste. The two categories are distinguished in the LWA by surface dose rate, and thus implicitly by activity; RH waste has a 200 millirem (**mrem**) per hour or greater surface dose rate, while CH waste has a surface dose rate less than 200 mrem per hour. The LWA prohibits disposal at WIPP waste with a surface dose rate greater than 1000 rem per hour.

The LWA gives the Environmental Protection Agency (EPA or Agency) the authority to certify WIPP's compliance with standards developed by EPA for disposal of radioactive waste. The LWA supplements EPA's authority, under the Atomic Energy Act and Reorganization Plan No. 3 of 1970, to establish environmental standards that protect the public and the environment from radioactive materials. Previously, EPA had no authority to ensure compliance with its radioactive waste standards. The LWA gave EPA that authority and prescribed the regulatory framework for implementing its responsibilities for the WIPP disposal system.

EPA's responsibilities under the LWA include:

- issuing final radioactive waste disposal standards that apply to all spent nuclear fuel, high-level radioactive waste, and transuranic waste disposal facilities not characterized under Section 113(a) of the Nuclear Waste Policy Act (notably Yucca Mountain);
- issuing criteria for the certification of WIPP's compliance with the final disposal regulations;
- certifying WIPP's compliance with the Agency's radioactive waste disposal regulations initially and, if certified, every five years thereafter; and
- verifying WIPP's compliance with all other applicable Federal environmental laws and regulations.

The final rule promulgating WIPP compliance criteria, Title 40 Code of Federal Regulations Part 194 (**40 CFR Part 194**), was signed by the Administrator on February 1, 1996, and was published in the *Federal Register* [61 FR 5224] on February 9, 1996. The final compliance criteria contain provisions regarding:

- procedures to be used to certify compliance with the 40 CFR Part 191 disposal regulations;
- methods to be employed to ensure the adequacy and quality of data and technical analyses;
- assumptions on which performance assessments and compliance assessments are to be based; and
- opportunities for public participation in the certification process.

In accordance with the WIPP LWA, the Department of Energy (**DOE**) operates the WIPP under EPA regulation. The LWA required that DOE submit an application to EPA to enable the Agency to render a certification determination. EPA received DOE's Compliance Certification Application (CCA) in October 1996, and immediately began the rulemaking process with publication of an advance notice of proposed rulemaking. After an exhaustive scientific review of DOE's application, consideration of public comments, and performance of audits, tests and inspections, EPA issued a proposed decision in the *Federal Register* on October 30, 1997 [62 FR 58792], that the WIPP complies with the disposal regulations provided that DOE meets certain conditions.

On May 13, 1998, EPA issued its final certification decision, to certify that WIPP is safe to contain TRU waste and will comply with the Agency's radioactive waste disposal regulations. EPA issued a final rulemaking in the *Federal Register* on May 18, 1998 at 63 FR 27354. EPA's decision allowed DOE to begin disposing of radioactive waste in the WIPP once all other applicable health and safety standards have been met. EPA's final certification decision included four conditions of compliance. One of these conditions stated that DOE waste generator sites may not ship waste to the WIPP until two things happen: 1) EPA approves the site's Quality Assurance (QA) program for TRU waste characterization activities and assumptions; and 2) EPA approves the TRU waste characterization processes used at the site. EPA QA audits examine whether the site's QA program complies with the requirements of 40 CFR Part 194.22 mandating implementation of American Society for Mechanical Engineers (**ASME**) Standards NQA-1 (1989), NQA-2 Part 2.7 (1990), and NQA-3. EPA technical inspections examine compliance of the site waste characterization activities with the requirements of 40 CFR Part 194.24, which mandates that a system of controls be in place to ensure quantities of waste emplaced in the WIPP do not exceed those amounts approved by EPA.

When EPA approved the CCA in 1998, it explicitly excluded approval of the characterization process for RH waste. For example, EPA stated in its Compliance Application Review Document (**CARD**) 24: waste characterization (Section 24.F.5):

> "EPA determined that the CCA did not identify any waste characterization methods for RH-TRU waste, nor did it discuss specifically how DOE will quantify the RH-TRU waste. Chapter 4 addresses only contact-handled transuranic (CH-TRU) waste, with the exception of Table 4-13 (p. 4-49), "Applicable CH- and RH-TRU Waste Component Characterization Methods." There was no discussion in the CCA of 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."

As a result, all waste characterization programs approved to date by EPA for shipment of waste to the WIPP have pertained to only CH waste. These CH waste characterization programs operate under QA programs that have been audited and approved by EPA, and using characterization methods that have been inspected and approved by EPA. DOE describes the WIPP QA program requirements internally under the Department of Energy/Carlsbad Field Office (**CBFO**) Quality Assurance Program Document (**QAPD**), and requires generator site characterization programs to meet requirements contained in the WIPP Waste Acceptance Criteria (**WAC**); however, each generator site QA program is defined individually by site program documents.

Similar to CH waste characterization, RH TRU waste characterization will involve obtaining chemical, radiological, and physical data for this waste to ensure compliance with the EPA requirements of 40 CFR Part 194. DOE presented in its RH TRU Waste Characterization Program Implementation Plan (**WCPIP**) a proposal for an RH characterization program which RH site would implement after EPA approval. DOE believes that waste characterization methods included in the proposed WCPIP will allow RH sites to satisfy EPA's regulatory requirements in 40 CFR Part 191 (Subparts B and C) and Part 194 (EPA, 1993; EPA, 1996), the EPA final certification decision, and the WIPP LWA.

The WCPIP is intended to serve as a programmatic document which specifies how RH waste characterization is to be implemented at sites that generated and/or store RH waste. The DOE provided this document to comply with EPA requirements that DOE "...must provide advance notice to EPA on intent to implement a significant change, pursuant to 194.4(b)(3)(i)." DOE first submitted its RH proposal to EPA in June of 2002. EPA reviewed this document for technical completeness and adequacy, providing comments to DOE on September 24, 2002. DOE prepared a revised RH Submission (Revision 0), which was submitted to EPA in December of 2002. DOE submitted a third revision (Revision 0a) on March 10, 2003, and EPA provided commentary to DOE in a letter dated March 31, 2003. Revision 0b was submitted by DOE to EPA on April 30, 2003. EPA provided Revision 0b comments to DOE on August 5, 2003, which was followed by DOE's submission of Revision 0c to EPA in September of 2003. DOE submitted Revision 0d to EPA in October 2003, and it is this latest revision 0d upon which EPA based its formal approval.

EPA's review was limited to evaluating the proposed waste characterization program with respect to adequacy of characterizing important waste characteristics and components identified by DOE in its CCA. Specifically, EPA examined compliance with 40 CFR 194.24(c)(2-4), assessing whether the proposed system of controls –which incorporated elements of the approved CH program- would adequately characterize RH waste characteristics/components. EPA did not examine other aspects of 40 CFR 194.24 important to waste characterization, including inventory changes, characteristics/ components reanalysis, changes to limiting values, or waste loading requirements. Any modifications to these elements shall be presented in the Compliance Recertification Application **(CRA)** and other documents that DOE may submit in future to EPA for review and approval prior to their implementation. EPA will examine these changes in the context of RH waste, and would make any modifications or changes to their RH decision accordingly, just as EPA will do for the CH program when the CRA is provided.

II. SUMMARY OF THE DOE's PROPOSED CHARACTERIZATION PROCESS AS PRESENTED IN THE WCPIP

A. Development of the Characterization Process

The WCPIP serves as the primary technical document presenting DOE's proposed characterization approach for RH waste. While DOE submitted other supplemental data with the WCPIP (for example, revised RH inventory, worker exposure to radiation when characterizing RH waste and the need to minimize exposure), EPA considered these submissions to be for informational purposes only. Some of these supplemental documents may be submitted in different contexts as part of the CRA. DOE's characterization approach, as presented in the WCPIP, Rev 0d, is summarized below.

DOE stated (DOE, 2003, p.7) that "the requirements for the characterization of RH TRU waste that are relevant to the EPA's oversight of the WIPP come from two sources: those established by EPA's certification of the repository and those established by the LWA. The primary purpose of the characterization requirements based on the LWA is to ensure that the CBFO operates the repository in accordance with the statutory limits and mission established by the Congress." DOE also recognized that EPA specified that any characterization program, including that for RH, must quantify the following parameters and the uncertainty associated with their quantification:

- Cellulose, plastics, and rubber (**CPR**)
- Radionuclide content
- Residual liquids
- Ferrous metals
- Non-ferrous metals

The DOE's RH TRU characterization program presented in the WCPIP was established to quantify these parameters, as specified by EPA. DOE's approach was to first develop characterization requirements following the Data Quality Objective (**DQO**) evaluation process presented in EPA Guidance EPA QA/G-4, August 2000. EPA QA G/4, EPA Guidance for the Data Quality Objectives Process, August 2000, states that "DQOs are qualitative and quantitative statements, developed using the DQO Process, that clarify study objectives, define the appropriate type of data, and specify levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. DQOs define the performance criteria that limit the probabilities of making decision errors by considering the purpose of collecting the data; defining the appropriate type of data needed; and specifying tolerable probabilities of making decision errors." Using this process, DOE identified the following DQOs for the WIPP with respect to management of RH waste:

- Defense Waste Determination
- DQOs for Radioactive Properties
  - TRU Waste Determination,
  - RH Waste Determination, and

- Activity Determination

- DQOs for Physical and Chemical Properties

  - Residual Liquids
  - Physical Form
  - Quantity of Metals
  - Quantities of Cellulosics, Plastics, and Rubber

DOE also determined Quality Assurance Objectives (**QAOs**) which are quality characteristics used to determine that the quality of data is acceptable. DOE defined the following QAOs for the RH TRU characterization program:

Data precision – A measure of the mutual agreement between comparable data gathered or developed under similar conditions.

Data accuracy – The degree to which data agree with an accepted reference or true value.

Data representativeness – The degree to which data accurately and precisely represent a characteristic of a population, a parameter, variations at a sampling point, or environmental conditions.

Data completeness – A measure of the amount of valid data obtained compared to the amount that was expected.

Data comparability – A measure of the confidence with which one data set can be compared to another.

DOE's WCPIP stated the following concerning both DQOs and QAOs:

> "DQOs and QAOs serve two separate functions. First, DQOs support decision-making and are developed in order to satisfy the requirements that significant waste components must be tracked and controlled to assure that the inventory-related assumptions in the Performance Assessment (**PA**) and Performance Assessment Verification Test (**PAVT**) remain valid. These objectives ensure compliance with legal and regulatory requirements (i.e., they are the bases for decisions on whether compliance is achieved). Second, QAOs are data characteristics used to determine that the quality of data is acceptable. They also support decision-making by assessing the integrity of the data used. In the strictest sense, QAOs are used to assess the quality of analytical data and therefore are quantitative. However, in order to maintain regulatory and programmatic consistency, QAOs may be used with qualitative information. In this case, all of the QAOs (precision, accuracy, representativeness, comparability, and completeness) may not be applicable"

DOE also defined method-specific QAOs (Table 2-1 of the WCPIP, Rev 0d) and developed DQOs based upon regulatory requirements identified in the EPA's Certification Decision. DOE subsequently developed QAOs, recognizing that the regulatory requirement provides a quantitative limit that the total waste inventory must meet. In some cases, the requirement also specifies acceptable methods for assessing compliance with the limit and the amount and nature of documentation needed to demonstrate compliance.

In addition to DQOs and QAOs, DOE established Waste Acceptance Criteria "to ensure that RH TRU waste is managed and disposed of in a manner that protects human health, safety, and the environment" (Section 2.4 of WCPIP). These criteria include, as summarized below:

- Payload Container Acceptance Criteria: requires generators to report to the WWIS and number and type of payload containers in the WIPP, and established limits for metals (minimum of 2×10^7 kilograms (kg) for ferrous metals and 2×10^3 kg for nonferrous metals). DOE states that the limits for ferrous and nonferrous metals will be met by disposed payload container count and average container material of construction weights. This parameter will be tracked by the WIPP as reported in the WWIS. Also, only approved payload containers (55 gallon drums, RH Canister-Direct Loaded, RH Canisters containing 55/30 gallon drums) will be accepted at WIPP, with specified weights and volumes.

- Physical Properties Acceptance Criteria: requires that total residual liquid in payload containers shall not exceed 1% of that payload container, recognizing that liquid waste is prohibited at WIPP.

- Physical Form Acceptance Criteria: The repository limit for CPR is a maximum of 2×10^7 kg (DOE, 1996, Appendix WCL), and simplifying assumptions regarding calculation of CPR is allowed (i.e. assuming all CPR within and S5000 container is plastic, etc).

- Radiation Surface Dose Rate Acceptance Criteria: The LWA defines "remote-handled transuranic waste" as TRU waste with a surface dose rate of 200 mrem per hour or greater. The LWA prohibits the receipt of TRU waste with a surface dose rate in excess of 1000 rem per hour, and no more than five percent by volume of the RH TRU waste received at the WIPP may have a surface dose rate greater than 100 rem per hour. The external radiation dose equivalent rate of individual payload containers shall be greater than or equal to 200 mrem per hour and less than or equal to 1000 rem per hour at the surface of the payload container. The total dose equivalent rate, the neutron contribution to the total dose rate, and associated uncertainty shall be reported in the WWIS for each payload container. The WIPP will track the dose rates and volumes of containers, using WWIS, to ensure that no more than five percent by volume of the RH TRU waste received at the WIPP has a surface dose rate in excess of 100 rem/hr.

- TRU Alpha Activity Concentration Acceptance Criteria: The LWA defines "transuranic waste" as waste containing more than 100 nCi of alpha-emitting TRU isotopes per gram of waste, with half-lives greater than 20 years. Payload containers shall contain more than 100 nCi/g of alpha-emitting TRU isotopes with half-lives greater than 20 years. These criteria include requirements for TRU Waste Determination, Total Activity, Activity per Canister, and Defense Determination (detailed in Section 4.2 of the WCPIP).

B. DOE's Proposed RH Waste Characterization Process

1. Characterization Overview

Based on the need to meet DQOs (40 CFR 194.24) and QAOs (40 CFR 194.22) coupled with an understanding of applicable and useable characterization processes derived through the CH program, DOE proposed a waste characterization process for RH TRU waste (Section 2.3 of WCPIP):

> "The RH TRU waste characterization program consists of characterization requirements and objectives that must be met by the DOE and participating TRU waste generator sites before RH TRU waste may be shipped to the WIPP facility. ... The Acceptable Knowledge (**AK**) process uses information concerning materials or processes used to generate the waste, and analyses and results from prior testing activities. This information may include records; administrative, procurement, and quality control records associated with the processes that generated the waste; past sampling and analytical data; material inputs to the process that generated the waste; and the time period during which the waste was generated... Acceptable knowledge information, qualified by one or more of the processes described in Section 4.3, will be used to characterize RH TRU waste. AK information will continue to be collected, evaluated, and qualified until <u>all</u> AK DQOs have been met...Generator sites may use information that is contained in the AK record and was obtained prior to implementation and approval of a quality assurance (**QA**) program at the generator site that meets the requirements of the CBFO QAPD....When characterization relies on information that was not generated under a QAPD-compliant program (e.g., previous visual examination (**VE**) data, VE audio/videotapes, radiography data, audio/videotapes, radiological characterization data), that information will be qualified using one or more of the methods allowed by 40 CFR §194.22(b). These methods are:
>
> 1. Peer review in accordance with NUREG 1297, *Peer Review for High-Level Nuclear Waste Repositories*, February 1988
> 2. Corroborating data
> 3. Confirmatory testing
> 4. Demonstrating that the QA program that was applied to the data was equivalent in effect to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1)

In summary, DOE's proposed RH program requires the collection of Acceptable Knowledge (**AK**) as the primary characterization methodology, with this information being necessarily qualified by Peer Review, Corroborating Data, Confirmatory Data, and/or equivalent QA program demonstration. Figure 1 presents the characterization process proposed by DOE for EPA approval.

As shown in Figure 1, a RH site will first collect AK information that allows determination of the waste stream and identification of specific drums within that waste stream. DOE defines a waste stream as "consisting of waste material generated from a single process or activity, or waste with similar physical, chemical, and radiological properties". DOE mandates the

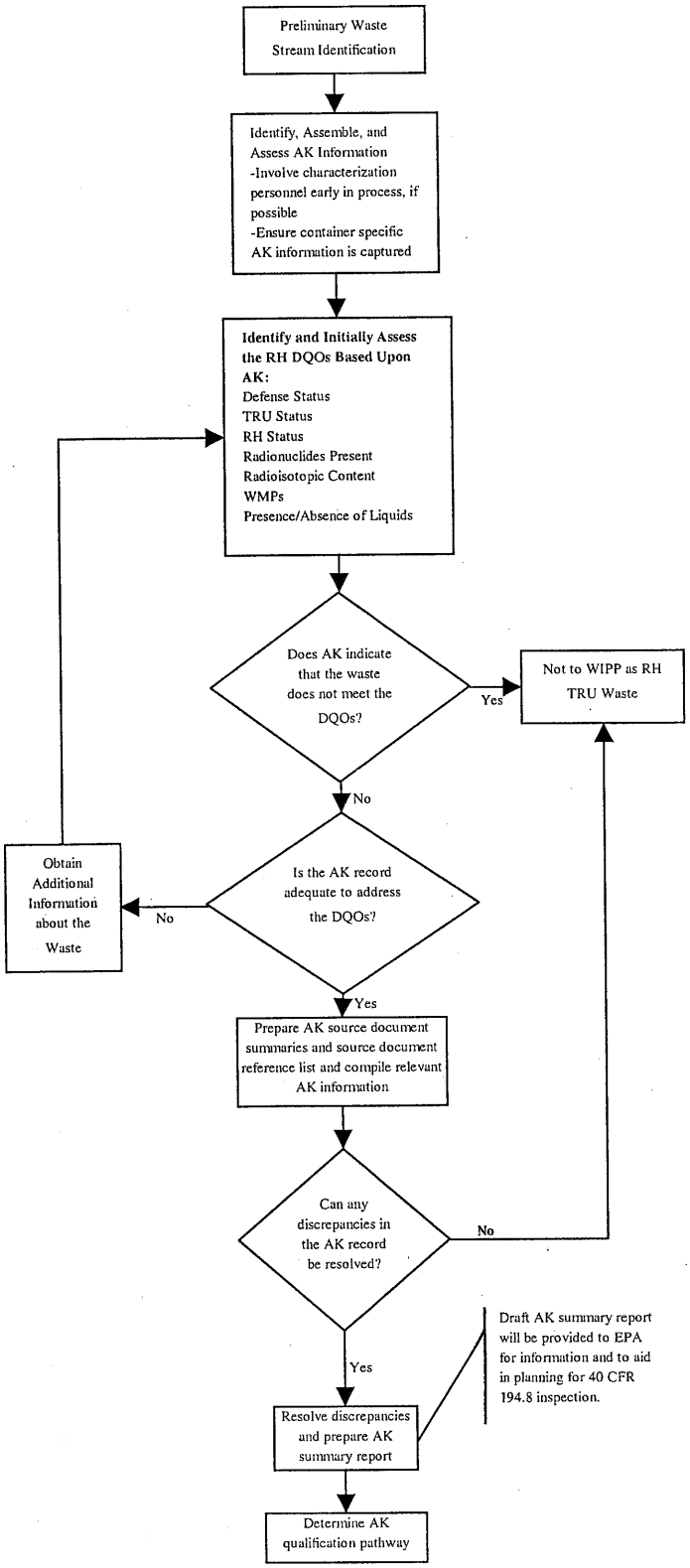

Figure 1 – RH Characterization Process

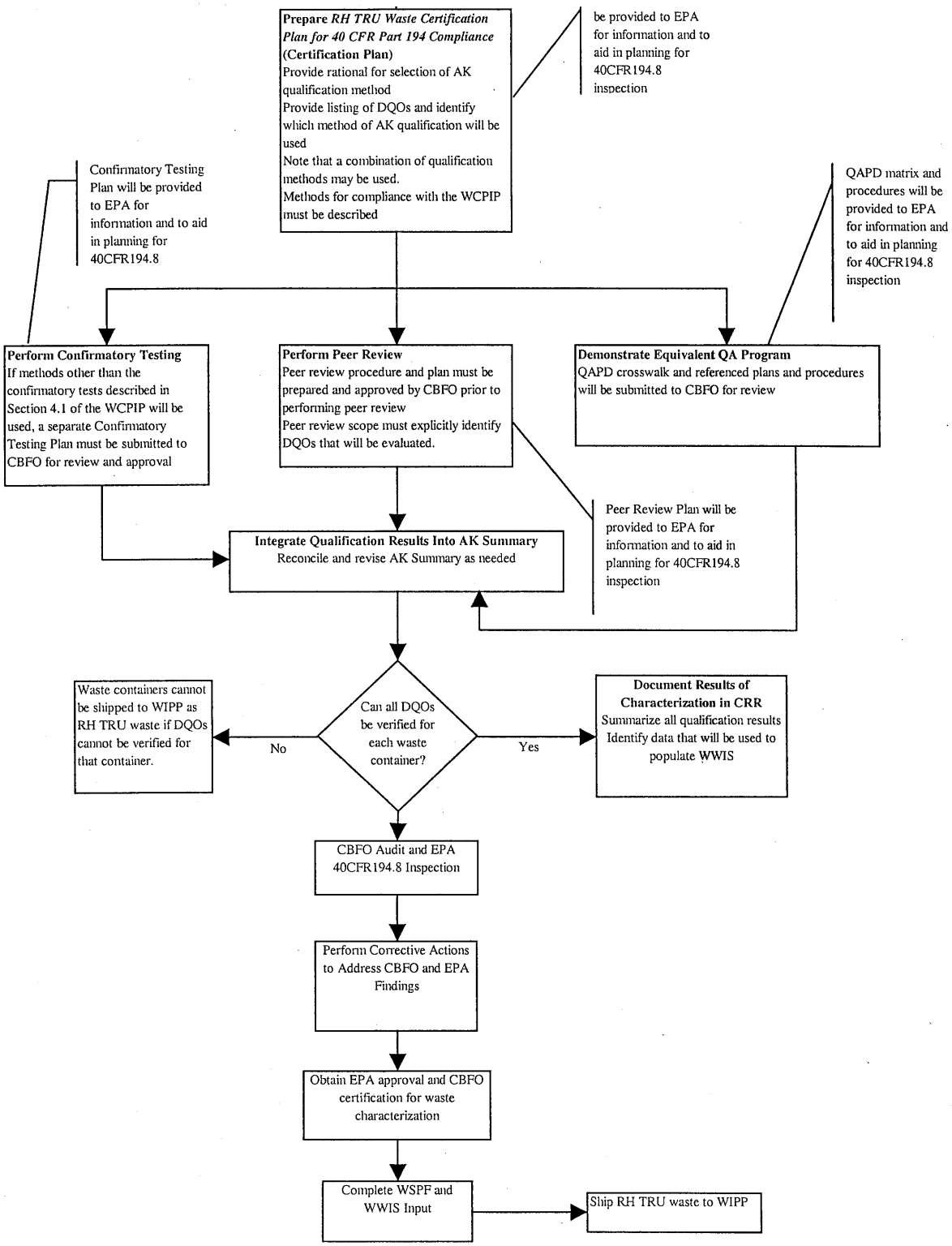

Figure 1 – RH Characterization Process (continued)

acquisition of container-specific data; that is, the acquisition of manifests or other identifiers specific to each container to ensure that the most detailed information for that container is available and is used to assist with waste stream assignments. A site will then assess information for available DQO information, and if the AK record is inadequate to address certain DQOs, "additional information" shall be obtained.

Following acquisition of all necessary AK information, a site will prepare an AK Summary and will then assess the appropriate qualification pathway for this AK data; this is required when AK is collected prior to the establishment of the CCA-required QA program (1999).

As shown in Figure I.B.1, a site may collect measurement data or use old measurement data to meet any or all of the DQOs. Specifically, a site may choose to collect additional measurement information under the approved QA program to augment the AK record or bolster the characterization information. Further, a site may choose to collect measurement information to confirm AK. Specific measurement and AK characterization methods are described in section 5 below.

2. Documentation Requirements

DOE stated (Section 3.1) that each site'sTRU waste site program shall be described in an RH TRU Waste Certification Plan for 40 CFR Part 194 Compliance that shall be approved by the CBFO prior to the certification of any RH TRU waste from the TRU waste site..At a minimum, the TRU Waste Certification Plan shall contain the following:

- A description of the rationale for attaining each DQO, including the selection of peer review, equivalent QA program, or confirmatory testing as methods of qualifying AK information for each DQO

- A listing of the DQOs, and identification of which methods will be used to assess compliance with the DQOs, and the rational for the selection of the method(s), including specific methods of AK qualification."

DOE also mandated the preparation of standard operating procedures (**SOPs**) for activities affecting program quality, and, as applicable:

- Sampling Plans when radiochemistry is performed

- Peer Review Plans when Peer Review qualification is performed

- Confirmatory Testing Plans when confirmation of AK is performed

- QAPD Matrices when a demonstration of equivalent QA programs is sought

- Dose to Curie (DTC) Technical Reports when this radiological characterization method is used

DOE stated that a site must submit to the CBFO for review and approval the applicable program documents, and "Any waste characterization activities performed prior to approval of the

generator site's program documents by both CBFO and EPA is 'at risk' and may have to be repeated."

3. Assessment and Oversight

DOE will implement specific assessment actions during the program to ensure all parties are adhering to the requirements of the WCPIP: "These actions include periodic audits as well as management and independent assessments conducted in accordance with the QAPD, the details of which will be specified in the program documentation. Corrective actions shall be taken when conditions adverse to quality are identified. The results of these actions will be summarized in semiannual reports, nonconformance reports, and audit reports. Through this system of assessment and response, overall quality improvement of the program will be realized." Similar to the CH program audits, DOE shall perform audits of management and technical aspects of the program, and corrective actions will be taken if any conditions adverse to quality are identified by DOE. DOE states that generator and storage sites must pass an initial site certification audit where adequate and effective implementation of these programs is assessed, and must be recertified annually. DOE states: "After approval of the generator site's program documents, the EPA will perform an audit or an inspection of a CBFO audit of the generator site to verify a QA program and a waste characterization program have been properly implemented. These activities are performed in accordance with the requirements of 40 CFR 194.8. The EPA may perform additional audits of the generator sites, under the authority of 40 CFR 194.8, 194.22 and 194.24, to verify continued compliance with the QA and technical requirements for waste characterization."

4. Data Management and Tracking/Control

DOE provided data management requirements applicable to waste characterization data, as well as tracking/control of waste components, wherein RH waste characterization information will be entered into the WWIS, as is done under the CH program. DOE states (Section 3.5 of WCPIP) "Sites will enter required RH TRU waste characterization information into the WWIS. WIPP Operations will review and track this information and administratively control the repository inventory to stay within compliance and performance limits."

DOE distinguishes between data management pertinent to measurement systems and that for AK. DOE specifies (Section 3.5.1): "The SPM or designee reviews the documents generated through the AK process to determine if the AK documentation is complete and if the information contained therein is adequate to characterize the waste stream. The SPM or designee reconciles AK characterization with the required DQOs and documents the reconciliation. This reconciliation ensures that AK characterization has provided documented evidence that the waste stream meets the DQOs. Specifics of the AK process and the required reconciliation steps are established in the Acceptable Knowledge Procedure for Remote-Handled TRU Waste (Attachment A).

With regard to data validation requirements for measurement systems, the WCPIP specifies that "all measurement data must be reviewed and approved by qualified personnel prior to being reported. At a minimum, the data must be reviewed by a technical reviewer and approved by the Site Project Manager (**SPM**) or designee." The WCPIP provides specifications for testing batch data reporting/validation for radiography, radioassay (including radiochemistry), dose to curie, and visual examination, defining batch size, analytical/sampling, etc. Specifically, DOE states

that "All measurement data must be reviewed and approved by qualified personnel prior to being reported. At a minimum, the data must be reviewed by an independent technical reviewer. This review shall be performed by an individual other than the data generator who is qualified to have performed the initial work." The information that the independent technical reviewer must verify is provided. DOE also specifies that all data must be approved by the SPM or designee, and provides verification requirements for the SPM.

QA requirements with respect to measurement and AK data are also addressed in the WCPIP. DOE states: "To ensure that data of known and documented quality are generated, each participating measurement facility shall implement a documented facility QA program. Any measurement technique used for RH TRU waste must be performed in accordance with calibration and operating procedures that have been written, approved, and controlled by the site or testing facility. Laboratory procedures must contain applicable quality controls. Facility QA programs shall specify qualitative and quantitative acceptance criteria for the QC checks of this program, and corrective actions to be taken when these criteria are not satisfied. Only appropriately trained and qualified personnel shall be allowed to perform data validation/review."

A significant and important aspect of the characterization process proposed by DOE is the reconciliation of DQOs and QAOs. That is, DOE must examine information and data obtained as part of the characterization process to ensure that the specified DQOs and QAOs are met. DOE states (Section 3.5.2.1) that sites are responsible for this reconciliation process, including documentation thereof. Further, DOE states "Reconciliation must be completed prior to submittal of the Waste Stream Profile Form (**WSPF**) except for the surface dose rate measurements used to establish the dose rate for the payload container. This measurement must be taken and entered into WWIS prior to the waste being accepted for transportation to the WIPP." It is the SPM's responsibility to ensure that DQOs and QAOs are met. Note that if the SPM determines that sufficient data have not been collected to make the DQO/QAO determinations, DOE states that "additional data collection efforts must be undertaken".

Once a waste stream is fully characterized and DQOs/QAOs are met, the SPM will submit the completed WSPF and characterization reconciliation report (**CRR**) for the waste stream to the CBFO for approval. DOE states (Section 3.5.2.1) that "Written approval of the WSPF must be obtained prior to shipment of the waste stream to the WIPP. For each WSPF submitted for approval, the CBFO will verify that each submittal (i.e., WSPF and CRR) is complete and will notify the originating generator site in writing of the WSPF approval." Further, DOE indicates that nonconformances will be identified, addressed, and documented, and that "For any non-administrative nonconformance related to applicable requirements specified in this WCPIP that is first identified during reconciliation of DQOs and QAOs at the site project level, the CBFO shall receive written notification within five calendar days of identification and shall also receive a nonconformance report within 30 calendar days of identification. The site must implement a corrective action to remedy the nonconformance prior to management, storage, or disposal of the affected waste at the WIPP."

Section 3.5.3 of the WCPIP specifies raw data reporting, collection, and management requirements. This includes specific requirements for reporting raw data and sampling/analytical batch report contents, including documentation of associated uncertainty. DOE commits to maintaining batch data reports, raw data, and applicable instrument calibration reports as nonpermanent records. Further, DOE states that "Sites shall transmit required characterization,

certification, and shipping data to WIPP using the WWIS. The WWIS is an electronic database equipped with edit/limit checks to ensure that the data representing the waste payload containers are in compliance with this WCPIP. Before shipping RH TRU waste payload containers from a WIPP-accepted waste stream, the site shall transmit the required waste characterization, certification, and shipping data via WWIS to WIPP. WIPP will not accept any waste shipments for disposal if the waste payload container information has not been correctly submitted and approved for shipment by the WWIS Data Administrator. The WWIS User's Manual provides the information needed by TRU waste sites to perform tasks associated with transmittal of the payload container's characterization, certification, and shipment information to WIPP."

5. Characterization Methodologies

Section 4.0 of the WCPIP contains the specific characterization methods that shall or may be employed as part of the RH Waste characterization process. As shown in Figure I.B.1, all sites are required to collect AK information as a foundation or starting point for their characterization program. As part of the program, sites may choose to qualify AK data via confirmation and measurement data collection, or they may also collect this information under an existing qualified program to obtain the information necessary to meet DQOs. The primary measurement systems that can be employed are non-destructive assay (**NDA**), dose-to-curie (**DTC**), radiochemistry/destructive assay (**DA**), radiography (**RTR**), and visual examination (**VE**). Also, Section 4.0 of the WCPIP also provides ". . . direction regarding the methods that may be used to obtain particular information. In addition, QAOs for characterization methods are provided."

a. Acceptable Knowledge

DOE states in Section 4.1 that "AK consists of information about the materials and processes that generated a waste and the procedures and policies that were used to package and manage the waste. AK includes, but is not limited to, information about the physical form of the waste, the base materials composing the waste, the radiological characteristics of the waste, and the process that generated the waste. Implementation of the AK process, which involves the compilation and qualification of AK information, forms the foundation for the characterization of a RH TRU waste stream." DOE then describes the AK process, which is detailed in Attachment A of the WCPIP. To summarize, the AK process includes the collection of information to define waste streams, assign summary categories and includes process knowledge (**PK**) or previous examinations and measurements (e.g., radiography, VE, or radioassay). Generator sites are required to "compile, summarize, and qualify AK in accordance with this WCPIP for any waste streams for which approval is sought for disposal at the WIPP".

The proposal states that "The result of the AK process is an auditable record and an AK Summary Report...The AK Summary Report describes the physical form of the waste. This description will identify the waste as debris, soil/gravel, or homogeneous solid...[and]...the waste stream description...The AK Summary Report must include radiological information about the waste stream...The AK Summary Report must also specifically address residual liquids and describe the policies or procedures that were used to exclude or remove residual liquids. ...the AK Summary Report should address the expected variability in radionuclide concentrations among the containers in the waste stream. This variability will be important to understand when trying to use AK information to relate waste stream characteristics to individual containers for reporting and tracking."

The WCPIP then states that "AK information that is relied upon to satisfy DQOs (except for the defense waste determination) must be qualified in accordance with Section 4.3" This qualification could include confirmatory testing, Peer Review, or demonstration of that AK data were collected under an equivalent QA program. DOE then states when qualification by confirmatory testing is selected, confirmation alternatives for radiological properties are:

- 100% NDA or DTC of waste containers
- DA used to establish activity per unit volume or mass for homogeneous waste
- Analysis of a representative number of samples to confirm isotopic ratios derived from modeling
- Modeling (e.g., ORIGEN) used to confirm isotopic ratios derived from sampling and analysis

Confirmation alternatives for physical/chemical properties are:

- 100% VE of waste requiring packaging or repackaging
- VE or radiography of a sub-population of waste that is already packaged in payload containers (10-10-All)

AK QAOs are then provided in the WCPIP.

b. Visual Examination Method

The WCPIP states in Section 4.1.2 that "VE is used to identify or confirm waste parameters, including physical form and the absence of residual liquids in excess of one percent.". Section 4.1.2.1 states "VE involves operators looking at every item that goes into a payload container. The examination will be recorded on a signed data form accompanied by visual evidence such as video/audiotapes, photographs, or some other form of unalterable media. In lieu of a video/audiotape or other unalterable media, two trained operators may look at every item and document their examination on a signed data form." ...At a minimum, the VE data to be entered on the VE data form must include:

- container number
- container waste stream designation
- operator(s) performing the VE
- description of the container contents including waste material parameters that are present
- determination of whether the waste matches the waste stream description in the AK summary report
- determination of whether residual liquids exceed one percent by volume of the waste container
- description of packaging including any liners used
- fill percentage range of the container: 0-25%, 26-66%, 67-90%, or 91-100% (required to implement DTC)

- determination of whether the container contents are primarily concrete, primarily steel, or primarily organic materials (required to implement DTC)

Other information regarding waste matrix properties, if required by the TRU waste site program, to implement DTC or NDA

- date of VE
- videotape or equivalent media identification number (if applicable)
- videotape or equivalent media start and stop time (if applicable)
- title and revision number of the VE procedure used
- signature of first trained operator
- signature of second trained operator (if not using videotape)

The WCPIP in Section 4.1.2.2 states that the site must have a training program that provides VE operators with both on-the-job training (**OJT**) and formal training, specifying the contents of these training programs, qualification requirements, etc. Sites must have a trained and qualified VE expert, and DOE also specified QAOs pertinent to VE, stating "If a site intends to use records of visual examination performed prior to implementation of this WCPIP to demonstrate compliance with a DQO, it must demonstrate that the information collected regarding the waste stream and individual containers is sufficient to meet the QAOs and the programmatic DQOs that can be satisfied using VE."

c. Dose-to-Curie Conversion

The WCPIP in Section 4.1.3 states that "The curie content of RH TRU waste containers can be derived based on a dose rate measurement taken with calibrated instrumentation. This process, referred to as DTC, can be used to establish isotopic activity, total activity, and activity per canister, when used in conjunction with adequate AK information." Attachments B and C of the WCPIP provides detailed information concerning implementation and procedural requirements of the DTC method.

Section 4.1.3.1 of the WCPIP states that the "DTC method uses a standard profile of the waste to relate the quantity of gamma-emitting radionuclides to the activities in the waste. DTC conversions are based on a dose rate measurement taken with calibrated instrumentation. The measurement is associated with documented isotopic distributions within the waste through the use of empirically developed conversion factors. The external dose rate can be correlated to the activity in the container, such as ^{137}Cs, by taking into account such factors as matrix and container geometry. The calculated ^{137}Cs activity is then correlated to other radionuclides by scaling or conversion factors. The radionuclide conversion factor derivation shall be documented. For some RH TRU wastes, the distribution can be calculated based on fuel characteristics, sampling, and computer modeling (from a program such as ORIGEN). Sites will confirm AK information related to radionuclide distribution derived from modeling, by sampling and analysis (see the Representativeness QAO). AK information that was obtained by previous sampling and analysis may be qualified in accordance with the requirements of Section 4.3 of the WCPIP."

DOE indicates that when smears, swipes, or material samples are used for determining radionuclide distribution, "the generator site must demonstrate that sampling does not bias the results (i.e., removable contamination has similar radionuclide distribution when compared to fixed contamination). The assumption will be that the radioactive source material is the same for each waste stream or waste stream lot. This assumption is expected to be valid for most sites where the processes that generate RH TRU waste involved studies of reactor fuel specimens. At sites where the sources varied, the assumption may not be valid and, as a result, greater sampling may be needed to represent the waste stream. When sites designate waste streams, they will be required to determine the applicability of the DTC method and the sampling and analysis required to determine conversion factors."

The WCPIP requires that modeling used to implement the DTC method shall be documented in a technical report by the generator site as a controlled document under the generator site QA program. It further states that "the technical report will contain a quantitative description of the compliance of the model(s) with the QAOs listed in Section 2.2.4. The guidance in EPA QA/G-5M, *Guidance for Quality Assurance Project Plans for Modeling*, shall be used in developing the models used to implement DTC. All software used to implement DTC models will be managed in accordance with the software QA requirements described in the CBFO QAPD....Generator sites must use Attachment B, *Dose-to-Curie Survey Procedure for Remote Handled TRU Waste,* to perform dose measurements and conversions for RH TRU wastes. The sites must also use Attachment C, *General Procedure for Dose-to-Curie Estimation For Remotely Handled Transuranic (RH TRU) Radioactive Waste,* to develop the standard isotopic mixes and models used for DTC." QAOs for the DTC process are also included in this section of the WCPIP. In addition to these QAOs, "measurement facilities must document the following attributes:

> Lower Limit of Detection (**LLD**)–The LLD for the DTC method shall be determined for all measured radionuclides. When used for TRU/low-level waste discrimination, measurements must have an LLD of 100 nCi/g or less. Site-specific environmental background and container-specific interferences must be factored into LLD determinations. The LLD is that level of radioactivity which, if present, yields a measured value greater than the critical level with a 95% probability, where the critical level is defined as that value which measurements of the background will exceed with 5% probability. Because the LLD is a measurement-based parameter, it is not feasible to calculate LLDs for radionuclides that are not determined primarily by measurement (e.g., ^{90}Sr). In such cases, the site shall derive the equivalent of an LLD (i.e., a reporting threshold for a radionuclide) when it is technically justified. This value may be based on decay kinetics, scaling factors, or other scientifically based relationships and must be adequately documented in site records. For purposes of reporting radionuclide data in the WWIS, this value will be the equivalent of an LLD."
>
> Total Measurement Uncertainty (**TMU**) – The TMU must be determined for the DTC method."

d. Radiography Method

The WCPIP in Section 4.1.4.1 states that "Radiography involves the use of penetrating radiation to examine the contents of containers. The examination will be recorded on a signed data form accompanied by visual evidence such as videotape or other unalterable media. Radiography shall consist of a qualitative evaluation of the waste container contents and shall be recorded on videotape (or another equivalent unalterable medium). A radiography data form shall be used to

document the data that are collected by a trained radiography operator. Sites that use radiography must use controlled procedures that identify all data that must be collected during radiography and entered on the radiography data form. At a minimum, the radiography data to be entered on the radiography data form must include:

- container number
- container waste stream designation
- operator(s) performing the radiography
- description of container contents including waste material parameters that are present
- determination of whether the waste matches the waste stream description in the AK summary report
- determination of whether residual liquids exceed one percent by volume of the waste container
- description of packaging, including any liners used
- fill percentage range of the container: 0-25%, 26-66%, 67-90%, or 91-100% (required to implement DTC)
- determination of whether the container contents are primarily concrete, primarily steel, or primarily organic materials (required to implement DTC)
- Other information regarding waste matrix properties, if required by the TRU waste site program, to implement DTC or NDA
- date of radiography
- videotape or equivalent media identification number
- videotape or equivalent media start and stop time
- title and revision number of the radiography procedure used
- signature of trained operator

The WCPIP specifies: "At the beginning of each day, prior to performing radiography on any waste containers, the radiography equipment must be checked by observing a known test target to verify image quality. A videotape recording (or a recording on an equivalently unalterable media) shall be made of the test target and each waste container scan. Independent replicate scans shall be performed on one waste container per day or once per testing batch, whichever is less frequent. Independent observations of one scan (not the replicate scan) shall also be made once per day or once per testing batch, whichever is less frequent, by a qualified radiography operator other than the individual who performed the first examination. A testing batch is a suite of waste containers undergoing radiography using the same testing equipment. A testing batch can be up to 20 waste containers. The radiography data form shall be used to document the data that are collected. Sites that use radiography must have trained radiography operators who can scan the waste container, generate the recorded image, interpret the image, and complete the radiography data form. A second trained operator is necessary for the independent observation."

As with VE, each site using RTR must have a training program that provides radiography operators with both OJT and formal training. The WCPIP provides a description of these training programs and elements, including the use of radiography test containers as part of the radiographer qualification. QAOs for radiography are then provided. It also specifies "if a site chooses to use records of radiography performed prior to implementation of this WCPIP to demonstrate compliance with a DQO, it must demonstrate that the information collected regarding the waste stream and individual containers is sufficient to meet the QAOs and the overall programmatic DQOs that can be satisfied using radiography...Sites are required to have their plan to qualify radiography data approved by the DOE/CBFO to assure consistency with RH TRU waste characterization program objectives." The plan must demonstrate compliance with the requirements of Section 4.3.

e. Non-Destructive Assay Method

The WCPIP in section 4.1.5.1 states that "NDA, in conjunction with adequate AK, can be used to establish TRU activity, total activity, isotopic activity, and activity per canister. NDA is used in conjunction with AK information or a documented study that provides the needed relationship between NDA and the isotopic characteristics of the waste.

At a minimum, NDA programs must be capable of identifying, measuring, and reporting the presence or absence of the ten radionuclides identified in Section 2.4.6 for tracking of the WIPP radionuclide inventory."

DOE imposes requirements on NDA for RH characterization that are similar to those imposed upon NDA programs for characterization of CH waste. Specifically, DOE states that

"In support of the above requirements, each site must evaluate, document, and technically justify the following determinations.

> Lower Limit of Detection – The LLD for each NDA system must be determined. Instruments performing TRU/low-level waste discrimination measurements must have an LLD of 100 nCi/g or less. Site-specific environmental background and container-specific interferences must be factored into LLD determinations. The LLD is that level of radioactivity which, if present, yields a measured value greater than the critical level with a 95% probability, where the critical level is defined as that value which measurements of the background will exceed with 5% probability. Because the LLD is a measurement-based parameter, it is not feasible to calculate LLDs for radionuclides that are not determined primarily by measurement (e.g., ^{90}Sr). In such cases, the site shall derive the equivalent of an LLD (i.e., a reporting threshold for a radionuclide) when it is technically justified. This value may be based on decay kinetics, scaling factors or other scientifically based relationships and must be adequately documented in site records. For purposes of reporting radionuclide data in the WWIS, this value will be the equivalent of an LLD.
>
> Total Measurement Uncertainty (TMU) – The method used to calculate the TMU for the quantities in Section 2.4.5 (TRU Alpha Activity Concentration) and 2.4.6 (Radionuclide Activity) must be documented and technically justified for each CBFO-certified NDA system. Compliance with this requirement will be evaluated by CBFO in reviews of the TMU documentation package for each assay system.
>
> Calibration Procedures and Frequencies – Each NDA measurement system shall be calibrated before initial use. During calibration or recalibration, system correction factors

shall be established and algorithms adjusted such that the value of %R is set equal to 100% (i.e., the system is calibrated to 100%R). The range of applicability of system calibrations must be specified in site procedures. The matrix/source surrogate waste combinations used for calibration shall be representative of the:

- activity range or gram loading
- relevant waste matrix characteristics (e.g., densities, moderator content, container size) planned for measurement by the system

Calibration shall be performed in accordance with consensus standards, when such standards exist. If consensus standards are not used, full documentation of the calibration technique must be provided to and approved by CBFO prior to performing WIPP-related assays. Primary calibration standards shall be obtained from suppliers maintaining a nationally accredited measurement program. When primary standards are not available, the standards used shall be correlated with primary standards obtained from a nationally accredited measurement program.

Calibration Verification – Notwithstanding the need to calibrate individual components for replacement, changes, or adjustments (e.g., energy calibration of a detector), verification of NDA measurement system calibration shall be performed after any one of the following occurs:

- major system repairs and/or modifications
- replacement of the measurement system's components (e.g., detector, neutron generator or supporting electronic components that have the capacity to affect data)
- significant changes to system software
- relocation of the system

Calibration verification shall consist of demonstrating that the system is within the range of acceptable operation. Secondary standards can be used for the calibration verification if their performance has been correlated with the calibration standard. If a verification of the measurement system's calibration or other test demonstrates that the system's response has significantly changed, recalibration of the system shall be performed.

Calibration Confirmation – In order to confirm that the calibration of the NDA system was correctly established, the accuracy and precision of the system are determined after each calibration or recalibration by performing replicate measurements of a non-interfering matrix. Calibration confirmation replicate measurements shall be performed on containers of the same nominal size as those in which actual waste is assayed and according to approved waste assay procedures. The number of replicate measurements to be performed shall be documented and technically justified. The replicate measurements shall be performed using nationally recognized standards, or certified standards derived from nationally recognized standards that span the range of use. The standards used to calculate accuracy shall not be the same as those used for the system calibration. Accuracy is reported as percent recovery (%R). The applicable range for accuracy shall not exceed ± 30% on a non-interfering matrix. Precision is reported as percent relative standard deviation (**% RSD**). The %RSD shall not exceed the values listed in Table 4.1 for the corresponding number of replicate measurements

in a non-interfering matrix. Measurement facilities may develop alternate limits for accuracy and precision subject to approval by CBFO prior to certification of waste.

Table 1. Upper Limits for %RSD vs. Number of Replicates

Number of Replicates	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Max %RSD	1.8	6.6	10.0	12.3	14.0	15.2	16.2	17.1	17.7	18.3	18.8	19.3	19.7	20.0

The values listed are derived from the measured standard deviation of the replicate measurements using:

$$\frac{s}{\mu} \bullet 100\% < \sqrt{\frac{(0.292) \bullet \chi^2_{0.05,n-1}}{n-1}} \bullet 100\%$$

where s is the measured standard deviation, n is the number of replicates, μ is the true value,

$\chi^2_{0.05,n-1}$ is the critical value for the upper 5% tail of a one sided chi-squared distribution with n-1 degrees of freedom, and 0.292 corresponds to a 95% upper confidence bound on the true system precision limit of 29.2%."

The WCPIP imposes the following additional requirements in Section 4.1.5.1:

Quality Control (**QC**) – "To ensure that data of known and documented quality are generated, each participating measurement facility shall implement a documented facility QA program. Any NDA technique used for TRU waste must be performed in accordance with calibration and operating procedures that have been written, approved, and controlled by the site or testing facility. Laboratory procedures must contain applicable quality controls. Facility QA programs shall specify qualitative and quantitative acceptance criteria for the QC checks of this program and corrective action measures to be taken when these criteria are not satisfied."

Training – "Only appropriately trained and qualified personnel shall be allowed to perform NDA and data validation/review. Standardized training requirements for NDA personnel shall be based upon existing industry standardized training requirements (e.g., ASTM C1490, *Standard Guide for Selection, Training and Qualification of Nondestructive Assay (NDA) Personnel* ANSI N15.54, *Radiometric Calorimeters – Measurement Control Program*) and shall meet the specifications in the QAPD. Requalification of NDA personnel shall be based upon evidence of continued satisfactory performance and must be performed at least every two years."

Software QC – "All computer programs and revisions thereof used for NDA shall meet the applicable requirements in the QAPD." EPA believes that DOE means 'Software QA' in this instance, not 'Software QC.'

NDA QC – "The assay procedures cited in various American Society for Testing and Materials (**ASTM**) and American National Standards Institute (**ANSI**) standards and Nuclear Regulatory Commission (**NRC**) standard practices and guidelines are recommended for use at all testing facilities.

Background Measurements – Background measurements must be performed and recorded daily, unless otherwise approved by CBFO. Contributions to background due to radiation from nearby radiation-producing equipment, standards, or wastes must be carefully controlled or more frequent background checks must be performed.

Instrument Performance Measurements – Performance checks on calibrated and operable gamma and neutron NDA instruments must be performed and recorded once per operational day. Performance checks shall include efficiency checks (when applicable), matrix correction checks and, for spectrometric instruments, peak position and resolution checks.

Both radioactive sources and surrogate waste matrix containers (both non-interfering and interfering) are used. At least once per operational week an interfering matrix must be used to assess the long-term stability of the NDA instrument's matrix correction. Surrogate waste containers must reflect the type of waste (e.g., debris, sludge) currently being assayed. To verify calibration, radioactivity standards must be selected such that, over a six-month period, the operating range of the assay system is tested in each applicable surrogate waste matrix. The use of interfering and non-interfering matrices provides a realistic assessment of the assay system's performance over time, and will assist measurement personnel in detecting potential problems relative to the matrices currently assayed by the measurement system.

Interfering surrogate matrix containers must be constructed in such a way that the waste characteristics do not change over time.

Radioactive sources should be long-lived, easy to position relative to the detector, and of sufficient radioactivity to obtain good results with relatively short count times."

Data Checks – "Background and performance measurements shall be reviewed and evaluated at least weekly to determine continued acceptability of the assay system and to monitor performance trends. If daily performance checks result in data that are outside the acceptable range, the required responses in Table 4.2 shall be followed."

The DOE requires RH NDA to programs to meet a set of QAOs similar to those for the CH NDA program. The WCPIP states these QAOs in section 4.1.5.1 as follows:

"The following QAOs apply to the NDA method:

- Precision QAO – Precision is reported as %RSD. The %RSD shall not exceed the values listed in Table 4.1.
- Accuracy QAO – Accuracy is reported as %R. Accuracy will not exceed ±30% on a non-interfering matrix.
- Representativeness QAO – Representativeness is ensured through assay of each waste container when NDA is used to satisfy DQOs.
- Completeness QAO – Required completeness is 100%. All NDA data used to satisfy a DQO must be valid and usable.
- Comparability QAO – Comparability is ensured through a site meeting the training requirements and complying with the minimum standards used to implement the NDA process.

Table 2. Range of Applicability

	Acceptability Range	Required Response
Acceptable Range	Data[b] $2\sigma^a$	No action required.
Warning Range	$2\sigma^a$ < Data $3\sigma^a$	The performance check standard shall be run no more than twice. If the rerun performance check results in data within ± 2σ, then the additional performance checks shall be documented and work may continue. If the system does not fall within ± 2σ after two performance checks, then the required response for the Action Range shall be followed.
Action Range	Data> $3\sigma^a$	Work shall stop and the occurrence shall be documented and appropriately dispositioned (e.g., initiating a nonconformance report). The NDA system shall be removed from service pending successful resolution of all necessary actions, and all assays performed since the last acceptable performance check are suspect, pending satisfactory resolution. Recalibration or calibration verification is required prior to returning the system back to service.

[a]σ - The standard deviation is only based on the reproducibility of the data check measurements themselves. This is not TMU.

[b]Absolute Value"

f. Destructive Assay or Radiochemistry

The WCPIP in Section 4.1.6.1 contains a description of the DA (also referred to as radiochemistry) that uses radiochemical methods to destructively analyze samples of the waste material in order to develop isotopic profiles or total isotopic content. DOE recognizes that DA methods will depend strongly upon the type of waste being analyzed, the methods available to the laboratory, and the purpose for which the analysis is being performed. Thus, rather than impose specific methods for DA upon all generator sites, a site interested in using DA as a radioassay method must develop sampling and analysis plans that must be operated under an approved QA program. DOE states this as follows:

"Representative samples of RH TRU waste may be analyzed by NDA or DA techniques. The decisions regarding the use of such techniques shall be made by the waste measurement facility and will be technically justified and documented by each facility. If a waste characterization facility chooses to collect and analyze representative samples of the TRU waste material, the site must technically justify and document that the samples collected are representative of the waste material with respect to nuclear properties/radiological characteristics and physical or chemical aspects that significantly affect the measurement process. While it is anticipated that analysis of these samples will be used mainly to determine or confirm a sample's isotopic composition, in some cases it may be possible for a site to use this type of data to directly quantify WIPP-required radionuclides. TRU waste sites that plan to use DA to characterize waste for disposal at WIPP must develop a sampling plan. The requirements for sampling plans are described in Section 4.1.8.

The analyses of samples may produce isotopic distribution values, radionuclide- or element-specific mass values, or both. These data may stand alone or be used in conjunction with other techniques (i.e., as model inputs) to derive values for other wastes with similar origins. The measurement facility will document their measurement capabilities and technically justify the applications of data collected on those systems. Sample collection and analysis will be controlled by the use of written procedures in accordance with the CBFO QAPD.

Depending on the medium and target analyte, the sample preparation can involve considerable processing (e.g., the use of strong acids and solvents for sample digestion and separation). Following separation, purification and appropriate preparation, the sample is assayed for alpha, beta, or gamma radiations, and the instrument outputs are converted to meaningful data by applying calibration and sample-specific correction factors. Radiochemistry techniques can provide isotopic distributions, gross activities, and radionuclide-specific concentrations."

The WCPIP imposes general requirements upon the content of the plans and procedures used for DA, as follows:

"Each laboratory used for TRU waste assay by DA shall demonstrate that the analytical methods are appropriate to assay the specific wastes for which they are proposed. These methods must contain the following general provisions:

- Assay standards must be prepared and used as indicated in the standard test methods.
- The sample taken from the waste must be representative and traceable to its specific waste batch or waste container.
- The test result for each sample must be associated with a specific lot, batch number, or container.
- Lower Limit of Detection – The LLD for each DA method must be determined. Site-specific environmental background and sample-specific interferences must be factored into LLD determinations. The LLD is that level of radioactivity which, if present, yields a measured value greater than the critical level with a 95% probability, where the critical level is defined as that value which measurements of the background will exceed with 5% probability. Because the LLD is a measurement-based parameter, it is not feasible to calculate LLDs for radionuclides that are not determined primarily by measurement. In such cases, the site shall derive the equivalent of an LLD (i.e., a reporting threshold for a radionuclide) when it is technically justified. This value may be based on decay kinetics, scaling factors, or other scientifically based relationships, and must be adequately documented in site records.

All methods will be preceded by radiochemical separation and/or preparation for measurement. Table 4.3 presents a list of laboratory control procedures that must be performed by laboratories involved in the TRU waste DA process."

The following QAOs apply to the DA method:

- Precision QAO – Precision is reported as relative percent difference (**RPD**). The RPD is derived from analysis of laboratory duplicates as listed in Table 4.3. The RPD shall not exceed the values listed in Table 4.3.

- Accuracy QAO – Accuracy is reported as %R. The %R is derived from analysis of laboratory control samples and matrix spikes as listed in Table 4.3. The %R shall not exceed the values listed in Table 4.3.

- Representativeness QAO – Representativeness of DA data shall be achieved by the collection of unbiased samples.

- Completeness QAO – Completeness of DA data shall be expressed as the ratio of the number of samples that are analyzed with valid results to the total number of samples that are submitted for analysis, expressed as a percent. Acceptable DA data shall be obtained for 90 percent of the samples acquired for waste characterization. Valid results for radioassay data are those that were obtained when the laboratory or testing facility demonstrated that the instrumentation and method were in control.

- Comparability QAO – Comparability is ensured through a site meeting the training requirements and complying with the minimum standards used to implement the DA process.

g. Surface Dose Rate

Surface dose rate measurements provide evidence that the waste canister meets the LWA requirements for being declared as RH waste. These measurements also provide the single measured data point that is used to generate the isotopic content of an RH canister under the DTC characterization method. The surface dose rate measurement is controlled under the WCPIP as follows:

> "Measurements must be conducted to determine surface dose rates of RH TRU waste containers. Dose rate surveys will be performed only by trained and qualified personnel using properly calibrated instruments appropriate for the types, levels, and energies of the radiation encountered, and appropriate for the existing conditions in which the instruments will be used. Surveys for radiation must be performed as specified by the Radiological Control Organization, Radiological Work Permits, or other technical documents. The Radiological Control Organization should review the adequacy of dose rate measurement systems when facility or operational changes occur. Records must be maintained to document changes in monitoring equipment, techniques, and procedures. Generator sites shall determine the uncertainty associated with dose rate measurements.

Assessment of container surface dose rates shall include a sufficient number of measurements to characterize the radiation present and to determine compliance with the surface dose rate DQO. Surface dose rate measurement results shall be reviewed by the cognizant radiological supervisor. The review shall ensure that all required measurements have been performed and that the documentation is accurate and complete. Surface dose rate measurements shall be recorded on appropriate standard forms and include the following common elements:

- Date, time, and purpose of the measurement
- General and specific location of the measurement
- Name of the person performing the measurement

- Pertinent special information needed to interpret measurement results (e.g., unusual background levels, special survey distances)
- Survey maps illustrating where measurements were performed and the results
- For RH TRU wastes, the SPM or designee shall review the payload container data packages to verify that the maximum contact radiation dose rate (beta + gamma + neutron) at any point on the RH TRU payload container is equal to or greater than 200 mrem/hr and no greater than
  1000 rem/hr."

The WCPIP also imposes QC controls on the surface dose rate measurements. These requirements are defined in Table 4.4 of the WCPIP.

The following QAOs apply to surface dose rate methodologies:

Precision QAO – Precision established and maintained within the recommendations of the manufacturer of the instrument used to measure dose.

Accuracy QAO – Calibration established and maintained within the recommendations of the manufacturer of the dose measurement instrument used.

Representativeness QAO – The measurement applied to the entire waste container.

Completeness QAO – 100% of the measurements needed to determine surface dose rate are performed and useable.

Comparability QAO – Dose rate measurements are performed by site health physics personnel in accordance with the DOE Orders governing radiological control.

h. Count Containers

DOE states the following related to Count Containers:

"The counting of containers will be accomplished by information provided in the WWIS. Information collected by counting containers will be used to calculated amounts of ferrous and nonferrous metals. No method description or associated QAOs are provided for this method. This will be performed by WIPP based on shipment data input into WWIS by the generator sites for each shipment."

i. Sampling

The WCPIP describes requirements for sampling program in Section 4.1.8. Issues that have been past concerns to EPA, such as determining the representativeness of samples relative to the waste being shipped, have been addressed by DOE in this section as follows:

"The methods used to collect samples of RH TRU waste shall be such that the samples are representative of the waste from which they were taken. However, the physical and chemical diversity of RH TRU waste, as well as the dissimilarity of storage facilities (tanks, drums, hot cells, storage wells, underground caissons, etc.) and sampling equipment associated with them, preclude a detailed description of any specific sampling plan in this WCPIP. Consequently, the

burden of responsibility for developing a technically sound sampling plan rests with the TRU waste generator site.

For TRU waste sites that plan to use DA to directly quantify WIPP-required radionuclides (e.g., analysis of homogeneous solids to develop a curie per unit weight or volume value) or to develop or confirm the mix of isotopic ratios to implement the DTC method, the requirements of the sampling plan are listed below:

- A sampling plan shall be developed and documented for each RH TRU waste stream. The sampling plan is a critical component in the development of representative samples and shall be developed using the guidance provided in EPA QA/G-5S, *Guidance on Choosing a Sampling Design for Environmental Data Collection for Use in Developing a Quality Assurance Project Plan*, and EPA QA/G9 *Guidance for Data Quality Assessment.*

- The sampling plan shall be designed to keep personnel radiation exposure to as low as reasonably achievable (**ALARA**) and result in samples that are representative of that waste stream.

- The form, distribution, and type of waste comprising RH TRU waste shall be considered in developing a sampling plan.
  - The variety in operations and the nature of the generation of RH TRU waste is such that a single method of sampling the waste cannot be applied across the DOE complex.
  - Some waste streams (e.g. well mixed sludge) may be relatively easy to sample, but the method used to collect the sample must be representative of the waste.
  - Newly generated waste or waste not yet packaged shall be sampled prior to packaging.
  - If existing sampling data cannot be qualified in accordance with Section 4.3 of the WCPIP, waste already packaged shall be directly sampled.
  - RH TRU material embedded in concrete or other solid material may require samples to be obtained from within the material.
  - Each site shall consider the best means for obtaining samples that are representative of the RH TRU content of a particular waste stream.

QC requirements for sampling RH TRU waste include collecting co-located samples to determine precision and radiological measurements to verify cleanliness of the sampling tools and sampling equipment. Sampling of RH TRU waste shall comply, at minimum, with the following QC requirements.

Duplicate co-located samples shall be collected to determine the precision of the sampling procedures. A co-located sample may be collected from a sample (e.g., scoop) collected from approximately the same location in the waste stream. Co-located samples shall be collected side by side as close as feasible to one another, handled in the same manner, visually inspected, and sampled in the same manner at the same randomly selected sample location(s). If the visual examination detects inconsistencies such as color, texture, or waste type in the waste at the sample location, another sampling location may be randomly selected, or the samples may be invalidated and co-located samples may again be collected. Co-located samples shall be collected at a frequency of one per sampling batch or once per week, whichever is more frequent.

A sampling batch is a suite of RH TRU waste samples collected consecutively using the same sampling equipment within a specific time period. A sampling batch can be up to 20 samples (excluding field QC samples), all of which shall be collected within 14 days of the first sample in the batch.

Sampling equipment (e.g., bowls, spoons, chisels, swipes, coring tubes, grain thiefs, and calawasas) shall also be cleaned or purchased clean. Sampling equipment, at least that portion that contacts the waste during sampling, shall be verified to be free of radiological contamination prior to use. This can be verified by normal radiological control survey techniques. The results of cleanliness surveys of sampling equipment shall be traceable to sampling equipment batches.

Inspection of sampling equipment and work areas shall include the following:

Sample collection equipment in the immediate area of sample collection shall be inspected daily for cleanliness. The waste sampling work areas shall be maintained in a condition to minimize the potential for cross contamination between waste streams. Sampling equipment shall be visually inspected prior to use. All sampling equipment that comes into contact with waste samples shall be stored in protective wrapping until use. Prior to removal of the protective wrapping from sampling equipment, the condition of the protective wrapping shall be visually assessed. Sampling equipment with torn protective wrapping should be discarded or returned for cleaning. Sampling equipment visibly contaminated after the protective wrapping has been removed shall not be used and shall be returned for cleaning or properly discarded. Cleaned sampling equipment will be physically segregated from all equipment that has been used for a sampling event and has not been decontaminated.

Chain-of-custody on field samples (including field QC samples) will be initiated immediately after sample collection or preparation. Sample custody will be maintained by ensuring that samples are custody sealed during shipment to the laboratory. If custody sealing is not practical due to radiological considerations associated with the sample, the generator site may implement administrative controls to ensure that samples are not tampered with. After samples are accepted by the analytical laboratory, custody is maintained by assuring the samples are in the possession of an authorized individual, in that individual's view, in a sealed or locked container controlled by that individual, or in a secure controlled-access location. Sample custody will be maintained until the sample is released by the site project manager or until the sample is expended. The sampling plan or site-specific procedures shall include a copy of the sample chain-of-custody form and instructions for completing sample chain-of-custody forms. This form will include provisions for each of the following:

- Signature of individual initiating custody control, along with the date and time.
- Documentation of sample numbers for each sample under custody.
- Sample numbers will be referenced to a specific sampling event description that will identify the sampler(s) through signature, the date and time of sample collection, type/number containers for each sample, sample matrix, preservatives (if applicable), requested methods of analysis, place/address of sample collection and the waste container number (if applicable).
- For off-site shipping, method of shipping transfer, responsible shipping organization or corporation, and associated air bill or lading number.
- Signatures of custodians relinquishing and receiving custody, along with date and time of the transfer.

- Description of final sample container disposition, along with signature of individual removing sample container from custody.
- Comment section.
- Documentation of discrepancies, breakage or tampering.

All samples and sampling equipment will be identified with unique identification numbers. Sampling equipment will be identified with unique equipment numbers to ensure that all sampling equipment is traceable to equipment cleanliness survey records.

All samples will be uniquely identified to ensure the integrity of the sample and to identify the generator/storage site and date of collection. Because of the high radiation dose rates associated with samples of RH TRU waste, traditional sample tags or labels may be impractical and are not required."

6. Implementation of Characterization Methodologies to Satisfy DQOs

The WCPIP indicates that any of the above characterization methodologies may be called upon to satisfy DQOs. While AK will be collected for every waste stream following the procedures presented in the WCPIP, a site may choose to use the AK data (qualified by confirmation, Peer Review, and/or equivalent QA). The WCPIP also states (Section 4.2): "For all RH TRU waste streams, the AK record must address each of the DQOs. The AK information is then qualified by confirmatory testing using the characterization methods described in Section 4.1 or qualified in accordance with Section 4.3, with the exception of the defense waste determination.

DOE identified data quality objectives for waste intended for disposal to WIPP. While AK shall be collected to address all objectives, the WCPIP states that each of the characterization methods may be used as follows with respect to determining DQOs:

Table 3 Characterization Methods and DQOs/Acceptance Criteria

Characterization Methods	Acceptance Criteria
Acceptable Knowledge	TRU Waste Determination, Total Activity, Activity per Canister, Defense Determination, Physical Form, Residual Liquid
Dose-to-Curie	TRU Waste Determination, Total Activity, Activity per Canister
Visual Examination	Physical Form, Residual Liquid
Radiography	Physical Form, Residual Liquid
Radioassay	TRU Waste Determination, Total Activity, Activity per Canister
Surface Dose Rate	Surface Dose Rate
Count Containers	Metals

(Note that DOE calls this "acceptance criteria" in the WCPIP, but the actual elements correspond directly with DQOs and therefore EPA has assumed that this section deals with addressing DQOs, which would also include meeting acceptance criteria)

Of the DQOs and related Acceptance Criteria presented in Section 2 of the WCPIP, DOE believes that these may be addressed as follows:

- TRU Waste Determination: AK, Dose to Curie, Radioassay
- Total Activity: AK, Dose to Curie, Radioassay
- Activity per Canister: AK, Dose to Curie, Radioassay
- Physical Form: AK, Visual Examination, Radiography
- Residual Liquid: AK, Visual Examination, Radioassay
- Surface Dose Rate: Surface Dose Rate (measurement)
- Metals: Counting Containers

While AK, DTC, DA, VE, and RTR techniques are discussed in Section 4.1, Section 4.2 of the WCPIP provides addition information regarding the use of techniques in certain applications:

Visual Examination and 10-10-All

The WCPIP states, in Section 4.2.16.2: "For RH TRU waste that requires packaging or repackaging, 100 percent of the waste will be subjected to VE in accordance with the requirements of Section 4.1.2. A subpopulation of those RH TRU wastes that are already packaged in payload containers may be subjected to VE (or radiography). A minimum of 10 percent of the packaged waste will be subjected to VE (or radiography). If the physical form of the waste does not match the waste stream description (including the packaging configuration) in this subpopulation, an additional 10 percent of the packaged waste will be subject to VE (or radiography). If additional waste is identified that does not match the waste stream description (including the packaging configuration) in this second subpopulation, the entire waste stream must be subjected to VE (or radiography). This is referred to as 10-10-All. When implementing the 10-10-All method, VE shall be performed in accordance with Section 4.1.2 and radiography shall be performed in accordance with Section 4.1.4. If the generator site requires other waste characteristics to be determined, (e.g., fill percentage, primary container contents, or other matrix information) in order to implement NDA or DTC, these characteristics will be evaluated as part of the waste stream description when implementing the 10-10-All method. ...Alternatively, for RH TRU waste that is already packaged in payload containers, AK information concerning the physical form of the waste may be qualified."

Determination of Cellulose, Plastic, and Rubber (CPR)

Section 4.2.7 of the WCPIP states: "Visual examination, radiography, and qualification of AK information are the primary methods for determining this parameter on a waste stream basis. Each is capable of determining the physical form of the waste. The amount of CPR for debris waste (S5000) will be determined by multiplying the volume of the waste container by the maximum loading density of plastic (620 kg/m^3). Weights up to the net weight of the waste will be assigned using this method. The derived weight will be entered into WWIS with a waste material parameter type of "plastic." For soils and gravel (S4000), the net weight of the waste will be entered into the WWIS with a waste material parameter type of "soil." For homogeneous solids (S3000), the net weight of the waste will be entered into the WWIS with the waste material parameter type appropriate to the waste (e.g., solidified inorganic material, solidified

organic material, cement). For S3000 and S4000 wastes that also contain debris, the generator sites will estimate the weight of debris in each payload container of waste. The debris in S3000 and S4000 wastes will be entered into WWIS with a waste material parameter type of "plastic." For all summary category groups, weights for plastics in packaging (e.g., drum liners) will be entered into the WWIS. The total CPR mass in RH TRU waste will be tracked and controlled through the WWIS such that the repository limit on CPR is not exceeded".

7. Qualification of AK Information

The WCPIP states that while the DQOs can be met by using any of the above methodologies, Section 4.3 discusses that: "There may be some RH TRU waste streams for which detailed characterization information exists that was generated prior to the generator site establishing an approved QA program that implements the requirements of the CBFO QAPD." For this characterization information, a site may seek to qualify these data in accordance with 40 CFR §194.22, using one or a combination of the following four methods:

a. Peer Review

The WCPIP states that "Peer reviews conducted to qualify AK characterization information must comply with the following requirements:

- Generator sites must develop a peer review procedure that complies with the requirements of NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*, February 1988.
- The generator site must obtain DOE/CBFO approval of the peer review procedure and the peer review plan prior to conducting the peer review.
- The peer review scope must explicitly define the waste characterization DQOs and QAOs that the peer review panel will be evaluating. The peer review scope must explicitly require the peer review panel to determine whether the data being reviewed satisfy the defined DQOs and QAOs."

A CBFO audit and approval of each peer review process and data approved by peer review will be necessary.

b. Corroborating Data

At this time, the use of corroborating data is not approved by CBFO for qualification of AK information as waste characterization data.

c. Confirmatory Testing

The WCPIP states, in the WCPIP that AK Confirmation methods include:

- 100 percent VE at the time of packaging
- 10-10-All
- obtaining a representative number of samples from the waste stream or waste stream lot to confirm AK on isotopic distribution
- 100% NDA

- DA
- DTC

All confirmatory testing methods will be described in the Waste Certification Plan, and if a generator site proposes to qualify AK information by means of confirmatory testing other than that described in Section 4.1, site must first seek and acquire DOE approval of that process. Generator sites that propose to use confirmatory testing to qualify AK information as characterization data must submit a confirmatory testing plan to CBFO for review and approval.

A CBFO audit and approval of confirmatory testing processes and data qualified via confirmatory testing will be necessary.

d. Equivalent QA Program

The WCPIP states that to qualify AK information using an equivalent QA program, the generator site must be able to demonstrate that the program in use at the time the data were generated implemented requirements equivalent in effect to the applicable requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1). Generator sites proposing to use the equivalent QA program method for qualifying AK information as characterization data shall submit a "procedure matrix" providing a crosswalk that identifies the generator sites plans and procedures which show that applicable requirements of ASME were implemented. Prior to shipping waste to the WIPP that has been characterized using data qualified under an equivalent QA program, the site's documentation of an equivalent QA program shall be audited and approved by the DOE/CBFO.

Following performance of these qualification elements, a site shall revise the AK Summary and prepare a Characterization Reconciliation Report, the later of which reconciles all data acquired and presents the results of the total characterization process in a single report.

III. EPA'S ANALYSIS OF DOE'S PROPOSED RH PROGRAM

EPA evaluated the RH proposal, examining the contents of the proposal for technical adequacy and regulatory compliance. Our review included observation of RH waste characterization implementation at two different sites, as well as detailed examination of the WCPIP proposal with respect to applicable regulatory requirements presented in 40 CFR 194.24 and 22, as well as technical viability of the proposed approach. EPA's analysis of DOE's RH proposal is summarized in this section.

A. EPA Observation of RH Waste Characterization Activities

EPA participated in RH characterization activities as observers at Battelle Columbus Laboratory (**BCL**) and at the Los Alamos National Laboratory (**LANL**). These activities afforded EPA the opportunity to examine, first hand, how the proposed RH characterization process would work at two waste generator sites, both elected to use dose-to-curie (albeit in with different input), but chose different AK qualification pathways (BCL did not specify an AK qualification pathway, and LANL specified the equivalent QA AK qualification pathway).

EPA observed the BCL activities in August 2001 and the BCL program was performed without benefit of a WCPIP. Comments and observations made by EPA concerning the BCL program and LANL programs demonstrate the evolution of both DOE's programs and our understanding of the proposed RH waste characterization process.

1. Battelle Columbus

a. Introduction

EPA observed the CBFO surveillance (S-01-37) of the BCL's RH Waste Characterization Program from August 27-29, 2001. EPA observed surveillance activities related to AK and radioassay, as well as VE activities performed on RH waste. Since 1943, BC (also known as Battelle Memorial Institute, BMI) has been involved with atomic energy research and development activities. BCL supported DOE, nuclear power industry, U.S. Navy, Army and Air Force nuclear research projects. The Hot Cell Laboratory, located at the BMI Columbus Laboratories West Jefferson North site, is among the buildings and facilities that are being or have been decommissioned under the Battelle Columbus Laboratories Decommissioning Project (BCLDP). The Hot Cell Laboratory is in the JN-1 Building, and was the subject of the audit; other areas (i.e., JN-4, which may include CH TRU waste) were not included in the audit.

The Hot Cell contained waste materials generated from years of ongoing research; this waste had not been previously containerized or described, and included what BC believes to be "hopelessly commingled" defense and commercial wastes. BCL initiated a VE program to inspect JN-1 wastes whereby all wastes were videotaped during examination and packaging. Although the waste has been present in the cell for several years, BCL considered the waste to be "newly generated", and the VE program thus satisfied the analogous CH requirements that newly-generated wastes are to be visually examined while generated. BCL believed that approximately 10 waste streams may ultimately be identified (almost all of which will be classified as debris waste). Representatives also estimated that approximately 100 drums of RH waste will be generated, and approximately 60 drums had been generated prior to the date of our site visit.

b. Technical Elements Examined

Acceptable Knowledge. The AK Program implemented at BCL is similar to CH programs used at other TRU waste generator sites. Data assembly, management, roadmapping, and compilation are performed in a similar manner. This approach is acceptable. However, the program at BCL did not include sufficient depth with respect to radionuclide information, and BMI's attempt to use the same data for AK "confirmation" and AK record development was not acceptable.

At the time of the EPA's visit to BCL WCPIP was nonexistent, so comparisons were made to the existing CH program. At that time, we determined that the BCLs' RH Program would not satisfy the CH program, nor would it satisfy an RH program with similar or more stringent Acceptable Knowledge requirements. This is primarily because: 1) the program was incompletely implemented; 2) the AK record and supporting documentation were incomplete with respect to radionuclide information; and 3) radioassay information intended to replace NDA was actually AK information and not measurements, and should have been completely documented and reflected as such in the auditable record. The program did not integrate key elements of the CH AK program elements, including prescribed data compilation, assembly, and review, and preparation of AK summary documentation using an AK roadmap.

Also, the BCL's RH Waste Characterization Program was deficient with respect to 40 CFR 194.24 requirements for a number of reasons. For example, the AK data assembly results were incomplete and would require additional radionuclide information. Supporting documentation (i.e., document DD-98-04) needed additional information, and AK "confirmation" (i.e., acquisition of radioassay data as part of the characterization program) using the proposed data was determined to be not acceptable.

The BCL implemented an RH AK Program that was similar to CH AK Programs observed at other DOE sites and, as such, was technically sufficient with respect to initial/basic data gathering. The program, however, did not sufficiently integrate all applicable sources of radionuclide information. Instead, it relied solely on data collected for non-waste characterization purposes to replace NDA as the source of AK isotopic data. BCL did not adequately explore all AK sources of information with respect to radionuclides; instead they relied on "non-waste" data as the absolute source of isotopic distribution information. Specifically, the JN-1 standard isotopic mix, purported to be representative of waste managed in the Building JN-1 hot cell, was developed using AK data obtained for health and safety and not waste characterization purposes. Although the standard mix results were supported by ORIGEN2 calculations, all of this information should be considered AK information, and be included in the auditable record as such. Additionally, the site used the same data as both the source of AK information and for "confirmation" of AK isotopics; the same data should not be used for this dual purpose.

At the time of the inspection, EPA concluded that BCL's RH program could be improved through more diligent acquisition and integration of AK-based radionuclide information to determine isotopic distributions using actual waste-related and experimental data. The AK process must include a better description of the document hierarchy, and ensure that all relevant information is collected and appropriately referenced (for example, additional health and safety information such as that used to determine the JN-1 standard mix should be acquired and assessed).

EPA noted several concerns with respect to the AK. For example, the study performed to use swipe samples and the ORIGEN2 code to determine the JN-1 standard needed to either include or reference additional information, and this information should be available in the AK reference either through individual references or generation of a single supporting reference. Also, the AK record should include all swipe sample data, including those *not* included in the 69 sample assessment supporting the JN-1 standard development. Further, the defense/non-defense commingled argument needed additional support, particularly since non-defense waste comprises the majority of RH waste. EPA also concluded that reference TCP-98-03 did not include enough historic radionuclide information. The document included only the information presented in DD-98-04, but did not include sample/shipment-specific information or examples which would support the general assumption that fuel grade material (only) was accepted. TCP-98-03 should be revised to include this additional information, particularly since reliance on DD-98-04 results was critrical to the entire radionuclide identification process. Specifically, ensure that TCR 98-03 includes isotopic information above and beyond that presented in DD-98-04 to ensure that the AK data collection process is thorough and complete. Further, all VE records, including tapes, should be included and/or referenced in the AK record. Finally, the site roadmap or analogous terminology needs to include further clarification to explain the document preparation/flow process. For example, it is not readily apparent that the Technical Basis Process descriptions are "post" characterization reports, while the TCP document is the AK summary, etc.

Battelle assumed that 69 swipe samples would suffice for both the AK isotopic determination and the AK confirmation (i.e., analytical data replacing NDA information) activities. This information, however, cannot serve a dual purpose. The AK record must be thorough and complete, and a separate analysis must be performed (see Section 3.2, below). While 100% sampling/analysis may not be necessary, EPA has clearly indicated that the AK record alone cannot provide adequate waste characterization data without actual analytical data for waste representative waste samples specifically collected to assess the waste stream(s) being audited. The swipe samples were not collected with the specific intent of identifying radioisotopes representative of wastes managed in the cell, and therefore should not be used as a substitute for samples taken for the purpose of NDA analysis. As such, the sampling activity (and associated supporting information as presented in Comment 1, above) used to generate the JN-1 standard mix should be considered part of the AK record.

Battelle used 69 swipe samples of the Hot Cell collected between 1996 and 2000 to determine the JN-1 standard isotopic mix. Adequacy of the mix was assessed using the ORIGEN2 code; information from this modeling also augmented the JN-1 mix for certain isotopes. The use of radiochemistry rather than NDA to assess isotopic mixture and isotopic content is not necessarily problematic or unacceptable, nor is the radioassay of <100% of the containers. The assay sampling program must be designed and performed with the intent of determining radioisotopic content/mix in RH waste. The 24 cask swipes collected are more related to determining actual waste content than the swipe samples assessed as part of the JN-1 standard mix determination, but the sampling methodologies, applicability of sampling to RH waste determinations, etc. must be documented and placed in the auditable record.

Radioassay. The EPA identified a number of issues with the radioassay program. The radioassay program at Battelle had not been conducted under an approved NQA-1 program or equivalent. Accordingly, all sample data taken to date would not satisfy the requirements of 40 CFR194.24, but could be included as part of the AK record.

The sampling and analysis program did not comply with the 40 CFR 194.22 data quality requirements. Usually, the unit being assayed is a drum (or standard waste box), and 100% of the units are assayed. This system immediately meets the requirements for being representative and comprehensive, and the inspection program can then focus on the precision and accuracy of the methods being employed, and whether the methods provide complete results. In the Battelle system, the unit being assayed is the item from which a swipe sample was taken. This item may or may not be something that was actually going to be put into a drum and disposed of at WIPP. Conversely, not all material destined for WIPP was being swipe sampled. Accordingly, the program must also demonstrate that the sampling being performed was adequately representative of the waste destined for WIPP, and that the sampling program was comprehensive, in addition to the usual requirements of precision, accuracy, and completeness. No evidence was presented to show these additional program requirements were addressed.

The assay program depended on the results of the total dose measurement combined with the assumed isotopic mix. This relationship is known as the dose-to-curie conversion. The process for performing the modeling required to determine the JN-1 standard mix and the dose-to-curie conversion needed to be documented to include required inputs and outputs, review of modeling results, required qualification and training, and identification/disposition of records that will be generated. The DOE CBFO surveillance report also identified this deficiency.

Justification demonstrating that Latin Hypercube Sampling was the proper choice for sampling and that the assumption of a lognormal distribution was appropriate should have been incorporated into waste characterization documentation. In particular, a number of the sampled values were beyond what the documentation indicated as the valid range of the data. The DOE CBFO surveillance report also identified this as a deficiency. Also, at the time of the inspection, there did not appear to be any estimate of the uncertainty in the assay results.

Visual Examination. Although not formally part of the surveillance, EPA had the opportunity to view the RH waste visual examination process and facilities in the JN-1 Hot Cell. Documents that describe the VE process included but were not limited to TCP-98-03.1, HP-OP-019, RCP 98-03.1.1, 03.1.2, and 03.1.3.

The interior of the Hot Cell had two video cameras that recorded all activities performed in the cell on a 24 hours basis, including waste sorting and packaging activities. Operators examined and sorted waste present in the cell using remote manipulators. Each portion or piece of waste is sorted, examined, described, and placed in liners (drums). All waste packaging activities were recorded on videotape, with the VE operator performing the actual waste sorting remotely outside of the Hot Cell and the VE expert recording all waste material placed in containers in a written log. Waste was segregated by material "type" and is weighed on a unit (i.e., "berry can") basis. Absorbents were also added, as necessary. Summary reports were prepared on a daily basis, with a TRU Waste Package Loading Record filled out for each drum liner. When filled, the liners were stored in a shielded vault area. Note that surface swipes of the containers were taken. Approximately 60 drums/liners had been filled at the time of the audit.

c. Conclusions

During Summer/Fall 2001, we were unable to determine whether the BCL's RH waste characterization program satisfied EPA regulatory requirements as we did not have DOE's RH

Waste Characterization Program to evaluate BCL RH program. We, however, compared the program to that currently in place for CH waste, recognizing that the proposal to be submitted by DOE for RH waste could differ from that for CH. The BCL RH program would not comply with CH waste program requirements because NDA/radioassay is not performed on each waste container, and the AK program data assembly/compilation elements were not complete. Additionally, EPA questioned whether the BCL's RH program documentation adequately justified the defense status of the waste, since much of the waste was actually generated during non-defense support activities. EPA was also concerned about using elements of the proposed RH program to delineate RH and low level wastes. We, however, concluded that the selected radioassay approach to RH waste characterization had merit, although the activities performed to that date were technically not adequate.

2. Los Alamos National Laboratory RH Waste Characterization Observation

a. Introduction.

On August 5 and 6, 2003, we observed the Surveillance S-03-07, related to a RH Waste Characterization Demonstration at the LANL for Waste Stream CMR RH Hot Cell Debris Waste. The waste stream consisted of 16 RH-72B canisters, 12 of which each contained up to three 55-gallon drums; these 55-gallon drums each contained up to 12 1.5-gallon cans of waste. The remaining 4 canisters contained a total of twelve 55-gallon drums containing pieces too large to place in the 1.5 gallon cans. LANL was demonstrating their implementation of the AK qualification path contained in a proposed WCPIP. The intent of this qualification process is to allow sites to demonstrate that an equivalent QA program was in place at the time the waste was generated and packaged. The waste stream used for the demonstration was RH TRU Debris Waste packaged from January 31, 1986, to June 5, 1991. LANL was attempting to qualify AK data using the QA equivalency pathway as proposed in the WCPIP, Section 4.3. During the demonstration, EPA focused solely on the technical merits of the proposed approach, which was to use various historic measurement data coupled with current ORIGEN 2.2 and MCNP modeling to determine the radiological characteristics of each canister in the waste stream.

b. Technical Elements Examined

Acceptable Knowledge. The WCPIP includes Appendix A, Acceptable Knowledge Procedure for Remote-Handled Waste. This procedure is similar to CH AK procedures both in content and format, with significant differences including the elimination of the requirement in the RH program to collect mandatory and supplemental information. The purpose of our observation was to evaluate how well the site implemented this procedure and how data are identified, compiled, assessed, assembled, and presented; since AK confirmation was not part of the activities performed, AK confirmation was not evaluated.

The AK data assembly process was similar to that used under the CH program where information is identified, gathered, compiled, evaluated, and assembled in an AK Summary. The "logic" behind the proposed characterization process was based upon the knowledge that since construction of the Chemical and Metallurgical Research (**CMR**) facility in 1952, a number of different campaigns entered cells/alpha boxes. Information on the specific nuclear material manipulated in the boxes was known (i.e., process knowledge generating the material managed in the boxes). The CMR was decontaminated and decommissioned from 1986-1991, so any waste generated through this destruction process would potentially contain any of the nuclear

material that was previously managed in that cell or box. LANL AK personnel assembled process information to provide data showing how material handled in the boxes was generated and, how that material would represent an output waste stream content. EPA needed to determine whether data obtained prior to the Fuel Examination Program (1968) were assembled and assessed, as part of this waste stream since that too would have "traveled through" the various cells and glove boxes. Any approach assuming waste characteristics based on a long history of varying processes and blending of subsequent wastes requires that the AK data/processes/waste segregation activities be well understood. This would ensure that broad assumptions made by AK personnel regarding AK were appropriate.

Key AK information pertaining to waste configuration and radiological content was assembled outside of the AK program. The site should have referenced all AK data in the AK Summary, and the results of any additional analysis should have been rolled up into the AK record. Specifically, 16 Canisters of Prepackaged Waste are included in the Waste Stream and radiological information is available. Twelve (12) of the 16 canisters contained 55-gallon drums, and in each of these drums was up to 12 individual waste cans; there is a total of 364 individual waste cans within the 12 canisters. Four (4) of the 16 canisters contained bulk waste items. The 364 individual waste cans underwent Passive-Active Neutron (PAN) analysis. Also, LANL identified data showing that fuel rod/pin examination was conducted in the glove boxes and has estimated fuel pin burnup information for 1498 of these pin. The information often included ^{235}U enrichment, ^{240}Pu enrichment, and U/Pu ratio. Some of these fuel pins had samples extracted that were analyzed by mass spectrometry; 98 mass spectrometry results were found. The site chose to use this mass spectrometry and PAN information, coupled with modeling and dose-to-curie analysis, to characterize the waste. The site's AK Summary must reflect that adequate linkage between AK and other characterization activities has occurred.

The WCPIP proposes that already packaged waste undergo 10-10-All visual examination. That is, 10% of the prepackaged waste would be opened, and if the contents compared favorably to waste stream descriptions, then additional VE would not be required. However, the site did not intend to follow the proposed 10-10-All procedure, as it believed that if CBFO and EPA approve the QA equivalency determination for AK data and considers that the AK data are sufficient. To show this, the site assembled all of the existing VE data, and stated that all of the information required by the WCPIP could be identified in the historic VE record. The site should document this equivalency comparison for each of the VE elements. The site also assembled procedures specific to the historic VE process in an attempt to show that procedures used then were adequate, and that personnel performing VE were adequately trained. This approach, if adequately and thoroughly implemented may be acceptable if the site has adequate documentation for all VE elements in the AK record.

The site claimed that this LANL waste was defense related because some defense waste was managed in the cells/alpha boxes thereby potentially contaminating all waste generated through decontamination and decommissioning (D and D) with defense related material, thus making all of the D and D waste defense related. This argument needs to be significantly substantiated, particularly if individual 55-gallon containers (364 of them) can be traced to specific canisters and presumably specific cells, and the site can show that non-defense related material was handled in those cells and was cross contaminated with defense-related waste.

Radiological Characterization: To characterize the radiological constituents of the waste, LANL

proposed to use AK information in combination with modeling performed under their existing quality assurance (QA) programs. AK information used for radiological characterization included fuel composition and burnup records submitted by research sponsors to the fuel examination program, mass spectrometry records from the fuel examination program, passive-active neutron (PAN) assay measurements of the 1.5-gallon cans made during the packaging of the waste, and dose rate measurements for the 1.5-gallon cans and the 55-gallon drums of bulk waste. Modeling efforts include the use of ORIGEN 2.2 to estimate the ratio of different radionuclides in the waste and the use of MCNP to estimate the quantity of radioactivity in a container based on the measured dose rate.

LANL used the PAN radioassay system to assay the 364 1.5-gallon cans. Each of the 364 1.5-gallon cans was assayed on a PAN radioassay system. The PAN was designed to measure the quantity of fissile and/or fissionable material in the presence of the very high gamma-ray fields expected for RH waste.

EPA reviewed the method to estimate the activities of the individual radionuclides in the 364 1.5-gallon containers. To estimate the activities of individual radionuclides based on the RH-PAN assay results, described above, the ratio of the radionuclides in the waste must be known or determined. LANL proposed to estimate the radionuclide ratios using AK information about initial fuel composition and burnup of 1,498 of the approximately 1,600 fuel pins examined as part of the fuel examination program. As part of the program, research sponsors were required to provide LANL with information about each fuel pin, including the ^{235}U enrichment, the ^{240}Pu enrichment, the U/Pu ratio, and the estimated burnup. The relative abundances of the various radionuclides for each of the 1,498 pins was estimated using ORIGEN 2.2, a computer model used to perform fuel burnup calculations, and the information provided by the research sponsor.

In addition to the information provided by the research sponsor, mass spectroscopy results were previously performed for 98 of the approximately 1,600 fuel pins. LANL compared these mass spectroscopy measurements with the ORIGEN 2.2 calculations. LANL developed adjustment factors for the uranium and plutonium isotopes to be applied to the ORIGEN 2.2 results, based on the mass spectroscopy results. Average adjustment factors, as calculated by LANL varied from 0.42% to 38%. Differences between the adjusted ORIGEN 2.2 results and the mass spectroscopy results were less than 1% for the most abundant isotopes (i.e., ^{235}U, ^{238}U, ^{239}Pu, ^{240}Pu) and several percent for less abundant isotopes (i.e., ^{236}U, ^{238}Pu, ^{242}Pu). LANL derived ratios of the activity of each radionuclide to the fissile gram equivalent (FGE) using the adjusted ORIGEN 2.2 results.

To estimate the activities of individual radionuclides in each of the 364 1.5-gallon cans, LANL applied the adjusted ORIGEN 2.2 radionuclide ratios to the reported quantity of fissile material measured on the RH-PAN. Radionuclide ratios are likely to vary somewhat from can to can, and that the calculated ratios are average values over the population of waste containers. As such, the total activity of a given radionuclide in a canister or collection of canisters is likely to be more accurate than the reported activities in any given can or drum. Additionally, because ^{60}Co is an activation product and cannot be accurately estimated using ORIGEN 2.2, LANL estimated the activity of ^{60}Co using the difference between the measured dose rate and calculated contribution of ^{137}Cs to the dose rate, estimated from the RH-PAN assay result and ORIGEN 2.2 ratio.

EPA reviewed the method used to estimate activities of the individual radionuclides in the 12 55-gallon drums. The radionuclide ratios, used to calculate the radionuclide activities for the 364 1.5-gallon cans, were assumed to also apply to the 12 55-gallon drums containing bulk waste. Since the RH-PAN was never used to assay 55-gallon drums, LANL intends to use a measurement of the dose at a point several meters away from the drum to quantify the activity of the radionuclides in the drums. LANL calculated the dose rate at a distance of one meter for ^{60}Co and ^{137}Cs per unit activity as a function the waste matrix density over the range from 0.4 to 3.5 g/cm^3 using MCNP, a modeling code commonly used to model radiation transport in nontrivial geometries.

The comparison between the ORIGEN 2.2 results and the results of the 98 mass spectrometry measurements included uranium and plutonium isotopes. While this comparison may provide evidence that ORIGEN 2.2 can predict the relative abundances of the uranium and plutonium isotopes, it does not directly address the ability of ORIGEN 2.2 to predict the generation of fission products, such as ^{90}Sr and ^{137}Cs. A comparison of the quantity of one or more fission products, such as neodymium isotopes, relative to uranium and/or plutonium measured by mass spectrometry with that calculated by ORIGEN 2.2 would provide evidence that ORIGEN 2.2 can predict the quantity of fission products, most notably ^{90}Sr and ^{137}Cs.

The radionuclide ratios calculated by ORIGEN 2.2 and/or measured by mass spectrometry are average ratios estimated for the waste in all 16 RH canisters. As such, the TRU alpha concentration and the activities of individual radionuclides for each canister are in part based on ratios which are estimated for the waste stream as a whole. Ratios and the total activities derived from them are likely to vary from canister to canister. LANL did not provide explanation of how it would handle canisters where the TRU concentration is near 100 nCi/g or for the four canisters with bulk waste, where assay results estimating the quantities of fissile material (i.e. plutonium and/or uranium) are not available.

c. Conclusions

The EPA did not determine whether LANL has demonstrated adequately its implementation of QA equivalency in compliance with the 40 CFR 194.22 requirements. Also, the site did not discuss extending this approach to any other RH waste streams at the facility. EPA believes that the technical approach equivalency proposed by LANL is technically valid, and could possibly be used in this specific instance to characterize this RH waste stream. EPA identified issues and observations related to the approach.

B. EPA's Regulatory Analysis of DOE's Proposed Revision

EPA examined DOE's proposal with respect to applicable characterization requirements at 40 CFR 194.24. EPA limited its review of regulatory compliance to 194.24(c)(2)–(4).

40 CFR 194.24(c)(2) requires the DOE to "Identify and describe the method(s) used to quantify the limits of waste components identified in paragraph (b)(2) of this section." DOE had already considered RH waste in its initial CCA, therefore no new waste components specific to RH waste need to be identified. Under the CH program, quantification of waste components occurred primarily through measurement, that is, use of NDA and NDE, supported by an

acceptable (process) knowledge base. This portion of the rule requires DOE to present how each of these methods was to be used to quantify the significant components, scale to which this measurement applied, instrumentation and sensitivity, and the specific parameter that would be characterized by the method. Data obtained by the approved method were to meet or exceed QAOs and DQOs. EPA also specifically addressed the use of acceptable (process) knowledge data in it's rule, stating in 194.24(c)(3) that DOE must provide..."information which demonstrates that the use of process knowledge to quantify components in waste for disposal conforms with the quality assurance requirements found on 194.22". EPA requires that when AK was used to either quantitatively or qualitatively characterize TRU waste, activities will be performed under a quality assurance program as required in 194.22(a)(1).

194.22(a)(1) states: "...the Department shall adhere to a quality assurance program that implements the requirements of ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, Part 2.7, to ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition...". 194.22(b) goes on to state that "Any compliance application shall include information which demonstrates that data and information collected prior to the implementation of the quality assurance program required pursuant to paragraph (a)(1) of this section have been qualified in accordance with an alternative methodology, approved by the Administrator or the Administrator's authorized representatives, that employs one or more of the following methods: "Peer Review...corroborating data; confirmatory testing data; or a quality assurance program that is equivalent in effect to ASME NQA-1-1989 edition..." In short, waste characterization measurement data obtained must adhere to NQA quality standards, and if DOE sought to use data obtained prior to the establishment of these standards (that is, AK data), then the data were to be qualified by one of four methods. Applicable requirements presented in 40 CFR 194.24 were assessed with respect to the WCPIP's proposed RH program.

1. 194.24 (c) Compliance Analysis

194.24 states:

(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: ...

(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."

As part of its analysis, EPA evaluated the methods DOE used to quantify specific components.

Section 4 of the WCPIP presented several waste characterization methods to identify the physical and radiological properties of the waste. Of these, NDA, RTR, VE, and AK are common to the CH program. However, the DTC and DA procedures are new to the RH proposal, as are the 10-10-All approach for visual examination and limiting assumptions with respect to CPR. Each of these differences is assessed with respect to compliance with 40 CFR 194.24 requirements.

Because EPA has evaluated AK, VE, RTR, and NDA methods under the CH program, we did not pursue a detailed assessment. The information presented in the CARD 24 for CH waste still holds true. EPA focused on DOE's proposed new waste characterization information and methods to quantify waste components.

As stated in the EPA's Compliance Application Guidance (pp. 32-33), 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 waste 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.

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

Similarly, EPA expects RH sites to also specify the above with respect to RH waste. EPA expects the RH program to demonstrate DOE's ability to quantify each of the listed waste components (for purposes of control, at a level of precision and accuracy adequate to assure that limiting values will not be exceeded in the inventory shipped to WIPP). Also, 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. As with the CH program, the quantification results must still be summed and tracked against the limiting values to ensure that the limits will not be exceeded.

DOE is required to address the identification of waste components within the context of the characterization program. Under the CCA, DOE identified waste components that were not expected to have a significant effect on disposal system performance, which included the following physical characteristics/components (Appendix WCL, Table WCL-1):

- 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.

- Nonferrous metals (metals other than iron)—minimum of $2x10^3$ kilograms

With respect to radiological compounds, DOE identified the waste components expected to have a significant effect on disposal system performance and used in PA. Ten radionuclides are among those components identified by DOE as very important to PA (Appendix WCA). These ten radionuclides are:

- ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu
- ^{241}Am
- ^{233}U, ^{234}U
- ^{90}Sr
- ^{137}Cs and
- ^{244}Cm.

Seven of the ten radionuclides identified for TRU waste are specific to CH waste, and three are specific to RH waste. The seven CH waste-specific radionuclides are ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Pu, ^{241}Am, ^{234}U and ^{244}Cm. The three RH waste-specific radionuclides include ^{137}Cs, ^{90}Sr and ^{233}U. Note that any of these radionuclides can be found in either CH or RH waste. RH waste is expected to have significantly higher fission product activities (such as ^{137}Cs or ^{90}Sr) than CH waste.

Other radiological parameters of importance to compliance are:

- Uncertainties in the isotopic quantities
- Total TRU activity
- Activity Concentration in RH Canister
- Determination of RH Waste
- Total Activity

a. Proposal Methods to Quantify Each Waste Component §194.24(c)(2)

CPR

The WCPIP did not include any performance-based proposal to eliminate the need to characterize these components. Rather, DOE committed to performing visual examination of all to-be-packaged waste (>95% of RH waste expected to be disposed of at WIPP) to determine the waste stream and other physical characteristics. However, instead of measuring the above physical parameters as is done in the CH program, DOE proposed and EPA approved the use of limiting assumptions with respect to CPR. As part of the CCA, DOE successfully demonstrated that plastic was the CPR component contributing most to gas generation and, hence, to successful repository performance. Because the RH inventory is much more limited than the CH inventory from a volumetric perspective and because of the potential risk to workers that

exposure to RH waste could cause during the "typical" CH-type VE and CPR determination process, EPA approves DOE's proposal as presented in the WCPIP:

> "The amount of CPR for debris waste (S5000) will be determined by multiplying the volume of the waste container by the maximum loading density of plastic (620 kg/m^3). Weights up to the net weight of the waste will be assigned using this method. The derived weight will be entered into WWIS with a waste material parameter type of "plastic." For soils and gravel (S4000), the net weight of the waste will be entered into the WWIS with a waste material parameter type of "soil." For homogeneous solids (S3000), the net weight of the waste will be entered into the WWIS with the waste material parameter type appropriate to the waste (e.g., solidified inorganic material, solidified organic material, cement). For S3000 and S4000 wastes that also contain debris, the generator sites will estimate the weight of debris in each payload container of waste. The debris in S3000 and S4000 wastes will be entered into WWIS with a waste material parameter type of "plastic." For all summary category groups, weights for plastics in packaging (e.g., drum liners) will be entered into the WWIS. The total CPR mass in RH TRU waste will be tracked and controlled through the WWIS such that the repository limit on CPR is not exceeded."

Ferrous-Non Ferrous Metals

With respect to ferrous and non-ferrous metals, DOE proposed to quantify ferrous and non-ferrous metals by "counting containers", not by quantifying the materials within the containers to show compliance with the CCA limits. DOE provided information pertaining to nonferrous metal limits in Chapter 4.2.2 (p. 4-29) and Appendix BIR (Chapter 1, pp. 17-20; Chapter 2, pp. 6-7; Appendix M, pp. 1-3). DOE derived the quantity of nonferrous metals (i.e., metals other than iron) from the amount of nonferrous metal impurities in the drum shells and the total number of drums expected to be emplaced in the repository. DOE asserted that a minimum limit of $2x10^3$ kilograms of nonferrous metals will be exceeded. Therefore, DOE stated that quantification beyond tracking the number of drums to be emplaced in the WIPP is not necessary. EPA expects the DOE to specifically include, in the AK record, container metal content (quantitative and qualitative) that can be used to demonstrate that these limits are indeed being tracked as part of the RH program. EPA agrees that the assumption that container counting will satisfy the ferrous metal tracking requirements is consistent with that currently accepted under the CH program. Note that DOE bears the responsibility of maintaining all waste limits as presented in the CCA for CPR, Ferrous, and Nonferrous metals under the RH program.

Liquids

In Chapter 4.2.2 of the CCA (p. 4-29), DOE also proposed a limitation on the amount of water that may be present within a container. This limit was based on the maximum amount of water allowed (1% of total waste volume) by the WAC and the CH-TRU design basis of the repository (168,485 m^3) at the time of the CCA; these limits are also common to the RH program. DOE calculated that with the assumed 1% limitation, the water content will not exceed the maximum limit of 1684 m^3. DOE asserted, in the CCA, that additional quantification is not necessary because the effect of water in the waste is a function of the percentage of water and not the absolute quantity of water. However, DOE quantified the water content in CH waste as part of the VE/RTR program to ensure that the limitation was maintained. The RH program has proposed no modification to the limitation, and states in Section 2.4.2: under acceptance criteria

...Liquid waste is prohibited at the WIPP. Waste shall contain as little residual liquid as is reasonably achievable. The total residual liquid in any payload container shall not exceed one percent by volume of that payload container. If VE methods are used, the detection of any liquids in non-transparent internal containers will be addressed by using the total volume of the internal container when determining the total volume of liquids within the payload container.

DOE must visually examine each of the waste containers to be packaged or repackaged to ensure that this acceptance criterion is met. EPA also expects that containers already packaged shall undergo the appropriate non-destructive technique (VE, RTR, etc, including as part of the 10-10-All process) to ensure that this acceptance criteria is met.

Radiological Components

Quantification of the 10 isotopes identified in the PA, determination of total TRU activity, determination of total activity and determination of activity concentration in the RH canister

DOE provides in section 4.2.1 of the WCPIP, a discussion of the methods used to determine the activity for each of the ten isotopes identified as critical in the PA, as well as the method for determining Total TRU activity. DOE states that "an assessment of the TRU curie-per-gram concentration of waste in each waste stream is necessary to demonstrate [that] the waste contains greater than 100 nCi/g of alpha-emitting TRU radionuclides with half-lives exceeding 20 years. In addition, the radionuclide activity (including ^{241}Am, ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{242}Pu, ^{233}U, ^{234}U, ^{238}U, ^{90}Sr, and ^{137}Cs) must be reported in the WWIS in order to track the radionuclides of interest."

DOE proposes to allow sites to use the following methods for this determination:

- Dose-to-Curie Conversion: Dose-to-curie conversions for radionuclide activity are estimates based on a dose rate measurement taken with a calibrated instrument. An isotopic conversion factor is used to relate the dose to radionuclide activity. The conversion factor is based on documented studies related to the isotopic mix in the waste as defined by its origin and computer modeling (from a program such as ORIGEN) or by sampling and analysis. The study will be referenced in the site's certification documentation.

- Qualification of AK Information: Radiological characterization information obtained prior to implementing a QA program that meets the requirements of the CBFO QAPD may be qualified in accordance with Section 4.3 of the WCPIP. Plans for qualification of such data require review and approval by CBFO and the process used must be audited by CBFO before waste characterized in this manner may be disposed of at the WIPP.

- Radioassay Method: If a site has a radioassay system that is capable of performing measurements on containers of RH TRU waste, and the system meets the program requirements of Section 4.1.5.1, a site can make measurements with this equipment. Sites may also use DA to determine the TRU curie-per-gram concentration of the waste. Sites are to report activity to meet two requirements: the calculation to show that the waste meets or exceeds the threshold for classification as TRU waste (100 nCi/g), and the requirement to report the radionuclide activity for purposes of tracking.

Similarly, DOE intends to use DTC conversion and radioassay methods for determination of the total activity, for calculating the activity of the canister, and for calculating the total TRU activity.

Regarding the determination of total TRU activity and the activity concentration in the RH canister, EPA also expects DOE to evaluate the presence and activity of isotopes which are not included on the list of ten isotopes identified as impotant to the PA. Since the LWA specifically calls out limits on RH canister activity and total activity, DOE must account for all isotopes present in the waste to the maximum extent feasible. EPA will examine the determinations as part of the inpsection and approval process.

Uncertainties in the Isotopic Quantities

DOE states in section 4.2.1 of the WCPIP that the reported value for each of the above methods will indicate the related uncertainty of the measurements. The quantification will include documentation that establishes the basis for the calculation of isotopic distributions. EPA expects each method used by DOE to include a description of the method used to calculate the total uncertainty for the method. EPA will evaluate these methods and their implementation as part of the inspection program.

Determination of RH Waste

DOE proposes to use the surface dose rate method for this determination, as described in section 4.2.4, stating "Payload container dose rates must be measured and reported using calibrated field instruments that meet calibration tolerances defined by the manufacturer."

Characterization Methodologies Common to the CH Program

Non-Destructive Assay

DOE proposes in section 4.1.5.1 of the WCPIP a Non-Destructive Assay (NDA) method that is essentially identical to that used in the CH program. EPA has examined this proposed program, and has identified only one significant difference between the RH NDA program and the CH NDA program. This difference is caused by the RH program not requiring NDA instruments to participate in an inter-site comparison program such as the Performance Demonstration Program required for CH NDA instruments. EPA does not consider this difference to be of significance, since so few RH sites are expected to opt for NDA as the primary methods for assessing radiological contents of RH waste containers that such a program would be of limited value.

Characterization Methodologies Unique to the RH Proposal

10-10-All Approach

In Section 4.6.4.2 of the WCPIP, DOE proposes the following unique use of visual examination:

Visual Examination

> For RH TRU waste that requires packaging or repackaging, 100 percent of the waste will be subjected to VE in accordance with the requirements of Section 4.1.2. A subpopulation of those RH TRU wastes that are already packaged in payload containers may be subjected to VE (or radiography). A minimum of 10 percent of the packaged waste will be subjected

to VE (or radiography). If the physical form of the waste does not match the waste stream description (including the packaging configuration) in this subpopulation, an additional 10 percent of the packaged waste will be subject to VE (or radiography). If additional waste is identified that does not match the waste stream description (including the packaging configuration) in this second subpopulation, the entire waste stream must be subjected to VE (or radiography). This is referred to as 10-10-All. When implementing the 10-10-All method, VE shall be performed in accordance with Section 4.1.2 and radiography shall be performed in accordance with Section 4.1.4. If the generator site requires other waste characteristics to be determined, (e.g., fill percentage, primary container contents, or other matrix information) in order to implement NDA or DTC, these characteristics will be evaluated as part of the waste stream description when implementing the 10-10-All method

EPA has reviewed this use of VE process, noting that it does not comport with the use of VE in the CH program whereby VE is used to examine each container if radiography is not used, and whereby the miscertification rate with respect to identification of prohibited items by radiography is determined by using statistically selected containers for visual examination of the waste. EPA believes that because nearly all RH waste (approximately 95% of all RH waste at DOE sites) will be repackaged the waste would be visually examined as being packaged and the site would confirm the waste stream as identified by AK. DOE would apply the proposed 10-10-All process to that limited portion of waste for which it is proposed (already packaged RH waste), as it will capture waste stream information without the need to re-open RH containers, which could prove difficult to achieve depending upon the packaging configuration.

Dose to Curie

DOE has proposed, in section 4.1.3 of the WCPIP, a method for determining the radiological content of a canister referred to as Dose-To-Curie, or DTC. DOE contends that this can be used to establish isotopic activity, total activity, and activity per canister, when used in conjunction with adequate AK information.

DOE describes the DTC method in section 4.1.3 as follows:

"The DTC method uses a standard profile of the waste to relate the quantity of gamma-emitting radionuclides to the activities in the waste. DTC conversions are based on a dose rate measurement taken with calibrated instrumentation. The measurement is associated with documented isotopic distributions within the waste through the use of empirically developed conversion factors. The external dose rate can be correlated to the activity in the container, such as ^{137}Cs, by taking into account such factors as matrix and container geometry. The calculated ^{137}Cs activity is then correlated to other radionuclides by scaling or conversion factors. The radionuclide conversion factor derivation shall be documented. For some RH TRU wastes, the distribution can be calculated based on fuel characteristics, sampling, and computer modeling (from a program such as ORIGEN). Sites will confirm AK information related to radionuclide distribution derived from modeling, by sampling and analysis (see the Representativeness QAO). Acceptable knowledge information that was obtained by previous sampling and analysis may be qualified in accordance with the requirements of Section 4.3 of the WCPIP.

When smears, swipes, or material samples are used for determining radionuclide distribution, the generator site must demonstrate that sampling does not bias the results (i.e., removable contamination has similar radionuclide distribution when compared to fixed contamination). The

assumption will be that the radioactive source material is the same for each waste stream or waste stream lot. This assumption is expected to be valid for most sites where the processes that generate RH TRU waste involved studies of reactor fuel specimens. At sites where the sources varied, the assumption may not be valid and, as a result, greater sampling may be needed to represent the waste stream. When sites designate waste streams, they will be required to determine the applicability of the DTC method and the sampling and analysis required to determine conversion factors.

The use of this technique is well-established in the commercial power industry to characterize and classify wastes that are difficult to measure, such as dry active waste. In this application, surrogate samples such as floor smears are used.[1] Typically, two relationships must be established to use the DTC method: the radionuclide distribution anticipated within the waste and the relationship between the measured radionuclide (usually ^{137}Cs) and its concentration within the container. Obtaining these relationships (also referred to as scaling factors or conversion factors) can be problematic if it requires extensive sampling and analysis of radionuclides. Fortunately, the limited nature of RH TRU waste, in terms of its sources, facilitates the calculation of radionuclide distributions based on the characteristics of the waste, the reactor operation, and the waste-generating process. Such modeling calculations, when coupled with sampling programs, can establish the conversion factors. Modeling used to implement DTC method shall be documented in a technical report by the generator site. The technical report shall be reviewed and approved as a controlled document under the generator site QA program. The technical report will contain a quantitative description of the compliance of the model(s) with the QAOs listed in Section 2.2.4. The guidance in EPA QA/G-5M, *Guidance for Quality Assurance Project Plans for Modeling*, shall be used in developing the models used to implement DTC. All software used to implement DTC models will be managed in accordance with the software QA requirements described in the CBFO QAPD."

Additional procedural descriptions of the method are provided in Attachments B and C of the WCPIP.

As an overall procedure, DTC uses a profile of the waste to relate a dose rate measurement performed on the outside of the container to the activities of all isotopes of interest in the waste. This profile is developed using AK information, modeling, radiochemical analysis, NDA, or some combination of these. The results of the DTC method are individual isotope activities in the RH canister. If sufficient modeling information is available, then the isotopic results can provide total canister activity, TRU activity, and activity concentration in the canister. The DTC method is scalable to any size canister, being limited more by the quality of information available for use as modeling inputs than by physical container characteristics.

Implementing the DTC method typically involves two tasks, development of the isotopic profile in the waste and calculation of the relationship between the measured dose rate external to the RH waste container and the activities of the gamma-emitting isotopes in the waste. Both of these steps must demonstrate that the activities involved are performed in accordance with EPA requirements.

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[1] See for example EPRI Report TR-107201, "Low Level Waste Characterization Guidelines." A description of this report is available at the EPRI Website at www.epri.com.

Profile development involves calculating the relative activities of the isotopes of interest in the waste, including any isotopes that may contribute to the dose rate measured external to the container. The isotopic profile is typically developed using a combination of modeling or radiochemistry combined with AK information. Modeling activities are often used when the waste is derived from spent fuel; if the fuel history is known from AK, then codes such as ORIGEN2 may be used to calculate activities for the isotopes of interest. DOE is responsible under the RH program for ensuring that all modeling activities are performed using qualified software, that the modeling code inputs meet predefined data quality objectives, and that the results of the modeling process meet all applicable QAOs. Sites will confirm AK information related to radionuclide distribution derived from modeling, by sampling and analysis in order to meet the Representativeness QAO.

In other cases, particularly when activation products may be in the waste, direct sampling and/or radiochemistry analysis may be used to develop the isotopic profile. When smears, swipes, or material samples are used for determining radionuclide distribution, DOE must demonstrate that sampling does not bias the results, and that sampling is complete and comprehensive with respect to the waste intended for disposal at the WIPP. When sites designate waste streams, they will be required to determine the applicability of the DTC method and the sampling and analysis required to determine conversion factors.

Determining the relationship between the measured dose rate and the gamma source inside the waste container also involves extensive modeling. The shielding calculations require more than just information regarding the isotopic content of the waste; the waste matrix properties, spatial distributions of the gamma-emitting isotopes, the design of the container itself, and the characteristics of the measurement instrument all must be accounted for in the modeling. Similarly to developing the isotopic profile, the dose rate-to-source calculations performed in this step may rely on AK or other data for input. DOE must again show how the input data meets the applicable data quality objectives, and that the modeling is performed using qualified codes and methods.

DOE must document the modeling used to implement the DTC method for all waste streams. The documentation will contain a quantitative description of the compliance of the modeling activities with the QAOs listed in Section 2.2.4. The guidance in EPA QA/G-5M, *Guidance for Quality Assurance Project Plans for Modeling*, shall be used in developing the modeling plans used to implement DTC. All reports describing the DTC method shall be reviewed and approved as a controlled document under the generator site QA program, where it will be available for review by EPA inspectors. All software used to implement DTC models will be managed in accordance with the software QA requirements described in 40 CFR Part 194.22.

EPA has examined DOE's proposed method for DTC and has also observed an initial implementation of the method at LANL, and believes that the method can in principal produce results that meet EPA's characterization requirements. EPA understands that each implementation of the DTC method will be unique to the site and waste stream in question, as the quality and content of historical information will significantly vary. EPA will examine each activity in the DTC method used at a site to verify that DOE has properly calculated Total Uncertainty, including how input uncertainties in modeling affect the model results through sensitivity and uncertainty analysis.

Destructive Assay

The WCPIP provides generalized requirements for Destructive Assay (DA) sampling and analytical process. The purpose of obtaining DA results is to obtain container-specific radionuclide concentrations by using DA results directly or to provide isotopic ratios that can be used in DTC modeling calculations. The objective of the DA process is therefore comparable to the objective of the NDA process. It is important for purposes of data comparability that the DA processes have the same level of data confidence and quality as the NDA process. The majority of the NDA data quality requirements have also been identified in the DA process. However, the WCPIP does not specify a lower level of detection (LLD) of 100 nCi/g as does the NDA and DTC methodologies. If DA results are used either in DTC calculations or as "stand-alone" results for purposes of radiological characterization, it is necessary that the same 100 nCi/g minimum LLD is applied to the DA analyses.

The WCPIP does not include requirements regarding DA measurement uncertainty, calibration requirements, and background determination. Consequently, EPA's process to review and approve program or site specific implementation of DA activities may include examination of requirements and criteria not included in this WCPIP. Specifically, EPA will assess initial and continuing calibration requirements, background determination requirements, criteria for reporting and use of uncertainty in DA measurements. In the absence of specific criteria in the WCPIP, EPA will assess this information on a site-by-site basis, and EPA will also ensure that this determination was implemented reasonably consistently between sites. EPA review and approval of site-specific Detailed Assessment Plans and Confirmatory Testing Plans would be necessary prior to a site initiating RH waste characterization using DA.

The WCPIP contains criteria for method blanks in Table 4-3 that indicate that site-specific statistical procedures will be used to assess method blanks. The WCPIP does not clarify what statistical method will be used to assess method blanks for DA. The site documents will have to specify a procedure to assess method blanks. Typically, in the radiochemical community, method blanks are assessed and used in data validation/assessment based upon the relative concentration of blanks that exceed the blanks specific minimum detectible concentration (MDC) to the associated samples. Additionally, accuracy and precision control limits provided in Table 4-3 of the WCPIP could not be verified through referenced literature, statistical considerations, study data, or from limits derived from similar analytical methods.

b. Proposed Methods with Respect to AK Process Summary §194.24(c)(3)

As stated in the EPA Compliance Application Guidance (CAG) (p. 31), EPA expected the compliance application to:

- Provide information, including standardized guidance or directives, training documents, etc., used in connection with control of the use of process knowledge.

- Cite (and make available for field review) 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.

- Provide an implementation plan for application of quality assurance requirements to process knowledge at remaining sites.

EPA evaluated each of these requirements with respect to the RH Proposal.

Provision of Standardized Guidance, Training Documents, etc.

With respect to provision of information regarding standardized guidance or directives, training, etc., DOE provided Attachment A, *Acceptable Knowledge Procedure for Remote Handled TRU Waste.* As discussed below, we believe that provision of this Attachment meets the requirements under 40 CFR 194.24(c)(3) and that DOE provides a standardized approach to collecting and assessing acceptable knowledge (process knowledge) information related to the AK element of the RH waste characterization program.

The AK Procedures provided by DOE describes the process for the identification, compilation, documentation, qualification and reconciliation of AK for RH waste to be disposed of at the WIPP. The procedure first outlines the responsibilities of various personnel involved with AK, including "AK personnel" who assemble data, compile data, resolve discrepancies, etc. The Site Project Manager (SPM) reviews AK source document summaries for source documents listed on the source document reference list to ensure adequacy of AK information, reviews results of the qualification of AK data, documents AK reconciliation of confirmation vs. the AK record, and reviews and approves the AK Summary Report. The SPM takes responsibility for determining whether the AK record is adequate, and what additional information would need to be gathered, if it is not included in the AK record. The SPM is also responsible for the adequacy of the overall characterization process and the completion of the Waste Stream Profile Form. The Site Project Quality Assurance (SPQA) Officer ensures that all required data reviews have been performed and documented, reviews the AK Summary Report to assess compliance with the WCPIP, and prepares the AK Accuracy report (see WCPIP Section 4.1.1.2).

The AK Procedure then specifies training that all generator/storage site personnel involved with the characterization of the RH TRU waste via AK must undergo. These personnel must be training to the WCPIP, Attachment A, and other relevant regulatory and technical documents.

The AK process begins with the compilation of AK documentation, requiring that sites "Research relevant information to support characterization of the RH TRU waste stream." It also requires personnel that are responsible for characterization of the RH TRU waste stream(s) of interest be involved in the process of AK compilation to ensure that adequate AK information is compiled. A listing of AK source information is then presented which includes databases, unpublished data, etc. Note that this AK procedure does not distinguish between mandatory and supplemental information as the CH program requires; instead, the procedure requires that adequate AK data be collected to satisfy DQOs with the acceptability of this information assessed on audit.

The DOE's AK procedure says that "information as compiled should include as much <u>container-specific</u> information as is available such as radionuclide, waste material parameter data and the presence of prohibited items from waste container input forms, data sheets, or logbooks." EPA believes this requirement is critical, container-specific data must be assembled for each container

in a waste stream when AK is used as the sole characterization methodology. The AK procedure then addresses the use of correlating data between sites and the use of surrogates. While EPA has no immediate objection to using this approach, its applicability, use, etc. will be scrutinized for acceptability by EPA during audits. Sites must justify all surrogate and correlation data uses; these must also be addressed in the AK Summary Report. EPA is cautious of this data use, because our inspection experience has shown that the only acceptable correlation seen to date may be where waste generated at one site is shipped to another for storage with no further processing of waste in containers prior to characterization. Processes between sites can be quite different, and any use, for example, of isotopic distribution data for one site is likely not applicable to other sites except as stated above.

The AK procedure then requires sites to "Identify the source documents and records that will be used in the process of compiling the AK record to assist in characterizing the waste, assign them a number unique to the site and list them on the AK Source Document Reference List.... "and to also a "... source document summary shall be developed for each source document (or interview) that provides a summary of the relevant information in the AK source document. Limitations of the information in the AK source document shall be listed on the AK source document summary. The AK Source Document Summaries and the AK Source Document Reference List shall be maintained in an auditable file and reviewed and updated as necessary."

Sites must also identify and resolve any AK data discrepancies and place this resolution in the auditable record. DOE has committed to assigning the "most conservative characteristics" to the waste stream when discrepancies arise, but EPA is concerned that this could lead to simply assuming, for example, any and all radionuclides could be present without a concerted effort to understanding or obtaining representative data. EPA will evaluate the use of most conservative characteristics during inspections. DOE also states "If discrepancies in the AK record cannot be resolved or if the resolution results in failure to meet a DQO, the waste cannot be approved for shipment to the WIPP without further evaluation." We agree with this statement and will verify its application during EPA site inspections.

Following review of the AK documentation, the DOE procedure requires AK personnel to delineate a waste stream consisting of waste material generated from a single process or activity, or waste with similar physical and radiological properties. Appropriate delineation of the waste stream is a critical component of the characterization process, and shall be assessed for adequacy by EPA during inspections. AK personnel must examine the compiled information to determine whether this information shows compliance with each of the RH DQOs. DOE states (Section 6.2) that "If there is insufficient AK information to address each of the DQOs, the sites shall collect additional AK."

EPA recognizes that "additional AK" could mean any type of information, including measurement data. EPA, therefore, requires that when "additional AK" is collected involving measurements, that this process be documented in relevant test plans or other documents and that these documents be provided to EPA for review and approval prior to implementation. DOE states "For each of the DQOs listed in the report, the AK personnel must clearly identify the DQO and supporting AK information, justify the assignments/conclusions, reference the AK source documents and applicable pages supporting the assignments/conclusions, and indicate by which method of 40 CFR §194.22(b) these AK data are being qualified (if applicable). Information used to establish compliance with a DQO, with the exception of the defense waste determination, *must be qualified* [emphasis added] in accordance with Section 4.3 of the WCPIP,

or qualified by confirmatory testing using the characterization methods described in Section 4.1 of the WCPIP."

DQO-specific review parameters are then presented, including those for defense generation and nuclear properties (that is, TRU activity of the waste stream greater than 100 nCi/g of waste; is this TRU waste; dose equivalent rate equal to or greater than 200 mrem/hr and less than 1,000 rem/hr at the surface of the payload container). The procedure requires sites to report activity of the 10 WIPP-tracked radionuclides (TRU isotopes ^{238}Pu, ^{239}Pu, ^{240}Pu, ^{242}Pu, and ^{241}Am; and non-TRU isotopes ^{137}Cs, ^{90}Sr, ^{233}U, ^{234}U, and ^{238}U), and total activity in each canister (must be less than 23 curies per liter). DOE explicitly states that if the waste is not defense, TRU, or RH, it will be "reassigned", but that the "defense determination will be made on an entire waste stream." This is appropriate delineation of waste streams, and EPA will examine the waste stream designations to determine whether "non defense" waste are part of a waste and whether available information allows the differentiation of the non defense component.

DOE indicates that data collected as part of a qualified program or prior to a qualified program (if subsequently qualified) may be used. This would result in the use of highly variable information when characterizing a waste stream and AK personnel could require expertise in the areas of not only AK but also NDA, DTC, and DA methods used to qualify AK or collect radiological data to substantiate AK-derived isotopic information for 10 WIPP-tracked radionuclides. EPA cautions that even if data are qualified in accordance with 40 CFR 194.22 with respect to performance of a Peer Review or Equivalent QA program demonstration, EPA will still evaluate the data used for technical adequacy. DOE states that "additional radionuclide information, if collected by a CBFO- and EPA-approved technique, could be used without further qualification to supplement the characterization process". Method(s) used to collect additional data requires EPA approval prior to its implementation.

DOE states that AK personnel review source document information to determine the physical form with respect to Summary Waste Category Group (S3000, S4000, S5000). EPA requires that this analysis also specifically include the examination of source documentation for physical description of waste streams, as the type of material within, for example, the S5000 category can be highly variable and indicative of different waste generating processes. This is echoed by DOE "AK personnel shall also compile sufficient information regarding the waste stream waste material parameters to provide a detailed description of the waste stream in accordance with the format of the AK Summary Report."

DOE requires that AK personnel review AK information to "determine the absence of residual liquids". EPA regulations require that residual liquids must be less than 1 percent by volume of the waste container. EPA's CH experience has been that AK records do not adequately and definitively "determine the absence of residual liquids". Under the CH program since all containers undergo RTR, a discussion of the lack residual liquids in the AK record is not that critical. In the case of RH program, however, EPA expects AK records to discuss the absence of residual liquids upon its assessment during NDE.

AK personnel are required to prepare an AK Summary Report following a specified format (Attachment 1 in the WCPIP). EPA does not specify the report format, but does require that all of the report contents be included DOE states that "AK personnel will provide a <u>detailed</u> description of the waste stream including information on, for example, specific waste matrix materials and fill volumes. The report shall address all of the DQOs as noted in previous steps

with appropriate justifications and references in the text". EPA will examine the record to ensure that information critical to applicable regulatory requirements are included and are adequately supported and referenced.

DOE then requires that "AK personnel send the completed AK Waste Summary Report, AK Source Document Reference List, Correlation and Surrogate Summary Form, AK discrepancy resolution documentation and the AK source document summaries to the SPM for review...AK personnel recommend to the SPM the process(es) for the qualification of the AK information based on an assessment of which are most appropriate for the type of AK information complied."

Specific to qualification of AK data, DOE states that "Information compiled into the AK record and applied in the AK Summary Report to RH Characterization DQOs *may* be qualified by one or more of the four processes listed in 40 CFR 194.22(b)." EPA interprets this to mean that DOE may choose not to qualify AK data, and may obtain the DQO information following an alternative data acquisition route. If a site chooses not to qualify AK data and opt to take an alternate data acquisition approach, the site must notify EPA of this decision, and provide relevant test plans prior to implementation for EPA review and approval. The only time that such additional plans or documents are not required are if sites implement 100% NDA or NDE of RH waste container in the same technical manner as performed for CH waste. EPA will review procedures prior to/during inspections as is currently performed.

Reconciliation of the AK record is the responsibility of the SPM, who reviews the AK Summary Report, AK Source Document Reference List, Correlation and Surrogate Summary Forms, the referenced source document summaries, if applicable, batch data reports from any confirmatory activities such as VE or NDA and, if applicable, supplemental data collected during repackaging using an approved technique, to determine if the AK record is reconciled and is adequate to characterize the waste stream or waste stream lot and satisfy the relevant DQOs. DOE states that "Discrepancies between the AK record and confirmatory test results identified during this reconciliation process must be resolved and documented. The discrepancy resolution process may involve a reevaluation of the AK record, reassignment of waste stream parameters and a revision to the AK Summary Report." The SQAO then reviews the AK Summary Report, confirmatory test data and identified AK discrepancies, and prepare an AK Accuracy Report. DOE states that the AK Accuracy Report "will identify the percentage of containers that have been assigned to another SCG. It will also identify the percentage of containers for which there are significant discrepancies in radionuclide information between the AK record and measured values. What constitutes a significant discrepancy will depend on site- and waste stream-specific considerations. The AK Accuracy Report will be updated annually. If AK accuracy falls below 90%, the site shall document this as a significant condition adverse to quality as defined by the CBFO QAPD." EPA recognizes that AK Accuracy could require site-specific considerations, but we also expect that "significant discrepancies" will be defined in detail by sites in a quantitative fashion.

The SPM also reviews the qualified AK characterization information and the corresponding required DQOs and documents this review in an RH TRU waste AK Characterization Reconciliation Report (CRR). DOE states that, at a minimum, the CRR shall include:

- Specification of applicable site and waste stream.
- A listing of each DQO

- Data from the AK record that addresses each DQO
- AK source document references that support/provide the data
- A listing of AK record discrepancy resolutions, if any, that are relevant to each DQO
- Documentation, including specific references, of how the AK data for each DQO were qualified, such as batch data reports, corroborative data, proceedings of a peer review, etc.
- Radiography and/or visual examination summary to document that liquids greater than 1 percent are absent from the waste and to confirm AK concerning the physical properties of the waste.
- A summary presentation of radiological measurement data used to meet the DQOs and to confirm AK
- A complete AK summary
- A complete listing of all container identification numbers used to generate the WSPF, cross-referenced to each batch data report.
- A listing of AK discrepancies generated by an AK qualification process and the corresponding resolutions
- Signature of the SPM

In addition to the items listed above, additional information could become necessary based on site-specific considerations and inspection results. DOE also states that "the SPM also verifies that the applicable QAOs (accuracy, completeness, representativeness, and comparability) associated with the AK process have been met. Changes to the AK Summary Report and attachments based upon this review will be reviewed by AK personnel and properly documented." DOE states that the SPM is responsible for completion of the Waste Stream Profile Form, and that the WSPF, the RH AK Summary Report and the Characterization Reconciliation Report, resulting from waste characterization activities, shall be transmitted to the Department of Energy Carlsbad Field Office (DOE/CBFO). Also, only RH TRU waste that is characterized in accordance with the EPA requirements and the WCPIP will be disposed of at the WIPP.

EPA requires that the site concurrently send to EPA same information provided in the CBFO package for informational purposes, and EPA may comment on this information. During inspections, EPA will review these documents as part of the AK record leading to approval of sites' RH waste characterization program and waste streams.

Objective Evidence Substantiating the Degree of Implementation of Quality Assurance

This Technical Support Document does not address the adequacy of the DOE's quality assurance (QA) program, nor does this document approve the DOE's QA program. EPA QA program staff will evaluate the adequacy of RH sites' QA programs separately and will follow the process used for the CH program. The following are provided simply to show that DOE has included implementation of QA in its WCPIP, thus satisfying only the aspect of the objective evidence of a QA program.

DOE states, in the WCPIP, that "Before characterizing waste for shipment to the WIPP,

generator sites must establish a QA program governing waste characterization activities that meet the requirements of the DOE/CBFO QAPD. This QA program must be reviewed and approved by CBFO. The QAPD is the quality management document that identifies federal, state, and industry quality requirements applicable to CBFO programs. The QAPD specifically establishes the QA program requirements applicable to this RH TRU waste characterization program, as specified in 40 CFR §194.22." In Section 3.2, the WCPIP presents the RH TRU waste characterization program that includes a hierarchy of documents that will guide and control characterization activities and QA activities. Figure 2 shows the hierarchy and relationship of program QA documents. Each site's program documentation shall identify the organizations and positions responsible for their QA implementation and reference site-specific documentation that details how each of the required elements of the program will be performed. The TRU waste site QA program shall be described in an RH TRU Waste Certification Plan for 40 CFR Part 194 Compliance that shall be approved by the CBFO prior to the certification of any RH TRU waste from the TRU waste site. The required QA plan shall be approved by the CBFO and may be incorporated into the Certification Plan. Likewise, either or both plans may be incorporated as separate and distinct sections in existing TRU Waste Certification Plans and QA plans if deemed appropriate by the participating TRU waste site.

DOE also plans to perform assessment and oversight activities. Section 3.3 states that "specific assessment actions will be taken during the program to ensure all parties are adhering to the requirements of this WCPIP. These actions include periodic audits as well as management and independent assessments conducted in accordance with the QAPD, the details of which shall be specified in the program documentation. Corrective actions shall be taken when conditions adverse to quality are identified. The results of these actions will be summarized in semiannual reports, nonconformance reports, and audit reports. Through this system of assessment and response, overall quality improvement of the program will be realized. Audits shall include management and technical aspects of the program outlined in this WCPIP and in site program documentation. In addition to audits, management and independent assessments shall be regularly performed. The goal of these assessments is to improve overall program quality by focusing on management systems and work processes."

DOE further states that "Corrective actions shall be taken if any condition adverse to quality is detected during an audit or assessment. The cause of any adverse condition, identified by any means, that affects compliance with the Quality Assurance/Quality Control (**QA/QC**) requirements specified in this WCPIP shall be promptly determined and action taken to preclude its recurrence. The identification, cause, and corrective actions for conditions not complying with the quality requirements for the program must be documented and reported to appropriate levels of management." Certification audits shall be performed "at least annually thereafter [the initial certification audit], including the possibility of unannounced (not regularly scheduled) audits. These audits verify that the generator site has implemented a QA program for all certification activities. After approval of the generator site's program documents, EPA will perform an audit or an inspection of a CBFO audit of the generator site to verify a QA program and a waste characterization program have been properly implemented. These activities are performed in accordance with the requirements of 40 CFR 194.8. EPA may perform additional audits of the generator sites, under the authority of 40 CFR 194.8, 194.22 and 194.24, to verify continued compliance with the QA and technical requirements for waste characterization."

Section 3.5.2.2 of the WCPIP addresses nonconformances, which states that "the status of work and the WCPIP activities at participating TRU waste sites shall be monitored and controlled by

the SPM and Site Project QA Officer (**SPQAO**). This monitoring and control shall include nonconformance identification, documentation, and reporting... Nonconformances are uncontrolled and unapproved deviations from an approved plan or procedure. Nonconforming items and activities are those that do not meet the WCPIP requirements, procurement document criteria, or approved work procedures. Nonconforming items shall be identified by marking, tagging, or segregating. Participating TRU waste sites shall reconcile and correct nonconforming items as appropriate in accordance with the CBFO QAPD. Disposition of nonconforming items shall be identified and documented. The TRU waste site SOPs shall identify the person(s) responsible for evaluating and dispositioning nonconforming items." Additional requirements pertaining to nonconformance resolution and disposition are also provided, including report requirements and responsibilities. The WCPIP states "For any non-administrative nonconformance related to applicable requirements specified in this WCPIP that is first identified during reconciliation of DQOs and QAOs at the site project level, the CBFO shall receive written notification within five calendar days of identification and shall also receive a nonconformance report within 30 calendar days of identification. The site must implement a corrective action to remedy the nonconformance prior to management, storage, or disposal of the affected waste at the WIPP."

Implementation Plan for Application of Quality Assurance Requirements to Acceptable (Process) Knowledge

Section 4.3 of the WCPIP addresses specifically qualification of AK information. This section states "There may be some RH TRU waste streams for which detailed characterization information exists that was generated prior to the generator site establishing an approved QA program that implements the requirements of the CBFO QAPD. The CBFO QAPD incorporates the EPA-required QA elements from ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1) as required by 40 CFR §194.22. A QA program meeting these requirements must be applied to waste characterization activities performed under this WCPIP. 40CFR §194.22 also allows qualification of information collected prior to the establishment of a compliant QA program. The information may be qualified by one or a combination of the following four methods:

- Peer review, conducted in a manner compatible with NUREG-1297, *Peer Review for High-Level Nuclear Waste Repositories*, February 1988
- Corroborating data
- Confirmatory testing
- Evidence of a QA program that is equivalent in effect to ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1)."

Section 4.3 goes on to state that "For all qualification methods, the following requirements apply:

The qualification process shall be conducted in accordance with approved procedures that provide for documentation of the decision process, the factors used in arriving at the choice of the qualification method, and the decision that the data are qualified for their intended use. Factors to be considered include:

- qualifications of personnel or organizations generating the data
- technical adequacy of the equipment and procedures used to collect and analyze the data
- environmental conditions under which the data were obtained (if germane)
- quality and reliability of the measurement control program under which the data were generated
- extent to which data demonstrate properties of interest (e.g., physical, chemical, or radiological)
- extent to which conditions generating the data may partially meet requirements of the ASME NQA-1-1989 edition, ASME NQA-2a-1990 addenda, part 2.7, of ASME NQA-2-1989 edition, and ASME NQA-3-1989 edition (excluding Section 2.1 (b) and (c) and Section 17.1).
- prior uses of the data and associated verification processes
- prior peer or other professional reviews of data and their results
- extent and reliability of the documentation associated with the data
- extent and quality of corroborating data or confirmatory testing results
- degree to which data generating processes where independently audited"

The WCPIP then provides implementation requirements for Peer Review (Section 4.3.1), Confirmatory Testing (Section 4.3.3), and Equivalent QA Program (Section 4.3.4). With respect to corroborating data, the WCPIP states in Section 4.3.2 that "At this time, the use of corroborating data is not approved by CBFO for qualification of AK information as waste characterization data. Generator sites may propose to use corroborating data as a method of data qualification. The use of corroborating data will require revision of this WCPIP and approval of CBFO and EPA prior to shipment to the WIPP of waste characterized using this method." Also, with respect to confirmatory testing, DOE states the following:

"....Confirmation methods include:

- 100 percent VE at the time of packaging
- 10-10-All
- obtaining a representative number of samples from the waste stream or waste stream lot to confirm AK on isotopic distribution
- 100% NDA
- DA
- DTC

If a generator site proposes to qualify AK information by means of confirmatory testing other than that described in Section 4.1, the requirements of Section 4.3 apply. Confirmatory testing methods that could be proposed include, but are not limited to:

- Qualification of existing VE or radiography audio/videotapes by the review of a percentage of the tapes by qualified operators

- Qualification of existing radiological characterization data by analyzing representative samples of the waste
- Qualification of existing waste container packaging records by VE or radiography of a representative subpopulation of the waste
- Qualification of existing radiological sampling and analytical information by the use of confirmatory modeling (e.g., ORIGEN)
- Generator sites that propose to use confirmatory testing to qualify AK information as characterization data must submit a confirmatory testing plan to CBFO for review and approval."

EPA requires that all confirmatory approaches be presented in appropriate Confirmatory Testing Plans or other similar documentation, and that the only time such a plan need not be prepared is when 100% NDE/NDA is being performed as per the current CH program. EPA believes that the information presented in Section 4.3 shows a commitment by DOE to qualify AK data as required by EPA.

c. Proposal Methods with Respect to System of Control Requirements §194.24(c)(4)

EPA expected the RH proposal to: describe the system for maintaining centralized control over the waste characterization activities; describe the mechanism for maintaining chain of custody over waste and waste records; describe controls currently in place for receipt of waste at the WIPP; describe the record keeping/accounting system for controlling limited waste components for verification of emplacement of waste; and provide the current WIPP Waste Acceptance Criteria (WIPP WAC) document and identify all (WIPP WAC) requirements or controls that are relevant to compliance with 40 CFR Part 194.

The WCPIP includes requirements for measurement, sampling and analysis, as well as documentation, assessments and oversight, and data management and tracking (see Section II, above). These systems, as summarized in Section II, are not repeated herein. However, note that there is no RH-WAC equivalent to the CH-WAC, with the WCPIP serving as the single programmatic RH baseline document.

The WCPIP provides information pertaining to documentation, assessment and oversight, and data management, tracking, and control. Also, there are certain elements of the CH program, namely the WIPP Waste Information System (WWIS) that shall be maintained and used in the RH system as it is being used under the CH program. (For details, refer to EPA's CARD 24 for detailed discussion of the WWIS and EPA's expectations and requirements of this system.) For elements common to the CH program that are not detailed in the WCPIP, EPA shall assume that that the requirements and standards set forth under the CH program shall continue under the RH program, unless EPA approval of the modification is sought and acquired.

DOE identified 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 identified four important waste components that must be tracked because limits were required for compliance (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.

- Nonferrous metals (metals other than iron)—minimum of $2x10^3$ kilograms

The WWIS is a computerized data management system used by the WIPP to gather, store, and process information pertaining to TRU waste. The WWIS collects information into one source and provides data in a uniform format whose accuracy is verifiable. The WWIS is used to store all information pertaining to characterization, certification, and emplacement of waste at the WIPP. It has features such as automatic limit, range and QA checks, automatic report generation, and the ability to track compliance with 40 CFR part 194.24 requirements. With respect to the WWIS, EPA shall assess each element requiring tracking at RH sites to ensure that adequate data manipulation and input occurs with respect to the WWIS. Similarly, EPA shall audit the software quality assurance for the WWIS system itself to verify that the program complies with the regulatory requirements for software control defined in 40 CFR 194.22. EPA also expect the WWIS to continue to track waste components and associated uncertainties against their upper and lower limits and provides notification before the waste component limits are exceeded, in accordance with 40 CFR parts 194.24(e)(1) and (2) for RH waste. The records contained within the WWIS will be reviewed periodically by DOE management and to track performance against the established limits. EPA will receive this information on an annual basis through DOE's Annual Change Reports. Additionally, the emplaced inventory will receive close scrutiny during any EPA audit/inspection or recertification.

The CCA (Chapter 4.3.2 (pp. 4-36 and 4-39)) stated that there are 130 data fields associated with the WWIS and referenced Appendix WAP, Appendix C13, for this information. The WCPIP indicates no changes to these fields for RH waste and therefore, EPA assumes that these data fields will remain applicable to tracking of RH waste emplacement and inventory, and that DOE will immediately notify EPA of any changes to these fields pertinent to RH waste. The CCA lists the following data fields (including waste material parameters) as relevant to compliance:

- Assay date

- Disposal date

- Nondestructive examination

- ^{239}Pu fissile gram équivalent

- Radionuclide activity

- 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 Material Parameters (WMPs)
- Waste Matrix Code (WMC).

The CCA referred to the WWIS Software Design Document (**SSD**) (DOE 1997i) in Chapter 4.3.2. The WWIS SDD communicates software design information about the system's application software by relating requirements for implementation to a description of software structure, components, interfaces and data. 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. 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. EPA requires that this document (latest version) shall be maintained and used with respect to the WWIS.

The proposal included the WIPP WAC (DOE 1996c) as a reference to the CCA and identified the container-based limits imposed by the WAC, as well as the waste characterization requirements detailed in the WAC (Chapter 4.2.3, pp. 4-30 to 4-34, and Chapter 4.4, pp. 4-44 to 4-49). Chapter 4.2.3 of the WCPIP summarizes the container-based limits imposed by the WIPP WAC in Table 4-12, including limitations on fissile gram equivalents per 55 gallon container, limitations on ^{239}Pu equivalent activity, waste container surface dose rates, RH waste thermal power, RH waste curies per liter, liquid in waste, explosives, compressed gas, pyrophoric materials, and polychlorinated biphenyls (PCBs). With respect to RH waste, there is no RH WAC, and therefore DOE has included RH-specific waste acceptance criteria in the WCPIP. Should the DOE develop an RH WAC in the future, EPA will require this document for review and approval should components important to EPA compliance be included.

C. EPA's Review of the WCPIP

Based on the regulatory requirements presented in 40 CFR 194.24(c)(2) to (4) and 194.22(a)(1) and using experience gained as part of the CH waste characterization program, EPA examined the DOE's RH Waste Characterization Proposal as presented in the WCPIP. EPA sought to understand DOE's intended RH waste characterization process, and specifically whether the proposed methods outside of the current CH program were acceptable as proposed.

Tables III.C.1 and III.C.2 present a comparison of the RH and CH characterization elements, which show commonalities and differences between the two programs. For CH waste, AK provides a basis upon which waste streams were designated, radionuclide isotopic distributions were obtained, general physical characteristics of wastes were determined, etc., but the EPA rule always required measurement data, not allowing AK alone to determine critical waste characteristics and components (although AK did provide, in some instances, critical inputs such as isotopic distributions). Under the CH program, sites perform 100% radioassay of each CH TRU drum, and also visually examined or radiographed each drum. Under the proposed RH program, sites would rely more heavily on the AK information and would confirm AK by measurement of <100% waste containers, Peer Review, or QA equivalency determination. DOE is not proposing the use of corroborating data as an option for AK confirmation.

Table III.C.1 Overview of CH TRU and RH TRU Characterization Program

Characterization Objectives	Waste Type	PACKAGED WASTE		WASTE REQUIRING PACKAGING	
		Characterization Method	Confirmation Method	Characterization Method	Confirmation Method
DEFENSE DETERMINATION	RH TRU	AK	Approved AK Program	AK	Approved AK Program
	CH TRU	AK	Approved AK Program	AK	Approved AK Program
RADIOLOGICAL PROPERTIES					
RH vs. CH DETERMINATION	RH TRU	Surface Dose Rate under an EPA approved program	None	Surface Dose Rate under an EPA approved program	None
	CH TRU	Surface Dose Rate under an EPA approved program	None	Surface Dose Rate under an EPA approved program	None
ACTIVITY[2]	RH TRU	AK, DTC, DA, or NDA	AK must be qualified under 40 CFR §194.22(b) or determined by assay	AK, DTC, DA, or NDA	AK must be qualified under 40 CFR §194.22(b) or determined by assay
	CH TRU	AK, DA, or NDA	100% NDA to confirm AK	AK, DA, or NDA	100% NDA to confirm AK
TRU WASTE DETERMINATION	RH TRU	AK, DTC, DA, or NDA	AK must be qualified under 40 CFR §194.22(b) or determined by assay	AK, DTC, DA, or NDA	AK must be qualified under 40 CFR §194.22(b)or determined by assay
	CH TRU	AK, DA, or NDA	100 % NDA to confirm AK.	AK, DA, or NDA	100% NDA to confirm AK
PHYSICAL AND CHEMICAL PROPERTIES					

[2]Includes data to determine 10 tracked radionuclides, compliance with 23 Ci/l limit, and total RH Ci limits.

Characterization Objectives	Waste Type	PACKAGED WASTE		WASTE REQUIRING PACKAGING	
		Characterization Method	Confirmation Method	Characterization Method	Confirmation Method
RESIDUAL LIQUIDS	RH TRU	AK, radiography, or VE	VE or radiography on 10% of the containers[3]	100%VE or VE Technique	None required
	CH TRU	AK, radiography, or VE	100% Radiography or VE of AK	100 %VE Technique or radiography	None required
FERROUS METALS	RH TRU	None	None, count containers	None	None, count containers
	CH TRU	None	None, count containers	None	None, count containers
CPR[4]	RH TRU	AK, radiography, or VE	Assume CPR content based on SWCG	VE or VE Technique; assume CPR content based on SWCG	None required
	CH TRU	Estimate based on 100 percent radiography or VE	Confirmed only when VE is used as a QC check on radiography.	VE Technique or radiography	None required

1. Overall Characterization Process

EPA has examined the overall characterization process within the final DOE submission of the WCPIP Rev 0d, and concludes the following:

EPA does not believe that the RH proposal is the "same" as the current CH program. DOE has proposed to characterize RH waste using AK as the sole characterization process primarily to address ALARA issues – with the goal of minimizing workers' exposure to radiation during waste handling for radiological analysis and nondestructive evaluation. This AK would then be qualified by confirmation, QA program equivalency demonstration, or Peer Review. DOE asserts that this approach is the same as is currently being used for CH waste characterization, but we disagree. While there are certainly common elements to both programs, practical implementation of the CH approach has ***not*** been the same as that proposed for RH.

The current CH program has a heavy dependence upon measurement data, in accordance with 40 CFR 194.24(c). The DOE's proposal allows use of AK data if appropriately qualified, and while in principle this is acceptable, the application of these methods to waste characterization activities entails significantly different considerations. It should also be noted that the QA requirements in 40 CFR 194.22 (Condition 2 of the WIPP Certification Decision) necessitates that data used to demonstrate compliance must also be assessed for their quality characteristics, including precision, accuracy, representativeness, completeness, and comparability. Any AK data used for characterization must meet defined standards for these QA characteristics.

The characterization methodology proposed by DOE for RH waste calls for the preparation of waste certification plans, confirmatory testing plans, sampling and analysis plans, and other documents intended to either summarize the overall characterization proposal for a site or

[3] Using the "10-10-All" approach described in Section 3.3.3.1 of the WCPIP

[4] For RH TRU waste, CPR is established using a bounding value for density and container volume based on SCG, CPR in packaging is accounted for as is done on CH TRU waste.

present a certain aspect of the characterization methodology. Also, the WCPIP does not include detail commensurate with the CH-WAC in certain areas such as waste characterization element-specific QA objectives, for example, the RH program does not include specific technical criteria and QA requirements for DTC and DA which are proposed as alternatives to NDA which has been the sole characterization method for CH waste. This could be because these criteria/requirements could vary between sites. Because of the flexibility inherent in the RH proposal, EPA mandates that sites provide to EPA for review and approval all test plans, confirmatory testing plans, sampling and analysis plans, or other documents which present the proposed characterization pathway prior to implementation for review and approval. This includes plans for all measurements taken to meet DQOs even if they are not part of an AK confirmation process.

In light of DOE's current use of ten drum overpacks (TDOP) in the CH program, we are compelled to clarify the use of overpacks as payload containers For RH, our working assumption under the proposal would be that an overpack can be used only when surface contamination is discovered on an individual drum/canister. That is, overpacking would not be used as a method for achieving compliance with the TRU waste threshold or the concentration limits on RH waste. If DOE plans to use overpacks for such purposes (load management), DOE must notify EPA and provide for EPA review and approval overpacking or load management plans. Also, RH drums belonging to the same waste stream can be used for load management purposes. Further, mathematical averaging or manipulation of data from measured containers within a payload container for load management must first be approved by EPA on a site-specific basis.

Public comment on the WCPIP raised several questions pertaining to the proposed RH waste characterization approach. Upon consideration of public comment EPA agrees with the following issues raised by commenters and requires that the following be addressed either in the WCPIP or in site documents:

- Because measurement of each container shall likely not take place, it is imperative that AK adequately define the waste stream to ensure that the data for that waste stream are accurate and apply to each container in the waste stream. Therefore, we require that the definition of waste stream be precise and consistent, as suggested in public comments. The definition of waste stream should be consistent with the CH TRU WAC (DOE/WIPP-02-3122, Rev.0), modified to reflect radiological requirements: "A waste stream is waste material generated from a single process, or from an activity which is similar in material, physical form, and radiological constituents".

- Revision of WCPIP, Section 3.3, as follows: "Specific assessment actions...WCPIP. These actions....QAPD, ~~the details of which shall be specified in program documentation~~."

- Modify the text of Section 3.3 to indicate that conditions affecting compliance with QA/QC requirements of the WCPIP, as well as EPA approved site implementing documents, will be subject to corrective action.

- Revise the definition of nonconformance in the WCPIP, Section 3.5.2.2 to comport with the definition in NQA-1, Supplement S-1.

- Revise section 4.1.2.1 to state that during packaging, only materials from the same waste stream, with similar relative abundances (isotopic ratios) may be packaged in the same waste container.

2. Nondestructive Assay

NDA is used to estimate the activities of the radionuclides present in the waste. The NDA program proposed as part of the RH WCPIP is essentially identical to that used in the CH program, including the commitment to perform NDA on 100% of the containers, when NDA is used to characterize the radiological components. Departures from performing NDA on each container would be considered non-standard and will require EPA review and approval of the approach and related test plans (such as a Confirmatory Testing Plan). A major departure from the CH NDA program is the absence of the performance demonstration program (PDP) in the RH program as NDA is not the primary assay method for RH waste. DOE uses the PDP program for internal quality control checks to ensuring radioassay data comparability among sites using different radioassay equipment and to demonstrate the ability of NDA systems to meet data quality objectives.

As part of the PDP program, waste containers with known activities of typically plutonium and americium radionuclides in one or more typically homogenous waste matrices, are assayed multiple times to assess the accuracy and precision of the NDA instrument for the matrices tested. To pass a PDP cycle the average (or mean) activity and the sample standard deviation must fall within a predefined range. The EPA inspectors currently do not rely on results from the CH PDP to determine the acceptability of any specific CH program, so the lack of the PDP from the RH program will not necessarily hinder the EPA inspection/approval of NDA process. The absence of the PDP, however, will require EPA to assess the rigor and validity of any other intercomparison, mockup tests, or other standards-based testing done on the systems to ensure they are capable of performing over the expected analysis ranges.

Approval of any RH NDA program will require close attention to items such as accounting for deadtime, shielding, and high scattering signals. These are not of concern in the CH program. If the DOE site uses NDA in non-standard manners (that is, to obtain additional AK data or in a less than 100 percent NDA confirmatory action), EPA's early involvement in the discussion is necessary to ensure that the technical validity of systems used and that the approach comports with the intended use of the data.

3. Dose to Curie

The WCPIP, including Attachments B and C, provides a set of general requirements and a description of the DTC method to estimate the activity of the radionuclides present in the RH waste. This revision of the WCPIP addresses many of EPA's earlier comments, and the most important issues relating to the DTC method are discussed, or at least mentioned, in Attachment C. DTC could, in theory, provide the information necessary to characterize the radiological constituents of RH waste, and the WCPIP could provide useful guidance to generator sites that choose to use the DTC method. However, Attachment C does not provide objective criteria by which one could assess the application of the DTC method as part of an EPA inspection because the use and applicability of DTC could vary based on waste, site, AK data quality, etc. In particular, EPA believes that Section 6 of Attachment C implies that only the 10 isotopes

identified by PA as important will be quantified. EPA believes that this could lead to underestimation of the total container activity in some cases, or lead to improper development of isotopic profiles. Since RH waste may have significant quantities of other TRU isotopes, activation products, or fission products other than ^{137}Cs and ^{90}Sr, EPA will evaluate the capability of sites to identify all isotopes in the waste that contribute more than 1% to the total activity in the canister.

In the CH program, waste characterization inspections of NDA systems are based largely on CCA and CH WAC, which provide a common understanding between the sites, CBFO, and EPA about what is expected. EPA waste characterization inspections for an RH program using the DTC method, based solely on the WCPIP, would have to rely on higher level documents, yet-to-be developed site-specific documents/procedures, and expert opinion. As such, EPA's RH inspections would be more subjective than the CH inspections presently conducted.

Additionally, EPA believes that 40 CFR 194.23 applies to the modeling required as part of the DTC method. This includes both modeling to develop isotopic profiles and container shielding. EPA approval of the modeling required for the DTC method will be necessary. Also, in response to public comments, EPA clarifies that we expect any implementation of the DTC method to involve both modeling and sampling.

4. Destructive Assay

The WCPIP provides generalized requirements for DA sampling and analytical process. The purpose of performing DA is to obtain container-specific radionuclide concentrations directly or to provide isotopic ratios that can be used in DTC modeling calculations. The objective of the DA process is therefore comparable to the objective of the NDA process for purposes of data comparability, confidence and quality as the NDA process. The majority of the NDA data quality requirements have also been identified in the DA process. However, the WCPIP does not specify a lower level of detection (LLD) of 100 nCi/g for DA but is defined in the discussion for NDA and DTC methodologies. If DA results are used either in DTC calculations or as "stand-alone" results for purposes of radiological characterization, the same 100 nCi/g minimum LLD must apply to the DA analyses.

The WCPIP does not include requirements regarding DA measurement uncertainty, calibration requirements, and background determination. Consequently, EPA's process to review and approve program or site specific implementation of DA activities may include examination of requirements and criteria not included in this WCPIP. Specifically, EPA will assess proposed initial and continuing calibration requirements, background determination requirements, sample custody and integrity procedures, and criteria for reporting and use of uncertainty in DA measurements. In the absence of specific criteria in the WCPIP, EPA will assess this information on a site-by-site basis, and EPA will also have to ensure that this determination was implemented consistently between sites. EPA review and approval of site-specific Detailed Assessment Plans and Confirmatory Testing Plans would be necessary prior to DOE conducting RH waste characterization by DA at a particular RH TRU waste generator/storage site.

The WCPIP contains criteria for assessment and use of method blank results in Table 4-3 that indicate that site-specific statistical procedures will be used to assess method blanks, but no mention is made of what statistical method will be used to assess method blanks for DA. Typically, method blanks are assessed and used to determine potential bias in sample results by

comparing the relative concentration of blanks that exceed the blanks specific minimum detectible concentration (**MDC**) to the associated samples activities. Additionally, accuracy and precision control limits provided in Table 4-3 of the WCPIP could not be verified through referenced literature, statistical considerations, study data, or from limits derived from similar analytical methods. Numeric control limits should be based upon justifiable sources and/or methodologies and should not be arbitrary in nature.

5. Acceptable Knowledge

The AK process proposed for RH waste is similar to that implemented under the CH program, except for example, that sites are required to collect all drum/container specific data possible. Under the RH program, sites could use AK data alone to characterize waste upon successful qualification of AK by confirmation, determination of QA equivalency, or Peer Review. For AK to be used as a sole characterization methodology, the AK program for RH waste must be more rigorous than that implemented for the CH program particularly with respect to how the AK confirmation process will take place and how it will be determined whether confirmation has occurred and is adequate. Each RH site will have to develop specific quantitative or semi-quantitative requirements for determining when "AK is good enough." Also, sites will have to provide supporting documentation and justification in the auditable record showing that "AK is adequate. For those RH programs that would mimic the CH program, the AK-data reconciliation would take place as is currently performed for the CH program (that is, the measured data takes precedence and is the source of data entered in the WWIS).

Public comment raised a concern related to AK that EPA assessed and has determined must be included in a revised WCPIP:

- Revise Section 4.1.1.1 and the related AK procedure to require that the auditable record consist of documents that contain the source material used to make decisions regarding waste characterization, and that this record must include documents that establish a parameter that addresses DQOs or the absence of these parameters, as must also include AK data limitations.

6. WIPP Waste Information System

RH data input to the WWIS could require site-specific calculations or determinations. As such, EPA will incorporate WWIS into their inspection programs, as appropriate, and expects sites to be able to specify how RH data will be populated in the WWIS. Any modification to WWIS fields or input decision criteria to accommodate RH waste characterization information must be documented and be approved by EPA prior to implementation of the RH program at a given site.

7. Additional Considerations

EPA will observe all RH waste measurement activities as they are being performed; this could occur prior to the 194.8 inspection, or simultaneous with this inspection depending upon the specific circumstances of data acquisition. Once the RH site submits to EPA all of the requisite plans and acquires approval of the requisite plans, and other necessary pre-inspection activities are performed, using the 40 CFR 194.8 inspection authority, EPA will inspect each site-specific RH waste characterization program. EPA will inspect RH sites according to the proposed

changes to 40 CFR 194.4 inspection process. EPA will not inspect RH sites until after the proposed 40 CFR 194.8 changes are finalized and are effective. The 40 CFR 194.8 proposed changes allow flexibility with regard to tiering of waste characterization systems and processes approval scope/limitations.

Under the current CH program, DOE performs 100% NDA and NDE, so EPA has been able to approve instrumentation applicability and use for broad spectrums of wastes, rather than on a waste stream basis. EPA is unlikely to follow this inspection/approval approach as waste characterization processes would be customized and unique to each of the RH waste streams as the DOE has proposed a process that can and will be tailored to waste-stream specific data availability. Therefore, EPA requires the RH sites to provide all documents associated with AK qualification and measurement data collection (that is, sampling and analysis plans, etc) or modeling when it is performed as part of the RH characterization process (DQO reconciliation).

Preparation of the AK Summary for RH program is similar to the CH program. However, EPA does not review a draft AK summary report for CH waste. For RH waste EPA intends to review draft AK summary reports that would be useful in identifying gaps which would help a site to find ways to obtain supplemental AK information before identifying AK qualification pathway(s). This step is critical since available AK data would come from data collection activities pursued prior to the establishment of a QA program that adheres to the requirements of 40 CFR 194.22. Also, EPA requires that sites provide Certification Plan containing justification for selecting a certain AK qualification pathway, for EPA review and approval prior to implementation.

If confirmatory testing is performed, EPA expects all Testing Plans, Sampling Plans, or other documents be provided to EPA prior to implementation for review and approval. Similarly, EPA requires provision of the Peer Review Plan prior to implementation, and EPA shall attend all Peer Reviews performed to support the RH program. For demonstration of an equivalent QA program, a QAPD crosswalk will be prepared and EPA expects this crosswalk to be provided to EPA for review and approval. DOE has not sought the use of corroborating data, and EPA does not approve its use at this time. Following performance of these qualification elements, DOE shall revise the AK Summary and prepare a Characterization Reconciliation Report, the later of which reconciles all data acquired and presents the results of the total characterization process in a single report.

EPA expects the approval process for the RH characterization program at a site to be performed in two steps. DOE will first provide a Certification Plan to document the full RH waste characterization process, including the listing of the DQOs which must be met and a description of the rationale for attaining theDQOs. This Certification Plan will also describe the characterization techniques to be utilized, the qualification methods for data that were gathered outside the approved QA program, and list any additional program documents to be developed, such as testing plans and standard operating procedures. EPA will evaluate the Certification plan to ensure that all applicable requirements are being addressed in the RH program for that site.

Following approval of the Certification Plan the site-specific documentation will be prepared whenever measurement information is obtained, including but not limited to Confirmatory Testing Plans, Sampling Plans, or other site-specific documents. These plans and procedures will be developed in accordance with the Certification Plan and the revised version of the DOE's WCPIP, Rev. 0d dated October 2003. EPA expects this documentation to be prepared when data

is acquired using measurement techniques that are anything other than the 100% NDA/NDE currently implemented at CH sites. This is to ensure that regardless of the inference in the WCPIP, EPA expects and requires appropriate documentation of all RH activities. EPA will also require provision of these documents prior to audit or inspection, and cautions RH sites that implementation of these activities prior to EPA approval is done "at risk."

Both the Certification Plan and the WCPIP will be placed in the EPA Air Docket according to 40 CFR 194 requirements for giving public opportunity to comment on site inspection-related documentation provided to EPA prior to EPA inspection of a TRU waste site.

IV. PUBLIC COMMENT AND RESPONSE

On December 19, 2003, EPA issued its preliminary decision on the DOE's RH proposal as presented in the WCPIP, Rev 0D. In that letter EPA stated that the DOE-proposed RH waste characterization framework was acceptable and identified additional information RH sites must provide to EPA for approval before implementing WCPIP. EPA received public comment on the proposed preliminary decision. The comments received are summarized below, followed by the Agency's response. The pertinent technical sections of the Technical Support Document that address the WCPIP technical issues in question are presented in parenthesis following the comment. Each commenter was assigned a comment letter, with each comment made by the public then assigned a sequential number. The table, below, identifies each commenter and the related comment numbers.

Commenter	Comment Number
Citizens for Alternatives to Radioactive Dumping, Concerned Citizens for Nuclear Safety, Creative Commotion: Voices for Social Change, Loretto Community, Nuclear Watch of New Mexico, Southwest Research and Information Center, Attorney General of New Mexico	A.1-A.3
Environmental Evaluation Group	B.1-B.7 Cover Letter; B1.1-B1-18 Attachment
Anonymous	C.1
Oak Ridge Reservation Local Oversight Committee	D

Comment A.1: EPA must conduct a rulemaking to approve RH TRU waste characterization plans and emplacement of RH waste in WIPP. EPA must notice a rulemaking for RH wastes to provide for full notice and comment procedures mandated by the WIPP Act and the Compliance Criteria.

Response to Comment A.1: EPA's WIPP Certification Decision included RH waste, and the Agency believes that no further rulemaking is necessary to approve its disposal. EPA's Certification Decision considered a TRU waste inventory comprising both CH and RH components. The Agency concluded that "DOE's development of the stored, projected, and disposal inventory of RH-TRU waste was sufficient for PA [performance assessment]." (Docket A-93-02, Item V-C-1, EPA Response to Comments on Final WIPP Certification Decision (EPA 1998), p. 6-33) Furthermore, the effects of RH waste on the WIPP's performance were fully assessed through the performance assessment and performance assessment verification test: "EPA's certification decision addresses emplacement of RH-TRU wastes in the repository since it is included in the PA and PAVT." (EPA 1998, p. 6-34; see also p. 1-37, 1-38, 6-33; CARD 24, pp. 24-78 et seq.)

In the 1998 Certification, we also determined that DOE met the applicable waste characterization requirements of Section 194.24, subject to certain conditions on its implementation of waste generator sites. EPA acknowledged in the Certification Decision that DOE had not provided

detailed information on characterization techniques for RH waste, but nevertheless found DOE in compliance with the applicable requirements, with the understanding that further information on RH waste characterization would be necessary before its disposal:

> "DOE did not provide any waste characterization methods for RH-TRU waste . . . . [S]hould DOE determine that it intends to emplace RH-TRU wastes from a waste generator site in the repository at some time the future, it will have to demonstrate that such waste generator site can adequately characterize RH-TRU wastes to ensure that the RH-TRU waste inventory assumptions incorporated in the PA and PAVT are not violated. " (EPA 1998, pp. 6-34 to 6-35; see also p. 6-33).

The EPA described the site-specific inspections and approval process under 40 CFR 194.8 as the appropriate vehicle for achieving this demonstration:

> "Conditions 2 and 3 [regarding inspection and approval of site-specific quality assurance and waste characterization programs] change neither the performance assessment assumptions nor the terms on which the WIPP is authorized for disposal, but rather ensure that the assumptions on which the compliance certification is based are adhered to in practice." (63 FR 27359)
>
> "RH waste cannot be accepted until the information required in Section 194.8(b) is submitted." (EPA 1998, p. 6-25)

Thus, the Agency explicitly included RH-TRU in its certification and clearly envisioned that further evaluation and eventual approval of RH waste characterization and authorization for disposal would occur through site inspections rather than through rulemaking.

In summary, WIPP is certified to accept RH wastes. Like CH waste, RH waste must comply with Conditions 2 and 3 of the WIPP Certification Decision. Under these conditions, the WIPP may accept waste only after EPA has determined through a site-specific inspection and approval process that the waste is acceptable for WIPP disposal. No rulemaking was required and in fact, no public participation measures under Section 194.8 (or other portions of the WIPP Compliance Criteria) was mandated in advance of a site inspection announcement. However, to ensure public awareness and input on the earliest steps in implementation of RH waste characterization, we issued a letter with our preliminary decision, sought public comment on the decision and supporting documents, and docketed the letter and DOE submissions for public review. Our approach in approving the RH waste characterization framework is fully in accordance with EPA's earlier statements and the terms of the certification, which was upheld in its totality by the DC Circuit Court.

Comment A.2: EPA's decision regarding RH waste should follow issuance of the final rule on the pending revisions to the Compliance Criteria. EPA should finalize the pending rule before proceeding to consider any DOE request related to RH waste characterization and before proceeding with the RH rulemaking.

Response to Comment A.2: We believe that finalizing changes to the site-specific waste characterization approval process in the WIPP Compliance Criteria has no effect on the development of site-specific RH waste characterization programs and the approval of the RH

waste characterization framework. Approving the DOE proposal is only the first step that would allow RH sites to develop their site-specific waste characterization programs for EPA consideration. Once sites complete that step, the final action issued today requires that each site seek EPA approval of its RH waste characterization procedures before implementation. Only after EPA approval can the site begin analyzing RH waste to obtain data for determining radiological composition of the waste for disposal at WIPP. This additional approval step is necessary regardless of the 40 CFR 194.8 procedures in place. Sites also will still be required to undergo a site inspection and obtain written approval from EPA before shipping RH waste for disposal at WIPP. We expect that the first site-specific evaluation for RH waste would occur no earlier than Summer 2004. We anticipate that EPA's 40 CFR 194.8 and 194.24 changes would be finalized and effective prior to the first RH inspection. Note that DOE must also receive approval from the New Mexico Environment Department for disposal of any RH waste with hazardous waste components.

Comment A.3: The WCPIP is totally inconsistent with the certification decision and must be rejected. (General Comment; entire WCPIP).

Response to Comment A.3: As presented in Table III.C.1, the RH and CH programs do share many common technical elements for characterizing TRU waste. These include AK, NDE, data validation/verification, and data transfer. However, for worker health and safety reasons, the WCPIP deviates from certain CH requirements. For example, the WCPIP does not mandate 100% confirmation as currently performed under the CH program, instead allowing implementation of a flexible approach depending on the nature and quality of information available for specific RH waste streams. This does not mean, however, that 100% radiological measurements will never be required; EPA believes that this determination will be site-specific. Similarly, WCPIP allows the use of estimated weights for the CPR contents of the waste. (See response to comment B.3 regarding determination of CPR.) Additionally, like CH waste, sites intending to dispose of RH waste at WIPP must demonstrate to EPA that they can adequately characterize the waste in question to demonstrate compliance with 40 CFR 194.24 limits for waste components and waste data must meet the quality assurance requirements at 40 CFR 194.22. Also, like CH waste sites, RH sites will be subject to EPA inspection to verify that sites have adequate capabilities to characterize their waste and only upon EPA approval of the waste characterization program elements and waste stream(s) sites may dispose of the waste at WIPP. RH waste will be subject to the same regulatory requirements and EPA oversight/approval as CH waste. For these reasons, EPA believes that the RH waste characterization framework and methodologies contained in the WCPIP will allow the characterization of RH waste consistent with the TRU waste certification decision.

EPA's certification decision explicitly incorporated an inventory encompassing RH waste. Furthermore, the Agency determined in its certification decision that DOE met the waste characterization requirements of 194.24 even without detailed information on RH waste characterization methods. The Agency understood that RH waste characterization could differ in some ways from CH waste. [See EPA 1998, p. 6-34; CARD 24, pp. 24-50, 24-58, 24-59, 24-78]. In light of this, the Agency included RH in the certification and explicitly deferred the evaluation of more detailed waste characterization to the implementation phase in accordance with site-specific procedures under Section 194.8. Our approach in approving this framework and site-specific plans is fully in accordance with EPA's earlier statements and the terms of the certification. See also EPA's Response to Comment A.1 of this document.

Comment B.1: The preliminary decision by EPA to allow DOE sites flexibility in developing site-specific RH waste characterization programs is reasonable However, this does put a greater burden on EPA in approving site specific plans and in site audits. (General Comment; entire WCPIP)

Response to Comment B.1: Through the nearly two-year review process, EPA determined that customized site-specific characterization activities would be the only approach available to adequately characterize the spectrum of TRU RH-Waste present at DOE sites. The proposed process does put a greater burden on EPA because site-specific plans must be pre-approved before implementation, and EPA must inspect and approve characterization of each waste stream. However, the DOE did not provide, in the WCPIP, a cohesive program similar to the CH program wherein specific technical requirements are spelled out in detail that can be broadly implemented. EPA believes that considering the site inspection and waste approval experience of past five years and EPA RH surveillances at two sites (BC and LANL) we are confident that we are equipped to take a larger oversight role burden.

Comment B.2: The WCPIP has less stringent requirements for RH waste characterization compared to the CH waste characterization requirements. The primary requirements that are less stringent are: (1) determination of CPR by bounding estimates; (2) the 10-10-All requirements for AK confirmation by visual examination or radiography; (3) less than 100% confirmation of isotopic ratios; and (4) no performance demonstration program (PDP) for RH. (II.B.1, II.B.5.b, d; II.B.6)

Response to Comment B.2: EPA agrees that the CPR determination, 10-10–All approach, the possibility of less than 100% radiological confirmation, and lack of a PDP may differ from the current CH program. DOE has proposed these requirements in consideration of worker health and safety concerns or waste packaging method. We believe that the adaptations for RH may be reasonable in light of such considerations. However, we will evaluate the appropriateness of these methods on a site-specific basis before approving their implementation and reserve the right to require more stringent waste characterization.

For example, DOE proposed 10-10-All as a method for confirming physical characteristics of waste and absence of prohibited items. Based on the DOE proposal EPA understands that <5% of RH waste would not be repackaged. It is this population that would most likely follow 10-10-All procedure for AK confirmation via VE/RTR. EPA believes that using the less stringent approach for confirming AK for such small population of RH waste is acceptable. During a site inspection, if we have reason to believe that this level of evaluation does not support the site's compliance, we can use our discretion to required 100% NDE.

Comment B.3: The commenter agrees that a bounding determination of CPR (see comment B2) is satisfactory as long as these bounding values, when combined with measured values for CH TRU wastes, still indicate an adequate margin of safety for localized areas in waste disposal rooms. (II.B.6)

Response to Comment B.3: EPA retains the option to require CPR determination if necessary on a site-specific basis. However, EPA decided to allow the bounding approach because RH waste represents, volumetrically, such a small portion of the total waste entering the WIPP. The specific configuration of waste in the subsurface and the impact this would have on the WIPP's

containment capabilities has been assessed as part of the Performance Assessment (PA). Also, CPR contents would be tracked as RH waste is emplaced in WIPP. DOE must monitor total TRU waste inventory in WIPP and if CPR inventory reaches the WIPP limit then TRU waste cannot be emplaced at WIPP until DOE seeks EPA approval thru the performance assessment.

Comment B.4: The commenter states that on the whole, these changes to characterization approaches could still allow adequate confirmation of waste characterization if EPA's site approval and audit process is thorough and if there is a strong AK process. The AK process described in this document appears to be adequate. (II.B.7)

Response to Comment B.4: EPA agrees that the AK process described in the WCPIP is more rigorous than that implemented under the CH program in some instances, and EPA intends to ensure that all technical aspects of the AK program and linkages, relationships, and input to measurement/modeling systems are rigorously assessed to make sure that the AK program is adequately implemented at RH sites.

Comment B.5: The commenter states that radionuclide assay of RH TRU will now be acceptable by DTC and DA methodology as well as by nondestructive assay. The DTC and DA methodology should be acceptable, but we believe there will be a shakedown period before these approaches are as well understood as NDA. The commenter points out that this will require considerable oversight by EPA. (III.C.3, III.C.4)

Response to Comment B.5: Because RH waste characterization approaches sought by DOE in the WCPIP mandate flexibility, we have determined that Agency review and approval of appropriate site implementing documents, as part of a comprehensive review of RH characterization activities and decisions, will be necessary. For example, EPA review and approval of plans that involve less than 100% NDA, as well as review and approval of DTC and DA-related plans prior to implementation, is required. We may have to conduct surveillance visits to sites implementing DTC and DA and work with the site's radioassay staff responsible for analyzing RH waste for radiological contents.

Comment B.6: The commenter states that Section 2.2.2.1 implies, but does not state that waste cannot be shipped to WIPP that is below the LLD of the assay method. Nothing is said about the practice of placing low level waste containers with TRU Waste containers and producing an RH TRU canister containing three 55-gallon drums whose <u>average</u> concentration is >100nCi/g. The commenter contends that the DOE should modify Section 2.2.2.1 to explicitly state that waste with concentrations below the LLD cannot be brought to WIPP. (II.B.5c, e, and f; III.C.4)

Response to Comment B.6: EPA considers only those measurements that exceed the lower limit of detection (LLD) of the method or instrument to be technically adequate for the characterization of the radiological components of waste, and concurs with the commentator's recommendation to explicitly state this in the WCPIP. In Section 2.4 of the WCPIP, DOE has specified waste acceptance criteria for payload containers. Similar to what is approved for CH waste, the practice of including inner containers with TRU alpha activity concentrations below 100 nCi/g would be allowed, provided that all reported activities exceeded the LLD and the TRU alpha activity concentration for the payload container exceeded 100 nCi/g. (See also Comment B7).

Comment B.7: The commenter states that the August 8, 2003, letter from EPA to DOE

cautioned the DOE about overpacking low level waste with TRU waste for purposes other than controlling contamination or damaged drums. For RH TRU, the EPA may need to make clear that EPA expects the DOE to specify that the 100 nCi/g lower limit applies to an individual container at the time of assay, not after it is averaged with other containers. The DOE reports that the expected volume of RH TRU is greater than the 7,080 m^3 limit set by the Consultation and Cooperation Agreement. The commenter emphasizes that it would appear prudent not to exacerbate this volume problem by including low level waste. (III.C.1)

Response to Comment B7: The RH TRU Waste Acceptance Criteria specified in Section 2.4 of the WCPIP apply to payload containers, including 55-gallon drums, direct Loaded RH canisters, RH canisters containing 55-gallon drums, and RH canisters containing 30-gallon drums. The requirement to report the practice of overpacking is applicable to both RH and CH waste. DOE will have to inform its intent to perform RH load management and provide relevant documents for EPA review and approval before an RH site can begin load management for shipment to and emplacement of RH waste in the WIPP. EPA will assess the use of overpacking and averaging techniques as part of its inspection process. EPA encourages DOE to use the limited space allowed for RH waste in a manner that protects human health and safeguards the environment. (See also Comment B6)

Comment B1.1: The commenter stressed that the discussion of Quality Assurance Objectives (QAOs) in the first paragraph of Section 2.2 is erroneous and should conform 194.22 requirements. The commenter recommends that the discussion of QAOs in Section 2.2 either be rewritten or simply dropped. (II.B.5.a-h; II.B.6; III.B.1.a; III.C.1-8)

Response to Comment B1.1: The Agency concurs that the DOE discussion of QAOs as presented in Section 2.2 of the WCPIP could be implemented in a way that's not consistent with the definition of quality characteristics as defined in 40 CFR 194.22(c). The Agency agrees that the implementation of QAO from Section 2.2 of the WCPIP should conform with QA requirements in 40 CFR 194.22. Additionally, Table 3-4 of the WCPIP appears to be identifying quality characteristics as opposed to QAOs. In subsequent sections of the WCPIP, DOE has provided additional clarifying information that provides characterization method specific QAOs that provide qualitative or quantitative criteria for assessing data. However, the Agency has also identified several characterization areas in which DOE has not defined QAOs or have not provided adequately justified or defined QAOs. Subsequent sections of the WCPIP contain additional and more appropriate discussion of QAOs in subsequent sections. We will fully evaluate the justification and adequacy of QAOs in our review of site-specific characterization plans. We suggest, however, that DOE make conforming changes to the QAOs in Section 2.2 of the WCPIP to reflect the language of 40 CFR 194.24(c) and encourage consistency across the DOE complex.

Comment B1.2: In the commenter's opinion, most of the "DQOs" discussed in the subsections to Section 2.2 fail to meet what appears to be the criterion used in this document for DQOs. Since Section 2.4 of this document establishes the requirements listed as "DQOs" in Section 2.2 in a more effective manner, perhaps Section 2.2 and its subsections should simply be dropped from the document. The commenter believes that these DQOs are poorly developed and would serve no useful waste characterization function even if properly developed. References to "DQOs" in the remainder of the document could be changed to refer to the waste acceptance criteria described in Section 2.4. (II.A; II.B.1; II.B.2; II.B.5; II.B.6; III.B.1.b; III.C.1; III.C.7)

Response to Comment B1.2: The Agency concurs with the commenter that the definition of DQO as provided in EPA QA/G-4 indicates that DQOs may be qualitative or quantitative statements in which tolerable levels of decision error are defined as the basis for determining the quantity and quality of data needed. Consequently, it would be appropriate for DOE to establish qualitative DQOs for project objectives that are not amenable to establishment of the typical precision, accuracy, representativeness, comparability, and completeness that are associated with many environmental data collection activities. However, the Agency requires that tolerable errors for these qualitative DQOs be adequately addressed as part of the AK record for RH waste (especially given the increased reliance of AK for RH waste characterization). Additionally, quantitative DQOs associated with DA sampling and analysis must be adequately defined.

Comment B1.3: The commenter indicates that Section 2.2.3.2, DQO for physical form, states that the purpose of the DQO is "To determine the physical form of the waste (i.e., CPR, ferrous metals) as required by the final certification rule". As pointed out in Section 2.1, the requirement is to quantify the "physical form", not merely determine its existence. By analogy with the other DQOs in the WCPIP, this one should at least establish the requirement to quantify these physical forms. (II.A, III.B.1)

Response to Comment B1.3: Identification of physical form with respect to ferrous metals and CPR will be accomplished through visual examination or RTR of RH wastes. We agree that strict quantification of CPR, as is performed under the CH program, is not required under the RH program, but the RH VE process does require that sites record a "description of the container contents including waste material parameters that are present" (Section 4.1.2.1 of the WCPIP). Note that the ferrous metal determination under the RH and CH programs is the same (i.e., counting containers, since the EPA requirement is to establish a minimum presence of ferrous material). See response to comment B3.1 regarding CPR determination.

Comment B1.4: The commenter stated that the "waste stream" definition in Section 2.3 is in conflict with that in WIPP waste characterization documents. The commenter believes that adding a conflicting definition for the term "waste stream" in this document is not only unnecessary but an invitation to chaos, and recommends that the definition be changed to reflect the more common understanding of the term. (II.B.1)

Response to Comment B1.4: EPA agrees that the definition of waste stream varies between documents, and the version included in the WCPIP is less stringent than that of the CH WAC (although consistent with the WAP, also a document referenced in the CCA). To ensure consistency between the CH and RH programs, EPA will review site-specific waste characterization plans to confirm that waste streams are defined (and used in practice) as "waste material generated from a single process or from an activity which is similar in material, physical form, radiological constituents, and radiological constituents." We also suggest that DOE make conforming changes to the WCPIP to reflect this definition and provide additional guidance to RH sites in developing their site-specific programs.

Comment B1.5: The commenter states that Section 2.3 indicates that Generator sites may use information that is contained in the AK record and was obtained prior to implementation and approval of a quality assurance (QA) program by qualifying this information via peer review, corroborating data, confirmatory testing, demonstrating an equivalent QA program to the NQA

standards.] However, the commenter points out that this is a misinterpretation of 40 CFR 194.22(b), which makes it clear that this alternate method is only to be used for "...information which demonstrates that data and information collected prior to the implementation of the quality assurance program required pursuant to paragraph (a)(1) of this section..." The commenter also emphasizes that any information "collected" after approximately August 13, 1996, should not be allowed to undergo the alternate qualification methodologies, the date that a site's waste characterization QA plan is accepted is not the correct "start" date.

Also, since 40 CFR 194.22(b) only directs these processes to be used for "Any compliance application...", the commenter questions whether "previous visual examination (VE) data, VE audit/videotapes, radiography data, audio/videotapes, radiological characterization data" be sent to the EPA as part of a "compliance application". Additionally, the commenter indicates that 40 CFR 194.22(b) also requires that the alternate methodology be "approved by the [EPA] Administrator or the Administrator's authorized representative", but the WCPIP does not indicate that an approval from the EPA must be sought before the alternate methodology is used. The commenter concluded by suggesting that EPA may also want to consider allowing qualification on non-NQA data for waste characterization under NQA-3 Supplement 3SW-1, rather than using the less appropriate 40 CFR 194.22(b) process. (II.B.1)

Response to Comment B1.5: EPA agrees with the commenter that the wording in 194.22(b) is intended to require that the DOE perform waste characterization activities under a QA program that adheres to the NQA standards. At the time the EPA rule was written sites responsible for performing waste characterization had not demonstrated implementation of a QA program that adhered to the NQA standard. Paragraph (a)(1) of 40 CFR 194.22 recognized this fact by stating "*As soon as practicable* after April 9, 1996, the Department [DOE] shall adhere to a quality assurance program that implements the requirements..." (italics added). It is only after EPA has determined that the QA program under which the site is performing waste characterization activities adheres to the applicable NQA standards that EPA approves the site for shipment of waste to the WIPP. When making the determination as to whether a site has a QA program that adheres to the NQA standards referenced in 40 CFR 194.22, EPA does not rely upon DOE internal assessments, but rather performs independent audits. These audits determine the time at which EPA considers a site QA program to be in compliance with the requirements of 40 CFR 194.22. If DOE plans to use for waste characterization any data collected prior to EPA approval of DOE's QA program, the Agency would need to confirm the QA equivalency determination or otherwise validate the data (through confirmatory measurements, etc.) per Section 194.22.

Comment B1.6: The commenter states that Table 2.1, RH TRU Waste Characterization Method Quality Assurance Objectives appears to be problematic, in that while precision, accuracy, representativeness, completeness, and comparability are defined in 40 CFR 194.22(c), the application of these terms to waste characterization methods in Table 2.1 is not in accordance with these definitions. Specifically, all QAOs for VE are of question, as are some of the numerical QAOs in Table 2.1. Also, Table 2.1 QAO's are also sometimes overly complicated (.e.g. consideration of "Sampling" as a separate waste characterization method in Table 2.1, and subsequent presentation of QAOs is of question). The commenter points out that the bulk of the QAOs in Table 2.1 and Section 4 are inappropriate. Also, the DQOs, the QAOs established in this WCPIP should not be considered acceptable in their current form. (II.B.1)

Response to Comment B1.6: EPA concurs that the implementation of precision, accuracy,

representativeness, completeness, and comprehensiveness for visual examination in the RH program are qualitative in nature rather than quantitative. (Also see response to comment B3.) Regarding precision, the reconciliation process is not intended to eliminate differences but rather to note these discrepancies so that the overall quality of the VE process can be evaluated. EPA will evaluate the quality of the VE process in part by examining the reconciliation process, and the degree to which discrepancies between operators occur. EPA also agrees that accuracy in a qualitative process like VE relies upon the ability of the operator to make the correct determination. The best indicator of quality in accuracy is the demonstrated ability of the operator to correctly identify the component.

EPA agrees that the representativeness QAO should not be based solely on the description of the contents, but rather whether the description is representative of the important characteristics of the waste in the container, and also whether the waste selected for VE is representative of the waste stream. These will be evaluated during the VE inspection process.

EPA expects completeness to be demonstrated by including all relevant waste parameters in the examination. EPA evaluates comparability in the VE program by examining the training and methods used by sites to determine if the results from the various programs would produce comparable results.

Other method-specific QAO's are expected by EPA to be defined in the site program documents. EPA will evaluate these QAOs using criteria such as the EPA Quality Assurance Project Plan (QAPjP) guidance documents during the inspection process.

Comment B1.7: The commenter states that Section 2.4.6 lists the ten radionuclides whose activities and masses must be reported. The commenter is pleased that the EPA has insisted that all of these radionuclides must be required for RH TRU. An additional point that must be kept in mind is that the short-lived progeny of ^{137}Cs (^{137m}Ba) and ^{90}Sr (^{90}Y) must also be included in the 23 Ci/liter limit. This is important because the CRA inventory shows some waste streams that exceed this amount. However, the commenter stresses that EPA should require the listing of ^{241}Pu since this radionuclide decays to ^{241}Am, a reported radionuclide and, currently, ^{241}Pu is the predominant radionuclide at the WIPP, making up approximately 60% of the activity currently emplaced. (III.B.1.c)

Response to Comment B1.7: The Land Withdrawal Act requires that "[r]emote-handled transuranic waste received at WIPP shall not exceed 23 curies/liter maximum activity level (averaged over the volume of the canister)." The activity of the progeny of ^{137}Cs decay (^{137m}Ba) and ^{90}Sr decay (^{90}Y) are typically not included in health and risk assessment, nor in shielding and dose analysis, because the radiations emitted by ^{137m}Ba and ^{90}Y are traditionally credited to the decay of the parent. This is generally considered acceptable because of the very low probability that the progeny emissions will be found separate from the parent transformation. Since it is also very unlikely that the progeny will be found in other than secular equilibrium with the parent, there is no consequential effect to considering the emission of the progeny to have been derived from the parent. Regarding the applicability of this traditional approach to the 23 Ci/liter limit, it is necessary to understand the basis for the 23 Ci/liter limit. If the limit is based on dose analysis or risk assessment, then it is likely that the limit implicitly includes the progeny activities as they were likely credited to the parent radionuclide. In this case, separately including the activities of the progeny would result in a double accounting of their effect. EPA believes that the activity of

all radionuclides present, including short-lived progeny, were to be included in the 23 curies per liter limit, and shall assess the inclusion of radionuclides accordingly.

Comment B1.8: The commenter states that Section 3.3, Oversight and Assessment, indicates "Specific assessment actions will be taken during the program to ensure all parties are adhering to the requirements of this WCPIP. These actions include periodic audits as well as management and independent assessments conducted in accordance with the QAPD, the details of which shall be specified in the program documentation." The "program documentation" is apparently the generator site documents described in the previous section of the WCPIP. The commenter contends that specifying the details for independent assessments by the CBFO or other outside organizations in generator site documents would compromise the independence of those assessments, and recommends that the second sentence be amended to eliminate that suggestion. (II.B.3)

Response to Comment B1.8: EPA understands that the reference to the program documents is intended only to guide the topics which will be addressed at any given site; for example, oversight activities will not be performed on NDA if the site program documents describe radiological assay as being performed using Dose-to-Curie.

EPA agrees that specifying the oversight program in the site documents would compromise the independence of the oversight.

Comment B1.9: The commenter points out that Section 3.3 indicates: "Corrective actions shall be taken if any condition adverse to quality is detected during an audit or assessment. The cause of any adverse condition, identified by any means, that affects compliance with the Quality Assurance/Quality Control (QA/QC) requirements specified in this WCPIP shall be promptly determined and action taken to preclude its recurrence." However, the commenter contends that the identification of causes and action to preclude recurrence for adverse conditions discovered in the RH TRU waste characterization program should not be limited to only those that affect QA/QC requirements in the WCPIP. The implementing requirements will be in generator site documents, and these are as important as the upper tier requirements of the WCPIP. (III.B.1.b)

Response to Comment B1.9: The Agency did not specifically assess the CBFO QA Program described in the WCPIP. Use of the term QA/QC in regards to the RH TRU waste characterization program and the 40 CRF 194.22 (a)(1) requirements for the implementation of a QA Program in accordance with NQA-1 to NQA-3 suggests a totality of the quality implementing, quality ensuring, and quality verifying activities that are required to be conducted by a generator/storage site, including generator/storage site implementing documents and requirements. The Agency agrees that narrow interpretation of the language in Section 3.3 to include only WCPIP requirements would be inappropriate. Corrective actions are required in response to adverse conditions affecting compliance with QA and quality control requirements of the WCPIP as well as any site implementing documents eventually approved by EPA.

Comment B1.10: The commenter states that Section 3.3 further says: "An initial audit is conducted at each generator site performing waste characterization activities prior to the formal acceptance of the waste-stream profile forms and/or any waste characterization data supplied by site personnel. This formal acceptance is referred to as site certification." The commenter stresses that, as with other terms in this WCPIP, the term "site certification" should be the same

throughout the WIPP program. (II.B.3)

Response to Comment B1.10: EPA agrees that the terminology and process for TRU waste site certification should be as similar as possible between the CH and RH programs. EPA agrees that the process of site certification for RH waste programs to be similar to that for CH waste programs, including the successful completion of QA audits and technical assessments as well as formal acceptance of the waste stream profile forms and characterization data. We gather that the paragraph in question refers to the fact that this process must be satisfactorily completed prior to a site being certified, since the waste stream profile forms and the waste characterization data cannot be accepted until the QA audits and technical assessments have been completed with satisfactory results.

Comment B1.11: The commenter points out that Section 3.5.2.2 states, in part, that "Nonconformances are uncontrolled and unapproved deviations from an approved plan or procedure. Nonconforming items and activities are those that do not meet the WCPIP requirements, procurement document criteria, or approved work procedures." However, the CBFO QAPD, Revision 5, defines a nonconformance as (p. A-6), "A deficiency in a characteristic or record that renders the quality of an item or sample unacceptable or indeterminate." This same definition is in NQA-1 Supplement S-1. The commenter believes that the same definition should be used throughout the CBFO quality assurance documents–and that this WCPIP should be in agreement with the NQA Standards required by 40 CFR 194.22(a)(1). (III.B.1.b)

Response to Comment B1.11: The Agency concurs with the comment. The definition of a nonconformance as found in Section 3.5.2.2 of the WCPIP limits non-conformances to items or activities that do not meet WCPIP requirements, approved work procedures, or procurement document criteria. This definition does not address items or activities that may meet these requirements yet be deficient for purposes of RH waste characterization. The NQA-1 Supplement S-1 definition of a nonconformance is a more appropriate definition and must be applied in the development of site-specific documentation. We suggest that DOE make conforming changes to the WCPIP to provide additional guidance to RH sites in developing their site-specific plans.

Comment B1.12: The commenter points out that Section 4.1.1 discusses the use of acceptable knowledge for characterizing waste, and defines AK as consisting of "information about the materials and processes that generated a waste and the procedures and policies that were used to package and manage the waste. AK includes, but is not limited to, information about the physical form of the waste, the base materials composing the waste, the radiological characteristics of the waste, and the process that generated the waste." The commenter states that missing from this discussion is any reference to sampling and analysis of the waste that may be available- the most valuable type of AK. (II.B.5.a)

Response to Comment B1.12: EPA agrees that AK can and should include sampling and analysis data and although not explicit in this paragraph, we expect this information, as available to be included in the AK record. We believe that the phrase "AK includes, but is not limited to…[listing of data requirements]" allows inclusion of this information in the AK record.

Comment B1.13: The commenter contends that the auditable record should consist of all the

AK information, not just that which is used to make decisions as implied in Section 4.1.1.1 of the WCPIP. The commenter also believes that a possible alternative is that the second sentence be altered to indicate that AK records must include any evidence that "demonstrate limitations of AK information", rather than "can" include these data. (II.B.5.a)

Response to Comment B1.13: The AK record must establish a clear, auditable path for assessing decisions made, and should include information that impacted these decisions. We do agree that AK records must include documentation of data limitations as is currently included in the CH program.

Comment B1.14: The commenter states that Section 4.1.1.1 also offers four "Confirmation alternatives for radiological properties". One of these alternatives–"Analysis of a representative number of samples to confirm isotopic ratios derived from modeling"–is not by itself a possible alternative, but must be used in conjunction with another of the four, "Modeling (e.g., ORIGEN) used to confirm isotopic ratios derived from sampling and analysis." The commenter points that if ORIGEN or other decay calculation codes are used, then sampling to confirm the isotopic ratios from the code should also be performed. These two alternatives should be combined and considered as one alternative. The commenter also notes that Section 4.1.3.1 states for DTC that "at some times," modeling will be used in conjunction, and then specifies that when this is, so sampling and analysis for isotopic ratios must also take place. (II.B.5)

Response to Comment B1.14: The WCPIP is sometimes confusing with respect to when sampling and analysis will be performed. EPA expects that when modeling is used to acquire necessary radiological data, then sampling and analysis to confirm isotopic ratios derived from modeling should also take place. EPA expects any implementation of the DTC method to involve both modeling and sampling.

Comment B1.15: The commenter states that Section 4.1.1.2, Quality Assurance Objectives, contains definitions of the precision, accuracy, representativeness, completeness, and comparability data characteristics. All of these definitions are useful, and some are at least reasonable facsimiles of the definitions in 40 CFR 194.22(c). However, this WCPIP's Section 1.0 states that the document "...identifies waste characterization requirements and methods to satisfy requirements in Title 40 Code of Federal Regulations (CFR)...194"; the document should therefore not redefine the terminology already defined in that CFR. (II.A)

Response to Comment B1.15: The definitions for precision, accuracy, representativeness, completeness, and comparability contained in section 4.1.1.2 of the WCPIP are substantially in agreement with the definitions contained in 40 CFR 194.22. Any use of these terms by DOE for compliance determination must be in accordance with the definitions in 40 CFR 194.22. Where applicable, the acceptance criteria for determining compliance with any of these terms must be quantitative in nature. Since a site may use a wide variety of characterization methods for RH characterization, EPA expects method-specific QAO's to be described in the site plans and procedures for characterization. These will be evaluated prior to implementation or as part of the inspection program, as appropriate.

Comment B1.16: The commenter states that Section 4.1.2.1 indicates in part that "During packaging, only materials from the same waste stream, with similar radiological properties may be packaged in the same waste container." These "similar radiological properties" should be

delineated. The commenter suggests that there should be good evidence that the wastes placed in a waste container have the same radionuclides in similar relative abundance ("isotopic ratio"). (General Comment)

Response to Comment B1.16: As the commentator implies, the term "similar radiological properties" is ambiguous, and we understand that the intent of Section 4.1.2.1 is that only materials with radionuclides in similar relative abundance should be packaged together. The packing of only materials with similar radionuclide ratios is critical to the application of the DTC method to quantify the activities of individual radionuclides. In implementing the requirements of Section 4.1.2.1, we expect that sites will provide more precise descriptions of the term will be interpreted in practice; we will evaluate the adequacy of these interpretations in our review of site-specific documents and through on-site inspections. We suggest that DOE make conforming changes to the WCPIP to provide additional guidance to sites in developing their site-specific characterization plans. Furthermore, EPA expects sites to quantify and propagate uncertainties in the ratios of radionuclides whether estimated by NDA, DA, or modeling.

Comment B1.17: The commenter states that Section 4.1.2.1 also lists the information that should be on a VE data form. Missing from this list are estimates or measurements of the pertinent waste material parameter masses in the container. While this WCPIP uses the total mass of the waste in the container (for debris wastes, the most likely kind to be packaged as described in this section) to establish the "plastic" to be reported in the WWIS, the commenter indicates that an estimate or measurement would make the value reported much more accurate. The current CH TRU VE uses estimates of waste material parameter volumes, and look-up tables to convert the volumes to mass, and the commenter stresses that the same tables would be applicable to RH TRU wastes for both radiography and VE.

Response to Comment B1.17: We agree that DOE could acquire a quantitative determination of the amount of CPR components present in RH waste during the VE/RTR processes. However, DOE asked for a less stringent approach to the VE/RTR process because of the inherent difficulties associated with visually examining RH waste (i.e., has to be done remotely, etc). EPA requires that a general estimate of the percentage of each waste material parameter in RH waste containers be determined and recorded as part of VE/RTR. EPA has also determined that because RH waste constitutes such a small portion of the total waste intended for WIPP and because the CH program for determining CPR/waste material parameters is sufficiently rigorous, the approach proposed by DOE is acceptable if anything it would overestimate the CPR content of waste. DOE understands an inherent risk associated with this approach. That is, DOE knows that if, in the future, allowable CPR quantities are exceeded, DOE cannot "go back" and recalculate the "correct" amount in RH waste because DOE chose not to collect sufficiently detailed information during the VE/RTR process to do so.

Comment B1.18: In commenter's opinion, contrary to Section 4.1.8.1 of the WCPIP, that the methods for marking samples with unique identification by nontraditional methods needs to be specified, or required to be specified in the waste characterization site documents (perhaps in the sampling plan required for each waste stream earlier in the section). (II.B.5.f; II.B.5.i; III.C.4 – Destructive Assay)

Response to Comment B1.18: DOE has not provided scenarios in which "non-traditional" sample identification would be necessary. However, EPA understands that DOE developed the

WCPIP to be flexible, thus accommodating a number of different waste sample collection scenarios. Therefore, EPA would evaluate sample custody and integrity as part of Sampling and Analysis Plan review, Confirmatory Testing Plan Reviews, etc, submitted by an RH TRU waste generator/storage site. Provision of this information as part of the appropriate plan is necessary to ensure adequate custody and integrity of samples collected for purposes of RH waste characterization.

Comment C: The commenter has a real concern on the WIPP's approach to RH characterization. Specifically regarding the use of the "Dose to Curie" determination, (s)he finds it substantially flawed and suggest EPA evaluate it in greater depth. DOE has assumed that the verification of a given dose rate validates the waste contents but have not undertaken any real error analysis on uncertainties in the waste matrix itself. For example, if they did measure the same dose rate within error that they predicted, they still have no idea what the false negative probability for attaining that result in fact is. If, for example, there was much more activity than expected, this could be compensated by having more waste of a higher atomic number or higher density than expected providing more shielding than modeled and so a yet to be quantified amount of higher activity would be present in the waste and still get the predicted dose rate within their stated tolerance. (II.B.5.c, III.C.3)

Response to Comment C: EPA understands that the DTC method does not verify a predicted dose rate, but instead it relates the total TRU alpha activity, and the activities of individual radionuclides, to the measured dose rate when the relative abundances of relevant radionuclides are known and when the shielding properties of the container and its waste are adequately known and correctly modeled. If, as in the example cited by the commenter above, the amount, density, and/or effective atomic number of the waste is greater than that modeled in the DTC method, the activity would, in fact, be underestimated. EPA expects any application of the DTC method to characterize RH waste will include an estimate of the uncertainty in the activity, including appropriate contributions from the uncertainty in the dose rate measurement, uncertainties in the relative abundances of radionuclides, and uncertainties in the shielding calculations used to model the waste.

Computer modeling is critical to the DTC method. EPA expects that the site's waste characterization plans will describe in detail the modeling process being used at the site for DTC and that such modeling efforts will follow guidelines in EPA's *Guidance for Quality Assurance Project Plans for Modeling* (EPA QA/G-5M), which requires a detailed description of the modeling process including accounting for uncertainties. EPA will evaluate the modeling process not only for the isotopic mix determination, but also for the signal-to-source calculation (the shielding calculation that relates measured dose rate to gamma source). Any shielding model evaluation must include the effects of potential heterogeneities in the matrix and in the source; it must also describe either why these are not an issue or account for them by some sort of uncertainty evaluation.

Comment D: The commenter support EPA's approval of DOE's proposed RH WCPIP since it would help to address removal of RH waste stored/generated at the Oak Ridge site.

Response to Comment D: EPA is approving the RH WCPIP because we've determined that it provides an adequate framework for the characterization of RH waste for disposal at WIPP.

Specific sites are not authorized to begin RH waste characterization or shipment to WIPP without additional approvals from EPA.

IV. CONCLUSIONS

Upon review of the WCPIP, we conclude that the proposed plan provides an adequate general framework for RH sites to follow, and also now includes detailed technical information lacking in earlier submissions. We accept this proposal for RH waste characterization provided to EPA on October 2003 with the understanding that sites will provide EPA with all supporting documentation necessary to understand the proposed characterization process for each waste stream prior to implementation of the process, and that EPA is allowed access to all necessary documentation required to make a full and informed approval decision for a specific waste stream. This will ensure that characterization processes are not performed that EPA ultimately cannot approve, unnecessarily exposing individuals to radiation.

We have concluded that DOE proposed an RH characterization program that shares common elements with the CH program, but does not mandate 100% NDE/NDA and which can use AK data alone to meet requirements, if appropriately qualified using the three qualification methods (namely, confirmation testing, peer review, and QA equivalency determination). EPA approval will be necessary of the processes used in implementing any of these qualification methods. EPA believes that the approach presented by DOE allows RH sites to use the most appropriate method available to characterize waste (i.e., meet DQOs), and defines the specific components of this process mandating that AK be collected for all wastes and that a specific process be followed if this AK data is used to meet a DQO (assuming the AK data are acquired prior to an approved QA program).

Public comments identified a number of technical issues which do not alter the approach of the WCPIP. These issues will be thoroughly evaluated by EPA in our review of site-specific waste characterization documents implementing the WIPP. For several areas, we suggest that DOE make conforming changes to the WCPIP to provide additional context and guidance to sites in developing their site-specific plans:

Suggesting Conforming Changes to WCPIP Based on Public Comment	
Change	Revision and Location
Comment B1.8 The commenter believes that specifying the details for independent assessments by the CBFO or other outside organizations in generator site documents would compromise the independence of those assessments, and recommends that the second sentence be amended to eliminate that suggestion.	Revision of WCPIP, Section 3.3, as follows: "Specific assessment actions…WCPIP. These actions….QAPD ~~the details of which shall be specified in program documentation~~."
Comment B1.9. The commenter believed that identification of causes and action to preclude	Modify the text of Section 3.3 to indicate that conditions affecting compliance with QA/QC

recurrence for adverse conditions discovered in the RH program should not be limited to only those that affect QA/QC requirements in the WCPIP.	requirements of the WCPIP, as well as EPA approved site implementing documents, will be subject to corrective action.
Comment B1.11. The commenter believed that the definition of nonconformance in the WCPIP was not consistent with that throughout CBFO quality assurance documents.	Revise the definition of nonconformance in the WCPIP, Section 3.5.2.2 to comport with the definition in NQA-1, Supplement S-1.
Comment B1.13. The commenter believed the auditable record should be required to include AK data limitations.	Revise Section 4.1.1.1 and the related AK procedure to require that the auditable record consist of documents that contain the source material used to make decisions regarding waste characterization, and that this record must include documents that establish a parameter that addresses DQOs/ or the absence of these parameters, as must also include AK data limitations.
Comment B1.14. Implementation of the WCPIP with respect to sampling and DTC is confusing.	EPA expects any implementation of the DTC method to involve both modeling and sampling.
Comment B1.16. The commenter indicated that packaging should mandate that wastes with similar relative abundance (isotopic ratios) be placed in the same waste container.	Revise section 4.1.2.1 to state that during packaging, only materials from the same waste stream, with similar relative abundances (isotopic ratios) may be packaged in the same waste container.