Thank you for providing the Environmental Protection Agency (EPA) with the opportunity to review the Department of Energy’s (DOE) Draft Notification of Planned Change concerning characterization of remote-handled transuranic (RH-TRU) waste. We have reviewed the proposal in order to provide DOE with guidance for preparation of a final proposal for characterization of RH-TRU waste.

The draft proposal represents a considerable advance from previous drafts that DOE has presented (such as the plans delivered to the National Research Council in 2001), inasmuch as it now incorporates information that is specifically intended to address questions that EPA has raised in the past. Nevertheless, we continue to have concerns about both the content and presentation of the proposed approach to RH-TRU waste characterization. In general, we observed three areas where improvement is needed in order for DOE to present an RH-TRU plan that will comply with the terms of our certification of the Waste Isolation Pilot Plant (WIPP) and will be fully defensible: basis for departing from the contact-handled (CH-TRU) waste program; organization of the proposal; and qualification of acceptable knowledge. The enclosure to this letter contains our comments on specific elements of the draft proposal.

Departure from CH-TRU Program

The waste characterization program that DOE presented in the Compliance Certification Application (CCA), and has implemented for CH-TRU waste, has proven effective. DOE has proposed a different program for RH-TRU waste. In order for EPA to consider departures from the CH-TRU program, DOE must justify in its proposal why the CH-TRU program cannot or should not be applied to RH-TRU waste. DOE states in the draft proposal that concerns over
high surface dose rates are the basis for the differences in the program. If so, the proposal must show that the methods used in the CH-TRU program could cause significantly higher doses to workers when applied to RH-TRU waste, and could cause applicable worker dose limits to be exceeded. Similarly, if used as justification for departing from the CH-TRU waste characterization scheme, other safety and technical challenges associated with RH-TRU waste should be fully explained in the proposal, including a discussion of alternatives.

Organization of the Proposal

EPA identified a significant amount of overlap, redundancy, absence of information, and/or contradictory information in the proposal. It is essential that the proposal provide a clear distinction between (1) explanatory information to assist EPA's decision making and (2) the complete set of requirements that will be given to the sites that will characterize RH-TRU waste. The enclosure offers our suggestions for how to achieve this purpose.

Qualification of Acceptable Knowledge

Acceptable knowledge is information that must be qualified if it was generated and collected outside of the EPA-certified WIPP quality assurance (QA) program (40 CFR 194.22(b)). Based on the draft proposal, it remains unclear which qualification methods DOE would allow sites to use under various circumstances. EPA is prepared to allow DOE to apply conservative assumptions where appropriate in order to cap uncertainties associated with acceptable knowledge. However, we also believe that some level of confirmatory measurement may be unavoidable in order to establish a reliable inventory of those radioisotopes that are important to the WIPP's performance during the regulatory time frame.

We share your interest in determining the path forward for disposal of RH-TRU waste at the WIPP. Therefore, I would like to suggest that EPA and DOE meet in Washington within the next few weeks. The purpose of the meeting will be to answer any questions about our expectations for the RH-TRU waste characterization proposal, and to discuss DOE's plan of action for addressing the items in the enclosure. Rajani Joglekar of my staff is coordinating EPA’s actions on RH-TRU waste. Ms. Joglekar may be reached at (202) 564-7734.

Sincerely,

Elizabeth K. Forinash, Director
Center for Federal Regulations

Enclosure

cc: Clayton Oist (CBFO)
    Russ Patterson (CBFO)
Enclosure: EPA Comments on DOE's Draft Plan for RH-TRU Waste Characterization

The following comments are based on EPA's preliminary review of the Carlsbad Field Office (CBFO) document entitled, "Notification of Planned Change to the EPA 40 CFR Part 194 Certification of the Waste Isolation Pilot Plant, Revision 2," DOE/WIPP-DRAFT-3213, June 2002. These comments are grouped according to the overall presentation of the RH-TRU waste characterization program and several key technical elements.

I. Organization and content of the proposal

The proposal is composed of the following elements:

- Notice of Planned Change
- RH-TRU Implementation Plan, with appendices:
  - Radioassay requirements
  - Acceptable knowledge requirements
- Comparison of CIF-TRU and RH-TRU programs
- Analysis of RH-TRU impact on performance
- RH-TRU inventory report
- Guidance for sites on key technical areas
- Examples of site reconciliation reports

EPA found numerous instances of apparently redundant, conflicting, or absent information in the proposal. For example:

1. The proposal does not adequately explain why the change is justified. Also, it does not clearly identify how the new requirements satisfy the regulatory requirements at 40 CFR 194.22 and 24.

2. The proposal does not address quantification of important radioisotopes for the purpose of distinguishing between transuranic and low-level waste, and for determining that waste is remote-handled. The proposal does not require quantification of alpha emitters other than 239Pu and the determination of 137Cs and other gamma emitters to classify the waste as RH-TRU.

3. The proposal offers sites a number of characterization options so long as data quality objectives (DQOs) and Quality Assurance Objectives (QAOs) are met. Some DQOs, however, are excluded without adequate explanation, and the basis for some QAOs is confusing or inadequately explained.

4. The characterization through packaging (CTP) procedure is inadequately explained, particularly with regard to its purpose and how it would verify AK information.
5. The Acceptable Knowledge (AK) standardized procedure is not explained adequately and does not integrate 194.22(b) requirements for AK confirmation.

6. The Dose-to-Curie (DTC) conversion method lacks needed guidance specific to computer modeling and representativeness of samples for radioassay.

7. The proposal does not appear to present the criteria that will be used to determine whether sites may use peer review to qualify data.

   EPA suggests that CBFO restructure the proposal so that a clear distinction is made between information that is intended for EPA as the audience (referred to below as "EPA proposal") and information that is intended for sites as the audience (referred to below as "site requirements"). This approach will greatly facilitate EPA's review of the final proposal.

   The EPA proposal section should address the following topics:

8. **Justification:** The draft proposal identifies a number of areas where DOE intends to depart from current practice for CH-TRU waste, including the role and use of acceptable knowledge, quantification of radioisotopes, and qualification of data. EPA assumes that the essential information about RH-TRU waste will be obtained using processes and techniques that are the same as or essentially equivalent to those used for CH-TRU waste, unless DOE demonstrates that it is unreasonable or impractical to do so. In other words, DOE must present a factual basis to justify why allowances should be made for RH-waste characterization that are not applied to CH-TRU waste.

   If the higher surface dose rates from RH-TRU waste are the primary motivation for changing methods already in practice (nondestructive assay, nondestructive examination, and visual examination), then EPA expects DOE to present a dose assessment to show that the application of those methods would result in unacceptably high worker dose in comparison with applicable DOE occupational standards. Similarly, if gamma emissions limit the effectiveness of certain radioassay methods, then DOE should consider whether other available methods will be more effective. EPA needs this information in order to present a reasoned argument for allowing the change.

   The effect on RH-TRU waste on performance calculations on its own is insufficient to justify applying different approaches to CH-TRU and RH-TRU waste. RH-TRU waste must be clearly shown to present technical and safety challenges that cannot be overcome using the established CH-TRU characterization program.

9. **Regulatory Requirements:** The EPA proposal should summarize how site requirements address applicable regulatory/statutory requirements, particularly those listed below.
**Land Withdrawal Act**

Section 2(19): Only waste that is generated by atomic defense activities may be disposed in the WIPP.

Section 7(a)(1)(A) and (B): No transuranic waste received at WIPP may have a surface dose rate in excess of 1,000 rems per hour. No more than 5 percent by volume of the remote-handled transuranic waste received at WIPP may have a surface dose rate in excess of 100 rems per hour.

Section 7(a)(2)(A) and (B): Remote-handled transuranic waste received at WIPP shall not exceed 23 curies per liter maximum activity level (averaged over the volume of the canister). The total curies of the remote-handled transuranic waste received at WIPP shall not exceed 5.1M curies.

Section 7(a)(3): The total capacity of WIPP by volume is 6.2 million cubic feet of transuranic waste.

**40 CFR Part 194**

Section 8(a) and (b): For each waste stream or group of waste streams at a site, DOE must describe the use of process knowledge and implement a system of controls in accordance with 194.24(c)(4) to show compliance with established limits on waste components. The system of controls and use of process knowledge are subject to applicable quality assurance (QA) requirements.

Section 22(b): Data and information collected outside of the WIPP quality assurance program must be qualified using an EPA-approved method, which may be peer review, corroborating data, confirmatory testing, or an equivalent QA program.

Section 24(c)(3): Use of process knowledge must conform to established QA requirements.

Section 24(c)(4) and (5): DOE must demonstrate that a system of controls is in place and is effective for the purpose of confirming that key waste components in the WIPP comply with established limits. The system of controls must conform to established QA requirements.

**40 CFR 194, Appendix A**

Conditions 2 and 3: DOE may not ship waste to the WIPP for disposal until EPA has approved the processes for characterizing the waste and the QA program for waste characterization activities.
Waste Component Limits: The Certification Decision established limits on the following waste components: radioisotopes, cellulosics, rubbers, plastics, ferrous and non-ferrous metals, and free liquid. In accordance with 40 CFR 194.24(c), waste may not exceed or fall below these limits, as appropriate. The maximum or minimum allowable amount of each component is discussed in chapter 4 of DOE’s Compliance Certification Application and EPA’s Compliance Application Review Documents for Sections 24 and 31.

10. **Technical Elements**: The EPA proposal should summarize the technical elements of the RH-TRU program listed below and indicate where they are addressed in site requirements:

- Acceptable knowledge and data adequacy
- Description of and rationale for AK confirmation alternatives
- Sampling approach
- Characterization Through Packaging process
- Dose-to-Curie method
- Radioassay
- Data reporting
- Changes to WWIS and software documentation
- Applicable QA requirements

DOE has indicated that only a small fraction of existing RH-TRU waste will not be repackaged. It should be immediately apparent which requirements apply to which waste streams, depending on whether they are (A) retrievably stored and not repackaged, or (B) to-be-packaged, repackaged, or to-be-generated.

11. **Inventory**: Information on the estimated RH-TRU inventory should be included in the EPA proposal section.

12. **Performance impact**: In order for EPA to accept the results of Sandia National Laboratory’s assessment of the effects of RH-TRU waste on performance, we expect to conduct an independent review of the calculations, including but not limited to whether the work was completed using qualified codes, and whether assumptions about RH-TRU waste parameters were consistent with those in the certification performance assessment and sensitivity analysis.

In the Certification Decision, EPA established that the WIPP complies with our disposal regulations using inventory estimates of CH-TRU and RH-TRU that DOE provided at that time. Assuming that DOE’s current estimates for the RH-TRU inventory are within the bounds of the original estimates, EPA considers SNL’s impact analysis to be supplemental but not essential for our decision making. For this reason, EPA does not consider it necessary to pursue further analysis of Sandia’s work at this time. If DOE is able to show the technical and/or safety basis for the proposed RH-TRU characterization...
program, then Sandia's analysis may prove useful as a demonstration of no consequence, provided that EPA finds that analysis was conducted properly.

II. Technical Elements of Proposal

Waste characterization is necessary to confirm the source term assumptions made in the WIPP performance assessment. Measurement of limited waste components (and identification of associated uncertainty) in the TRU waste disposed at the Waste Isolation Pilot Plant (WIPP) is necessary to ensure that, at closure, the cumulative levels of the regulated components will be consistent with assumptions used to demonstrate long-term performance.

13. For CH-TRU waste, DOE performs nondestructive assay (NDA) and nondestructive examination (NDE) on 100% of waste containers prior to disposal. This analysis is augmented by acceptable knowledge (AK) and visual examination (VE). Given questions about inconsistencies and gaps in the AK record, EPA concurred with DOE's proposed approach to waste characterization in the Compliance Certification Application (CCA). In order for EPA to authorize a less rigorous approach (i.e., <100% NDA and VE) for RH waste, CBFO must clearly explain which of the CH TRU waste characterization program components (AK, NDA, VE, radiography, data documentation, and transfer to WWIS) remain unchanged, which have been changed, and why the change was made.

14. The characterization process must be readily auditable; however, the current proposal does not clearly establish the steps for developing auditable records. Also, in some areas the proposal is open-ended with respect to the conditions under which the Site Program Manager will be allowed to make subjective decisions concerning adequacy of available RH-TRU data and what degree of confirmation is necessary. EPA anticipates that this ambiguity could pose significant difficulties during inspections of RH-TRU waste characterization programs at sites.

The RH-TRU proposal should contain at a minimum, the items discussed below.

Acceptable Knowledge

15. The proposal must clearly identify the criteria for making an adequacy determination for the AK record for radiological and non-radiological RH waste components.

16. The proposal must explain the decision-making process for ascertaining whether waste is: (a) transuranic; (b) from defense activities; (c) commingled with waste from non-defense activities and whether commingling is appropriate; and (d) RH waste.
The proposal (particularly the site requirements section) should address the following items related to AK:

17. Radiological characterization training and experience an AK Expert (AKE) should have to determine the radiological contents of individual containers.

18. When and how peer review may be used to qualify radiological data generated prior to the implementation of the WIPP quality assurance program in accordance with 40 CFR 194.22(b), including the approach used to revise AK data based on peer review results.

19. The basis on which a site is allowed to conclude, solely through the AK record, that a given RH-TRU waste container meets the statutory definition of transuranic (TRU) waste.

20. The basis on which a site is allowed to conclude that RH-TRU waste approved for disposal does not contain waste components from non-defense related activities.

21. The basis for allowing a given site to apply container-by-container isotopic data from one waste stream or subgroup to another waste stream or subgroup.

22. How sites will be allowed to determine the activity for all WIPP-tracked radioisotopes from the available isotopic ratios, in the absence of actual measurements for a key radioisotope (e.g., 239Pu).

23. Methods for determining that unexpected radioisotopes are not present in RH-TRU waste, or quantifying the activity of unexpected radioisotopes.

24. Methods for demonstrating that a site can comply with the container limit requirements in Table 4-12 of the Compliance Certification Application (CCA) without quantifying isotopic quantities individually.


26. Methods for using safeguard program data to determine the activity of each WIPP-tracked radioisotope in an individual RH waste container, and how such safeguard data would be qualified in accordance with 40 CFR 194.22(b).

AK Confirmation

27. Given the relatively low volume of RH-TRU waste, EPA may be able to accept bounding figures for limited waste components under certain circumstances, provided that such figures are consistent with the assumptions about these materials in the performance assessment and sensitivity analysis. (For example, the performance assessment evaluated the effects of organic components (cellulosics, plastic, and rubbers) individually.

28. The site requirements should present a verification process for AK information, including collection of NDA or destructive radiochemistry information. CBFO may propose a statistical sampling method whereby the number of samples taken would be predicated on the expected chemical composition or activity levels of the waste.
up on the type and adequacy of AK information. EPA expects that there will be at least some verification of information obtained through AK compilation.

29. EPA discerned from the proposal that:

- Alternatives for confirmation of radiological components are:
  - 100% NDA
  - <100% NDA using representative samples
  - DTC method
  - peer review of radiological AK data, without NDA.

- Alternatives for confirmation of non-radiological components are:
  - 100% VE
  - CTP
  - <100% VE using representative samples
  - default values, without NDE.

Depending on the adequacy of AK data, a site may select any of these AK confirmation alternatives to measure radioisotope contents and estimate quantities of cellulosics, plastic, rubber, ferrous and non-ferrous metal, and free liquid on a container basis.

Some degree of flexibility in decision making may be permissible for sites; however, the proposal must present a clearer definition of the sets of options available to sites, when a given option is allowable, and the method by which allowance is given. EPA approval of these AK confirmation alternatives will be necessary.

CBFO's proposal should address the following items in connection with the alternatives of <100% NDA and VE for AK confirmation:

31. Whether a Latin Square Sampling is appropriate for selecting RH waste containers for NDA to confirm AK radioisotope data and VE to confirm the absence of >1% free liquid (by volume).

32. What criteria would be applied when selecting samples that are representative of the waste subcategory or a broader waste summary group.

33. Whether other sampling procedures could serve the purpose and meet CBFO's sample selection criteria.

34. How the proposed sampling methodology complies with EPA's waste characterization and QA requirements.

Characterization Through Packaging

35. Based on estimates that 95% or more of RH-TRU waste is expected to be either packaged, repackaged, or newly-generated, DOE proposes a "Characterization Through
Packaging” (CTP) method. CTP would be used to estimate physical waste material parameters (WMPs) in the repackaged or newly-generated waste. The CTP, however, cannot be a substitute for AK confirmation or radiological quantification. EPA assumes that CTP would only be a variant of visual examination. However, the proposal implied that CTP also could include other characterization processes. This matter must be clarified.

36. DOE proposes to use default values as estimated values for non-radiological waste components in individual containers. The proposal must justify assumptions for selecting the default values. If EPA does not concur with the use of proposed default values, then it will be necessary for CBFO to outline for sites how to characterize these elements.

37. With respect to verification of waste material parameters, collection of verification information could occur through the CTP process. CBFO may also want to build in contingency pathways to allow collection of CTP information to augment data unavailable through AK, including how collection of this information would impact the number of verification samples collected.

38. CBFO should propose a method for collecting verification information for already-packaged waste using existing visual examination records or other records to mitigate the need for additional physical examination. The proposal should provide a description of the entire characterization process, including criteria for determining and selecting characterization options.

Also, the proposal must identify:

39. Required training (for identifying, segregating, and managing containers containing prohibited items and free liquid) and continuing education for personnel who repackage RH waste.

40. A method to verify non-radiological data records before the SPM certifies that information reported is accurate.

41. A procedure to report information concerning non-radiological contents in a waste container to the WIPP Waste Information System (WWIS).

Dose to Curie Conversion Method

42. As an alternative to 100% NDA, DOE proposes a Dose-to-Curie (DTC) method in the Program Implementation Plan. DTC may be appropriate for some waste streams if the relative radioisotope distributions can be adequately determined through sampling or modeling. However, without radioassay it is impossible to confirm the radioisotope distributions used to estimate the activities of individual radioisotopes. The proposal does not adequately explain how the confirmation of the ratio of only two plutonium isotopes will be sufficient to confirm the relative distribution of isotopes of different
chemical elements. EPA believes the introduction of expert judgment in this area could significantly complicate the auditing process for both CBFO and EPA.

43. In addition to confirmation of radioisotope distributions, more guidance to sites should be provided for computer modeling and sampling of swipes (or representative waste samples) to determine the relative radioisotopic distribution. Guidance should include the applicability and limitations of the method. For example, the “special radionuclide related activities” cited in Section 4.3.1 (page 34) of the Program Implementation Plan should be identified. Also, the proposal must explain the assumptions that CBFO made when developing dose-to-curie algorithms and the basis for those assumptions.

Radioassay

Radioassay of RH-TRU waste containers appears to be presented as an available option for sites, not a mandate. The proposal must identify when radioassay of RH-TRU waste containers will or will not be required by CBFO, as well the standards sites must meet in order to justify use of a different method. The proposal must address the reasons why:

44. RH waste containers cannot be analyzed remotely using NDA systems similar to those approved for CH waste.
45. A swipe or other representative sample from each container cannot be taken and properly shielded for radioassay measurements using analytical methods.
46. The active and/or passive measurement of neutrons emitted by plutonium or uranium in the RH waste to confirm AK at least partially is not technically feasible.
47. Modifications to the CH-TRU characterization program or addition of new equipment cannot be accomplished, including (but not limited to) why the existing NDA systems cannot be modified or redesigned to characterize RH-waste in the presence of a gamma-ray backgrounds. Possible modifications include, but need not be limited to:
   ▶ a low energy germanium (LGe) system with Compton suppression,
   ▶ an additional shielded high-purity germanium (HPGe) detector, and
   ▶ a passive/active neutron counter with fission chambers instead of $^3$He tubes

The proposal must including the following information in its description of the NDA requirements for RH waste:

48. A clear statement of the reporting requirements for the activities of the ten (10) WIPP-tracked radioisotopes, and other derived quantities, such as the alpha activity concentration.
49. An explanation of any requirements to determine the total measurement uncertainty (TMU) associated with above mentioned quantities.
50. A description of the minimum requirements to ensure that NDA systems are properly calibrated and remain in calibration (i.e., performance checks, background measurements)
51. A description of any minimum accuracy or precision requirements that an NDA system would have to meet to be used for characterization

52. A description of the training requirements for NDA operators and data reviewers.

Data Reporting

53. The proposal should contain those documents required for reporting (i.e., AK Summary vs. Characterization Reconciliation Report (CRR)), and should clarify those portions of the CH reporting processes that are still applicable to the RH program, as well as those portions of the CH program that are not applicable. Doing so will enable EPA to focus on what is different in the RH-TRU program.

54. The AK Standard Procedure should be a comprehensive document that establishes a hierarchy of information, not simply a checklist. The procedure should include WWIS Revision Documentation and Test Results, including all support documentation, implementation manuals, assumptions, WWIS test results, and WWIS calculation verification reports.

55. The proposal suggests that the WWIS will be used to track RH-TRU waste, but the WWIS is apparently going to be relied upon for several conversions, calculations, and other data manipulations it does not currently perform. The proposal must discuss the modifications to the WWIS that will be necessary to report and track AK data for RH-TRU.

III. Conclusion

Provided that CBFO is able to provide the information requested above, it should be possible to evaluate the technical adequacy of elements of the proposed RH-TRU characterization program. In preparing the site requirements for a final proposal, DOE should seek to present a well defined decision-making path for the RH-TRU waste characterization process that the generator sites will follow. This path should establish:

» a clear starting point for sites in terms of necessary information based on which they will make decisions about characterization
» specific processes/options available to sites for characterization of different RH wastes (particularly retrievably stored vs. repackaged or newly generated wastes), and
» criteria that must be met in order for a site to pursue each of the characterization pathways made available to them by CBFO.