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

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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

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).