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

ENTERED

AUG 1 2 2003

OFFICE OF
AIR AND RADIATION

Dr. Inés Triay, Manager
Carlsbad Field Office
U.S. Department of Energy
P.O. Box 3090
Carlsbad, NM 88221-3090

Dear Dr. Triay:

On August 1, 2003, we sent you our comments on the Department of Energy's (DOE's) proposal of April 30, 2003 regarding characterization of remote-handled (RH) transuranic waste for disposal at the Waste Isolation Plant (WIPP). Last week at the DOE's RH Demonstration, we noticed that the package sent to you did not contain Enclosure B. Enclosure B tabulated information presented in Enclosure A. We distributed the letter with both enclosures to people attending the RH Demonstration. With this letter we are sending Enclosure B for your records.

Sincerely,

Kenneth Czyzanski
for B. Forinash

Betsy Forinash, Director
Center for Federal Regulations

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

030818

Enclosure B
Summary of Comments Suggesting Changes to WCPIP and Seeking Information from DOE and RH Sites

WC Elements	Revise the WCPIP or site specific documents to include the following:	Information from DOE[1]	Information from RH Waste Sites in site-specific documents
1: General	1. To require that all RH Certification Plans also include: • mechanisms for assessing DQOs; and • justification for the selected confirmation pathways for each DQO 2. To require preparation and provision, as applicable, the Detailed Assessment Plans, Confirmatory Testing Plans, Peer Review Plans, and QAPD crosswalk/referenced Plans, or other plans developed to support the confirmation process; these must be provided, by RH sites, to EPA for review and approval prior to implementation. Also revise to recognize EPA's determination of "standard" techniques. State that any implementation of plans prior to obtaining EPA approval will be done so at risk by the DOE sites, and EPA cannot be held accountable for any actions occurring prior to EPA approval that may be contrary to that approval. 3. To reflect the following:	a. Provide a revised WCPIP. Specify information required by EPA that will be addressed in site-specific documents. b. Provide the "average container material of construction weights" and as appropriate, use this information in any PA calculations c. Provide estimates of S5000, S4000, and S3000 wastes to support an assumption that 49% of the container would contain plastic	i. Reflect all changes in the WCPIP within site-specific procedures in and/or in relevant plans, including but not limited to Items 1.1 through 6.1 (Also refer to Enclosure A) ii. Develop, for EPA review/approval, Data Acquisition Plans if additional AK information is collected that obtains this data through measurement (i.e. NDA, NDE, etc). Submit Data Acquisition Plans to EPA prior to implementation. Obtain EPA Approval of these plans prior to implementation. iii. Develop, for EPA review/approval, Confirmatory Testing Plans, Peer Review Plans, QAPD crosswalk/referenced Plans, and RH Certification Plans that address techniques or methodologies including but not limited to: • Peer Review or qualification of additional data to supplement or confirm AK; or • using "non standard" AK confirmation method with nonstandard being anything other than 100% NDA and/or 100% NDE Submit all above plans to EPA prior to implementation. Obtain EPA approval of these plans prior to implementation. iv. Show that qualification data generated complies with the QAOs at 194.22 (precision, accuracy, representativeness, comparability, and completeness)

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	• an overpack is used only when surface contamination is discovered on an individual drum/canister • the LWA limit of 23 Ci/liter is averaged over the canister and NOT the "payload container" or an overpack • RH waste is either direct loaded into canisters or emplaced in smaller containers in the canister, with the measurement technique and waste packaging configurations reviewed and approved by EPA • Mathematical averaging or manipulation of data from measured containers within larger containers must be approved by EPA on a site-specific basis 4. To include a revised 10-10-All approach that does not rely solely on the presence of liquids and which includes waste stream designation, waste material parameter contents (description only), waste stream description, packaging materials, including liners, fill percent (if the		v. Demonstrate that all requirements pertaining to RH waste characterization, loading, and packaging are complied with including that directly loaded waste is appropriately characterized. vi. Attach complete Characterization Information Summary consistent with that of the CH program to the WSPF vii. Reflect and implement, in site procedures, the requirement that all activities specifically not addressed by the RH proposal are performed in accordance with the current CH program viii. Provide all applicable procedures, processes, and documents to EPA should EPA elect to audit or inspect these activities. ix. Inform EPA, in writing, of all measurement related characterization activities that will be performed one month before implementation

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	container is used for DTC and NDA, if required), primary container contents, other significant matrix information, as identified in AK, prohibited items. 5. To require that a Characterization Information Summary consistent with that of the CH program is prepared and attached to the WSPF 6. To state that all activities specifically not addressed by the RH proposal are performed in accordance with the current CH program 7. To state that EPA has retained the right to assess and approve technical elements on a site-by-site basis, and request revisions, changes, or other modifications to the RH proposal as is technically and/or regulatorily warranted 8. To emphasize that EPA is not approving the use of corroborating data as a qualification method at this time.		

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2: NDA	1. To require calculation of TRU alpha uncertainty for all NDA, standard and non-standard. Also revise the WCPIP to require, in the site Certification Plan and/or Confirmatory Testing Plan, a method for calculating TRU alpha uncertainty on the measured container (i.e. canister or containers interior to the canister).		i. Provide EPA with test results to demonstrate compliance with data quality requirements. Ensure Item 2.1 is met. ii. Prepare all Confirmatory Testing and/or Detailed Assessment Plans that includes how the non-standard approach still meets the program requirements for data quality. iii. Ensure that any non-standard use of NDA methods is introduced in the site Certification Plan and described fully in the required Confirmatory Testing/Detailed Assessment Plans, including how the non-standard approach still meets the program requirements for data quality. Prepare and provide Certification Plans, Confirmatory Testing, and Detailed Assessment Plans to EPA before implementation. Obtain EPA approval of Plan(s) prior to implementation.
3: DTC	1. Quantitative DTC QAOs that address all components of the DTC methodology (i.e. modeling, sampling, dose rate measurement). These should be developed on a programmatic basis and included n the WCPIP, unless DOE can demonstrate the need for site-specific QAOs.	a. Provide written justification to EPA, for approval, if DOE determines it cannot include quantitative DTC QAOs in the WCPIP; EPA shall approve this justification.	i. Prepare site specific Confirmatory Testing Plan to address DTC activities, which will include the Sampling Plan, and provide to EPA prior to implementation. Obtain EPA approval. Ensure that Items 3.1-3.6 are presented in site procedures or other documents and are adequately implemented. ii. Provide, for EPA evaluation, DTC codes, input parameters to the code, and the validity of any

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	2. To describe the program by which the modeling process will be controlled 3. To require implementation of either the EPA QAPjP guidance for Modeling or a similar set of guides 4. To include an approach discussing application of quality requirements to the DTC modeling process 5. To include a requirement for determination of LLD in DTC using a definition of the LLD that is analogous to and consistent with that specified in the NDA section (section 4.1.5.1 of WCPIP) 6. To require that sites package in a given container only materials from the same waste stream, with similar radiological Properties		assumptions made in the code for each waste stream prior to its implementation, as well as any other information (procedures, etc) requested by EPA iii. Demonstrate that the DTC method provides results that meet data quality characteristics comparable to those that NDA systems must meet when characterizing the CH waste. If site-specific DTC QAOs are appropriate (see Item 3.a), obtain EPA approval of the approach prior to implementation at RH sites. iv. Document how values are derived from the activities of individual radionuclides and their associated uncertainty, including TRU alpha activity and its uncertainty for container activity in the event that individual drums are overpacked v. Require that personnel implementing the DTC method review all AK information pertinent to the DTC method vi. Check the dose rate measurement process to ensure that it conforms to the assumptions inherent in the shielding model producing the conversion factors
4: DA	1. Unless DOE can explicitly demonstrate that the following should be included in other documentation, revise the WCPIP or other documentation to: • Address and define	a. Provide written justification to EPA, for approval, if DOE determines it cannot include requirements in Item 4.1 in the WCPIP.	i. Prepare site specific Confirmatory Testing Plan to address DA activities, which will include the Sampling Plan; provide this to EPA prior to implementation. Obtain EPA approval. Also provide other information (e.g. procedures) as requested by EPA. Ensure that Item 4.1 is addressed. If requirements in Item 4.1 are

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	programmatic elements such as allowable error, data validation criteria, data usability criteria, and data assessment specifications • Provide sampling plan guidance to include sampling, analysis, data validation, data usability, and data assessment • Include more specific criteria and requirements addressing data uncertainties, validation, and usability criteria; as well as minimum performance standards • Clarify and define QC criteria: control limits for calibration activities, ICP-MS specific QC, chemical yields; and radionuclides in LCS and MS mixes and spike samples		not included in the WCPIP, generate site specific requirements. Obtain EPA approval of the approach prior to implementation at RH sites. RH sites must, for meet all DA requirements, for example, these sites must:: • Document process and results of random sample selection • Document process and results of control chart activities used to evaluate calibration and accuracy QAOs • Implement data management, validation, and usability criteria procedures • Produce DA batch data reports that document DA sample results and all QC results used to assess conformance to QAOs for precision, accuracy, representativeness, completeness, and comparability • Demonstrate that program level reviews of QAOs, as defined in the Confirmatory Testing Plan and/or Data Acquisition Plan, are performed and documented

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5: AK	1. To include specific quantitative criteria for comparing data generated to confirm AK with the AK record (include in Attachment A of the WCPIP).		i. Revise site documents to include quantitative criteria for comparing data generated to confirm AK with available AK prior to implementation ii. Demonstrate compliance of AK data with the quality characteristics of precision, accuracy, representativeness, completeness, and comparability when Peer Review or the QA Program qualification routes are selected. iii. Make available complete CRR and each available AK summary for EPA inspection . EPA shall determine the scope of the approval, in that approval of the CRR does not necessarily mean that all wastes with forthcoming CRRs may be approved.
6: WWIS	1. Revise the WCPIP to show how RH data will be populated in the WWIS in a manner to ensure consistency and accuracy amongst sites	*a. Seek and acquire EPA approval of any modifications to WWIS fields or input decision criteria and WWIS User Guide to accommodate RH WC information*	i. Demonstrate adequate WWIS data entry/transmittal in conformance with Item 6.1.

1 – DOE activity that must continue to address after EPA approval of the RH program are presented in italics. All others presented occur prior to formal approval. Note that this column is not necessarily all inclusive, and EPA may identify additional elements not specified on this chart requiring continued DOE attention through the course of RH Program implementation.