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CERTIFIED MAIL - RETURN RECEIPT REQUESTED

December 23, 2003

Dr. Inés Triay, Manager
Carlsbad Field Office
Department of Energy
P.O. Box 3090
Carlsbad, New Mexico 88221-3090

Dr. Steven Warren, President
Washington TRU Solutions LLC
P.O. Box 2078
Carlsbad, New Mexico 88221-5608

RE: NMED APPROVAL OF THE ADVANCED MIXED WASTE TREATMENT PROJECT FINAL AUDIT REPORT, AUDIT A-03-05
WASTE ISOLATION PILOT PLANT
EPA I.D. NUMBER NM4890139088

Dear Drs. Triay and Warren:

On November 13, 2003, NMED received the initial Final Audit Report of the Advanced Mixed Waste Treatment Project (**AMWTP**) Audit Number A-03-05 (**Audit Report**), from the Department of Energy's Carlsbad Field Office (**CBFO**). CBFO and Washington TRU Solutions LLC (**the Permittees**) were required to submit this Audit Report under the Waste Isolation Pilot Plant (**WIPP**) Hazardous Waste Facility Permit as specified in Permit Condition II.C.2.c. The intended scope of this initial certification audit was to ensure the adequacy, implementation, and effectiveness of specific AMWTP waste characterization processes for retrievably stored and newly generated debris, and retrievably stored homogeneous solids, contact-handled waste relative to the requirements of the WIPP Permit. The Audit Report further clarified that approval of debris waste would only be sought after a future audit was performed to evaluate visual examination to confirm radiography and headspace gas sampling and analysis for this Summary Category Group, and that analysis of homogeneous solid samples was contingent on approval of the analytical laboratory program at the Idaho National Engineering and Environmental Laboratory sought during audit A-03-15, which NMED granted on November 20, 2003. Following issuance of comments on the Audit Report by NMED on December 9, 2003, the Permittees responded with a revised narrative report, revised B6 checklists, and a replacement copy of a technical procedure in a submittal received on December 16, 2003. The revised Audit Report consisted of the following items:

- A revised narrative report
- Completed copies of relevant Permit Attachment B6 checklists (revised in redline/ strikeout format)
- Final AMWTP standard operating procedures (hardcopy only)
- Corrective action reports and items corrected during the audit
- Objective evidence examined during the audit
  - General information
  - Solids and soils/gravel sampling
  - Acceptable knowledge
  - Headspace gas
  - Real time radiography
  - Visual examination

NMED representatives observed the initial AMWTP audit on August 18 – 22, 2003 and the follow-up verification visit on October 15 – 16, 2003. NMED has examined the Audit Report for evidence of compliance with the requirements of Permit Conditions II.C.2 (Audit and Surveillance Program) and II.C.1 (Waste Analysis Plan [**WAP**]). The Audit Report indicates that during the initial audit there were six WAP-related conditions adverse to quality requiring the issuance of three CBFO corrective action reports; three deficiencies requiring only remedial actions that were corrected during the audit; seven observations identifying conditions that, if not controlled, could result in conditions adverse to quality; and five recommendations identifying opportunities for improvement. During the follow-up verification visit, the Audit Report states that the conditions adverse to quality were reevaluated and found to be acceptable.

NMED submitted an Observer Inquiry during the AMWTP audit questioning the applicability of solid sampling data collected by the previous contractor from the 3100 m^3 project to the entire population of the Rocky Flats first and second stage sludge waste stream. NMED was assured during the audit and follow-up verification visit that this issue was being examined and resolved by CBFO and AMWTP staff. On December 17, 2003, NMED received a response dated December 12, 2003 that reiterated the Permittees' position regarding preliminary samples that had been previously articulated in a response dated July 18, 2003 to an NMED Observer Inquiry for Rocky Flats ash at the Hanford Site. NMED has reviewed this recent response and continues to reject the Permittees' argument that no further sampling is necessary for containers in lot two because the Permittees believe that the seven preliminary samples are representative of both lots one and two of the Rocky Flats first and second stage sludge waste stream. This argument is invalidated by the requirement in Permit Attachment B2, Section B2-2a, which states, "Once segregated by waste stream, *random selection and sampling of the waste containers* followed by analysis of the waste samples shall be performed to ensure that the resulting mean contaminant concentration provides an unbiased representation of the true mean contaminant concentration for each waste stream." NMED believes the Permittees have failed to satisfy the fundamental criteria of demonstrating that random selection and sampling of the waste containers has been achieved for waste containers in lot two. Attached are pages from Attachment B2, Section B2-2a, that have been highlighted to draw attention to those portions that support NMED's interpretation of the permit.

NMED acknowledges the Permittees' concern in the transmittal of the revised Audit Report stating, "The Department of Energy does not believe that the issue identified in the Observer Inquiry that was prepared by NMED during the audit of AMWTP should be addressed in the final audit report." While NMED understands the basis of this concern, NMED cannot ignore issues identified in Observer Inquiry forms when evaluating whether to approve a specific Audit Report where unresolved differences remain.

NMED concludes that this revised Audit Report demonstrates that AMWTP has adequately implemented the applicable characterization requirements of the WAP. Therefore, NMED approves the Permittees' Final Audit Report for AMWTP Audit A-03-04 for the certification of retrievably stored homogeneous solids contact-handled waste. However, this approval is limited to only those waste containers remaining from the first lot of the original 3100 m^3 sampling "pool" described in the December 12, 2003 Response to Observer Inquiry letter and documented in Waste Stream Profile Number INW216.001, pending further discussions regarding preliminary sampling between the Permittees and NMED.

If you have any questions regarding this matter, please contact me at (505) 428-2512 or Mr. Steve Zappe of my staff at (505) 428-2517.

Sincerely,

Sandra Y. Martin
Acting Chief
Hazardous Waste Bureau

SYM:soz

Attachment: Permit Attachment B2, Section B2-2a (highlighted)

cc: Charles Lundstrom, NMED WWMD
Steve Zappe, NMED HWB
Tracy Hughes, NMED OGC
C. Steven Allred, ID DEQ
Kathleen Trever, INEEL Oversight
Laurie King, EPA Region 6
Betsy Forinash, EPA ORIA
Connie Walker, Trinity Engineering
Matthew Silva, EEG
Don Hancock, SRIC
Joni Arends, CCNS
Lindsay Lovejoy, NMAGO
File: Red WIPP '03

where M_{UCL} is the smallest value of M such that the probability of observing x or fewer miscertified containers in a sample of size n is less than or equal to α. That is, it is the smallest value of M such that the following inequality is true:

$$\sum_{k=0}^{x} \frac{\binom{M}{k}\binom{N-M}{n-k}}{\binom{N}{n}} \leq \alpha \qquad \text{(B2-3)}$$

where each term in parentheses has the usual combinatorial interpretation. For example:

$$\binom{M}{k} = \frac{M!}{k!\ (M - k)!} \qquad \text{(B2-4)}$$

Each term in the sum in Equation B2-3 is the hypergeometric probability of observing k miscertified containers in a sample size n from a population of size N in which there are M miscertified containers (and hence the population proportion of miscertified containers is p =M/N). The value M_{UCL} is obtained by substituting different values for M into Equation B2-3 until the largest value satisfying the inequality is found.

Note that in Equation B2-3, the upper confidence limit is dependent on x, the number of miscertifications observed in the sample, as well as on n, the sample size. To obtain the required sample size, the values of x that are likely to be seen shall also need to be considered. Sample size that shall be visually examined shall be determined by setting a desired upper confidence limit value and then manipulating x and n in Equation B2-3.

B2-2 Approach for Selecting Waste Containers for Statistical Sampling

B2-2a Statistical Selection of Containers for Totals Analysis

The statistical approach for characterizing retrievably stored homogeneous solids and soil/gravel waste and repackaged or treated S3000 waste that the generator/storage site demonstrates is not suitable for control charting using sampling and analysis relies on using acceptable knowledge to segregate waste containers into relatively homogeneous waste streams. Using acceptable knowledge, generator/storage sites will classify the entire waste stream as hazardous or nonhazardous rather than individual waste containers. Individual waste containers serve as convenient units for characterizing the combined mass of waste from the waste stream of interest. Once segregated by waste stream, random selection and sampling of the waste containers followed by analysis of the waste samples shall be performed to ensure that the resulting mean contaminant concentration provides an unbiased representation of the true mean contaminant concentration for each waste stream. The Permittees shall require each site project manager to verify that the samples collected from within a waste stream were selected randomly.

An end use of analytical results for retrievably stored homogeneous solids and soil/gravel is for assigning the Environmental Protection Agency hazardous waste D-codes that apply to each mixed waste stream and to confirm acceptable knowledge. The D-codes are indicators that the waste exhibits the toxicity characteristic for specific contaminants under the Resource Conservation and Recovery Act (**RCRA**). The RCRA-toxicity determination is made on the basis of sampling and analysis of waste streams and on whether or not the waste stream includes F-code wastes. If a waste stream includes one or more RCRA F-codes identified via acceptable knowledge, toxicity characteristic contaminants associated with the F-code waste(s) are not included in the RCRA-toxicity characteristic determination. That is, the F-codes take precedence over RCRA-toxicity D-code, and the waste stream is assumed hazardous regardless of the concentration. Therefore, toxicity characteristics contaminants associated with F-codes(s) for a waste stream shall be omitted from all calculations for determining the number of containers to sample because these wastes streams are assumed to be hazardous. In addition, each toxicity characteristic contaminant associated with the F-code(s) shall be excluded from evaluation of analytical results to determine D-codes. Contaminants of interest for the sampling, analysis, and RCRA-toxicity determination of a waste stream, then, excludes contaminants associated with F-codes that have been assigned to the waste stream.

The sampling and analysis strategy is illustrated in Figure B2-1. Preliminary estimates of the mean concentration and variance of each RCRA regulated contaminant in the waste will be used to determine the number of waste containers to select for sampling and analysis. The preliminary estimates will be made by obtaining a preliminary number of samples from the waste stream or from previous sampling from the waste stream. Preliminary estimates will be based on samples from a minimum of 5 waste containers. Samples collected to establish preliminary estimates that are selected, sampled, and analyzed in accordance with applicable provisions of the WAP may be used as part of the required number of samples to be collected. The applicability of the preliminary estimates to the waste stream to be sampled shall be justified and documented. The preliminary estimates will be determined in accordance with the following equations:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^{n} x_i \qquad \text{(B2-5)}$$

$$s^2 = \frac{1}{n-1} \sum_{i=1}^{n} (x_i - \bar{x})^2 \qquad \text{(B2-6)}$$

where $\bar{x}$ is the calculated mean and s^2 is the calculated concentration variance, n is the number of samples analyzed, x_i is the concentration determined in the *ith* sample, and *i* is an index from 1 to n.

Based upon the preliminary estimates of x and s^2 for each chemical contaminant of concern, estimate the appropriate number of samples *(n)* to be collected for each contaminant using the following formulas from SW-846 (EPA 1996):

$$n = \frac{t^2_{\alpha,n_0-1}s^2}{(RT-\bar{x})^2} \qquad \text{(B2-7)}$$

Where:

n_0 = the initial number of samples used to calculate the preliminary sample estimate.
n = the calculated number of samples in the preliminary estimate.
t^2 = the 90th percentile for a t distribution with n_0-1 degrees of freedom.
RT = Regulatory Threshold of the contaminant (TC limit for toxicity characteristic wastes, PRQL for listed wastes)

The number of samples to be collected will be based upon the largest n calculated for each of the contaminants of concern. The actual number of samples collected shall be adjusted as necessary to ensure that an adequate number of samples are collected to allow for acceptable levels of completeness.

All calculations should be rounded up to the nearest integer. A minimum of five containers shall be sampled and analyzed in each waste stream. If there are fewer than the minimum or required number of containers in a waste stream, one or more containers shall be sampled more than once to obtain the samples of the waste. Otherwise any one container may be selected for sampling only once.

The calculated total number of required waste containers will then be randomly sampled and analyzed. Waste container samples from the preliminary mean and variance estimates may be counted as part of the total number of calculated required samples if and only if:

- There is documented evidence that the waste containers for the preliminary estimate samples were selected in the same random manner as is chosen for the required samples.
- There is documented evidence that the method of sample collection in the preliminary estimate samples were identical to the methodology to be employed for the required samples.
- There is documented evidence that the method of sample analysis in the preliminary estimate samples were identical to the analytical methodology employed for the required samples.
- There is documented evidence that the validation of the sample analyses in the preliminary estimate samples were comparable to the validation employed for the required samples. In addition, the validated samples results shall indicate that all sample results were valid according to the analytical methodology.

Upon collection and analysis of the preliminary samples, or at any time after the preliminary samples have been analyzed, the generator/storage site may assign hazardous waste codes to a waste stream. For waste streams with calculated upper confidence limits below the regulatory

threshold, the site shall collect the required number of samples if the site intends to establish that the constituent is below the regulatory threshold.

B2-2b Statistical Selection of Containers for Headspace Gas Analysis

If a waste stream meets the conditions for representative headspace gas sampling in Permit Attachment B, Section B-3a(1), headspace gas sampling of that waste stream may be done on a randomly selected portion of containers in the waste stream. The minimum number of containers, *n*, that must be sampled is determined by taking an initial VOC sample from 10 randomly selected containers. These samples are analyzed for all the target analytes. The standard deviation, *s,* is calculated for each of the nine VOCs in Module IV, Table IV.D.1. The value of *n* is determined as the largest number of samples (not to exceed the number of containers in the waste stream or waste stream lot) calculated using the following equation:

$$n_{voc_i} = \frac{t^2_{0.9,n-1} s^2_{e_{voc_i}}}{E^2_{voc_i}} \qquad \text{(B2-8)}$$

Where:

n_{voci} is the number of samples needed to representatively sample the waste stream for the VOC $_i$ from Table IV.D.1
s_{evoci} is the estimated standard deviation, based on the initial 10-samples, for VOC$_i$ from Table IV.D.1
E_{voci} is the allowable error determined as 1 percent of the limiting concentration for VOC$_i$ from Table IV.D.1

Waste container samples from the preliminary mean and variance estimates may be counted as part of the total number of calculated required samples if and only if:

- There is documented evidence that the waste containers for the preliminary estimate samples were selected in the same random manner as is chosen for the required samples.
- There is documented evidence that the method of sample collection in the preliminary estimate samples were identical to the methodology to be employed for the required samples.
- There is documented evidence that the method of sample analysis in the preliminary estimate samples were identical to the analytical methodology employed for the required samples.
- There is documented evidence that the validation of the sample analyses in the preliminary estimate samples were comparable to the validation employed for the required samples. In addition, the validated samples results shall indicate that all sample results were valid according to the analytical methodology.