

**Subject:** Proposed Data Usability Criteria Outline

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Kerry, Mark -

Attached is an short paper describing NMED's proposed approach to developing data usability criteria for the WIPP waste characterization program. If you have any questions regarding this, please contact Bob Thielke at the e-mail address above or at his work phone number at TechLaw, (303) 763-7188.

Also, as I mentioned during our telephone conversation this afternoon, we are not ready to provide you with a paper clarifying NMED's position on the inapplicability of CLP Functional Guidelines for data usability purposes today, as we are still finalizing it. CBFO can expect this letter sometime next week after James returns to the office on Tuesday.

Steve

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# NMED's Proposed Data Usability Criteria Outline For WIPP Permit Data Usability Decisions

The EPA quality assurance guidance document, *Guidance on Environmental Verification and Validation (EPA QA G/8)* defines data usability as follows:

“an analyte and sample specific process that extends the evaluation of data beyond method, procedural, or compliance (i.e., data verification) to determine the analytical quality of a specific data set.”

Data usability as the term is used in the permit (*Attachment B3-1, Comparability*) is an activity in which data previously qualified during the data validation process is evaluated to determine the extent to which that qualified data can be used in the waste characterization process. Characterization activities that require data usability assessments include:

- Evaluation of Headspace Gas Sampling and Analysis Data
- Evaluation of Solids Data for Characteristic/F003 Analytes (VOC, SVOC, Metals)
- Evaluation of Solids Data for Listed Waste Analytes

Several assumptions can help guide the development of usability criteria. These assumptions include:

- A primary DQO of WIPP characterization activities is to confirm or update the hazardous waste codes assigned on the basis of AK
  - Provide data that confirms existing hazardous waste codes
  - Provide data that may prompt the addition/removal of codes as per permit requirements
- Criteria should guide decisions regarding the use of data based upon Permit AK requirements, which are generally conservative in terms of protecting human health and the environment. The emphasis when assessing data usability is to ensure appropriate code assignment, recognizing conservative assumptions in the Permit.
- Only data that has been validated in accordance with the data validation protocols specified in the permit and the QAOs presented in Tables B3-2 through B3-8 should be used to make data usability decisions

As stated above, a primary DQO for all measurement data is to confirm AK. Below are suggested general criteria for assessing the usability of data with respect to AK confirmation measurements:

- If the measurement data confirms AK
  - Data determined to be rejected or unusable will not be used
  - Data determined to be estimated may be usable as follows:
    - Data may be used if it confirms the AK assignment of hazardous waste codes
    - Data may require assessment to be sure permit intent and spirit are met if AK showed no codes, and measurement showed no codes
  - Data without qualification will be usable
  
- If the measurement data does not confirm AK
  - Data determined to be rejected or unusable will not be used
  - Data determined to be estimated will require further examination
    - Estimated data is used if Site decides to keep code not supported by confirmatory data
    - Estimated data requires assessment if Site elects to modify codes as per permit allowances (e.g., TC waste)
  - Data without qualification will be usable

Usability decisions for HSG and Solids characterization activities may be based on the comparison of sample results to specific action levels, or permit specified quantitation values at which characterization decisions are likely to be made. The characterization action levels that would influence data usability decisions include:

- Headspace Gas Sampling and Analysis
  - Analyte-specific UTL<sub>90</sub>
  
- Solids Data for Characteristic/F003 Analytes (VOC, SVOC, Metals)
  - TCLP concentration limit (UTL<sub>90</sub>)
  - F003 ignitability criteria
  
- Evaluation of Solids Data for Listed Waste Analytes
  - Analyte-specific MDL/PQL

As shown above, the use of rejected and estimated data requires the establishment of usability criteria specific to the analysis, media, etc. Below are examples of usability criteria for Headspace Gas (HSG) Sampling and Analysis with respect to the definition of unusable data and the use of estimated data. These examples are not intended to be inclusive of all definitions of unusable data or criteria for the use of estimated data. In addition, the Permittees would be expected to compile criteria for the VOC, SVOC, and metals solids data.

#### Examples of Unusable Data for HSG

- Non-detected results with Detection Limit greater than MDL
- Calibration RRF below acceptance criteria (non-detect only)
- Matrix Spike/LCS recovery lower than 3σ control limit

- Qualified data associated with blanks > 3 times the MDL
- Lack of evidence to demonstrate integrity of sample (leak check results, on-line system failures)

#### Examples of Estimated Data Requiring Further Examination for HSG

- Detected results below PRQL associated with low bias
- Detected results below PRQL that associated with exceeded precision and calibration criteria
- Qualified results associated with blanks >3 times the MDL and <PRQL

Several activities could be performed to evaluate estimated HSG data for which it is determined that further examination is required. These activities include:

- The event that should be prevented is to incorrectly fail to apply a hazardous waste code because low-biased data was used to determine that the UCL90 was below the PRQL. Therefore, determine if the final outcome would be different if:
  - Data with low bias (spike, LCS, hold time) and precision qualifiers are removed from data set
  - Data with low bias and precision qualifiers are adjusted to account for bias and precision (i.e., result with 50% LCS recovery is increased by 50%)
- If either test of the above tests is affirmative, then data should be removed from the data set or replaced with new samples. Whether new samples are collected is determined by:
  - If the completeness QAO (90%) is still achieved with the removal of some or all of the qualified data, then no further sampling is needed.
  - If the completeness QAO is not met for a drum lot, then additional drums may need to be sampled (reduced HSG option) or drums associated with poor data would need to be resampled. Drums should be available for sampling because they should not have been shipped until certified.

The Permittees should also develop appropriate tests for the examination of Characteristic/F003 and Listed Waste solids data.

In summary, the strategy for developing data usability criteria are specific to the type of sampling and analysis performed, as well as the end use of the data with respect to AK confirmation. Hazardous waste codes are assigned as required by the Permit. The purpose of AK confirmation is to ensure that appropriate codes are assigned, particularly if codes were missed via AK. To achieve that end the following general data usability examples could be followed:

- Data that causes a false negative (unusable non-detected results) to occur should not be used

- Data in which the integrity of the sample cannot be verified should not be used
- Data in which the identity of a compound cannot not be demonstrated should not be used (misidentified spectra, bad tunes)
- Results impacted by significant concentrations of analytes in blanks such that the results are reported as non-detects at levels greater than action levels should not be used
- All data with demonstrated positive bias or results that are greater than the action level may be used
- Results below action levels with associated precision problems or low bias require further examination
- Decisions to use data requiring further examination is based on whether use of the data causes a hazardous waste code to be added that should not have been added

Resampling or reanalysis is necessary if completeness QAOs or minimum sample quantities are not met when data is removed from the data set (i.e., if rejected data affects the achievement of the Completeness QAO). Usability determinations should not be made until data set (i.e., for a waste stream or waste stream lot) is complete, and usability assessments should be made before waste containers are sent to WIPP.