6183 U-004-408 .11

RESPONSE TO UNITED STATES ENVIRONMENTAL PROTECTION AGENCY COMMENT ON STATISTICAL METHODOLOGIES IN THE OPERABLE UNIT 2 FEASIBILITY STUDY

11/29/94

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NOV 29 1994

DOE-0216-95

Mr. James A. Saric, Remedial Project Director
U. S. Environmental Protection Agency
Region V-5HRE-8J
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

Mr. Thomas Schneider, Project Manager
Ohio Environmental Protection Agency
401 East Fifth Street
Dayton, Ohio 45402-2911

Dear Mr. Saric and Mr. Schneider:

RESPONSE TO UNITED STATES ENVIRONMENTAL PROTECTION AGENCY COMMENT ON STATISTICAL METHODOLOGIES IN THE OPERABLE UNIT 2 FEASIBILITY STUDY

This letter is in response to a comment made by the United States Environmental Protection Agency (U.S. EPA) on the Operable Unit 2 (OU2) Feasibility Study (FS) pertaining to statistical methodologies. The comment indicates that the methods used in the OU2 FS are a "significant deviation from guidance and are not consistent with other Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites." The Department of Energy, Fernald Area Office (DOE-FN) has conducted a thorough review of the related methods and applications both at the Fernald Environmental Management Project (FEMP) and at several other CERCLA sites. The results of this review indicate two basic facts: 1) the U.S. EPA Region V directed the DOE-FN to use these statistical methodologies at the FEMP and 2) these statistical methodologies are consistent with those used at other CERCLA sites, since these methods are standard techniques in statistical analysis.

The issue created by the U.S. EPA comment does not appear to be related to the statistical methods, but instead is related to the inter-relationship between the analytical methods, the Site-Wide CERCLA Quality Assurance Project Plan (SCQ), and the development of the FS risk assessment. The issue noted by the U.S. EPA had more to do with the detection limits than the concentration term reported. In the U.S. EPA comment and subsequent discussions, the major point of contention is that the concentration term is less than the "mean." It is important to note that, in cases where there are a majority of non-detect values, the data set has no defined (as determined using the appropriate statistical tests such as the Shapiro-Wilk, and others) distribution and therefore the term "mean" has no significance. In the example case cited by the U.S. EPA, there were 15 sample data points of which 12 were non-detect and three were detects that had a 'J' qualifier. The qualifier is placed on the detected value as a result of the Contract Required Detection

Limit (CRDL) being greater than the detected value. In the majority of cases, the non-detected value is significantly less (usually a factor of 3 to 10) than the CRDL, however the Contract Laboratory Program (CLP) Statement of Work (SOW) requires that the CRDL is reported. Detailed evaluation of the mass spectra provides insight to the potential for lower detection limits, with increasing uncertainty at lower values.

In the above referenced example, the three detected values ranged between 15 and 700 (ppb) parts per billion. The 95th percentile of the ranked values (non-detects are always ranked lower than detects) resulted in a non-detect. The appropriate application of the non-parametric 95th percentile test is to take the next higher ranked value that is a "detect." In this instance the value selected was the 15 ppb. In considering the representativeness of the results for use in risk assessment it is important to consider that, although the 15 ppb value is the lowest detected, there are 12 additional observations which were non-detect. Given that the same analytical methods and standards were used, it is extremely likely that the non-detects were on the order of or less than the detected 'J' values. Any other statistical approach for data sets such as this would merely be an exercise in evaluating detection limits and would therefore not add any substance to the risk evaluation.

The Sitewide CERCLA Quality Assurance Project Plan (SCQ), which was thoroughly reviewed and approved by the U.S. EPA, stipulates that the analytical methods used for Analytical Support Levels (ASL) C and D are to be used to obtain information for use in risk assessment. The methods used are required to be from the CLP SOW. Tables included in the SCQ identify the appropriate CLP method to be used for each media and contaminant being considered. The specific CLP methods identify the protocols for establishing the detection limits for specific organic and inorganic analyses. The contracts that the DOE-FN has with the U.S. EPA approved laboratories require that the CLP SOW dictated detection limits are met (requires the laboratories to meet the CRDL). The CRDL becomes the Sample Quantitation Limit (SQL) as identified in the CLP methods.

Using CLP methods for ASL C and D analyses, as stipulated in the SCQ, provides the DOE-FN and the U.S. EPA with the highest quality data available for use in risk assessment. In cases where the detection limit achieved by the laboratory exceeds risk based concentration values, the DOE-FN has reviewed the available data to determine whether the need for additional analyses would be necessary or appropriate. In the majority of the cases, the detection limits for Volatile Organic Compounds (VOC) and Semi-Volatile Organic Compounds (SVOC) are the lowest achievable given the media and the constituents considered. In these cases, the analytical results are reported as required by the CLP SOW as non-detect at the CRDL. Additional analyses cannot produce lower detection limits.

The above discussion which deals with details related to statistics, sample analysis, and risk, might be misinterpreted without a brief consideration of the overall picture. The issue identified by the U.S. EPA comment deals with a total of 26 separate and distinct data sets (26 contaminants of potential concern {COPCs}) out of a total of over 800 data sets. It is clear that this

situation is the exception rather than the rule and the overall impact on the risk assessment is negligible. A detailed discussion of the impact on the uncertainty associated with the risk assessment will be added. It is the position of the DOE-FN that the approach and methods used in the OU2 FS and all of the preceding approved and draft primary Remedial Investigation (RI) reports and FS reports (OU4, OU1, OU2, and OU5) are both appropriate and sufficient for characterizing risk at the FEMP. Deviation from these methods would constitute a significant and un-substantiated change from the direction previously received from the U.S. EPA.

If you have any questions concerning the above or if there are any additional questions regarding the enclosed submittal, please contact Randy C. Janke at (513) 648-3123.

Sincerely,

for Jack R. Craig
Fernald Remedial Action
Project Manager

FN:RCJanke

cc:

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