

ATTACHMENT B

Response to CDH letter "DOE Proposed Methodology for Statistical Comparison of Remedial Investigation Data at the Rocky Flats Plant" from G. Baughman to R. Schassburger, dated 10/13/93

1. To minimize any potential future misunderstandings of this agreement, the Division feels that it is critical for the Agencies to develop a formal guidance/policy document institutionalizing the agreement. The Strawman document was written for the purpose of facilitating agreement among the Agencies. However, the end users of this document will be the operable unit managers and sub-contractors preparing and reviewing RFI/RI reports. The majority of these people were not involved in the development of this methodology. It is critical to the future of this agreement that final documentation of this agreement be developed to clearly and concisely guide future end users in the implementation of this methodology. This formal guidance should be completed in parallel with the implementation of the agreement.

Concur. When the strawman has been completed and accepted by all concerned parties, it will then be rewritten as a procedure for statistical comparison of OU data to background.

2. The Division recommends that the title of this document be revised to more accurately reflect its content and intent, that being methodology and guidelines for the comparison of site data to background data. The Division proposes the title, "Guide for Conducting Statistical Comparisons of RFI/RI Data and Background Data at the Rocky Flats Plant," for consideration.

Concur. The CDH's proposed title is an improvement to the current title, and has been adopted.

3. One of the central themes of Dr. Gilbert's recommendations was the need for statisticians to be involved throughout the entire process. However, statistician involvement is not discussed in the methodology. The division requests that the role of the statistician in implementation of this methodology be clarified in this document.

Concur. Statisticians will be employed to verify that the methods used are correct. The strawman has been rewritten to incorporate this.

4. The Division does not believe that references to specific DOE sub-contractors are appropriate in this document. The Division recommends DOE review all references to sub-contractors and, where appropriate, modify the reference to more accurately reflect DOE's role and responsibilities.

Concur. References to DOE subcontractors have been eliminated.

5. This section (Determine Background and OU Target Populations) outlines the steps for matching site and background populations. However, it is unclear exactly how the matching will be implemented. The Division recommends that the rationale for combining media/geology groupings for testing be detailed in this section. For example, any criteria for minimum group size necessary for statistical testing should be specified. The Division further recommends adding a table or diagram depicting the general rationale for grouping data by media and geology.

Concur. The strawman states that the OU will match one or more of several specified background media. In addition, the strawman has been changed to require that a cross-reference be performed between the site and one or more background media.

6. As discussed during the September 29th meeting, and emphasized by Dr. Gilbert, it is critical to statistical hypothesis testing that the hypothesis to be tested is explicitly defined and clearly stated. The Division recommends a statement of the test and null hypotheses, in both "english" (narrative qualitative description) and statistical terms, be added to this section of the methodology so there is no misunderstanding of what is being tested. This statement should also address confidence and power requirements for the tests.

Concur. The strawman has been modified to require statistical and prose statements of the null and alternative hypotheses.

7. The Division does not agree with the blanket statement at the beginning of this discussion, "Under current IAG schedule conditions, analytical data will not be 'validated' when the background comparisons will be made in each draft report." This claim is not substantiated by the schedules submitted by DOE in the approved OU work plans and is in direct contradiction to Dr. Gilbert's Task 5 recommendations. Dr. Gilbert states that, "These data quality evaluations are conducted prior to descriptive graphical analyses and formal statistical tests." In finalizing this methodology, the Division recommends that DOE follow Dr. Gilbert's recommendations for data validation before formal graphical presentation and statistical testing. The need for variance from this approach will be considered by the Division on an OU specific basis.

Do not concur. Under the present system of data validation, the non-validated data are used only for the draft RFI/RI. The final RFI/RI is based solely upon validated data. The lag time between receiving data from the laboratory, and validated data from the independent subcontractor can exceed one month. Waiting for 100% validation may impact schedules, but will probably not change the results in the final RFI/RI. The potential impacts of using non-validated data at each OU will be discussed on a case-by-case basis.

8. The Division recommends DOE add a discussion of detection limits to this section of the methodology. In the past there has been confusion as to what detection limits are being reported and used (instrument detection limits vs contract limits vs reporting limits). Part of this confusion may be because detection limits have not been formally discussed. This section

should state what detection limits are to be used in statistical testing and how they are determined from the RFEDS data set.

Concur. The strawman addresses detection limits, and it specifies how determinations are made on how to handle non-detects.

9. The Division recommends that this section (Preliminary Exploratory Data Appraisal) be moved to the Data Presentation section.

Clarification. We have determined that this section is not necessary, and its steps are generally redundant with the Data Presentation sections, and so we have deleted this section.

10. The Division interprets this section as describing the informal data analysis conducted during RFI/RI preparation and not normally included in the formal RFI/RI report. The Division recommends adding language to indicate that this informal data analysis will be made available and reviewed with the regulators in evaluating the appropriateness of the scope of the formal RFI/RI proposal.

Clarification. We have determined that this section is not necessary, and its steps are generally redundant with the Data Presentation sections, and so we have deleted this section.

11. The Division does not agree with DOE's recommendations that box plots are applicable only when there are no non-detects. The problem of estimating percentiles for data sets with multiple non-detects was not resolved by Dr. Gilbert. The Division recommends that when a reasonably small percentage of non-detects are present, percentiles be estimated using Maximum Likelihood Estimation (MLE) techniques in constructing box plots.

Concur. We will provide box plots unless the percentage of non-detects exceeds 50%. The 50% figure is chosen for consistency with the 1993 Background Geochemical Characterization Report (September 30, 1993).

12. The Division does not agree with DOE's suggestion that histograms are not useful for small or highly censored data sets, such as inorganics. As stated by Dr. Gilbert, such histograms are not likely to be useful in visually assessing whether the data sets are better modeled by a normal or lognormal distribution. However, they may still be useful to visually compare the spread, central tendency, and skewness of the two data sets to look for differences that may be important.

Concur. We will provide histograms unless the percentage of non-detects exceeds 50%. Bars in the histogram will be shaded to indicate the percentage of detects and non-detects within each bar interval.

13. The Division recommends that a discussion be added to this section of the methodology to address what to do when a UTL 99/99 can not be reasonably estimated or is unknown (ie

small or highly censored background data set).

Concur. We have modified the strawman to state that professional judgement and use of geochemical standards will be used. The result will be a geochemical interpretation of data, subject to agency review and approval.

14. The reference in Footnote 2 to OU 1 is not appropriate and should be removed. The inferential tests conducted at OU 1 were the result of a compromise agreement, are not precedent setting for other OUs and are not the tests being proposed in this document. However, as stated in this note, limited professional judgement as presented later in this document may be applicable.

Concur. This footnote has been deleted.

15. This discussion (Footnote 3) should be moved to the DQOs or statistical test definition section of the document.

Clarification. This footnote has been deleted. We intend to use a p value of 0.05, and the footnote made that intent unclear.

16. The Division does not agree with the limitations DOE has placed upon the Slippage Test. The slippage test can be applied to data sets when the largest background point is a non-detect. If the largest background data point is a non-detect then logic must be applied to determine if the slippage test is applicable, but the test should not be categorically eliminated.

Concur. We have rewritten the strawman to state that, if the largest background data point is a non-detect, we will apply judgement to investigate whether or not the slippage test is applicable.

17. The Division recommends limiting the use of professional judgement to the first three criteria; spatial distribution, temporal distribution, and pattern recognition. In addition, it is recommended that the introduction to this section include acknowledgement that in applying professional judgement, the "burden of proof" lies solely on DOE. Professional judgement will only be considered by the Division on a limited basis where well documented and defensible evidence is presented.

Concur. We have eliminated the last five criteria from the strawman, and acknowledged that we will bear the burden of proof.

18. To make the process more efficient the task of eliminating non-detected analytes should be completed prior to data presentation. The flow chart should be modified to reflect this change.

Concur. We have changed the flowchart. CDH's comment improved the process.

19. This flow chart is confusing and difficult to follow due to the many multiple and

undefined branches. To minimize the potential for misunderstanding this chart must either be clarified or deleted.

Concur. The flowchart is too important to delete. It has been clarified. Lines denoting the flow of information have been deleted, keeping only the lines denoting flow of control, in accordance with common flowcharting techniques. Decision blocks have been transformed into diamond shapes. Alternative "No" paths have been added for the blocks labeled "No Non-Detect Present...OU Data Normally Distributed?", and "At Least One Test Significant?" Finally, the block representing the conditions which must be met prior to performing the t-test has been changed to reflect the conditions given in the text.