CORRES. CONTROL
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CARNIVAL, G.J.		
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DAVIS, J.G.		
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SETLOCK, G.H.		
STIGER, S.G.		
TOBIN, P.M.		
VOORHEIS, G.M.		
WILSON, J.M.		
Hopkins, J.	X	X
O'Rourke, T.	X	X
Hollowell, L.	X	X

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DOE ORDER # 5400.1

Department of Energy

ROCKY FLATS FIELD OFFICE
P.O. BOX 928
GOLDEN, COLORADO 80402-0928

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Mr. Martin Hestmark
U. S. Environmental Protection Agency, Region VIII
ATTN: Rocky Flats Project Manager, 8HWM-RI
999 18th Street, Suite 500, 8WM-C
Denver, Colorado 80202-2405

Mr. Joe Schieffelin, Unit Leader
Hazardous Waste Control Program
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, Colorado 80222-1530

Gentlemen:

The Department of Energy (DOE) has received your Human Risk Assessment template. This template will not be incorporated into the development of Technical Memorandums for Operable Units (OUs) No. 2, 3, 5, or 6 in its current form. These OUs are sufficiently advanced that redirection based on the template would negatively impact current schedules.

The DOE does not agree that the template is in a final form to be implemented, as several comments provided by DOE on a previous version were not incorporated. A copy of the additional comments on the template are attached, and a copy has been provided to Rich Schassburger of the Comprehensive Work Plan (CWP) negotiation team. The DOE proposes that continued development of the template occur under the CWP umbrella.

If you have any questions or comments, please contact Norma Castañeda at 966-4226.

Sincerely,

ADMIN RECORD

Steven W. Slaten
IAG Project Coordinator
Environmental Restoration

Enclosure

DOCUMENT CLASSIFICATION
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OCT 1994
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A-OU05-000540

cc w/Enclosure:
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R. Schassburger, ER, RFFO
N. Castañeda, ER, RFFO
S. Grace, ER, RFFO
B. Birk, ER, RFFO
K. Muenchow, ER, RFFO
P. Singh, ORNL
M. Guillaume, SAIC
E. Dillé, SAIC
J. Hopkins, EG&G
T. O'Rourke, EG&G

NOTICE:

INCOMPLETE DOCUMENT

The following document is missing several pages. This document was distributed in an incomplete state, and the microform copy is representative of the paper copy. If replacement pages are distributed, they will be microfilmed and included in the Administrative Record file.

The Administrative Record Staff

chemicals that may pose a hazard to health, whether they are nutrients or not, without these further requirements.

b) The last paragraph on page 12 contains the statement that "Due to the high level of uncertainties in sampling and analysis...". Could the authors please define what they mean by "high level"? The fact that there are "...small margins of safety between safe and toxic levels..." is true for many chemicals whether nutrients or not. This is taken into account in the RfD methodology.

11. Section 3.4 Frequency of Detection

a) Section 3.4 heralds in completely new scope under the auspices of "Frequency of Detection Analysis" and "SQL analysis." **This section represents a MAJOR addition of new scope to all OU Technical Memoranda.** Suddenly, comes the initiation of an analysis of non-detects and reported detection limits. Apparently, this section is an effort to get around the CRQLs/CRDLs that were created by EPA. In EPA Document ILM02.0, the EPA established a series of contract-required detection limits for inorganic analytes. (The CRQL is the equivalent EPA-established detection limits for organics). The question is; why did EPA establish the CRQLs/CRDLs if they are not to be used?

The discussion of the data with high SQLs is overly conservative and examples cited are unclear. For example, the text states that an analyte with 6% unacceptable SQLs would not be eliminated based on frequency of detection. However, the text does not state how these data would be used. The requirement of reanalysis of some samples by special analytical services to lower the detection limit is out of scope, and would have significant impact on schedules and costs.

12. Section 3.6 Concentration-Toxicity Screen

a) Last paragraph, page 16. The last sentence is not true: If several chemicals which contribute less than one percent (ratio of 0.01) are eliminated, the chemicals advanced into the quantitative risk assessment could represent much less than 99 percent of the risk. For example, if five chemicals had ratios between 0.0075 and 0.0099 and were eliminated the remaining chemicals would represent approximately 95 to 96.25 percent of the total risk.

13. Section 3.7 Professional Judgment

a) Section 3.7 brings another new angle into the COC-selection process. It seems that "professional judgment" now encompasses "public concern." (See Attachment 1 for comment on public opinion of scientific issues). Although keeping the public abreast of the scientific findings at RFETS is certainly a wise and correct thing to do, bringing in the opinions of a (generally) scientifically illiterate public to compete with the

recommendations of scientists — although a "politically correct" maneuver — is unwise.

The use of an RBC screen at this point would seem to defeat the purpose of the preceding section, Concentration-Toxicity Screen. This is aalso added scope within the risk assessment.

14. Section 4.1 Data Aggregation Methodology....

a) Paragraph 2. It would be useful to provide a brief rationale for defining "default exposure areas" in specified acreage units and a few but not all RFETS receptors. What is an occupational researcher? Perhaps "occupationally exposed individuals or receptors" is correct. Are office, industrial, and construction receptors included in this group. Are agricultural receptors to be considered? Is there a method for departing from the defaults as in the case of default exposure parameters.

b) At the top of Page 19 there is an assumption that, even for current land use exposure scenarios, random exposure is the most reasonable alternative to weighting time spent in different exposure areas or, presumably, in different parts of the same exposure area. For current land use, the configuration of major buildings and fencing perimeters would clearly present preferential contact inside and outside buildings and fenced security zones. For future land use, the topographic features may clearly present likely nonrandom mobility for the receptor. Is there a provision for departing from this sweeping assumption?

c) Section 4.1, page 19, addresses the uncertainty of estimating true means from a sample population. However, the wording here is misleading; the uncertainty of this estimate is related to the size of the sample population (as sample size increases, uncertainty decreases). To simply state, as is done in the guidance document, that "...the uncertainty associated with estimating the true arithmetic average...for a site is great...", is painting with too broad a brush. Also, it is unclear what is meant by the "reasonable maximum" mentioned in the last sentence of Section 4.1. Does this mean that outliers in OU data may be evaluated and excluded from the comparisons?

d) At the end of Section 4.1 there is a fleeting reference to the requirement for the average (central tendency) exposure and risk estimate in addition to the high-end (RME). No provision is made in the template for mean or median default parameters to carry out this requirement. Such parameters should be provided in Appendix C, or a strategy should be given for developing such default values from available published sources.

15. Section 4.2 Calculating the Exposure Point Concentration

a) Paragraph 1. The issue of detection limits (or, as stated in the guidance document, "sample quantitation limits") arises again in Section 4.2. Rather than confuse an already confusing issue with new terminology, why not simply state that "One-half of the *reported detection limit* will be used..."? The text should state that one-half the quantitation limit will be used for non-detect samples for PC analytes. Non-detect data are not censored data.

b) On the issue of detection limits, subpart 3 states that all COC data "...including data below background or detection limits..." be plotted on a map of the OU. To plot a bunch of

detection limits on a map adds no value to the map. It's the concept of "show us what's not there," and adds scope without adding value.

c) In the numbered paragraph 5, page 20, there is the requirement to present risks only for the exposure area representing the highest risk. This approach is antithetical to the requirement in Supplemental Guidance to RAGs (EPA, 1992) to develop both the high-end and typical exposures and risks. Such an approach would characterize risks solely on the basis of high-end and typical exposures within the "worst-case" exposure area. There should be a further requirement to present the high-end and typical risks for a *typical* exposure unit. Otherwise, risks will be over stated.

d) In Section 4.2, subpart 5a, the text reads that "The probability plot should show frequency of detection versus concentration." In fact, it is the *histogram* that shows frequency versus concentration.

e) Section 4.2, subpart 5b: "Data" is the plural of "datum", therefore, "data *are*...", not "data is...". Also in this section, geostatistics is used to *evaluate* the spatial continuity and distribution of data, not to "...incorporate spatial continuity..." as stated in the final sentence of page 20.

16. Section 4.3 Summary

a) The use of the terms "average best" and "average concentrations" is confusing since exposure calculations are based upon use of the 95UCL not the "average".

17. Appendix A

a) Appendix A, page 1 to 2, discusses the background data sets and lists the geologic units, but neglects even to mention the division of groundwater (and geologic materials) data into the upper and lower hydrostratigraphic units (UHSU and LHSU, respectively). This important concept has been supported by results from stable-isotope analyses, as well as major-ion chemistry. To ignore this important concept is a major oversight.

b) Where "soils" are mentioned, "subsurface soils" or "surficial soils" should always be specified for clarity.

c) Page A-3, under "Data Presentation": "Hit ratios" and "Non-detect rates" are redundant. Also, "hit" is technical slang and should not be used in a report. "Quantitation limit issues" are also noted here in the guidance; the question is really for EPA. What does EPA want to do with the CRQLs/CRDLs it created?

d) Also on page A-3, where construction of histograms is discussed, if any statistical tests are applied to a data set containing more than 50 percent non-detects, then histograms should be prepared down to the level of detects (say, 20 percent) that will be accepted in *any* of the statistical tests (including calculation of UTL values).

e) Page A-4, under "Bounding Benchmark...", the guidance states that "If the $UTL_{99/99}$ cannot be calculated or reasonably estimated...", but no "cut-off" limit is provided. Are we to assume from the previous page, that all analytes for which the non-detect rate is 50 percent or higher, are "inappropriate" for the calculation of UTL values?

f) Page A-4, third bullet. Please, do not indicate a possessive where only plurality is intended. (It should be written as "COCs", *not* "COC's".) Also correct this error in Figure 1.

g) Page A-5, paragraph five, last sentence. Please change to read that "...professional judgment...is applied to *determine the meaningfulness of the results of the statistical tests.*"

h) Page A-5, last sentence on page. What aspects of the detection limits should be discussed? It is completely vague as now stated in the guidance document.

i) Page A-7. What evidence is needed to label an OU datum as an "outlier"?

18. Use of UTLs From the 1993 Background Geochemical Characterization Report

a) Data Treatment and Calculation of UTL Values

Appendix A of the reviewed guidance document contains a series of tables (Tables C-1 to C-33) containing the calculated UTLs from the *1993 Background Geochemical Characterization Report* (September 30, 1993). It is important to note that the *1993 BGCR* was completed prior to initiation of the Gilbert methodology, so certain aspects of the report may not be directly applicable without minor modification. Certainly, the data on diskette contained within the report are still valid; however, if the UTL values from the appendices of the *BGCR* are used "as is", there is the potential problem of an inconsistent treatment of the data sets.

The UTLs in the *BGCR* were calculated utilizing a slightly different treatment of the data with regard to non-detects. In the *1993 BGCR*, the methodology for determination of "detect" and "non-detect" results and replacement of non-detects is spelled out in Section 1.4.4. Since release of the *1993 BGCR*, data-treatment methodology has been slightly modified to permit a less labor-intensive preparation of the data (see "Practical Suggestions for Users of RFEDS Data" 4-5-94). For this reason, the "DET" field of the background data set should not be used; rather, use the "RESULT", "QUAL", and "RL" (reporting limit) fields, to determine detects from non-detects, and treat both the background and OU data sets in the same manner.

In general, the differences in UTL values resulting from the slightly different treatment of the data are quite small; the major inconsistency that comes about in the reviewed guidance document relates to the distributional assumption used in the *1993 BGCR*. As stated in the text of the *1993 BGCR*, normality was assumed in the calculation of the means, standard deviations, and UTLs, even if it was known that the sample population was not normally distributed. The rationale for this assumption is provided within the *BGCR*, but, in light of the importance which the UTL has now assumed, it is inadvisable to use these *BGCR* UTL values "as is."

b) Outliers

There is also the question of outliers that has not yet been adequately addressed. For the *1993 BGCR*, at the request of EPA, outliers (both low-value and high-value) were flagged and excluded from the statistical analysis (see Section 1.4.3 of *1993 BGCR*). The list of excluded outliers is included in the *1993 BGCR* as Appendix E. It was recognized

that outliers may result from a number of factors, including data-entry errors, reporting errors, transcription errors, analytical errors, or real fluctuations/variations in chemistry. Outlier flags in the background data set (variables "T_FLG", "IQR_FLG") were established so that data would not be deleted, only flagged.

Because it is unlikely that the regulatory agencies will permit exclusion of isolated high values (i.e., outliers) from the OU data sets, it can be argued that exclusion of outliers from only the background data set leads to inconsistent treatment of the two data sets. Such inconsistency in the treatment of OU and background data biases the outcome of statistical comparisons.

Comments on the *1993 BGCR* from the regulators have not yet been received, despite the fact that EPA and CDH have had the document since September 30, 1993. Because of this, there are some unresolved questions regarding inclusion/exclusion of outliers.

19. Appendix B

a) Table 6, Appendix B. This table is not appropriate for the purpose for which it is proposed. All Values are given in mg/day. CDIs and RfDs should be in units of mg/kg/day. The numbers given are not RfDs and should not be referred to as such. As set up the table does not take into consideration sensitive populations such as children. Also, the RfD (sic) for Manganese is not correct; it should be 0.35 as shown in the table.

19. Appendix C

a) General. It was never intended that a Baseline Risk Assessment (BRA) would rely entirely on default exposure assumptions. Only screening level risk analysis should use all default factors. BRAs should develop site-specific factors using the best science available so subsequent revisions of remediation goals are grounded in objectivity. The tables in Appendix C rely too heavily an default parameters and deviate substantially from previously agreed upon pathways and receptors (e.g.; inclusion of fish eating scenario, the recreational scenario and agricultural exposure).

b) Table 2, note 1. The phrase "for carcinogens and kept separate for non-carcinogens" should be added to the end of the last sentence.

c) Tables 3 and 4. IR should be 1.4E+5 and 2E+5, respectively.

d) Table 5. The assumption for surface area is much too conservative and is counter to the RME philosophy. Surface area should be correlated to body weight.

e) Tables 6, 18, 26, 29, 41, 44, and 47. There is site-specific data with which to calculate the PEF. It should be used.

f) Table 7. Is this scenario for swimming? If so, it should be clearly stated, if not total submersion is not appropriate.

g) Tables 8 and 9. Adding the exposure route in Table 9 to that in Table 8 overestimates exposures to VOCs from groundwater. These tables should explicitly state that they apply

to VOCs with a Henry's Law constant of greater than 1×10^{-5} atm-m^3/mole and a molecular weight less than 200 g/mole.

f) Table 15 and 16. IRs should be 1.4E+5 and 2E+5, respectively.

g) Tables 45 and 48. The factors Se and Te need to be updated to 0.2 and 0.3, respectively.

h) All of the tables in this appendix need to be reviewed to determine if there are other details that need attention.

20. Appendix D

a) Table for radionuclides. The volatilization component was incorrectly used for all species except radon-222.

21. Other Specific Recommendations

1. First, and foremost, the UTL tables included in the guidance document as Tables C-1 through C-33, should not be used "as is." For the reasons stated in this review, the UTL values should be recalculated following distributional testing for all analytes in all media.

2. The issue of outliers in the background data set is still unresolved. DOE should request guidance from EPA on this issue. If clear guidance for identification of outliers is not given and applied equally to both background and OU data sets, then outliers should not be excluded from the background data set.

3. A huge amount of new scope is added in this "guidance document," and EG&G must strongly recommend that the client (DOE) not accept the document in its present form. In particular, the analysis of non-detect data and detection limits clearly is in excess of any reasonable request by the regulatory agencies.

4. Please have a good technical editor clean up the document.