05.01-04/12/94-D1092

DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
2510 WALMER AVENUE
NORFOLK, VIRGINIA 23513-2617

5090
Ser 64/01435
12 APR '94

From: Commanding Officer, Navy Environmental Health Center
To: Commanding Officer, Atlantic Division, Naval Facilities Engineering Command, Code 18231, Norfolk, VA 23511-6287

Subj: MEDICAL REVIEW OF INSTALLATION RESTORATION PROGRAM DOCUMENTS FOR OPERABLE UNIT NO. 1, MARINE CORPS BASE, CAMP LEJEUNE, NORTH CAROLINA

Ref: (a) Baker Environmental, Inc., Transmittal ltr of 1-7-94

Encl: (1) Medical Review of Draft Remedial Investigation Report for Operable Unit No. 1 (Sites 21, 24 and 78), Marine Corps Base, Camp LeJeune, North Carolina

1. We have completed a medical review of the document entitled "Draft Remedial Investigation Report for Operable Unit No. 1 (Sites 21, 24 and 78), Marine Corps Base, Camp Lejeune, North Carolina" (Report Volumes I and II and Appendix Volumes I - III) forwarded by reference (a). Our review comments and recommendations are provided as enclosure (1).

2. The point of contact for the medical review is Ms. Andrea Lunsford, Head, Health Risk Assessment Department. If you would like to discuss the enclosed information or if you desire further technical assistance, please call her at (804) 444-7575, extension 402.

3. To coordinate future medical reviews, please call Ms. Heidi Maupin, M.S., Installation Restoration Program Support Department at (804) 444-7575 or DSN 564-7575, extension 430.

W P Thomas
W. P. THOMAS
By direction

MEDICAL REVIEW OF
DRAFT REMEDIAL INVESTIGATION REPORT
FOR OPERABLE UNIT NO. 1 (SITES 21, 24 AND 78)
MARINE CORPS BASE
CAMP LEJEUNE, NORTH CAROLINA

References:

(a) *Standard Methods for the Examination of Water and Wastewater*, 14th Edition, APHA-AWWA-WPCF, 1975
(b) *The Water Encyclopedia*, 2nd Edition, Van der Leeden, Troise and Todd, Lewis Publishers, 1980
(c) OSWER Directive 9355.4-02, Interim Guidance on Establishing Soil Lead Cleanup Levels at Superfund Sites, 07 Sep 89
(d) OSWER Directive 9355.4-02A, Supplement to Interim Guidance on Establishing Soil Lead Cleanup Levels at Superfund Sites, 26 Jan 90
(e) U.S. EPA Region III Risk Assessment Guidance, March 26, 1991
(f) "Guidelines for Exposure Assessment" published in the Federal Register (57 FR No. 104) Friday, 29 May 1992

General Comments:

1. The draft document entitled "Draft Remedial Investigation Report for Operable Unit No. 1 (Sites 21, 24 and 78), Marine Corps Base, Camp Lejeune, North Carolina," (Report Volumes I and II and Appendix Volumes I - III), dated January 10, 1994 was provided to the Navy Environmental Health Center (NAVENVIRHLTHCEN) for review on 13 January 1994. The report was prepared for Atlantic Division, Naval Facilities Engineering Command by Baker Environmental, Inc. Our comments and recommendations are provided below.

2. The information presented in this draft remedial investigation (RI) is generally in accordance with guidance provided in pertinent Environmental Protection Agency (EPA) documents such as the *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A*, December 1989 (RAGS manual). Our primary concerns are related to the risk assessment; overly conservative exposure assumptions have been used and data gaps result from elimination of potential exposure pathways without sufficient justification.

3. The technical points of contact for this review of the draft RI are Ms. Andrea Lunsford, Head, Health Risk Assessment Department and Ms. Yvonne Walker, CIH, Environmental Programs Directorate, NAVENVIRHLTHCEN, who may be contacted at 444-7575, extensions 402 and 401, respectively.

Enclosure (1)

Review Comments and Recommendations:

1. Page 1-10, section 1.2.2 (Site History), subsection 1.2.2.2 (Site 24 - Industrial Fly Ash Dump)

<u>Comment</u>: The second sentence states that "spiractor" sludge from the waste water treatment plant was reportedly disposed of at this site since the 1940s. The term "spiractor" is not defined in the text. Readers may not be aware of its meaning, or know the general composition of spiractor sludge.

<u>Recommendation</u>: Define the word spiractor in the text and describe any special characteristics of the sludge.

2. Page 1-20, Table 1-3 (Summary of Detected Compounds from the Confirmation Study, Site 24 - Industrial Fly Ash Dump)

<u>Comments</u>:

a. Tables 1-2 through 1-4 indicate ranges of contaminant concentrations measured in ground water, surface water and sediment samples collected at Site 24. For most analytes, the lower end of the range is indicated by "ND," defined in the footnotes as "Not detected above method detection limits [MDLs]." The actual MDL values are not listed.

b. We agree it is important to indicate that specific contaminants were not detected in some or many samples. However, it is equally important to present the actual detection limit values in the tables or text, because these levels must be compared with federal and state action levels, risk-based concentrations (RBCs) and/or other cleanup criteria to determine if the detection level is sufficiently low. If the detection limit is significantly greater than a federal or state action level or standard, the contaminant cannot be eliminated from consideration based on non-detection.

c. Laboratory validation and the level of quality assurance/quality control (QA/QC) are not addressed in the text nor reflected on the data tables. If validation was conducted, the actual MDL values, as well as appropriate data qualifiers, should be presented on data tables. At a minimum, the MDL values should be provided in an Appendix and Tables 1-2 through 1-4 should include footnotes to cross-reference where the values are presented.

<u>Recommendations</u>:

a. Discuss laboratory validation and the level of QA/QC for all sample results.

b. Present the actual MDL values and data qualifiers.

c. Provide footnotes on Tables 1-2 through 1-4 to reference the sections or pages where the MDL values are provided.

3. Page 1-37, section 1.3.6.6 (Interim Remedial Action Feasibility Study for the Shallow Aquifer at HPIA)

Comment: The text addresses the "acceptance" of an interim remedial action (IRA) alternative by USEPA, the North Carolina Department of Health and Natural Resources (DEHNR) and the public. The text does not reference the document, meeting or other forum in which this acceptance was made.

Recommendation: Specifically reference the document and/or meeting (date) or other forum in which the IRA alternative was accepted by the USEPA, DEHNR, and the public.

4. Page 2-25, section 2.3.3 (Soil Investigation), subsection 2.3.3.1 (Site 21 Soil Investigation: Soil Sample Locations)

Comments:

a. The text states: "The preliminary, unvalidated data received from the laboratory indicated an elevated level of PCB-1260 (greater than 20,000 ug/kg [microgram per kilogram]). Finalized data received from Baker, however, indicated a much lower concentration (2,100 ug/kg) of PCB-1260, which is more representative of actual contamination levels."

b. No rationale is provided in the text for the significant difference between the pre-validated and validated data. Some explanation should be provided to justify use of the lower value. If the difference can be attributed to a transcription error, or to unavoidable matrix interferences or other sample specific problems it should be specifically stated. Such justification would lend credence to the finalized data.

Recommendation: If known, provide justification for the significant difference between the preliminary and finalized results for PCB-1260.

5. Page 2-35, section 2.3.3 (Soil Investigation), subsection 2.3.3.2 (Site 24 Soil Investigation: Field Screening and Air Monitoring - Soil Sample Locations)

Comment: The text states that air monitoring was performed with "a radiation meter" and that "no readings were obtained above background."

a. The text does not state if the radiation screening was performed in response to site-specific information indicating radioactive species are chemicals of potential concern (COPC) or whether the screening was performed as a standard practice for all sites.

b. The type of radiation meter used and the type(s) of radiation for which screening was conducted are not identified.

c. The level of background radiation is not described.

Recommendations:

a. Specifically state whether the radiation screening was performed as a result of information regarding site-specific COPCs or as a standard practice for all sites.

b. Provide information regarding the type of radiation meter used for screening purposes and the type(s) of radiation for which screening was conducted.

c. Describe the levels of background radiation in the area.

6. Page 2-47, section 2.3.4 (Groundwater Investigation), subsection 2.3.4.1 (Site 21 Groundwater Investigation)

Comments:

a. The first paragraph states that the seasonal variation in the water table is known to be between 2 and 4 feet. The time of year that samples were collected is not described in the text; no correlations between sampling times and high or low water table variations are made.

b. Ground water sample composition may vary with the time of the year. The text does not address the need for seasonal sampling. Uncertainties resulting from seasonal water table fluctuations are not addressed in the uncertainty section.

Recommendations:

a. Provide information regarding the level of the water table during ground water sampling event(s).

b. Address data uncertainties pertaining to the time of sample collection vice other seasons of the year.

7. Page 3-5, section 3.3 (Surface Water Hydrology), paragraph 2

Comments:

a. The text states that there are three main surface water bodies associated with Operable Unit (OU) No. 1, including Beaver Dam Creek, Cogdels Creek (and unnamed tributaries), and the New River. The location of Cogdels Creek is indicated on Figure 1-5 and the location of the New River is indicated on Figure 1-1. The location of Beaver Dam Creek is not indicated on any of the figures included with the text or on any of the blueprints that we received with the document.

b. The location of all creeks and other bodies of water associated with OU No. 1 should be indicated on a single map. This would help reviewers determine spatial relationships and potential connections of bodies of water.

<u>Recommendations</u>:

a. Indicate the location of Beaver Dam Creek on a site map.

b. Provide a single map/figure which indicates the location of all bodies of water associated with OU No. 1.

8. Page 3-35, section 3.8.1 (Sensitive Environments), paragraph 2

<u>Comments</u>: Section 3.8.1 states that "No wetlands have been identified **within** OU No. 1 from the NWI [National Wetlands Inventory] map with the exception of a limited area within the southern portion of Site 24. The NWI map does identify several forested wetland areas **just south of** OU No. 1 along Cogdels Creek."

a. The text does not discuss the potential impact of OU No. 1 on the nearby wetlands. From the information provided in the text it appears that surface water and ground water discharge from OU No. 1 may be of potential concern.

b. It is not clear whether the statement that "no wetlands are on-site" is intended to eliminate concern for potential transport pathways.

<u>Recommendation</u>: State whether or not the wetlands are potentially impacted by the contaminants at OU No. 1.

9. Page 4-44, section 4.2.3.2 (Groundwater Investigation), subsection entitled "Groundwater Field Parameter Results"

<u>Comments</u>:

a. Section 4.2.3.2 lists the pH ranges measured in the shallow, intermediate and deep water aquifers as "4.12 to 7.19," "6.04 to 11.34" and "7.18 to 12.15," repectively. The last sentence states that the pH values were "generally higher in the deeper ground water." No further discussion of the implications of these pH measurements is presented in the text.

b. We question the validity of the pH measurements. Reference (a) states that the pH of most natural waters falls within the range of 4 to 9. According to reference (b), the **critical range** for human domestic water supplies is pH 6.0 to 9.0 and the **critical range** for wildlife propagation is pH 6.5 to 8.5. Several of the reported pH measurements are outside these critical ranges. Water with a pH of 11.34 or 12.15 would not be potable and would not support wildlife propagation. As comparison values, the pH of limestone is 8.4, the pH of liquid ammonia is 11.3, and the pH of hydrated lime is 12.4.

c. pH measurements are important in determining the potential fate and transport characteristics of many chemical contaminants. Extremely low values of pH (i.e., below pH 4) indicate corrosive water that will dissolve metals, minerals and other substances that it contacts. High pH levels cause some metals to form salts and precipitate out; this may reduce or eliminate the dissolved fraction. For this reason, when unrealistically high or low values of pH are reported, the reliability of reported contaminant concentrations becomes suspect.

Recommendations:

a. Determine the validity of the reported ground water pH measurements.

b. Discuss the pH results and their potential impact on site contaminant concentrations.

c. Correlate the pH ranges with potability and usability of ground water.

d. In future investigations, ensure that pH measurements are realistic. If unrealistic measurements are obtained in the field studies, recalibrate pH electrodes and obtain a second set of readings.

10. Page 6-5, section 6.2.1.6 (Applicable or Relevant and Appropriate Requirements (ARARS)); page 6-14, section 6.2.2 (Selection of Contaminants of Potential Concern), subsection 6.2.2.3 (Groundwater COPC Selection); and pages 6-60 to 6-62, Table 6-11 (Groundwater Data Summary - Operable Unit No. 1)

Comments:

a. The third paragraph states that "the risk-based concentrations (RBCs) for residential soil ingestion developed by USEPA (Region III) were used as guidance criteria to evaluate soil concentrations. The RBCs were used as a benchmark for evaluating site investigation data and to assist in predicting single-contaminant health risks. These values were used in conjunction with other criteria to evaluate soil concentrations."

b. The RBC values used as comparison criteria are not provided in any of the tables in the document. Since significant changes were made to the Region III RBC tables between the first quarters of 1993 and 1994, it would be useful to list the RBC values used.

c. No further description of the method used to compare the site sample concentrations to the RBC values is provided. For example, the text does not state whether all chemicals detected at concentrations greater than the RBC concentrations were retained as COPC, or if chemicals detected at concentrations lower than the RBCs were excluded from consideration in the risk assessment. It is unclear how the comparison values were used to "evaluate" soil concentrations.

Recommendations:

a. Provide a table of the Region III RBC values used, or reference a specific quarterly table (i.e., by date of issuance).

b. Specifically state how the Region III RBCs were used to evaluate soil concentrations and how or if they were used to select chemicals as COPC.

11. Page 6-9, section 6.2.2 (Selection of Contaminants of Potential Concern), subsection 6.2.2.1 (Surface Soil COPC Selection), paragraph 4

Comments:

a. The last sentence states that "copper and lead were retained as COPCs due to their prevalence (detected in 9 out of 9 samples); however, **they were not evaluated in the BRA** [baseline risk assessment] due to inadequate toxicity data."

b. We agree that standard EPA toxicity values (e.g., reference doses and carcinogenic slope factors) are not available on the Integrated Risk Information System (IRIS) to assess risks from lead exposure quantitatively. However, comparison values and EPA computer models are available to evaluate health risk from lead contaminated media.

(1) Reference (c) established a soil lead cleanup level range of 500 to 1000 parts per million (ppm) for Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) sites characterized as residential. The established level was adopted based on a recommendation contained in a 1985 Center for Disease Control (CDC) statement on childhood lead poisoning. This directive also mentioned that the biokinetic uptake (UBK)

model developed by the EPA Office of Air Quality Planning and Standards could be used as a tool for site-specific assessment of total lead exposure.

(2) Since reference (c) was established, the UBK model was adapted, reviewed and validated for Superfund application. The EPA has provided reference (d), which is an update memorandum to reference (c). This memorandum provides strong scientific basis for affirming the 500 - 1000 ppm soil lead cleanup level. The scientific basis for this affirmation is the UBK model. In the absence of toxicity values, consideration should be given to using the UBK model to conduct a quantitative evaluation of risks posed by lead exposure.

c. In the absence of toxicity values, the risk assessor should, as a minimum, describe the effects of the chemical qualitatively and discuss the implications of the absence of the chemical from the quantitative risk assessment in the uncertainty section. Qualitative assessments for lead and copper do not appear to have been conducted.

Recommendations:

a. Consider using the UBK model to quantitatively assess risks posed by lead exposure.

b. For all COPC that have not been quantitatively evaluated, provide a qualitatively assessment of risk: describe the effects of the chemical and discuss the implications of the absence of the chemical from the risk assessment in the uncertainty section.

12. Page 6-13, section 6.2.2 (Selection of Contaminants of Potential Concern), subsection 6.2.2.3 (Groundwater COPC Selection); page 6-30, section 6.3.4 (Calculation of Chronic Daily Intakes), subsection 6.3.4.4 (Ingestion of Groundwater); page 3-30, section 3.6.2 (Site Hydrology); and page 6-91, section 6.0 (Tables), Table 6-33 (Incremental Lifetime Cancer Risks (ICRs) and Hazard Indices (HIs)...)

Comments:

a. Section 6.2.2.3 states that ground water samples were collected from shallow, intermediate and deep monitoring wells in and around OU No. 1. It also states that water bearing zones at OU No. 1 "were not segregated" for the selection of COPCs. The ground water data presented in the Appendix K.8 tables reflect this methodology; i.e., sampling results are not separated according to different water bearing zones on the tables.

b. Although it is not specifically stated in the text, the ground water sampling results from the different water bearing zones may have been combined because a hydraulic connection between the zones is assumed. However, conflicting statements are made in the text about the possible hydraulic connection:

(1) A hydraulic connection is implied in section 3.6.2 which states that "The similar ground water flow patterns observed between the shallow and deep water-bearing zones **may further support** the conclusion that the two water-bearing zones are hydraulically interconnected. Moreover, this conclusion is further supported by the fact that a laterally continuous confining layer between the two aquifers **is not present** in the vicinity of OU No. 1."

(2) Section 6.3.4 states that ground water [in the vicinity of OU No. 1] is currently not used as a potable water source. It then states that "development of the shallow aquifer for potable use is unlikely because of the general water quality in the shallow zone and poor flow rates; however, deep ground water may be used for potable purposes in the future." This statement implies that the two zones are separated, and that the water quality in the two zones differs appreciably.

c. In the section 6.0 baseline risk assessment sampling results from the various water bearing zones are not segregated to assess human health risks. However, no specific rationale for this methodology is provided in this section. If the contaminant concentration data are being combined because of an assumption of hydraulic interconnection, this should be specifically stated.

d. Table 6-33 indicates that the incremental cancer risks calculated for a potential future ground water ingestion pathway are $\mathbf{7 \times 10^{-4}}$ for children and $\mathbf{2 \times 10^{-3}}$ for adults. These values are significantly greater than the upper limit of the EPA benchmark risk range of 1×10^{-6} to 1×10^{-4}. Table 6-33 also indicates that the calculated hazard indices for a potential future ground water ingestion pathway are **29** for children and **13** for adults. Since hazard indices are quotients, these values **greatly exceed** the EPA benchmark hazard index of 1.

(1) It may be that contaminant concentrations in the shallow water bearing zone (vice the deep water bearing zone) are driving the risk.

(2) Since the risks and hazard indices calculated from the combined data are so high, the data from the two water bearing zones should be evaluated separately, to allow a determination of whether one of the zones is driving the risk. Since the deep water bearing zone reportedly would be more likely to be used in the future as a potable water source, the risk associated with this zone should, as a minimum, be calculated independently.

(3) If sampling results indicate both zones are equally contaminated, this should be specifically stated.

e. Because of the ambiguous statement about potential future use of the deep water zone, it is not clear that it has been firmly established that hydraulic interconnection exists between the upper and lower zones even if a single, laterally continuous, confining layer has not been found. Demonstration of significant differences in contaminant concentrations between the upper and lower water bearing zones may be a plausible argument for assuming that the multiple, stratified, yet non-laterally continuous confining layers are effective in separating the upper and lower water bearing zones.

Recommendations:

a. Specifically state, in the section 6.0 baseline risk assessment, the rationale combining the data collected in each of the water bearing zones.

b. Provide any existing evidence of large differences in contaminant concentrations in the upper and lower aquifers.

c. Develop separate risk estimates for two potential ground water risk scenarios, one scenario addressing the shallow water aquifer and the other addressing the deep water aquifer. Compare these to the combined data risk estimate.

13. Page 6-19, section 6.3.1 (Conceptual Site Model of Potential Exposure), Figure 6-1 (Conceptual Site Model, Operable Unit No. 1...); page 3-34, section 3.8 (Regional Ecology); and page 8-10, section 8.1.3 (Ecological Risk), paragraph 3

Comments:

a. Neither section 6.3.1 nor Figure 6-1 addresses potential exposure pathways associated with consumption of contaminated terrestrial wildlife. However, in a former section of the report (section 3.8) it was stated that "Wildlife on the base includes white-tailed deer, wild turkey, black bear, along with numerous small game species (e.g., bobwhite quail, morning dove, rabbit)."

b. Hunting activities may or may not extend into the OU No. 1 site. Also, evaluation of this pathway may not significantly impact the risk assessment. However, all potential exposure pathways should be adequately addressed in a remedial investigation and risks should be calculated for all completed pathways. If hunting activities are impacted by the site under investigation, risks from the consumption of wild animals should be assessed for all individuals who hunt at Marine Corps Base, Camp Lejeune.

c. Section 8.1.3 states that "terrestrial invertebrates probably inhabit the undeveloped areas of OU No. 1." The potential impact of contaminated invertebrates on the food chain is not addressed in the human health risk assessment; however, it is addressed in the ecological risk assessment (section 8.1.3). One of the conclusions of the ecological assessment is that there is "a high potential for pesticide bioconcentration in the fauna that feed upon the aquatic life inhabiting Cogdels Creek and Beaver Dam Creek." If any of these fauna (for example, ducks) are edible species the potential impact on the human food chain should be addressed in the human health risk assessment.

Recommendations:

a. Discuss potential hunting activities **on and around** this site.

b. If appropriate, assess the risks associated with consumption of wild animals and include the pathway associated with the consumption of terrestrial wildlife in Figure 6-1.

c. Address the human food chain and the potential for chemicals observed at OU No. 1 to bioaccumulate in edible species.

14. Pages 6-22 to 6-24, sections 6.3.3 (Quantification of Exposure) and 6.3.4 (Calculation of Chronic Daily Intakes)

Comments:

a. Sections 6.3.3 and 6.3.4 do not address how non-detect data is handled in computing average concentrations.

(1) The reference (f) exposure assessment guidance states that "data summary tables should contain the frequency of detection, range of detects, average concentrations and background concentrations. The non-detects should not be incorporated into the average concentrations." Elsewhere this guidance states that "if a contaminant is widely distributed throughout the site, the exposure point concentration should be based on the 95% UCL of the arithmetic average for all the site samples, including non-detects."

(2) Comparing concentration "averages" with other concentration "averages" is like comparing apples and oranges if some of the averages include non-detect values while others do not. For this reason, the methodology used should be specifically stated.

b. The text does not indicate whether or not substitute values are used for non-detects in computing average concentrations. In an earlier section of the report (page 1-20,

Table 1-3) the use of **MDLs** was mentioned in conjunction with confirmation study results of the fly ash dump. However, in the section 6.0 risk assessment, where risks from several sites are evaluated, the use of SQLs or MDLs as substitute values for non-detects is not stated or discussed.

(1) The RAGS manual recommends the use of one-half the **sample quantitation limit** (SQL) as a proxy concentration for non-detects if there is reason to believe that the chemical is present at a concentration that is below the SQL. SQLs are preferred over other detection limits such as MDLs, instrument detection limits (IDLs) and contract required quantitation limits (CRQLs) because they reflect sample specific characteristics. Only if SQLs are not available should other detection limits be used as proxy values for non-detects.

(2) Use of one-half the SQL, MDL or IDL is recommended because statistical studies indicate that this value would not unduly bias the results upward or downward, **provided that** the data are not highly skewed, and **provided that the number of non-detects is not greater than 10 to 15% of the data.** This recommendation and in-depth discussion of the rationale for using 1/2 SQL values, is provided in reference (f).

Recommendations:

a. Specifically state the methodology used to compute average concentrations; state whether non-detects were always included (regardless of frequency of detection), whether proxy values for non-detects were used, etc.

b. When it is appropriate to use substitute values for non-detects, use one-half the SQL. If SQLs cannot be obtained, then consider using one-half the CRQL, MDL or IDL, in that order, with caution.

c. If MDLs or other detection limits are used, state specifically that they were used because SQLs could not be obtained.

d. For future investigations, ensure that analytical laboratories are required to provide sample-specific SQLs.

15. Page 6-22, section 6.3.2 (Exposure Pathways), subsection 6.3.2.6 (Biota) and page 8-10, section 8.1.3 (Ecological Risk), paragraph 3

Comments:

a. Section 6.3.2.6 states that "Recreational fishing does not occur in Cogdels Creek or Beaver Dam Creek. Furthermore, future exposure by recreational fisher persons is unlikely.

Therefore, ingestion of fish by current or future fisher persons was not retained for quantitative evaluation."

b. Current exposure data may be available to allow a determination that recreational fishing does not currently occur, but the text does not indicate why recreational fishing is "unlikely" in the future. Given the information provided in Section 8.1.3 of the ecological assessment that "there is some aquatic life inhabiting Cogdels Creek and Beaver Dam Creek including fish, tadpoles and benthic macro-invertebrates" we do not know how it can be assumed that fishing will be unlikely in the future.

c. If adequate justification exists for assuming fishing will be unlikely in the future, it should be presented in the text. If such justification cannot be provided, a potential fishing/fish consumption pathway should be addressed in the human health risk assessment.

<u>Recommendation</u>: Provide adequate justification for eliminating the biota pathway from the human health risk assessment or include the biota pathway in the risk assessment.

16. Page 6-23, section 6.3.3 (Quantification of Exposures)

<u>Comments</u>:

a. The fourth paragraph of section 6.3.3 states that "**For the sake of conservatism**, the 95 percent UCL for the **lognormal** distribution was used for each contaminant in a given data set for quantifying potential exposure..."

(1) Since geometric means are associated with lognormal distributions, this statement suggests that **geometric means** (vice arithmetic means) were derived for each data set.

(2) Use of lognormal distributions (and associated geometric means) is usually **not conservative**. As discussed below, normal UCLs are often much **higher** values than the counterpart lognormal UCLs because EPA guidance requires arithmetic means to be modified by a statistical "H" parameter.

b. The fifth paragraph of this section states that "maximum values, **arithmetic means**, **geometric means**, standard deviations, and 95% UCLs [95 percent upper confidence levels] are presented in Appendices K and L." The data presented in Appendix L is consistent with this statement; Appendix L presents both **normal** 95% UCLs and **lognormal** 95% UCLs.

(1) It is not clear why both sets of values are provided, since the previous paragraph indicates the lognormal values were used for calculating risk equation parameters.

(2) If the purpose of providing both sets of values is to demonstrate that the lognormal UCLs are more conservative than the normal UCLs, it should be stated whether or not the normal UCLs were derived according to Region IV guidance (i.e., with the use of modifying "H" parameters).

c. Both Federal EPA and Region IV guidance recommend use of **arithmetic means** (and associated **normal UCLs**) to calculate the upperbound, reasonable maximum exposure (RME) estimates.

(1) The RAGS manual states "Because of the uncertainty associated with any estimate of exposure concentration, the upper confidence limit (i.e., the 95 percent upper confidence limit) on the **arithmetic** average will be used for this variable" unless the upper confidence level on the average concentration is above the maximum detected or modeled value.

(2) Region IV guidance (reference (e)) states that "the exposure point concentration should be the 95% upper confidence limit (UCL) of the **arithmetic** average unless it is higher than the maximum detected concentration."

d. The difference between normal and lognormal 95% UCLs may be significant. If only lognormal UCLs are used, an adequate justification should be provided. In our opinion, an appropriate rationale for using lognormal UCLs is that the normal UCLs are unrealistically high, necessitating the use of the maximum detected values in most cases.

(1) The Region IV risk assessment guidance provides an equation for calculating the 95% UCL of an arithmetic mean. The equation includes a statistical "H" parameter. Since the "H" parameter is an inversely proportional measure of statistical confidence, the value of H is very high for small data sets. Because the "H" parameter is an **exponent** value in the UCL equation, its value has a dramatic effect on the output value of the overall equation. For very small data sets, the 95% UCL value can be 4 to 5 **orders of magnitude** greater than the maximum value detected.

(2) When calculations show that use of arithmetic means and associated normal 95% UCLs result in unrealistically high concentration estimates (i.e., that are greater, in most cases, than the maximum detected values), it is more **practicable** to use geometric means and normal UCLs. In our opinion, this would be sufficient justification to shun arithmetic values and associated normal UCLs (modified by "H" parameter exponents).

Recommendations:

a. State whether the **normal** UCLs presented in Appendix L were calculated according to Region IV guidance risk equations;

i.e., state whether the "H" parameters were determined and used in the calculations.

b. Calculate and present the risk posed by the **normal** 95% UCL, or provide adequate justification for use of the lognormal values.

16. Page 6-23, section 6.3.3 (Quantification of Exposures)

Comments:

a. The risk assessment presents only the reasonable maximum exposure (RME) risk estimates. Presenting a one-point (upper-bound) estimate of risk often results in an upwardly biased assessment of risk.

b. Recent EPA guidance indicates that a single number used to represent the health risk to an individual or population may hamper the risks manager's ability to make an informed risk decision, and strongly recommends use of **several** risk estimates to more fully characterize the risk.

(1) A Deputy Administrator memorandum dated 26 February 1992 ("Guidance on Risk Characterization for Risk Managers and Risk Accessors") states: "Regarding exposure and risk characterization, it is Agency policy to present information on the range of exposures derived from exposure scenarios and on the use of **multiple risk descriptors** (i.e., central tendency, high end of individual risk, population risk, important subgroups, if known) consistent with terminology in the attached Appendix and Agency guidelines." The guidance further states: "This guidance applies to all Agency offices. It applies to assessments generated by EPA staff and those generated by contractors for EPA use."

(2) EPA published final guidelines for exposure assessment in the Federal Register (57 FR No. 104, Friday, May 29, 1992). This guidance reiterates that "**Several** statistical estimators of exposure should be identified, e.g., the 50th, 90th, or 95th percentiles. The distribution should reflect exposures, not just concentrations." Although the guidance discusses the concept at length, the bottom line is that risk estimates for both upper bound **and average** case should be presented.

Recommendation: Calculate and present several risk estimates; as a minimum, calculate and present risks posed by the **average** exposure concentrations in addition to the upper-bound, RME concentrations.

17. Page 6-34 to 6-36, section 6.3.4 (Calculation of Chronic Daily Intakes), subsections 6.3.4.7 (Incidental Ingestion of Surface Water), 6.3.4.8 (Dermal Contact with Surface Water and 6.3.4.9 (Incidental Ingestion of Sediment); and page 6-83, Tables 6-26 (Exposure Assessment Summary, Ingestion of Surface Water Contaminants...) and 6-28 (Exposure Assessment Summary, Ingestion of Surface Water Contaminants...)

Comments:

a. Section 6.3.4 and Tables 6-26 and 6-28 provide the exposure parameters used in calculating exposures involving incidental ingestion of surface water and sediment.

(1) The input values assume a swimming pathway. This is inconsistent with the information provided in paragraph 3 of section 6.3.4.8 which states that "...surface water bodies associated with OU No. 1 are not sufficient in size to allow for swimming (whole-body emersion)."

(2) Since the input values assume a swimming pathway where none exists, risk calculations for exposure to surface water and sediment are unrealistically high.

b. The input variables for the surface water ingestion pathway are generally the same values as those listed in Exhibit 6-12 of the RAGS manual, entitled "Residential Exposure: Ingestion of Chemicals in Surface Water While Swimming." For children and adults, a surface water ingestion rate of 0.05 L/hour is used to assess exposures during contact of surface waters. The 0.05 L/hour value is the EPA ingestion rate for surface water while swimming. Ingestion of surface water while wading in a body of water of insufficient size for swimming is highly unlikely.

c. A **sediment ingestion rate** of 200 mg/day is assumed. Ingestion of sediment as a result of wading in a body of water of insufficient size for swimming is highly unlikely.

Recommendations:

a. Eliminate ingestion as an assumed exposure pathway in surface runoff waters (i.e., swimming in bodies of water that are of insufficient size for swimming).

b. Fully address overestimations of risk based on conservative estimates in the uncertainties section.

18. Page 6-35 to 6-37, section 6.3.4 (Calculation of Chronic Daily Intakes), subsections 6.3.4.8 (Dermal Contact with Surface Water) and 6.3.4.10 (Dermal Contact with Sediment); and page 6-27, Tables 6-27 (Dermal Contact With Surface Water) and 6-29 (Exposure Assessment Summary, Dermal Contact With Sediment)

Comment: The text states that "the surface areas of the head, arms, hands, forearms, and lower extremities were used to estimate risk to adults (11,500 cm^2) and children (4,600 cm^2)." Exposure to the head appears to be unlikely since section 6.3.4.8 states that "...surface water bodies associated with OU No. 1 are not sufficient in size to allow for swimming (whole-body emersion)." (See also comment #18).

Recommendations:

a. For all sediment and surface water exposure pathways, reassess parts of the body likely to come in contact with the water and sediment; reassess exposures accordingly.

b. Fully address overestimations of risk based on conservative estimates in the uncertainties section.

19. Pages 6-45 to 6-48, section 6.6 (Sources of Uncertainty) and page 3-35, section 2.3.3.2 (Site 24 Soil Investigation), subsection entitled "Test Pit Sampling"

Comment:

a. Section 6.6 **generically** addresses uncertainty related to analytical data, exposure assessment, toxicity assessment and compounds not quantitatively evaluated in the risk assessment. Very little site-specific uncertainty is addressed. It is particularly important to summarize site-specific sources of uncertainty in order for calculated risks to be viewed in their proper perspective. For example, a few of the site-specific uncertainties which would normally be addressed include:

(1) Whether or not the analytical data are adequate to identify and examine exposure pathways and areas.

(2) Whether or not the analytical data are adequate to fully characterize exposure areas; any inadequacies such as sampling space limitations posed by the site, as addressed in section 2.3.3.2 should be discussed.

(3) The likelihood of exposure pathways actually occurring, such as the exposure pathways addressed in comment #18 which involves a swimming ingestion rate for swimming in bodies of water that are of insufficient size for swimming.

(4) How chemicals not included in the risk assessment, (such as copper, lead, selenium and thallium) will impact calculated risk values.

Recommendation: Address site-specific uncertainties in the discussion of uncertainties.