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047823

June 19, 1997

Dr. Bob Stewart
Department of Energy
PO Box 550
Mail stop: HD-12
Richland, WA 99352

Dear Dr. Stewart:

Enclosed please find a copy of my comments that I have submitted based on my review of Parts I and II of the CRCIA. I really appreciated meeting with you about this project and I hope some of these comments will be useful. I was very impressed with the enthusiasm, commitment and hard work that this group has devoted to this project on this very important topic.

Although I conducted this review as an individual technical reviewer for the Nez Perce, I will be sharing these comments and the CRCIA documents with the CRESP researchers. I feel that there are important risk assessment issues and challenges that are presented in Parts I and II that the CRESP group needs to understand. Thank you again for taking the time to meet.

I look forward to seeing how this project evolves over the next year.

Sincerely,

Elaine M. Faustman

Elaine M. Faustman, PhD, DABT
Professor, Department of Environmental Health
Director, Institute for Risk Analysis and Risk Communication

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Enclosure

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Page	Comments
General Comments, Part I	This reviewer saw many improvements that were made in this document and given the operational constraints this document was informative if not easy to read. Improvements include disucssion and interpretation, formating, and some improvements on assessing uncertainty. See comments listed below for specifics on how to continue refinement.
Pg. vii: Preface, Purpose, bullet 3	What is meant by "useful certainty?" I have no idea.
Executive Summary	Essential information from the report did not get transferred to Executive Summary. For example, on page xiv in the executive summary, paragraph 1 introduces the concept of study domain and spatial scale yet the definition of segmentation is not clearly given. Pulling a single sentence from the text forward-- (pg. I-3.3, second paragraph, lines 2-3) "A segment is a section of the river over which contaminant conditions can be expected to be similar and which captures the major influences to the Columbia River" would help this summary. This chapter needs to be carefully revised so it can stand alone without forcing the reader to wade through the entire impact statement. Tables and Figures should be self-explanatory with sufficient detail so the average reader can understand what the issues are and how conclusions were drawn. Everything must be transparent. Because of the use of too many significant figures, a naive reader might assume a greater degree of accuracy from Table S-1 than warranted. Please reduce the numbers. Bottom line is almost missed among the details and qualifications. Can any format changes improve this?
Editorial Suggestions	Although definitions are provided in a very good glossary attached to the document, for reader ease please include major definitions as part of the text of the executive summary. In general, the section entitled "Technical Approach" site characterization was useful (pg. 1i-xc). See a few specific comments below.
Pg. xiv	The section on contaminants of interest does not give an indication that both acute and chronic human toxicity was considered, only acute and chronic aquatic toxicity. Was this the correct impression? Reword.
Pg. xvi	This reviewer still has difficulty understanding why such a narrow search for data was done. Especially when in paragraph 2, extrapolation techniques had to be used to fill in data gaps. Wouldn't it have been easier to use earlier data than extrapolate across media?

Page	Comments
Pg. xvi	Ecological and human health assessment. What does "computer code application" mean? Should this be written as "a computer program in existence" was used to calculate human health risks? Perhaps even mentioning name of computer modeling program here would be useful (i.e., MEPAS)?
Pg. xvii	Define EHQ.
Results and Discussion, paragraph 1, line 3	Define elevated. Over background levels? Over regulatory action levels? Over what?
Results and Discussion, line 5	What do you mean here? "Risk" is always evident. Is it "unacceptable levels of risk?" Using what definition? I think what you mean is that with the exposure scenarios you considered risk levels exceeded generally accepted risk levels. This needs to be carefully re-worded. May want to use comments from Fig. S.1.
Figure S.1.	This is a very important figure. Enough definition is needed here so the figure can stand alone. Do not just say definition of ecological risks is buried in section 6.3. Also, what do #'s 1-27 refer to ? Label river segments for new reader. Put shading key into footnotes for figure.
Pg. xix, paragraph 2, lines 8-10	Wording here, "potentially hazardous" is very different than paragraphs on page xvii, Results and Discussion. This paragraph on xix is very good - should use this for developing footnotes for ecological risk, Figure S.1.
Table S.1	It is extraordinarily misleading to give the risk numbers with this level of significant digits. This must be modified! How do the risk estimates presented in this table consider background risk in Segment 1? Please indicate that all risks subtract risks from contaminants reaching Hanford site after Segment 1. Ensure that these figures match info in Figure S1. If insufficient information was available for evaluation then please designate this on Table S.1, perhaps by using an NA for not available, etc. This table is incomplete and misleading without this distinction from no risk situation. See paragraph 3, pg. xxv for example of type of info that should be present in this table.
Pg. xxv, paragraph 3, lines 4,5	Please clarify what "general lack of toxicity benchmark" means. Is this the same as they were not toxic under the conditions evaluated?
Pg. xxv, paragraph 4, last 3 lines	The statement is given here that says that there were minimal differences between any of the Native American Scenarios and recreational/residential risk assessment scenarios. A line of explanation should be given or referenced.

Page	Comments
	Was this lack of difference due to lack of sensitivity of the Native American scenarios to reflect critical exposures, do additional facts need to be considered or are these different exposures actually only qualitatively different with quantitative similarities?
Pg. xxvii	Copper: what does it mean that chromium is "one of the highest risk to biota and humans?" Explain context for this comparative statement.
Pg. xxx, paragraph 1	This paragraph could be improved. Scientific uncertainty is composed of two types of uncertainty, lack of knowledge and variability. I believe you are referring to lack of knowledge about reparion ecosystems. Please be more specific to help reader.
Pg. xxx, paragraph 3, last line	The word "may" should be removed and the word "thus" should be inserted.
Pg. xxxiii, paragraph 3	Great! Recognition that this is a "living document." Can you define how changes and updates would be incorporated?
Pg. 1i	Site characterization - In general, this section entitled Site Characterization was useful (pgs. 1i-1xc). See a few specific comments below.
Pg. 1vii, paragraph 2	River Flow rate?
Pg. 1xiv, paragraph 1	Statement is made that the unconfined aquifer will approach pre-Hanford site conditions. What assumptions about future land use is this making? Is this true if increased agriculture activities occur?
Pg. 1xix, paragraph 4	Was ground water used in this fish rearing activity?
Pg. 1xxii, paragraph 1	It was informative to learn that 87 lbs. of chromium was removed, however, this figure needs context. Is this approximately 1/10th total, 1/2? Please add. Also add reference if known.
Pg. 1xxii, paragraph 4, last line	Why does this sentence say "... volume of only 790 million liters....?" This seems like a very large amount where only seems inadequate.
Pg. 1xxv, paragraph 4	Statement is made that environmental monitoring was used to compare model with the actual releases. No indication of results. Were levels detected the same as model results? Don't just say "all results are published...", provide some clues.
Pg. xxxiii, paragraph 3	Great! Recognition that this is a "living document." Can you define/illustrate in executive summary how changes/updates would be incorporated.

Page	Comments
Pg. xxxvii-1, Glossary	Glossary was very useful.
Part I. SCREENING ASSESSMENTS	
Pg. I-1.5, paragraph 1, lines 2-3	What does the sentence "Toxic chemicals are those with a poisonous agent," refer to? This needs to be rewritten.
Pg. I-1.5, paragraph 2, line 4	Insert word "exposure" before "dose has been estimated."
Part I. CONTAMINANTS	
Pg. I-2.3-2.14	Excellent list of references. Thanks for providing an annotated bibliography.
Pg. I-2.15, paragraph 2, lines 1-2	When non-detects occurred, please give detection level.
Pg. I-2.20, Section 2.3.1	Definition of slope factors should indicate that slope factor is derived from upper 95% confidence limit not maximum likelihood estimate (MLE). As this section is now written, it sounds like MLE. Please clarify.
Pg. I-2.3.3, Section 2.3.1.3	For clarity, shouldn't the value 12.6 and 4.02 be separately listed in equations, footnotes, so all can follow.
Pg. I-2.48, paragraph 2-4	Good discussion of possibly questionable results.
Pg. I-2.52, paragraph 4, lines 3-4	Is this statement still true given recent findings of contamination under tanks?
Part I-3, DATA...	
Figure 3.2 and Figure 3.3	It was difficult for this reviewer to distinguish the original river segment boundaries on these figures. Legend needs improvement.
Pg. I.3.7	Distributional assumptions. This section highlights potential problems with the data and gives several good examples. However, this section is limited as it does not give the reviewer an indication of how the study dealt with these and other similar problems. Were these isolated problems or reflections of the types of problems encountered? If the latter, then how frequently were these encountered and is this information summarized?
Pg. I-3.16 -3.17	Data Quality. Minimal information on data quality is given.
Pg. I-3.17	Raw Data files. The statement is made that estimated fields in the databases are not available in the raw data provided in Appendix A (Vol. II). Are these explained elsewhere? Need to show to improve transparency of process.

Page	Comments
Table 3.3	Information on lack of data to analyze must get incorporated into earlier Table S.1 or Figure S.1, so non-detects are distinguished from not tested, no data.
Pg. I-3.29, section 3.4.2	It was unclear why rejected radiological analyses were retained when rejected, non-radiological data was not used.
Pg. I-3.51, Sidebar Box	It would seem that the statistic that "of the possible 3024 data values, 1153 have no data even after the substitution," is important and should be carried into the executive summary.
Part I-4, SCREENING...	Screening assessment of risk to the environment - This reviewer continues to have difficulty in accepting the extremely simplified assumptions that form the basis of this method to choose species to evaluate. For example, on page I-4.18, section 4.1.2.2.3 - an example is given for Chinook salmon versus Channel catfish. The rationale given for the scoring scheme is only the total length of time that the species remains in a potentially contaminated region versus consideration of sensitivity of that life stage. An argument could be made that the early life stages may be more sensitive therefore a species that only remains in the contaminated region at such a sensitive time would have a disproportionate risk of adverse effects from the contaminated sites that would not be reflected in a strict proportion of total life span statistic for the contaminated region. There are many other examples, some of which I highlighted in my first comments. If nothing else, at least these hidden assumptions should be delineated and impact assessed for total screening process. Also, the assumptions that are underlying the summary listed on page I-4.23-5, needs to be presented. What is the impact of these approaches?
Pg. I-4.11, Table 4.2	In the future, this reviewer would suggest adding other individuals to the panel of regular biologists developing criteria for screening study area species. Why was there not a representative from the Nature Conservancy, Sierra Club, Audubon Club? Why are all scientists either from PNNL or from government? Should this group include some public university researchers?
Pg. I-4.31	This page uses the term "benchmark" in two ways, only 1 of which is defined. "Toxicity Benchmarks" are defined in the first paragraph and used in paragraphs 2 and 6. In contrast, paragraph 6, last 2 lines, uses benchmark to refer to "benchmark species." Please define or rename. Pg. I-4.32 goes on to use "benchmarks" to refer to a variety of toxicity endpoints including 20% reduction in growth of plants

Page	Comments
	whereas the following pages use both benchmark species and toxicity benchmarks. Some of the assumptions delineated in section 4.2.1 are very conservative. For example, on page I-4.34, 4th paragraph - the form of the metal will not be considered. For chromium this is especially important due to the carcinogenicity of Cr^{+6} form.
Pg. I-4.40, paragraph 5	Finally the document initiates a discussion of uncertainty and begins the delineation of two types of uncertainty, i.e., variability versus lack of knowledge. However, these terms are not used and this very important discussion is buried. This discussion should reference an earlier discussion that clearly lays out these two types of uncertainty. There needs to be consistency across sections. Executive Summary should also clearly explain these concepts. See earlier comments on uncertainty. In the 7th paragraph, it was good to explain why the decision was made to use triangular distributions versus earlier decision to use lognormal. Add note contrasting this distributional assumption versus earlier decision.
Pg. I-4.42, paragraph 1	This reviewer was confused by this paragraph. How do these assumptions "All animals were assumed to spend their entire time at the Hanford Site within a single river study sediment," compare with assumptions in section 4.1.2.2.3 where designation of what life stages a specific origin has in contact with contaminated media. This needs explanation. If one assumption is used for screening then later changes in assumption needs to be discussed.
Pg. I-4.34, paragraph 6	The statement that when LOELs were unavailable "they were estimated using 1/15th the LC_{50}" value needs support besides just listing references. Add comment that says something like: "This approach has been used by three different groups to estimate LOELs and has been found to be in good agreement with known LOELs."
Pg. I-4.50	This reviewer had problems with both of these assumptions. The first assumption needs to be referenced if any data exists to support this assumption. The argument that is made that this is a conservative assumption also needs to be documented. If my experiences with nutrients and metals and their relationship with normal development is true, then these assumptions may not be true and this approach needs to be rethought.
Pg. I-4.51 and Figure 4.9	Does this graph really support assumption 2? It appears that the copper concentrations in the Northpoint area are significantly higher than segment 1 ranges.

Page	Comments
Pg. I-4.6, paragraph 2	Approximately 5,500 parameters were estimated. A note about the large number of parameters that were estimated might be informative in the executive summary.
Fig. 4.13	Why did symbols for lead, mercury and strontium change from Figure a to b? Very confusing, please keep consistent with Fig. 4.14.
Figure 4.15	This figure is very good and provides a strong basis for these estimated concentrations.
	In section 4 an assessment of ecological risk is undertaken. I feel very uncomfortable with the interpretation of this section. I think extreme caution should be exercised in reviewing these analyses.
	First of all, this assessment was modeled after the approaches used in human risk assessment where risk is evaluated for specific organisms and cross-species extrapolation is common. This may be sufficient for initial screening assessments however, this approach may lose a tremendous amount for assessing potential impacts of contamination. A key characteristic of the ecological landscape is its interrelatedness and dependency upon the maintenance of adequate resources of multiple layers of organisms. By conducting this assessment on isolated organisms and not evaluating the significance of impacts on these isolated organisms on the ecological web, we could be missing very significant impacts. This limitation must be specifically discussed in Part I and the executive summary. (Part II starts this discussion.)
Pg. I 4.65-66, paragraph 4	These are very important points about zinc. Unfortunately, these points were not carried forward to final summary document, executive summary.
Pg. I-4.66, paragraph 2	This paragraph highlights the problems with not using the form of metals during this assessment. Refer to my earlier concerns when this approach is first proposed. Most chemical analysis conducted during the time period that you have designated would have done specification as part of the assessment. This assumption is especially problematic for chromium and mercury.
Pg. I-4.69, paragraph 4	This paragraph talks about "endpoint benchmarks," introducing yet another use for "benchmarks." This is very confusing to the reader.
Pg. I-4.69-70	This reviewer does not think that these questions have been answered by this assessment. There is no discussion on what the possible impacts of hanges in these species (that have been identified as possibility being at risk) would have on the larger ecosystem.

Page	Comments
Pg. I-4.72, paragraph 1, line 1	This sentence should read "...exposures estimated using surrogated pond water were higher in 2/3 cases than they would have been had measured values been used."
Pg. I-4.79, paragraph 3, last 3 lines	Authors suggest that risks estimated for copper and zinc were suspect pending analysis of filtered pore water samples.
Pg. I.5.1, last sentence	These last 2 sentences need to be modified. All of these calculations represent potential risk. Please replace phrase "actual risk." Suggested rewording as follows: The risks estimated are potential risks if people in the near future were to start performing the activity postulated in the scenarios.
Part I-5, SCREENING...	
Table 5.1	This table was useful.
Pg. I-5.8, paragraph 4	Please expand explanation on why MTCACR parameters were not used for workplace water consumption. (Add also as footnotes to Table 5.2 or 5.3.)
Table 5.2	Please add explanation in footnote for "Intake/Contact Rate Range," "Shielding parameter." Remember tables and figures should "stand alone."
Pg. I-5.10, paragraph 2, last 2 sentences	The estimate of drinking 1 liter/day of river water while at work seems high yet the average of 1 hour per day dermal exposure seems low. Were these values obtained from the State Hatchery Program?
Pg. I-5.25, paragraph 5, lines 2-5	Horses are part of the human food chain but not commonly in the U.S. Sentence should be modified.
Pg. I-5.25-5.29	This reviewer enjoyed reading the details given in the Subsistence Resident Scenario. For example, the caloric intake discussion was well thought out.
Section 4.2.11, Analysis of Risk	This reviewer thanks the CRCIA team for providing this level of detail for the approaches used in the risk assessment; these were much more transparent. One point of the assessment that I feel needs to have a more in-depth evaluation is the sweat lodge exposure pathway. Recently, I was reviewing the new RBCA (risk based contaminant assessment) models from ASTM. They have developed risk assessment models for petroleum hydrocarbons many of which are very volatile. In these scenarios, the rate of vapor movement through soil was evaluated and of the exposure pathways they evaluated, the highest risks were calculated for vapor exposures within dwellings built over the plumes. In the sweat lodge scenario, this other pathway of exposure might be a significant addition to the vaporization of seepwater poured over rocks within the lodge. How was vaporization of volatile compounds handled in the residential

Page	Comments
	scenario? The volatile compounds listed in Table 5.17 should be examined.
Table 5.14	I have not been able to review/verify each individual value used in the risk assessments, however, I have been doing some random checking and some of these parameters need some careful checking. For example, the deterministic bioaccumulation factor listed in Table 5.14 for mercury is 1000. The minimum and maximum is also listed as 1000. Given earlier comments that specific forms of compounds would not be considered, it seems strange that at least some consideration of the maximum should include recognition that-for methyl mercury-this parameter would range from 10,000 to 100,000. Why is there no variation from minimum versus maximum value? Have other parameters values been double checked? References: *Clarkson, T.W. (1995) Environmental contaminants in the food chain. Am. J. Clin. Nutri. 61(3 Supple.):682S-686S.* *Bigham, G.N. and Vandal, G.M. (1996) A drainage basin perspective of mercury transport and bioaccumulation: Onondaga Lake, New York. NeuroToxicology 17:279-290.* *Bodaly, R.A., St. Louis, V.L., Paterson, M.J., Fudge, R.J., Hall, B.D., Rosenberg, D.M. and Rudd, J.W. (1997) Bioaccumulation of mercury in the aquatic food chain in newly flooded areas. Met. Ions Biol. Syst. 34:259-287.* *Boudou, A., Delarche, A., Ribeyre, F., and Marty, R. (1979) Bioaccumulation and of mercury compounds in a second level consumer. Gamusia affinis-temperature effects. Bull. Environ. Contam. Toxicol. 22:813-818.*
Pg. I-5.59, last paragraph	There are many hidden assumptions in using the adjusted TLV values to set public health standards. For example, the occupational limits are set for healthy working populations. Just scaling the values on a mg/kg body weight basis and extending occupational exposure scenarios to potential environmental exposures is inadequate to protect the diversity of individuals and children present in the public. This needs to be rethought or an extra safety factor is needed.
Pg. I-5.67, paragraph 4	Lack of lead data should not "pull down" risk when there is just a missing data point. These points where there is lacking data, should be designated separately on the figures.
Pg. I-5.71	This reviewer found the comparisons of the statistical and deterministic risk evaluations to be interesting. Thanks for providing these extra estimates so the range of possible values could be considered.
Pg. I-5.72, last paragraph	This paragraph suggests that the reference doses and potency factors are quite uncertain and that the risk factors used range in uncertainty from 10 to factors of 1000. This statement needs to be referenced. Our own research has

Page	Comments
	shown that for trichloroethylene these potency ranges are over 4 orders of magnitude (Lee, et al., 1997). Other investigators have identified this area of uncertainty and it has been larger than any other uncertainty in risk assessment (Cullen, et al.) This magnitude of uncertainty needs to be acknowledged.
Pg. I-5.107, paragraph 4	Statement in this paragraph says "results illustrated in Figures 5.36 and 5.37 correspond well with results described in the preceding section." I think this is mainly true, however, I do question the xylene data for segment 13. I thought risk for Native American subsistence resident scenario was 1.8×10^{-4} versus below detection levels for xylene in segment 1. Please double check.
Part I-6. SYNTHESIS...	
Pg. I-6.10, paragraph 4, last sentence	Please modify last sentence to say "...locations for which estimated risk to both the environment and humans is evident..."
SUMMARY Pg. II-iv	Define what is "predecisional participation" for readers. This is a very important point. Don't let it get lost.
Part II General Comments:	This reviewer had the opportunity to meet with members of the Part II phase of the CRCIA project and would like to thank these members for sharing their enthusiasm for the Part II project. It was obvious from that meeting, from individual contact with members and from reading this document, that this team really enjoyed working together on this project, that they had invested personal time on this project, and that they shared a tremendous respect for their team colleagues to approach the very complex Columbia River issues with fresh insight. I would compliment the members on their insistence on broadening the context for assessment of Columbia River impacts to include a more complete assessment of impacts for under-represented populations and to broaden the assessments to include cultural, economic and social impacts as well as human and ecological impacts. Also, their consideration of the interrelatedness of ecosystem impacts with cultural health is extremely important. This reviewer, however, feels that the team has a tremendous effort in front of them to put these ideas and concepts into a workable plan. This reviewer was very unclear about how the team was going to implement and accomplish these concepts. In places, the document was extremely detailed such as designation of "tolerance models" for dose response versus other areas of the document which were very unclear. Uncertainty is dealt with in many inconsistent ways throughout the document and this reviewer urges the team to see the specific comments listed below for

Page	Comments

detailed examples. In many places the document seemed incomplete, especially in the appendixes where details about approaches were to appear, but most sections had specifics missing that were referenced as examples to illustrate feasibility and labeling of Part II approaches.

Although admittedly biased, this reviewer felt that the public health and ecological impacts were neglected. Overemphasis of exposure assessment was evident compared to receptor impact assessment. To retain a comparable level of complexicity of modeling and assessment, the receptor component would need to be separated into an equivalent number of core tasks as was exposure assessment (i.e., approximately 5 tasks). This is especially true if the team is committed to looking at the tasks that are dominant and where value of information analysis would show the largest impact. (See specific comments on how receptor impacts have already been identified by many investigators as a dominant driver in assessments, yet is largely ignored.)

The Part II document is ignored in Part I; was this intentional? It would appear that the Part I document would be used to develop interim guidance on how to apply the principles of domain and fidelity. Why not use this data to identify examples to illustrate feasibility and liability of Part II approaches?

To move forward, the Part II team could convene several technical panels to address issues that remain unclarified in Part II. This would initiate activities on web design and model evaluation.

This reviewer has also listed numerous specific comments regarding what are the goals of this team. How will they impact the decision process? Many of these questions arise because the document is unclear on how the process will determine how recommendations and waste disposition goals will be met, how validation of waste disposition decisions and how advice will be sought and recommended to people down from Hanford. The implementation plans need to be delineated.

In some sections, Part II made some very specific specifications; for example, the specification of tolerance models. In other cases, such as with fidelity and consideration of fineness of definition in determining timing and resolution, no methods were specified. The team needs to work on giving an evenness to this level of specification. This is especially true if the goals of the CRCIA team to integrate across assessment models is to be achieved (see Pg. II-2.2, Section 2.2).

Each section of the appendix referred to additional materials that were in preparation, that were unavailable for review

Page	Comments
	but that would be inserted into final document. This reviewer felt very uncomfortable with this approach as insertion of new, unreviewed material into an appendix would then mean that the document would not be reviewed as a completed plan. Are you planning to send out another revision? What is the timing for this?
Pg. II-iv, paragraph 1	This reviewer is very supportive of the use of sensitivity analysis to identify key factors that have the largest impacts on the overall assessment.
Pg. II-5	Avoiding Duplication of Other Work is a very meritorious goal. Has the tie-in with other projects/decision making processes on site been implemented? Is there a clear plan for under intergration. Please see my later comments that suggest more tie-in in the Part I and interim plans are needed.
Pg. II-7	Summarize - This reviewer agrees with the discussion of value on actual analysis rather than expect elicitation. This reviewer also feels "value of information" approaches are extremely useful.
Pg. II-7	Uncertainty - Has the team considered defining the two types of uncertainty that are usually used in assessments; i.e., lack of knowledge versus variability? This reviewer would suggest including this in this discussion as it fits with your identification of "value of information" approaches. Specific methods to address each of these types of uncertainty could be proposed.
Pg. II-8	Development and use of Assumptions- This reviewer strongly supports the need for all assumptions to be clearly delineated. In life there are tremendous number of assumptions made by all of us everyday from assumptions about the sun coming up and making plans for the week based on that assumption to very tentative assumptions that if wrong will negate our assumption. I would suggest that you apply your principle of dominance to this issue. Requiring approval of all assumptions of the board seems unwieldy.
Pg. II-9	Research and Development of Analysis Methods - This reviewer would encourage the team to look at some of the analysis approaches that are used beyond the routine DOE risk assessment paradigm before reinventing new methods others have already struggled over. For example, on the topic of multigenerational mutagenic effects there are many interesting and relevant analyses that people have conducted in other disciplines but that have not been utilized in DOE risk assessments. Before developing new ones let's look at getting some ideas from researchers who have been wrestling with these concepts. In the area of cultural impacts there is

Page	Comments
	also an equally rich literature that has largely been ignored in the DOE community.
Pg. II-9, last two paragraphs	This reviewer is somewhat unclear about the plan and first and second phases of Part II.
Pg. II-10	Impact Comparison Baseline - This reviewer would caution the comparisons with upstream conditions as the only impact comparison. In the case of assessing impact from metals, mining activity in the Columbia River corridor North of the dams has caused considerable impacts in the region and the impacts of the DOE complex should not be judged acceptable solely because they are less than the other impacts. Some absolute criteria for impact based assessments is needed for reference that is independent of these geographical and historical comparisons. Some of the worst mining impacts were pre-Hanford times.
Pg. II-10	CRCIA Standards - This reviewer is a "Teratologist" -- one who studies teratogenic effects and I was somewhat surprised to read this section that said that the current regulations are written without consideration of teratogenic nor mutagenic effects. If this Part II assessment is going to use the IRIS data bases from EPA then the reviewers should be aware that teratogenic effects are included as part of those assessments. One can argue that those assessments are still inadequate (for example, limited multigenerational mutation studies), but this section should be rewritten to acknowledge these facts and to be specific enough so the readers of this document can understand what the team is interested in accomplishing. This reviewer would agree that minimal to nonexistent consideration of cultural effects has been done and that failure of the toxicological community to adequately assess impacts of mixtures is embarrassing. This section is very "all encompassing" and this reviewer would encourage some discussion here or later on how to stage this assessment. This reviewer was encouraged but confused by Figure 3 and approaches delineated in the remainder of the document to address this approach. It appears that approximately equivalent weight is given to this impact assessment in task 9 as to the 8 other factors listed in Figure C-1 (Pg. II-C.3). As noted in this reviewer's comments in Part I, the uncertainty present in impact assessment has been shown to be dominant in overall risk assessments and easily contributing over four orders of magnitude of uncertainty to the final evaluation. If your intent is truly to identify dominant factors in the impact assessment, then this team needs to look at the Structure of C-1, and allocation of efforts.
Section 1.0	What the assessment must include - This reviewer was surprised by Figure 3. Given the initial statement about the committee's commitment to assessment of impacts, this

Page	Comments
	figure seems very contrary to that emphasis. The majority 7/9 of the tasks are focused only on identification of the problem and only 1 or 2 of the tasks are focused on characterizing what the impact is. This seems to be slanted to environmental monitoring without an equivalent emphasis on assessing impacts. Task 9 should separated into at least an equivalent number of tasks if the content of the Part II CRCIA team is to assess health (human and ecological) and cultural impacts.
Pg. II-1.7	Chrome versus chromium. Please use chromium.
Pg. II-1.7, paragraph 3	It is unclear to this reviewer how the key species chosen by Part II process will differ from Part I. Could some specific examples be given? This reviewer is concerned that the same species-by-species approach will be taken in Part II as we taken in Part I. When assessing ecological health, the whole landscape should be looked at in total as impacts on a single species can result in magnification of effects across species related because of the interrelated nature of the ecological landscape. How will the species specific assessments discussed in this section be integrated with your concepts of ecological web assessment? Give an example if possible.
Pg. II-1.9, Section 1.9	Receptor Impact and Tolerance Assessment - Text needs to clarify whether individual or just population tolerance models have been accepted. This reviewer was surprised to read this proposal for tolerance models without specifications of endpoint, contaminant or population. How will tolerance models handle background effects? Will additivity be specified? This reviewer would need to see much more convincing support for this concept before the full scale acceptance of this specific approach for all assessments. This reviewer suggests caution in this "across-the-board" recommendation. Many assessors feel that biologically based models should be used rather than general tolerance models as is suggested. The CRCIA group should review these approaches as well before making such a specific recommendation.
Pg. II-1.10, Section 1.11	Hanford Site Disposition Baseline - This reviewer had several questions after reading this section. Does this section imply that the CRCIA team would never be envisioned to propose an alternative endpoint to evaluate if their analyses is suggestive that an alternative approach might be useful? From the reading in this section, it sounds as if no other considerations would be evaluated except for vadose zone characteristics. If this is not the case, then this section should be reworded to give the reader an understanding of what criteria would lead the CRCIA team to look at some other estimates (i.e., what criteria drives the need for CRCIA specific vadose zone characteristics).
Pg. II-2.1, Section 2.1, paragraph 2,	Fidelity of Detecting Harmful Effects, What does

Page	Comments
lines 1-2	"...requires the use of what one regards as important..." mean? Does this mean "....requires the identification of what is important..."?
Pg. II-2.1, Section 2.1, paragraph 3	There are statistical methods to determine both fineness of definition and geographic resolution that is required for a given level of fidelity. Has the CRCIA team reviewed these? What specifications have they made?
Pg. II-2.1, last 2 lines	Please define "trade study methods."
Pg. II-2.2, Section 2.3, paragraph 1	How does selecting "dominant effects" reconcile with statements made on pg. II-2.1, paragraph 2, where requirements are discussed to have "sufficient assessment sensitivity to check <u>any</u> potential adverse effects/impacts?" This reviewer is still unclear how the CRCIA team will manage or compare dominant factors. One of the issues that that has plagued traditional risk assessments is comparing methods where prioritization of diverse impacts has proven illusive. Examples include assessment of cancer versus noncancer impacts, chemical versus radiological impacts, human versus ecological risk and "health" versus cultural impacts. To conduct the sensitivity and decision analytic methods specific in this approach, major work needs to be done on these topics. As this research is being done, does the CRCIA team have continuing plans? There is also an unevenness about what decisions the CRCIA team will make versus what approaches and methods the "analysts" will complete. For example, the CRCIA will specify vadose zone characterization but for data quality the team will "leave it" to the analysts to complete the definitions of the assessments' data quality. Should the team play a more consistent/active role? Would this necessitate adding additional team members to cover these areas of expertise? Would this be preferable?
Pg. II-3.3, Section 3.6	Verification - What is "medical research of toxicity correlations?" *{Note: I am a medical researcher and toxicologist and I have no idea what is meant by this phrase.}*
Pg. II-4.1, paragraph 3	Describe here the methods that will be used to determine CRCIA representation.
Pg. II-4.2	Please provide more details on what would happen during the interim period. What would be the goals/specifications of this period? How long would this last or would this involve a gradual replacement of faulted assessment practices over time?
<u>Appendix II-A</u> Pg. II-A.2, paragraph 1	This reviewer suggests at a minimum the addition of two additional points for characterization: 1) Total amounts of

Page	Comments
	potential contaminants and source size, and 2) stability of contaminants under anticipated conditions. The extra 3-1/2 pages of detailed requirements were referenced but were not available for this reviewer to review. These should be put into a table at a minimum. {Note: the three missing pages of detailed requirements would have been good to review. The reviewer is not clear about how these contaminants will be ranked for significance of potential impact. Please add more details.
Pg. II-A.2, Section 2	The points detailed in this section on containment failure and release seemed appropriate, however, this section also had additional requirements that were not available for review.
Pg. II-A.6, P+A5.0-4	The document needs to define "...significantly contribute..." in the context of significance to habitat or drinking water contamination.
Pg. II-A.6, Section 6	It is unclear to this reviewer how critical habitats will be identified. This section lists some criteria but it does not seem to be complete. Hopefully, the missing pages will provide the necessary information.
Pg. II-A.7, Section (A7.0-1)	Does this set of receptors also include residential populations? If so, please list.
Pg. II-A-8, Section 8	Dose Assessment - It was difficult for this reviewer to understand the differences in dose assessment used in Section 8 in Part II from dose calculations from Part I. This Part II section makes reference to past exposures and states that these can be obtained from sampling and receptor measurements. It states that future doses must be estimated from models. This reviewer notes that for some contaminants, sampling cannot determine past exposures and models may also be necessary for this application as well. This section does not provide enough details for this reviewer to determine how "... a portion of the receptors of concern..." will be prioritized if fiscal constraints arise. This section also needs to give some hints on how background doses will be combined with new environmental doses.
Pg. II-A.9, Section 9	Receptor Impact and Tolerance Assessment - This is a huge category with many very large impacts together. Insufficient details are given to determine what the assessment must include. How is the team going to handle noncancer versus cancer effects? How is the team going to handle susceptible sub-populations such as children or the elderly? Many more details are needed to understand how the team would like to evaluate cumulative effects from multiple exposures. Will this be done by using additivity assumptions?

Page	Comments	047823
Pg. II-A.10, Section 10	This reviewer is confused by the reference to "normal" conditions. How is this different from the "current" conditions? Please clarify.	
Appendix II-B		
Pg. II-B.2, Section 1.0	Fidelity - It was difficult for this reviewer to determine what data assurance and data quality would be required by the team. How would these criteria differ from those used in Part I. This section needs more details. How will the team evaluate what is an adequate model (B2.04)?	
Pg. II-B.3, Section 3	This section does not provide enough details to determine how dominant threats are assessed and prioritized. How will dominant effects be identified and once identified, compared and prioritized for evaluation?	
Pg. II-B.4, Section 3.1	Hanford - This reviewer liked the reference to an iterative process to refine models.	
Pg. II-B..4, Section 3.2	This reviewer did not understand why this document states that "containment performance information should come from only one source, the US Department of Energy's...plans." Why was this specified? It would seem most technically defensible to use all available information and if it suggested that the DOE's containment calculations were off by 20 years then this information would be critical for accurate risk evaluations.	
Pg. II-B.6, Section 3.5, line 1	First sentence does not make sense - maybe missing text?	
Pg. II-B.6, Section 3.6	Insufficient details are provided for this reviewer to understand how good the assessment results must be.	
Pg. II-B.7, Section 3.8	Dose Assessment - This section needs to be reworked. Statements are included in this section that are not adequate. Two examples can illustrate these inadequacies. In the case of teratogenic effects, both dose and time of exposure define response. In fact, the same dose of teratogen l day later can cause no effect, whereas the day before, the embryo can have major malformations. Another example is immunological responses where strict dose response relationships are not clear. A DOE relevant example of such an immunotoxicant is beryllium.	
Pg. II-B.7, Section 3.9	This reviewer is unclear how adverse effects will be "...assessed with sufficient fidelity to reveal actual conditions..."	
Pg. II-B.8, Section 5.0	This reviewer could not determine what the quality assurance plan would look like for this Part II evaluation.	
Appendeix II-C		

047823

Page	Comments
Section 1.0	The second paragraph in this section provided a good description of in "iterative search for dominant process features" and described the potential impact of interrelated factors on evaluations. This reviewer did not necessarily believe the sentence in the first paragraph that stated "By focusing on dominant features, simplified approximations can be used in models without compromising their validity." This reviewer would suggest adding a qualifier to this statement that suggests "in the majority of cases" or "frequently."
Pg. II-C.4, Section 2	This reviewer would not obtain enough details from the section to understand the management of uncertainty. How do these three types of uncertainty relate to lack of knowledge uncertainty versus variability uncertainty?
Pg. II, C.5, Section 3	This reviewer felt these points a-d were important but felt that this document did not provide such an architecture.
Pg. II, I.3, Section 1.1	This reviewer applauds the commitment of the team to look at the overall future impacts of current and planned wastes scheduled to arrive at the Hanford site. Also the commitment to look at the overall lifetime of the contaminants' impacts at the site is essential.
Sections 3.1, 3.2, 4.0, 5, 6, & 7	These sections were incomplete and this reviewer could not assess.
Appendix II-D Pg. 11.02, Section 1.0 (D1.0-1)	Has the CRCIA team considered adding environmental advocates to the membership board? Is local business representation represented in "b) persons who use the Columbia River for sustenance, commerce or recreation?" Will Hanford workers be represented ? What about research communities? Several times in the document, reference is made to affected communities such as migrant workers - yet no specific position has been identified for this group. Has the team thought about adding this under represented group?
(D1.0-7)	This reviewer would urge that the openness of the meetings would include regular, scheduled time for public comment during the process not just at the time of final draft product release.
Pg. II, D.4, Section 3 (D3.0-3)	The statement "The performing contractor is responsible to ensure that the Board acts in all matters with a grasp of the relevant technical considerations" is a very large mandate. The Board may want to confirm this with the outside technical expertise that is described earlier.
Section 5	This reviewer was very interested to read points a, b, and c. The document does not provide details on how these points will be accomplished. If point a is true- i.e., that the Part II

Page	Comments	047823
	assessment would help determine the manner in which remediation and waste disposition should be done then shouldn't the plans for Part II include consideration of alternatives or outside sources as an assessment? This reviewer recalls specific statements being made that state "....containment performance information should come from only one source..." (Pg. 11-B4, Section 3.2.) Is this statement consistent with this large mandate. Similar inconsistencies in scope of alternative decisions could be raised for Part 6. How are revisions in planned criteria going to be accomplished?	
Section 6, Pg. 11-D.6 (D6.0-4)	Did this reviewer miss earlier discussion on "gates?" How are these designed? Need more details on how these will be defined.	