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DEPARTMENT OF ECOLOGY

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October 31, 1991

K. Michael Thompson
U.S. Department of Energy
P.O. Box 550
Richland, WA 99352



Re: Hanford Site Baseline Risk Assessment Methodology

Dear Mr. Thompson;

Ecology has completed its review of the Decisional Draft of the Hanford Site Baseline Risk Assessment Methodology, DOE-RL-91-45 (September, 1991). The apprehensions we expressed in the EPA/Ecology August 2 letter to you have materialized. Much of the draft is new material that was neither presented, nor discussed at any of the Working Group meetings. It appears either that the authors wrote the draft after the Group meetings and were unable to confer with the other Group members, or that the meetings were unproductive, as the authors had already outlined the document. Ecology envisions no less than a major redrafting of the Methodology to meet its original intentions.

The Methodology is in danger of becoming an inappropriate vehicle for fomenting dispute. The draft has raised volatile issues, such as threshold and cleanup levels, that do not belong in any risk assessment methodology. While there has been mention of "elevating" some of these issues, Energy itself has never addressed these questions to the regulators. Please formulate your questions concerning regulatory policy, and address them to the regulators as discrete packets. We will then be better able to provide Energy with guidance.

Topics have arisen which suggest the need for additional milestones or expansions of the existing milestone. Though swollen with a surfeit of issues and topics, this draft lacks much of the Hanford-specific guidance that should be its essence. If Energy wishes to vary from EPA guidance, then further efforts will be needed. However, we doubt that M-29 will be met if the original intention to follow regulatory guidance is not followed. Nor may the milestone be met if fundamental issues, such as cleanup levels or IRM decisions, are to be resolved within the context of the Methodology. These legitimate questions do not belong in the Methodology, which should be an objective and non-partisan document. The Methodology will be of little use as a technical tool, and it will provide no assurances to the public, if misused as a vehicle to raise policy questions. Ecology welcomes the resolution of the policy questions related to risk assessment in the appropriate forum.

The draft incorporates information in EPA guidance in a way that results in

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significant deficiencies of repetition and omission, which opens the door for confusion and controversy during application. As the objectives state in section 1.1:

"Development of the methodology has been undertaken so that Hanford Site risk assessments are consistent with current regulations and guidance, while providing direction on flexible, ambiguous, or undefined aspects of the guidance."

Consistency with current guidance can be best accomplished by simply referencing the guidance for certain risk assessment tasks. Integrating Hanford-specific guidance with rewritten standard material and extraneous rationalizing complicated our review, as it would also complicate practical application of the Methodology. We found the task of determining whether a protocol was a standard approach that had been rewritten, or was a Hanford-specific approach difficult and confusing. The Methodology contains a substantial amount of unnecessary information, omissions, inconsistencies and unsupported statements. We believe that more useful direction could be provided in less volume. The next draft would also benefit from editorial review.

The Methodology draft contains excessive explanation of rationale, which should have been decided by the Working Group before this draft was printed. It is inappropriate for the Methodology to contain rationales for proceeding inconsistently with the discussions of the Working Group. While the deliberations of the working group members should be memorialized in some form, the methodology document should remain "clean," to give straightforward directions to its end users.

Because the draft Methodology is fundamentally flawed and at variance with our expectations, line-by-line review was not conducted except to give specific examples of deficiencies. It is our understanding that the next draft of the Methodology will be provided for our review in December. With this letter are some general and specific comments on the Methodology to guide the authors.

Sincerely,



Steven F. Cross
CERCLA Unit
Nuclear and Mixed Waste Management Program

cc: Paul Day, EPA
Tim Nord, Ecology
Steve Wisness, Energy
Tim Veneziano, WHC

Washington Department of Ecology Comments
on the
Hanford Site Baseline Risk Assessment Methodology
DOE/RL-91-45, Decisional Draft

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1. Section 1.3, page 2

Deficiency: This section indicates that the Methodology will integrate CERCLA and RCRA risk assessment requirements. It does not list any guidance on the RCRA risk assessment process, and it mentions that RCRA risk assessment regulations have not been promulgated. The mandate of M-29 does not include integrating RCRA risk assessment methods.

Recommendation: Explain the source of the requirement for conducting RCRA risk assessments, and identify RCRA guidance on conducting risk assessments. If this cannot be done, then remove the implications that RCRA would be integrated with CERCLA.

2. Section 1.4, page 2-3

Deficiency: This section contains statements of the Methodology's approach to risk assessment and its intended application that are incorrect and inappropriate. Phrases in this section, such as "this streamlined approach" and "uses of the methodology represent a departure from the traditional baseline risk assessment," imply that the Methodology is designed to shorten the risk assessment process. Future users may incorrectly, though justifiably, assume that any omissions from the Methodology of references to standard practices were intentional.

Recommendation: Delete Section 1.4 and remove all references to intended application of the Methodology, in particular to cleanup levels, except in Section 4.0.

There being numerous inappropriate references to cleanup levels outside Section 4.0, this recommendation applies to the entire Methodology, and is not repeated.

3. Section 1.4, page 3, top paragraph, first bullet

Deficiency: The baseline risk assessment would be used to establish initial cleanup levels.

Recommendation: The purpose of the Methodology is not to establish cleanup levels.

4. Section 1.5.1, page 3, first paragraph of section

Deficiency: The methodology for the HHE is said to be primarily based on the MTCACR process, as opposed to the NCP process. MTCACR is not a risk assessment methodology, but a methodology for calculating a limited set of risk-based cleanup levels. MTCACR does not attempt to consider all significant pathways and media, as does the NCP. While the task group agreed to use certain aspects of MTCACR in section 2.2, reference to MTCACR in other areas of the Methodology would be incorrect and inappropriate.

Recommendation:

A) Follow the human health risk assessment process required by the NCP, as set forth in RAGS.

B) Delete all references to MTCACR, except in section 1.3 on ARARS and Section 2.2 to support selection of exposure assumptions. There being numerous inappropriate references to MTCACR outside the designated sections, this recommendation applies to the entire Methodology, and is not repeated.

5. Section 1.5.1, page 3, bottom paragraph

Deficiency: The HHE methodology of section 2 would incorporate the requirements of the MTCACR and CERCLA risk assessment guidance. This is inconsistent with section 1.1, which indicates that the Methodology would ensure consistency with, while providing site specific direction on the application of, regulations and guidance. There is undue emphasis on such catch words as "probable," "major," "significant," and "only."

Recommendation: Delete the paragraph.

6. Section 1.5.2, page 4, second full paragraph

Deficiency: The quoted material is truncated in a way that could be misleading. It is worthwhile to convey the information that the exposure levels will be used in developing remedial alternatives in the FS, as described in NCP 430(e).

Recommendation: Complete the second sentence of the quotation.

7. Section 1.5.2, page 4, third full paragraph, first sentence

Deficiency: It is stated that the overall goal of the environmental evaluation is to determine cleanup levels. Remediation goals are developed through the FS as part of establishing the remedial action objectives described at NCP 430(e)(2). Initially preliminary remediation goals are to be established based on readily available information such as chemical specific ARARs or other reliable information. Preliminary goals should be modified, as necessary, as more information becomes available. Final remediation goals are to be established when the remedy is selected.

Recommendation: Delete the last four words from the sentence, i.e., "to establish cleanup levels." List the objectives for environmental evaluations in federal guidance that were identified in the task group presentation.

8. Section 1.5.2, page 4, second paragraph from the bottom

Deficiency: It is stated that satisfaction of the NCP requirements will also meet RCRA and state requirements for environmental protection. This conclusion is not supported.

Recommendation: Do not make this statement with out providing a point by point comparison of which requirements will satisfy which other requirements. If this analysis would clutter the Methodology, then it may be provided separately.

9. Section 1.5.2, page 4, last paragraph

Deficiency: This paragraph contains rationale and definitions that are unnecessary and inappropriate. Including definitions that are not clearly referenced or required for use of the Methodology will lead to confusion during application.

Recommendation: Delete

10. Section 2.0, page 6, first sentence

Deficiency: The first point of this sentence contradicts RAGS. Section 1.1.2 of RAGS, at page 1.6, states that after an initial planning stage, "there are four steps in the baseline risk assessment process: data collection and analysis; exposure assessment; toxicity assessment and risk characterization." The Methodology should supplement RAGS, rather than rewrite it. Also, Section 5.0, Data Evaluation, is not

referenced as the basic guidance. As a result, much of the critical information in RAGS is not included.

Recommendation: Follow RAGS section 1.1.2. Use Data Evaluation as the title of the first step in an HHE and include a reference to Section 5.0 in RAGS. Clearly state that all components of Section 5.0 need to be included unless modified by the Methodology.

11. Section 2.1, pages 6-13

Deficiency: This section relates to the screening procedure of RAGS section 5.9. Yet, only one unbalanced excerpt from this section is provided (without a page reference). The balancing excerpt in the next paragraph should have been included with the first so that the reader would understand that screening may not be appropriate at Hanford. The theorizing and rationalizing is unnecessary, since the Methodology will follow RAGS section 5.9. Because this material was never presented to the Working Group during the period of its meetings, Ecology shall not fully analyze the substance of the screening method proposed in the decisional draft of the Methodology, but shall simply remind the authors that the regulatory members of the Group expressed their understanding that RAGS would be followed and that the regulated member of the Group accepted this.

Recommendation: Follow the screening procedures of RAGS section 5.9. Remove extraneous justifications for blanket applications of screening. The Methodology need only explain how the RAGS procedure will be applied at Hanford. If an alternate screening procedure is to be proposed, it will have to be done so in an effort supplemental to meeting Milestone 29.

12. Section 2.1, pages 6-7

Deficiency: This section contain rationale and explanation that is unnecessary and inappropriate. Philosophical discussion and justification for limiting the chemicals of concern is unnecessary and is misleading. The emphasis on limiting the chemicals of concern is not consistent with the philosophy expressed in RAGS. Discussion of TAL/TCL lists is irrelevant and unnecessary.

Recommendation: Delete.

13. Section 2.1, page 7, first full paragraph

Deficiency: Limiting selection of chemicals of potential concern to a comparison to background and preliminary risk-screening is incorrect and omits a significant number of steps recommended in RAGS.

Recommendation: Refer to RAGS Section 5.0 as the basic guidance. Clarify that the Methodology includes approaches to application of background data and preliminary risk screening levels that are supplementary to RAGS.

14. Section 2.1, page 7, first full paragraph

Deficiency: The Methodology includes the terms "control screening" and "control distribution" in relation to background. The terms are not clearly defined, and including it implies that the Methodology defines another type of background data not included in RAGS. This term broadens the standard definition of background and will lead to controversy over the selection of background locations.

Recommendation: Delete the term "control."

16. Section 2.1.1, pages 7-9, first four paragraphs of section

Deficiencies:

These four paragraphs are superfluous. These paragraphs contain misleading and inappropriate information. Implicit in the discussion is that areas of the Hanford site may contain elevated levels of chemicals related to man but unrelated to Hanford. This approach is in direct contradiction of recommendations in RAGS, Section 5.7.4, which states that chemicals from anthropogenic but not site-related sources should not be eliminated.

Statements such as the first sentence in paragraph 2, "The background or control locations must be selected on a project-specific basis," are not correct. Hanford-specific background data is being collected for use in the risk assessments. These data should be used as background unless project-specific data can be justified based on natural conditions such as differences in local geology.

Recommendation: Delete these four paragraphs. Insert discussion of Hanford

background data and clearly state that use of any other data needs to be substantiated. Anthropogenic chemicals not related to the site can be identified but not eliminated.

17. Section 2.1.1, third paragraph of page 9

Deficiency:

A) The background study may impose background levels on the risk assessor to some extent.

B) It is not stated that this approach to quantitatively identifying concentrations above background is specific to the Methodology, and no reference as to source is given.

Recommendation:

A) Reference the background study, and explain its applicability to risk assessment.

B) State that the approach is specific to the Methodology, and supply a reference.

18. Section 2.1.1, page 9, paragraph 3, 4, and 5 of page 9, and paragraph 1 of page 10

Comment: The terminology and descriptions in these paragraphs are unclear, unnecessarily complex, and difficult to understand.

Deficiency: This paragraph, particularly "an priori assumption of normality is objective . . . ," is an example of the above comment. How is an assumption of normality objective? The term "objective" is frequently used throughout the document in an unclear or undefined fashion.

Recommendation: Delete and review all uses of the term "objective" in the Methodology. Subject the draft to editorial/technical review.

19. Section 2.1.1, page 10-11, first six paragraphs of section

Deficiency:

The emphasis on limiting the chemicals of concern is not consistent with the philosophy expressed in RAGS. Although Region 10 guidance does provide for risk-based screening, we believe that these five paragraphs of discussion are unnecessary and unduly emphasize the potential to limit the list of chemicals of concern. Also,

much of the discussion concerns the rationale for eliminating chemicals which is unnecessary. Several of the rationales, eg, time and cost, are controversial and will reflect negatively on the Methodology.

Paragraphs 3-6 contain information available in RAGS. Rewriting this material results in omission of several critical aspects on how to interpret and apply the SQL rules. Also, the rewritten material is difficult to understand and could result in misapplication of the protocol.

Recommendation: Reduce discussion to one paragraph and omit discussion of rationales. Clearly state in the introduction to section 2.1 that all of RAGS section 5 apply unless specifically modified in the Methodology.

20. Section 2.1.1, page 12, first full paragraph

Deficiency: This paragraph contains unnecessary rationale that is misleading and philosophical in nature.

Recommendation: Delete

21. Section 2.1.1, page 12, third full paragraph

Deficiency: EPA and Ecology guidance documents are misquoted and misinterpreted. These documents do not designate certain pathways as driving risks at sites. Although these pathways are considered basic to any risk assessment, they are not identified as risk drivers. This is an important misinterpretation of these documents. The credibility of the Methodology is significantly undermined by this type of misinterpretation and unsupported decision-making.

Recommendation: Revise this paragraph. Any selection of pathways as risk-drivers must be accompanied by substantive documentation. To our knowledge, such documentation is not available in the scientific literature. Therefore, the Methodology should contain quantitative evaluation of exposure pathways to identify any pathways selected for screening purposes.

Please note that this issue was discussed at almost every meeting. Ecology made this same recommendation for quantitative screening to support any selection of specific pathways repeatedly.

22. Section 2.1.1, page 12, fourth paragraph

Deficiency: The decision on how to apply data to model exposure at a site should be made on a case-by-case basis. For example, national ambient air quality standards for particulates may not fairly represent Hanford site conditions. This issue was not discussed during the task group meetings and represents new information.

Recommendation: Delete. Our preliminary review has concluded that the best approach is to not specify how to apply site data as opposed to the limited discussion presented in the Methodology.

23. Section 2.2.3.2, page 20

Please refer to comment on section 2.1.1, page 12, third full paragraph.

24. Section 2.2.3, page 20, Figure 2-4

Deficiency: Some resuspension/redeposition pathways are not represented.

Recommendation:

A) Add a reverse arrowhead from wind back to soil.

B) Add a reverse arrow from sediments back to surface water.

25. Section 2.2.3.2, page 22, last paragraph

Deficiency: These pathways and the explanation for their exclusion is not clear. We do not recall that any pathways were completely excluded.

Recommended: Delete this paragraph. We are not aware of any pathways that can be totally excluded at this point.

26. Section 2.2.3.2, page 23, first two paragraphs of page

Deficiency: The ideas in these paragraphs are presented more clearly and concisely in RAGS, Section 10.5

Recommendations: Delete and refer to RAGS

27. Section 2.2.4, pages 23-25, general comment

Deficiency: The information in this section describing each exposure scenario is insufficient and needs to be supplemented by that in Appendix A. Please see comments on Appendix A.

Recommendation: Include information in Appendix A in this section.

28. Section 2.2.4, page 24, first sentence of each scenario brief

Deficiency: The commercial/industrial scenario would be the "typical scenario" assessed. The recreational scenario is said to be provided because current activities could result in exposure. The residential scenario is justified by adjacent and down stream residents, because there is "no current residential use." The agricultural scenario would be limited to offsite lands.

Recommendation: Commercial/industrial will not be the "typical" scenario. None of the scenarios are to be limited to current uses. None of the scenarios are to be limited to offsite uses.

29. Section 2.2.5.3, pages 27-28

Deficiency: This information is described more accurately and in greater detail in RAGS section 6.

Recommendation: Delete and refer to RAGS section 6.

30. Section 2.2.5.4, pages 28-30

Deficiency: This information is described more accurately and in greater detail in RAGS section 10.

Recommendation: Delete and refer to RAGS section 10.

31. Section 2.2.5.4, page 31, paragraph 2

Deficiency: Our understanding is that radiation risks are to be calculated with two methods, HEAST and IARC. The explanation in these paragraphs suggests the recommended method is a combination of the two approaches. This is not acceptable. As we discussed at length in the meetings and as is mentioned in the Methodology, the two methods are not comparable.

Recommendation: Revise and correct to recommend HEAST and IARC as parallel approaches.

32. Section 2.2.5.4, page 31, remainder of page - page 33

Deficiency: This information is described more accurately and in greater detail in RAGS section 10.

Recommendation: Delete and refer to RAGS section 10.

33. Section 2.3, (all) pages 33 to 41

Deficiency: This information is described more accurately and in greater detail in RAGS, Section 7.0. Rewriting text allows for misinterpretation of the standard protocols. We are not aware of that any Hanford-specific changes were discussed at the meetings.

Recommendation: Delete all except the first paragraph and refer to RAGS section 7.

34. Section 2.4, pages 41 to 46

Deficiency: This information is described more accurately and in greater detail in RAGS section 8. Rewriting text allows for misinterpretation of the standard protocols. We are not aware of any Hanford-specific changes discussed at the meetings other than to incorporate the IARC as a parallel methodology for radiation risks.

Recommendation: Delete all except the first paragraph and refer to RAGS sections 8 and 10.

35. Section 3.0, pages 47 et seq., Environmental Evaluation Methodology

Deficiency:

The changes made in section 3.0 to the material discussed in the task group meeting are unacceptable. The draft provides a very limited view of the ecological evaluation's role and the ways to identify ecological impacts. It significantly changes the intent and scope of the outline presented by Ecology at the task group meeting.

In particular, the information under Exposure Assessment and Toxicity Assessment is not an adequate substitute for that provided under Characterization of Effects and Characterization of Stress in EPA guidance documents.

The environmental evaluation methodology is quite different from that jointly presented by EPA and Ecology at a Group meeting, and discussed by all. There was no statement at that meeting that the proposed EE method was unacceptable. The proposed EE method was an assimilation of various methods under development at different levels and by different bodies, premised on the idea that something resembling those methods would eventually become regulatory guidance. Section 3.1 does not purport to assimilate methods under development, charts an idiosyncratic Hanford course.

Recommendation:

Use the format provided in the task group meeting on Ecological Evaluation. The Methodology should only contain information extracted from the EPA guidance documents referenced in the outline presented at the meeting.

36. Section 3.1, page 47, first paragraph, last line

Deficiency: The purpose of the environmental evaluation is not to determine site cleanup levels.

Recommendation: Replace this sentence with goals identified in the August 29 Working Group meeting.

37. Section 3.1, page 47, second paragraph, second sentence

Deficiency: The statement that a document "was not made available" implies that the document was asked for and refused. The fact is that all documents in the hands of the regulatory Group members were made freely available to all members of the

Group in the spirit of cooperation. For example, the framework document was provided, even though it was a recent draft peer review.

Recommendation: Remove this insinuation of intentional withholding of relevant documentation by the regulatory members of the Group.

38. Section 3.1, page 47, third paragraph, last sentence

Deficiency: The NCP is a long regulation, and this reference to it is not specific.

Recommendation: Specify the provision of the NCP which requires that the Methodology only address the releases of contaminants and only address the baseline conditions.

39. Section 3.1, page 47, paragraph 3

Deficiency: The statement that the Methodology EE will be more limited and will not need to address a broad range of potential stressors or evaluate action alternatives is incorrect and not in accordance with EPA guidance. This is a gross misrepresentation of discussion at the meetings that we would be able to focus the environmental evaluations more because of the large body of ecological information available on the site. This comment reflects on the entire Section 3.

Recommendation: Delete this paragraph and all suggestion in Section 3.0 that the environmental evaluation is more limited than the scope recommended in the cited references.

40. Section 3.1, page 47, fourth paragraph, first sentence

Deficiency:

The attempt to parallel the EE with the HHE is inappropriate. While correlations may aid in the understanding of those unfamiliar with EE, they do more damage to clarity by ignoring the distinctions.

The rationale for using one outline or the other is of interest only to the Working Group, and not to the end users of the Methodology. The end users will take the Methodology at face value, and will have no business reassessing the wisdom of the Groups product. Therefore, the rationale will be unnecessary, regardless of what form the Methodology ultimately takes.

Recommendation:

Use the outline suggested by the framework and discussed in the Working Group meeting.

If the authors wish to follow a course not envisioned by the Working Group, then the rationale for that proposal should be propounded in a separate proposal other than the Methodology itself. The Methodology should give direction rather than explanation.

41. Section 3.1, page 47, last two paragraphs, Figure 3-1, and page 49, first 4 paragraphs

Deficiency: These sections either reflect ideas expressed in the previous comment, or unnecessary compare human and environmental evaluations.

Recommendation: Delete

42. Section 3.2, pages 50-52

Deficiency: This section contains some of the material in the comparable Problem Definition section in the EPA Framework reference. However, some critical information is omitted.

Recommendation: The EPA Framework document should be included in the Methodology as an Appendix. It may not be readily available to many of the potential users of the Methodology. Any modifications can be presented in the body of the Methodology. Text in the Framework document should not be rewritten.

43. Section 3.2, pages 52, last paragraph, to page 56

Deficiency: This section contains valuable Hanford-specific information. However, technical editing is needed. In particular, section headings would be helpful. The logic and flow of these pages in a context of the whole section is not clear.

Recommendation: Technically edit these pages.

44. Section 3.2, page 57, all paragraphs

Deficiency: Inclusion of a preliminary toxicity screening component as a "stand-alone" basis for selecting chemicals of potential concern is inappropriate.

Recommendation: Refer to RAGS, Vol. B, for guidance on data evaluation in environmental evaluations. Delete page 57.

45. Section 3.2, page 58 to end of Section 3.0

Deficiency: These pages contain some of the material in the comparable Problem Definition section in the EPA Framework reference. However, some critical information is omitted. In particular, the draft limits risk characterization to comparison of dose-response under Toxicity Assessment with exposure under Exposure Assessment. This significant deficiency critically limits the scope of the environmental evaluation. This approach is very different from that discussed in the task group meeting.

Recommendation: Most of these pages can be deleted. Section 3.0 should follow the outline presented in the task group meeting. The EPA Framework document should be included in the Methodology as an Appendix. This document may not be readily available to many of the potential users of the Methodology. Any modifications can be presented in the body of the Methodology. Text in the Framework document should not be rewritten.

46. Section 4

Deficiency: This section does not reflect the original intent as understood by Ecology, but is a discussion of policy and how the policies will be applied at Hanford. We expected a section that dealt with methodologies not policy.

Recommendation:

Rewrite and remove all reference to policy, acceptable levels of risk, and alternative uses of MTCACR methods.

The following comments on this section are not to be taken as an indication that Ecology will agree to the incorporation of such topics in the Methodology.

47. Section 4.1, second paragraph of page 71, second sentence

Deficiency: It is not correct to state that the baseline risk assessment provides the basis for determining whether remedial action is necessary. It is evident from NCP §430(e) that the decision of whether remedial action is necessary is based on many factors.

Recommendation: Correct the sentence to state that the baseline risk assessment is one of the basis for determining whether remedial action is necessary, and explain how it relates to the other basis required by NCP §430(e) to be considered.

48. Section 4.1, second paragraph of page 71, third sentence

Deficiency: This reference to the NCP is not cited.

Recommendation: Provide the citation to the particular provision of the NCP that requires the baseline risk assessment.

49. Section 4.1, second paragraph of page 71, last sentence

Deficiency: The NCP does not call for a target risk range of 1E-4 to 1E-6. Developing remedial alternatives is not so simple as a target number. NCP §430(e) states:

Feasibility study. . . .

(2) Alternatives shall be developed that protect human health and the environment by recycling waste or by eliminating, reducing, and/or controlling risks posed through each pathway by a site. . . . In developing and, as appropriate, screening the alternatives, the lead agency shall:

(i) Establish remedial action objectives specifying contaminants and media of concern, potential exposure pathways, and remediation goals. . . . Final remediation goals will be determined when the remedy is selected. Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:

(A) Applicable or relevant and appropriate requirements under federal environmental or state environmental or facility siting laws, if available, and the following factors:

(1) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;

(2) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or

multiple pathways of exposure;

(3) Factors related to technical limitations such as detection/quantification limits for contaminants;

(4) Factors related to uncertainty; and

(5) Other pertinent information.

(B) Maximum contaminant level goals (MCLGs),

(C) . . .

(D) In cases involving multiple contaminants or pathways where attainment of chemical-specific ARARs will result in cumulative risk in excess of 10^{-4} , criteria in paragraph (e)(2)(i)(A) of this section may also be considered when determining the cleanup level to be attained.

Recommendation: If target risk levels are a proper subject of a risk assessment methodology, then revise the sentence to explain that the point of departure is $1E-6$, and explain all the other criteria. Since it is not, delete this paragraph.

50. Section 4.1, page 71, third paragraph from top of page, last sentence

Deficiency: The decision whether to use Method C is not limited to consideration of the five criteria. It is overly simplistic and misleading to quote only those five criteria and not the other applicable provisions. A complete decision would require consideration of WAC 173-340-706, and -745(1)(a), (c), (d), (e), (f), and (g).

Recommendation: Quote or cite all or none of the applicable provisions.

51. Section 4.1, page 71, third paragraph from top of page

Deficiency: The discussion of MTCA cleanup methods is inappropriate to the Methodology.

Recommendation: Delete this paragraph.

52. Section 4.1, page 71, last paragraph, first sentence

Deficiency: The Methodology should be primarily based on the NCP, rather than MTCA. One of the decisions at the foundation of the Risk Assessment Working

Groups efforts is nearly stated in the last three sentences of section 1.1 on page 1. The Group decided to rely on and incorporate EPA guidance, rather than be consistent with EPA guidance. Furthermore, MTCA does not require a baseline risk assessment, per se. The rest of the paragraph therefor becomes moot.

Recommendation: Delete this sentence, and therefor the rest of the paragraph.

53. Section 4.1, page 71, last paragraph, last sentence of page

Deficiency: This sentence does not specify that carcinogenic risks for individual substances may not exceed 1E-6 under Method B, or 1E-5 under Method C. The cleanup levels for individual substances may be adjusted downward in the case of multiple substances/pathways so long as the cumulative risk does not exceed 1E-5. Individual substances may not pose a risk greater than 1E-6 under Method B.

Recommendation: Revise this and the next sentence to provide for individual substance cleanup levels.

54. Section 4.1, page 72, first full paragraph, second sentence

Deficiency: The "target risk" is not 1E-5. Cleanup levels under Method B require 1E-6, as discussed with regard to the previous paragraph. The NCP sets a point of departure of 1E-6, as discussed with regard to the first paragraph of this section.

Recommendation: Put "target risk" in quotes to indicate the terms meaninglessness. Change 1E-5 to 1E-6.

55. Section 4.2, page 72, second paragraph of section, first sentence

Deficiency: Use of the Methodology to perform a qualitative risk assessment would not require definition of trigger levels or cleanup levels. The correct process is stipulated by NCP §430(e), which states:

Feasibility study. . . .

(2) Alternatives shall be developed that protect human health and the environment by recycling waste or by eliminating, reducing, and/or controlling risks posed through each pathway by a site. . . . In developing and, as appropriate, screening the alternatives, the lead agency shall:

(i) Establish remedial action objectives specifying contaminants and media of concern, potential exposure pathways, and remediation goals. Initially, preliminary remediation goals

are developed based on readily available information, such as chemical-specific ARARs or other reliable information. Preliminary remediation goals should be modified, as necessary, as more information becomes available during the RI/FS. Final remediation goals will be determined when the remedy is selected. Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:

Recommendation: Delete the second clause of this sentence, and provide an explanation of preliminary remediation goals, and a citation to the NCP.

56. Section 4.2, page 72, second paragraph of section, second sentence

Deficiency: Comparisons to trigger levels is not part of the Methodology.

Recommendation: Do not address trigger levels in this document.

57. Section 4.2, page 72, second paragraph of section, last two sentences

Deficiency:

There is no EPA 1991e in the list of references.

It is not appropriate for the Methodology to establish trigger levels. Both EPA and Ecology repeatedly made this clear during many of the Working Group meetings. Energy has never applied to the regulators for a determination on this question.

The Clay memorandum contains several other basis for taking remedial action than 1E-4 risk, which must be included in any complete explanation of when remedial action is warranted.

Recommendation: Delete these sentences from the Methodology, and seek to determine trigger levels through another vehicle.

58. Section 4.2, page 72, last paragraph

Deficiency:

The Methodology should not require the calculation of cleanup levels.

Exactly where does the NCP "generally consider insignificant" an incremental risk less than 1E-6?

Where is the rational basis for proposing the hazard quotient of exactly 0.3? How can a hazard quotient be a half order of magnitude different than the factor recommended for carcinogens?

Recommendation: Delete this paragraph from the Methodology, and address preliminary remedial goals through another method.

59. Section 4.2, page 7.3, first full paragraph on page

Deficiency: The Methodology is not the place to apply for use of Method C. The Methodology is not the place to establish cleanup levels. This is also discussed elsewhere in these comments.

Recommendation: Delete this paragraph.

60. Appendix A

Deficiency: The discussions of the four scenarios is intermingled with the explanation of the parameters listed in Table A. Identification of exposure pathways (RAGS §6.3) is the second step of the exposure assessment process, while calculation of intakes (RAGS §6.6) is the part of step three, quantification of exposure (RAGS §6.4).

Recommendation: The explanation of parameters should be directly linked to the resulting values in Table A, while the textual description of the scenarios should be discrete.

61. Appendix A

Deficiency: The rationale behind exposure assumptions developed for the Hanford site and not taken from EPA or MTCACR is not sufficiently explained. In most cases, a simple statement was made that all exposure assumptions not from EPA or MTCACR were taken from certain references. This is not sufficient.

This appears at Appendix A, page A-2, paragraph 4
Appendix A, page A-4, second paragraph
Appendix A, page A-6, paragraph 4
Appendix A, page A-9, paragraphs 2 and 3

Recommendation: Exposure assumptions developed from sources other than EPA or

MTCACR recommended values need additional support in the text. At a minimum, each value and the source need to be stated. Also, prepare a table in list form of the assumptions in each exposure scenario with a reference as to the source.

62. Appendix A

Deficiency: Pathways are designated as primary or secondary without adequate support for this selection.

Recommendation: Provide quantitative or literature-based support for the selection process.

63. Appendix A

Deficiency: The receptors and their activities for each exposure scenario are not clearly presented. This will make site-specific decisions on exposure pathways difficult and inconsistent between risk assessments.

Recommendation: More information on the receptors in each scenario and their activities is needed.

64. Appendix A

Deficiency: The Methodology states that one of the conditions for selecting groundwater as a pathway is that it is a likely source of drinking water. The concern is to evaluate how chemicals in the soil and groundwater will impact use of the groundwater as a drinking water source. Thus, this pathway should be included under future use unless it is physically impossible to use the groundwater or there is clear evidence that the chemicals in soil will never reach groundwater.

This appears at Appendix A, page A-2, paragraph 2
Appendix A, page A-4 paragraph 4
Appendix A, page A-7, paragraph 3
Appendix A, page A-10, paragraph 2

Recommendation: Revise and/or delete the sentence qualifying selection of groundwater as a pathway based on "likely" future use.

65. Appendix A

Deficiency: The task group decision to use the most conservative approach between EPA and Ecology's MTCACR is explained and defended with unnecessary detail in each exposure scenario.

This appears at Appendix A, page A-2, paragraph 4
Appendix A, page A-2, last paragraph
Appendix A, page A-4, first paragraph
Appendix A, page A-5, last paragraph
Appendix A, page A-6, paragraph 5
Appendix A, page A-8, paragraph 4
Appendix A, page A-9, paragraphs 4 and 5
Appendix A, page A-11, last paragraph

Recommendation: Explain in the introduction that the most conservative approach was used and omit details from each scenario. Prepare a table in list form of the assumptions in each exposure scenario with a reference as to the source.

66. Appendix A, page A-2, paragraph 3

Deficiency: Does this apply to groundwater or soil ?

Recommendation: Clarify

67. Appendix A, page A-2, paragraph 4

Deficiency: 20-year exposure not the most conservative.

This also appears at Appendix A, page A-9, paragraphs 4 and 5

Recommendation: Use EPA's value of 25 years for industrial

68. Appendix A, page A-3, last paragraph

Deficiency: Meaning of category 80 and 81 not clear

Recommendation: Clarify

69. Appendix A, page A-4, paragraph 4

Deficiency: Inhalation and dermal exposure during residential use of groundwater are omitted based on a qualitative and unsupported statement that these pathways are not significant. If groundwater were hooked up to recreational vehicles, than these pathways could double or triple exposure. We also consider the qualitative and unsupported pathway selection process used throughout the document a serious deficiency.

Recommendation: Delete the recommendation that inhalation and dermal do not need to be considered.

70. Appendix A, page A-5, paragraph 4

Deficiency: Discussion of cleanup levels and relative contribution of exposure scenarios is unsupported and irrelevant.

Recommendation: Delete

71. Appendix A, page A-6, first full paragraph, first sentence

Deficiency: The Methodology may not conclude that residential land appears unlikely in the foreseeable future based on the Hanford Site Development Plan. The historical and potential future use of the land is neglected.

Recommendation: Delete the second clause of this sentence. Point out the historical use of the land, and explicitly note the potential for future residential use.

72. Appendix A, page A-8, last paragraph

Deficiency: Ingestion of game is not listed in the table in Section 2.2 under Agricultural.

Recommendation: Add to table for consistency.

73. Appendix A, page A-11, paragraph 4

Deficiency: Discussion of cleanup levels and relative contribution of exposure scenarios is unsupported and irrelevant.

Recommendation: Delete

74. Tables A1-A8, general

Addressing the comments on Appendix A will correct many of the concerns with the tables. The relevant comments are not repeated.

Deficiency: The footnotes are inadequate as references to those exposure values not found in EPA or MTCACR guidance. The column headings could be adjusted to allow a larger point size.

Recommendation: Prepare a table in list form of the assumptions in each exposure scenario with a reference as to the source.

75. Table A-3

Deficiency: There is inconsistent use of age groups without explanation. Five pathways use children only (16 kg), three pathways are both children and adults (16 and 70 kg) and two pathways are adults only (70 kg).

Recommendation: Use consistent age groups and explain the receptors and their activities in the text. Provide clear rationale for varying age groups.

76. Table A-4

Deficiency: Dermal exposure is split between adults and children, an uncommon practice that is not justified in the text.

Recommendation: Use one age group for dermal or clearly explain why two are needed.

77. Table A-5

Deficiency: There is inconsistent use of age groups without explanation. Five pathways use children only (16 kg), one pathway is children and adults (16 and 70 kg) and eight pathways are adults only (70 kg). Also, dermal for soil is split between adults and children while the pathways more typically split, ingestion of soil, is not.

Recommendation: Use consistent age groups and explain the receptors and their activities in the text. Provide clear rationale for varying age groups.

78. Table A-6

Deficiency: Dermal exposure is split between adults and children, an uncommon practice that is not justified in the text.

Recommendation: Use one age group for dermal or clearly explain why two are needed.

79. Table A-7

Deficiency: There is inconsistent use of age groups without explanation. Five pathways use children only (16 kg), one pathway is children and adults (16 and 70 kg) and eleven pathways are adults only (70 kg). Also, dermal for soil is split between adults and children while the pathways more typically split, ingestion of soil, is not.

Recommendation: Use consistent age groups and explain the receptors and their activities in the text. Provide clear rationale for varying age groups.

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References (submittal of draft document):

1. Letter 9104289, Wisness, RL, to Day/Nord, EPA/Ecology, dated 9/30/91. 16688
2. Letter 9157209D, Wojtasek, WHC, to Bracken, RL, dated 9/27/91. C.K.

ldp, 6-7049