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MAY 05 1993

93-ERB-141

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Hanford Project Manager
U.S. Environmental Protection Agency
1200 Sixth Avenue
Seattle, Washington 98101

Mr. Roger F. Stanley, Director
Tri-Party Agreement Implementation
State of Washington
Department of Ecology
P.O. Box 47600
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Dear Messrs. Hofer and Stanley:

SUBMITTAL OF REVISION 2 OF THE HANFORD SITE BASELINE RISK ASSESSMENT METHODOLOGY FOR APPROVAL

The U.S. Department of Energy, Richland Operations Office (RL) is pleased to submit Revision 2 of the "Hanford Site Baseline Risk Assessment Methodology," (HSBRAM) DOE/RL-91-45 (enclosure 1), to the U.S. Environmental Protection Agency (EPA) and State of Washington Department of Ecology (Ecology) for approval. Also enclosed are RL's responses to EPA and Ecology comments on the HSBRAM rev. 1 (enclosures 2 and 3), as agreed by EPA and Ecology Hanford Site risk assessment leads. This action satisfies the intent of the Hanford Federal Facility Agreement and Consent Order (Tri-Party Agreement) Milestone M-29-03, "Submit risk assessment methodology document (primary document) and include document in Appendix F."

The HSBRAM rev. 2 is based upon agreements negotiated between RL, EPA, and Ecology over the past two years on the need to document Hanford Site specific elements of human health and ecological risk assessment. RL recognizes, in agreement with EPA and Ecology, that there is a current need to publish and use HSBRAM rev. 2. Further, RL acknowledges future revisions are necessary to satisfy remaining unresolved concerns of EPA and Ecology, and to incorporate ongoing regulatory and technical developments. When consensus is reached among Hanford Site risk assessment leads on the need to prepare a new revision of HSBRAM, RL is committed to working with EPA and Ecology in this process.

The HSBRAM rev. 2 is based upon EPA guidance provided by the EPA Risk Assessment Guidance for Superfund (RAGS), RAGS supplemental documentation including EPA Region 10 guidance, and EPA's Framework for Ecological Risk Assessment because of the direct requirement to conduct risk assessments pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980. The HSBRAM rev. 2 has also incorporated some of the risk assessment requirements of the Ecology Model Toxics Control Act Cleanup Regulations (MTCA) that relate to exposure assessment. RL recognizes that risk assessments conducted pursuant to HSBRAM rev. 2 should be evaluated to determine that they satisfy the requirements of the MTCA, if the risk assessments are critical to the cleanup decisions.

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As a member of Hanford Site risk assessment committee which developed HSBRAM, RL has agreed to address several other items of concern as appropriate information becomes available:

- Ecological risk assessments driven by remedial investigation and qualitative risk assessment tasks now under way will be reviewed and selected by the tri-parties as examples. Once selected, these examples will be published as an addendum to the HSBRAM, rev. 2.

- Control distributions for site background to determine contaminants of potential concern remain to be fully developed under the M-28-00 Tri-Party Agreement milestone.

- Application of the null hypothesis to environmental data as discussed in the Methodology remains to be verified to the satisfaction of the EPA and Ecology.

If you have any questions, please contact Mr. Eric Goller at (509) 376-7326 or Mr. Robert Stewart at (509) 376-6192.

Sincerely,

Steven H. Wisness
Hanford Project Manager

ERD:EDG

Enclosures: As stated

cc w/encls:
B. Austin, WHC
A. DeAngeles, PRC
S. Cross, Ecology
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L. Gadbois, EPA
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Administrative Record, H6-08

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R. Wojtasek, WHC

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Enclosure #2

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DISPOSITIONS TO EPA COMMENTS ON THE HANFORD SITE
BASELINE RISK ASSESSMENT METHODOLOGY,
DOE/RL-91-45, Revision 1, March 1992

Comments by the U.S. Environmental Protection Agency, D. R. Einan, EPA, to K. M. Thompson, RL, "Risk Assessment Methodology Document Comments," dated May 18, 1992.

EPA 1. Section 2.1.3.1, page 9, second paragraph

The text discusses the use of background information that is currently being compiled to meet milestone M-28 and states that use of this background information should be evaluated case-by-case. The text should also state that if milestone M-28 data are not used for background, the rationale for using project-specific background data (for example aggregate area data or operable unit data) must be provided in the risk assessment.

Initial Response: Accept. Additional Text as recommended will be added. Also see Ecology comment #12.

June 9, 1992 Status: Closed.

Final Response: Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC. The revised text is provided below. (see the last sentence)

2.1.3.1 Selection of Controls. The risk assessor must ensure that proper control or background data sets are employed in the contaminant identification process. Since many substances defined as hazardous by regulation are naturally occurring, failure to consider control data could lead, for example, to the error of attributing risks to a given site when the risks are, in fact, of natural origin. The purpose of a baseline risk assessment is to characterize the risks posed by the release of hazardous substances from a facility.

Control conditions do not refer to pristine or pre-industrial conditions because such conditions no longer exist. As stated by EPA in the final exposure assessment guidelines published in May (FR 22888 - 22938, Paragraph 3.5.2.4):

> Background presence may be due to natural or anthropogenic sources. At some sites, it is significant and must be accounted for. The exposure assessor should try to determine local background concentrations by gathering data from nearby locations clearly unaffected by the site under investigation.

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Furthermore, federal and state hazardous substance and waste statutes apply only to releases from specific sites as indicated above, not to wide-spread anthropogenic sources.

Background conditions are being compiled for the Hanford Site under Tri-Party Agreement Milestone M-28. Currently, background reports are available for the soil background for nonradioactive analytes (DOE-RL 1993) and the groundwater background (DOE-RL 1992b). The Hanford Site background data will generally be used to identify contaminants at a waste site, as discussed below in subsection 2.1.3.2.

Site investigation data should also include a characterization of control conditions for each parameter in the initial site-tailored data set in order to define control conditions on a project-specific basis. Appropriate project-specific control data for mobile environmental media (e.g., air, ground water, surface water) are especially important to ensure that site characterization, evaluation and remediation efforts are directed to the waste units actually releasing a given hazardous substance. Contamination can incorrectly be attributed to a waste unit, when the release is actually occurring from an upwind, upgradient, or upstream facility. Such data are necessary for the successful implementation of the IRM strategy which is focused on priority waste sites.

In the absence of appropriate Hanford Site background data or project-specific data, control data available from another project in a similar environmental setting — or those available from a regional, national, or global basis — may be used, with documented caution. Acceptable types of background data would be data from locations one can be reasonably certain are not associated with contamination and are representative of Site, regional, national, or global conditions. Generally, the further a control or background station is from the project area, the less likely the data from that station are representative of project-specific control or background conditions. The selection of control data and the rationale for selection of that data as the control data should be provided in the risk assessment.

EPA 2. Section 2.2.5.4, page 32, second paragraph

The reference given for standard EPA equations and Health Effects Assessment Summary Tables (HEAST) methods, EPA 1992, appears to be incorrect. The reference cited for HEAST methods and calculations on page 39 of the methodology is "EPA 1989e." The correct reference should be cited.

Initial Response: Accept. Correct reference will be cited.

June 9, 1992 Status: Closed.

Final Response: Correct reference has been incorporated in the text.

EPA 3. Section 2.2.5.4, page 33, fifth paragraph

The text states that all photons with energies less than 400 keV are effectively shielded if the source is at least 1 meter deep. A reference should be given to support this statement. In some cases, a high activity source at a depth of 1 meter can contribute significantly to the total risk for the site if the source is not contained and there is a possibility of 1) transport via infiltration or 2) excavation under industrial or future land uses. The

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methodology should indicate that when buried sources are present, a shielding calculation will be performed to verify that the external pathway may be eliminated.

Initial Response: Accept. A reference will be provided regarding shielding of low-energy photons. Text will be added to address excavation as a result of future land use, and use of shielding calculations to justify elimination of the external exposure pathway.

June 9, 1992 Status: Closed.

Final Response: Text of Section 2.2.5.4 has been revised overall. Discussion of external exposures has also been added to Section 2.2.3.2 to address the concern identified in this comment. See final response to Ecology Comment 22.

EPA 4. Section 2.2.5.4, page 34, third paragraph

The text should state that if radionuclide slope factors are not available from HEAST, the EPA Office of Radiation Programs will be asked to calculate the required slope factor.

Initial Response: Reject. The 1992 version of HEAST (OHEA ECAO-CIN-821, March 1992) provides a complete list of slope factors for radionuclides. Requesting additional slope factors from the Office of Radiation Programs is no longer necessary.

June 9, 1992 Status: Closed.

Final Response: No changes in the text have been made, as indicated above.

EPA 5. Section 2.3.2, page 36, first paragraph

The text refers to subsection 2.3.2.1 twice in the second sentence. The text should be corrected to read "Subsections 2.3.2.1 and 2.3.2.2 discuss the toxicity values."

Initial Response: Accept. The typographical error will be corrected.

June 9, 1992 Status: Closed.

Final Response: Correction has been made as indicated above.

EPA 6. Section 2.3.4, page 40, second paragraph

The next revision of the methodology should reflect new information regarding route-to-route extrapolation of toxicity values as provided in recently released EPA guidance (EPA 1991). In particular, oral toxicity values can be used to evaluate inhalation exposures.

Initial Response: DISCUSS. Require clarification of source of EPA guidance regarding route-to-route extrapolation.

June 9, 1992 Status: Open. Clarifications to be discussed with the PRC representative for closure.

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Final Response: Comment has been closed based on discussions with Audree DeAngles, PRC consultant to EPA. Text in paragraph will be modified to discuss route - to route extrapolation, but reference to oral and inhalation toxicity values will not be provided.

EPA 7. Section 2.4.1, page 42, second paragraph

The text states, "This linear equation . . . is an upperbound estimate based on the upper 95th percent confidence limit of the slope factor." This statement is incorrect. The equation is an upperbound estimate of the 95th percent confidence limit slope factor. The words "of the" should be deleted from the sentence.

Initial Response: Reject. Text in question has already been corrected.

June 9, 1992 Status: Closed.

Final Response: As indicated above; no additional changes in the text have been made.

EPA 8. Section 2.4.1, page 43, third paragraph

The text discusses combining radionuclide and chemical cancer risks and states that risks contributed by radionuclides and chemicals should be summed. However, Section 10.7.3 in the Superfund risk assessment guidance (EPA 1989a) discusses when summation is and <u>is not</u> appropriate. Therefore, the second sentence in this paragraph should be deleted. The text should refer to Section 10.7.3 (EPA 1989a) for summation of radionuclides and chemical cancer risks.

Initial Response: DISCUSS. Need to interpret and reconcile requirements of the NCP and guidance provided in 10.7.3 of RAGS. Points to consider:

- Section 10.7.3 of RAGS states (first paragraph that the cancer risk "resulting from radiological and chemical risk assessments may be summed in order to determine the overall potential human health hazard associated with a site."

- The possible "incompatibilities in the two estimates of risk" can be addressed as a source of uncertainty, but need not preclude the summation of these risks.

- There are certainly cases where summing risks from chemicals alone seems ludicrous (e.g., adding risks from Group A and Group C carcinogens). Likewise, adding internal and external radiation doses is fraught with uncertainty. However, both are routinely performed, and the "incompatibility" of the two numbers is considered a source of uncertainty.

June 9, 1992 Status: Closed.

Final Response: The quote from RAGS on page 43 of Rev. 1 the HSBRAM has been removed. Section 10.7.3 of RAGS is referenced. The word "must" has been changed to "may" in the 3rd sentence of the last paragraph of section 2.4.1.

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EPA 9. Section 3.1, page 49, first paragraph

The focus of the environmental evaluation should be on critical and sensitive habitats of protected species.

Initial Response: Accept. The paragraph will be clarified to demonstrate the focus of the environmental evaluation.

June 9, 1992 Status: Closed. After discussion it was determined that "with a focus on" should be changed to "especially" with appropriate change to sentence structure.

Final Response: Text has been changed to reflect June 9, 1992, discussion.

During the course of comment resolutions on "Chapter 3 Environmental Evaluation", the recently released EPA document "Framework for Ecological Risk Assessment" EPA/630/R-92/001 was reviewed by members of the RAC. At a meeting of the RAC held on August 28, 1992, it was agreed that Chapter 3 would be revised in format and content to incorporate the key concepts of the framework with modifications made to address the CERCLA-specific and Hanford-specific aspects of ecological risk assessment. At subsequent meetings, the revisions to Chapter 3 to incorporate the framework have been revised by the RAC, additional informal comments have been made and discussion of those comments has occurred. The text of Chapter 3 has been revised to reflect the negotiations made regarding the language of the text. Therefore, Chapter 3, as prepared in Revision 2 of the HSBRAM, reflects final resolution of all comments on Chapter 3.

The comments and initial responses provided below for EPA comments #9 through #24 all refer to Revision 1 of the HSBRAM. They are included because they are part of the initial phase of the comment resolutions for Revision 1 of the HSBRAM. Major format modifications have been made to Chapter 3. Consequently, the comments no longer refer to the same sections, paragraphs, or lines in Revision 2. Please note that the Revision 2 text incorporates the initial responses indicated for EPA comments #9 through #24 if they are appropriate for the revised text and if the language was agreed upon in negotiations on the text.

Chapter 3 and Section 3.1 have been revised as discussed above. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. Revised text is provided below.

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3.1 FRAMEWORK FOR CONDUCTING BASELINE ENVIRONMENTAL EVALUATIONS

The regulatory goal for the environmental evaluation component of a baseline risk assessment, as presented in subsection 1.5.2, is to characterize current and likely future ecological risks attributable to releases of contaminants from the site under investigation. The NCP specifies that [40 CFR § 300.430 (e)(2)(i)(G)]:

> Environmental evaluation shall be performed to assess threats to the environment, especially sensitive habitats and critical habitats of species protected under the Endangered Species Act (ESA).

The results of the environmental evaluation are used to help establish acceptable exposure levels for use in developing remedial alternatives [40 CFR § 300.430 (d)(4)].

In addition, the EPA framework is written generally enough to encompass both baseline and remedial action alternative evaluations. However, the application of the environmental evaluation component of the Hanford Site baseline risk assessment methodology presented herein is much more focused. Per the NCP, the methodology addresses only the releases (and subsequent fate and transport) of site contaminants (including indirect effects) within the context of the general framework and evaluates only the baseline condition(s) (see subsection 1.5.2).

Under CERCLA and related statutes, contaminants derived from a site release are the only relevant stressors from a baseline perspective. This is acknowledged by EPA (1992g) which states that ecological effects assessment links concentrations of contaminants to adverse effects in receptors. A commitment has been made by DOE-RL to develop a guidance document, in fiscal year 1993, for conducting risk assessments to support remedial alternatives evaluations performed under such statutes as CERCLA and NEPA (S.H. Wisness, DOE-RL [letter to P.T. Day, EPA-10 and D.B. Jansen, Ecology] March 31,1992). The upcoming document will need to adopt the broad-range stressor concept set forth in EPA (1992b).

Human health and environmental evaluation processes are compared in subsection 3.1.1, the integration of ecological knowledge and goals is addressed in subsection 3.1.2, the relationship between environmental evaluations and natural resource damage assessments is discussed in subsection 3.1.3, and qualifications for ecological risk assessors are presented in subsection 3.1.4.

3.1.1 Comparison of Human Health and Environmental Evaluation

Although the analogy to the human health evaluation process is evident in Figure 3-1, the environmental evaluation process has some significant differences. The first step, problem formulation, includes contaminant identification, which forms the initial step of the human health evaluation process. The terminology is broader for the environmental process as there is a need to identify, in addition to contaminants of potential concern, habitats of potential concern (e.g., sensitive or critical habitats) and biological species of potential concern (e.g., endangered or threatened, or structurally or functionally important, species) within such habitats. To date, there exists little guidance for the identification of environmental contaminants of potential concern. The preliminary risk-based screening

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procedure presented in Figure 2-1a and 2-1b is recommended for all baseline environmental evaluations. Comparison of contaminants with aquatic water quality criteria is expected as a minimum effort for scenarios involving aquatic life. Screening of contaminants using agreed upon environmental scenario(s) and risk levels is a possibility once sufficient ecotoxicological data are available for a given contaminant and a process has been agreed to by the Tri-Parties.

While human health evaluations focus on sensitive individuals within a single species, environmental evaluations are more complex. During the problem formulation phase, the ecological risk assessor is faced with a site at which there are numerous individuals of many species, the populations of which are organized into communities, which are the living parts of the ecosystem. The initial challenge to the ecological risk assessor is to focus, in a logical manner, the scope of the environmental evaluation to a manageable and meaningful level of effort. The appropriate focus is usually not on individuals, but on populations or higher levels of ecological organization (Barnthouse et al. 1986a).

A second departure from the human health evaluation process entails grouping the exposure and toxicity assessment into a single phase of analysis. This is done because the two assessments are often inseparable in many environmental evaluations. While biological effects on species or assemblages of species are the ultimate assessment endpoints of most baseline environmental evaluations conducted at sites with hazardous substance releases, it is often more efficient to assess these species indirectly. In conducting such indirect assessments, the boundaries of exposure and toxicity often become blurred.

An example of the indirect assessment that is quite applicable to the Hanford Site is evaluating the risk to the species comprising the freshwater aquatic community of the Hanford Reach of the Columbia River. A partial approach for such an evaluation could entail the comparison of documented, or projected, contaminant levels in the water column to water-quality criteria and standards established by the EPA (EPA 1986b) and Ecology to provide for the protection of some freshwater aquatic life. (No similar criteria for terrestrial organisms exist.)

Another significant difference between environmental and human health evaluations is that the analysis phase of the environmental evaluation process must take potential indirect effects into account. It is possible to have a significant adverse effect attributable to a release of a hazardous substance on a species of potential concern without a direct exposure or direct toxic effect on that species. An example, applicable to the Hanford Site, is the elimination of a migratory predator's prey species due to the toxic effects of a spill occurring during the predator's season of absence from the site.

Finally, a distinction needs to be made between the environmental evaluation and the biotic pathways component of the human health evaluation. These evaluations, while having the potential to share significant portions of data and much of the same methods of analysis, are separate. The species forming a major portion of the human food chain would be considered of interest from the perspective of the biotic pathways component of the human health evaluation, but may not necessarily be of interest from the perspective of the environmental evaluation. The environmental evaluation addresses ecological concerns which have been defined as those that exclude the concerns involving human ecology. These latter concerns are properly addressed within the context of the human health evaluation.

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EPA 10. Section 3.1, page 49, third paragraph

The following comment submitted as part of the October 30, 1991 technical review was accepted but is not adequately incorporated into the document:

> This paragraph discusses the reduction of the range of potential stressors to "only the releases of site contaminants." However, part of the environmental evaluation process is to determine potential exposure pathways. Factors that may affect site contaminant fate and transport, and therefore exposure pathways, include temperature, pH, salinity, water hardness, and soil composition (EPA 1989a). These factors should be included in the environmental evaluation.

The text should include a discussion the nonchemical factors noted above.

Initial Response: Accept. The text will be edited to accommodate the non-chemical factors.

June 9, 1992 Status: Closed. Factors cited in the comment will be added to the text.

Final Response: Chapter 3 and Section 3.1 have been revised as discussed and presented in the final response to EPA comment #9. The text of section 3.2.2.1 of Rev. 2 best addresses this comment. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office.

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EPA 11. Section 3.1, page 50, first paragraph

It is recommended that the term "scoping" be included in the ecological evaluation process. Additional items to be considered under scoping include: estimates of potential or actual release of contaminants into the various environmental media, exposure pathways to potential receptors, general characteristics of receptors potentially exposed to contaminants, and possible or actual ecological effects of the contaminants or remedial actions (EPA 1989b).

Initial Response: Acknowledge. The paragraph will be elucidated to explain the "scoping" and problem definition terms.

June 9, 1992 Status: Open. New text will be reviewed by EPA and Ecology for acceptance.

> Revised response: Paragraph will be revised to:
>
> Although the analogy to the human health evaluation process is evident, several differences remain. The first step, problem definition (although the concepts are retained, the term "scoping" is deleted to eliminate confusion, as this term has a specific, although not unrelated, meaning under CERCLA), includes

contamination identification, which forms the initial step of the human health evaluation process. The terminology is broader for the environmental process as there is a need to identify, in addition to contaminations of potential concern, exposed habitats of potential concern (e.g., sensitive or critical habitats) and biological species of potential concern that may be exposed within such habitats.

Final Response: Chapter 3 and Section 3.1 have been revised as discussed and presented in the final response to EPA comment #9. The specific text has been completely revised and is part of the first paragraph of 3.1. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office.

EPA 12. Section 3.1, page 50, third paragraph

The text discusses the use of indirect assessments and presents a freshwater example of such an assessment. However, indirect assessments in the terrestrial community may not be readily estimated quantitatively. Methods for qualitatively assessing the terrestrial community should be included. In addition, the freshwater example overlooks sediment contamination that is transferred into the food chain without ever being in the water phase.

Initial Response: Accept in part. The text discusses the use of indirect assessments in the environmental evaluation and uses one readily available indirect assessment example. This example is the water quality criteria for the protection of freshwater aquatic life. No similar criteria for terrestrial organisms exists. The text will be modified to clarify this (e.g., limited freshwater sediment quality criteria are available).

June 9, 1992 Status: Closed. It will be stated that no similar criteria for terrestrial organisms or some aquatic organisms exists.

Final Response: Chapter 3 and Section 3.1 have been revised as discussed and presented above in the response to EPA comment #9. The response is in the fourth paragraph of Section 3.1. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office.

EPA 13. Section 3.1, pages 50, fifth paragraph

Species forming a major portion of the human food chain may also be a major portion of the food chain for predacious animals and scavengers (for example, peregrine falcon,

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American white pelican, and bald eagle). Therefore, species should not be eliminated from the environmental evaluation based solely on their presence in the human food chain.

Initial Response: Acknowledge. The authors agreed to the comment and the text has explained the same concept. See section 3.2.2.1 for identification of sensitive habitat and the selection of species in the environmental evaluation.

June 9, 1992 Status: Open. New text will be reviewed by EPA and Ecology for acceptance.

Based on review of text, recommend discussion at August 12, 1992, meeting. The phrase "not necessarily of interest" in the third sentence of the paragraph addresses EPA's concern.

Final Response: Chapter 3 and Section 3.1 have been revised as discussed and presented above in the final response to EPA comment #9. The response is in the sixth (last) paragraph of Section 3.1. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office.

EPA 14. Section 3.2.1, page 54

Biota surveys are necessary to properly assess current site conditions, verify existing information, and identify chronic and acute stresses on the ecosystem. Biota surveys should be performed, or referenced if previously completed.

Initial Response: Accept. The text will be revised to include biota surveys that may be conducted for a project-specific ecological investigation.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The text referred to is now in Section 3.1.2.

EPA 15. Section 3.2.2.2, pages 59 and 60

This section should address the indirect toxicity of contaminants that stress receptors and ecosystems (for example, altered pH, reduced dissolved oxygen, increased salinity, reduced decomposition rates, and nutrient cycling). Bioaccumulation potential should be addressed. Physical and chemical properties of contaminants such as water solubility and adsorption to soil particles should also be considered.

Initial Response: Accept. The text will be modified to address the indirect toxicity of contaminants. Instead of modification in Section 3.2.2.2, the issues will be covered in other sections.

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June 9, 1992 Status: Closed. Insert physicochemical parameters into appropriate sections in the text and cite locations to EPA and Ecology.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. Indirect toxicity is addressed, as appropriate, in Sections 3.1.1, 3.2.2.1, and 3.2.2.3.

EPA 16. Section 3.2.2.2, page 60, second and third paragraphs

The text indicates that human health risk screening components are environmentally protective and applicable for the environmental evaluation. This may not be true in certain cases. There are numerous chemicals which are toxic or induce adverse behavior in organisms that do not cause cancer in humans. The environmental risk assessment should be evaluated by appropriate environmental methods as specified in EPA (1989c,d).

Initial Response: DISCUSS. The reference cited (EPA 1989c) has been requested from the EPA contractor.

June 9, 1992 Status: Open for further discussion. Best professional judgement is required. EPA and Ecology considered the concept sound to expand and utilize the human screening process. Reference has been provided for review.

Final Response: Chapter 3 has been reformatted as discussed in the final response to EPA comment #9. The text referred to in this section is now discussed in Section 3.2.2.1. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC. The revised text is provided below.

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3.2.2.1 Stressor Characteristics. The characterization of stressors begins with the identification of chemical, radionuclide or physical stressors. Chemical stressors include inorganic and organic substances. Physical stressors include extremes of natural conditions such as temperature change, habitat alteration or destruction. In accordance with the NCP, the baseline risk assessment addresses the release of contaminants from a site and the direct and indirect effects associated with the contaminant release. Therefore, the characterization of stressors for Hanford Site baseline environmental evaluations focuses on the identification of contaminants of potential concern, as discussed below.

The preliminary risk-based screening procedure has elements specifically intended to include any contaminant which could be of concern. These include risk-based calculations and comparison to potential ARARs for human health and comparison to potential ARARs and consideration of best professional judgement for environmental health. While judgement can be used to expand the list of environmental contaminants of potential concern, indiscriminant expansion of the list should be avoided. As noted in

Figures 2-1A and 2-1B, best professional judgement is significant in ecotoxicologic hazard evaluation of those contaminants of potential concern that do not exceed the specific ARARs. It is assumed that this process will be protective of both human health and ecological exposures.

EPA 17. Section 3.2.2.2, page 60, fourth paragraph

It should be noted that some ecologically harmful chemicals do not have water or sediment criteria (just as some chemicals harmful to humans do not have MCL's and the like).

Initial Response: Accept. A modification to the text will be added. It should be noted that many, or most, toxic chemicals have MCL and other criteria.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The text referred to in this section is now discussed in Section 3.2.2.1 (provided in the final response to EPA comment #16) and 3.1.1 (provided in the final response to EPA comment #9).

EPA 18. Section 3.2.2.3, page 61, first paragraph

The text states that assessment endpoints are analogous to receptor identification in the human health evaluation process. This statement is not always true and should be deleted.

Initial Response: Accept. The statement will be deleted.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The text referred to in this section is now discussed in Section 3.2.3.

EPA 19. Section 3.3.2, page 66, third paragraph

The text discusses certain aspects of biological transport. Metabolism and life cycles should also be addressed under biological transport.

Initial Response: Accept. The text will be modified to include metabolism and life cycles in the biological transport.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The text referred to in this section is now discussed in Section 3.3.1.1.

EPA 20. Section 3.4, pages 68, 73, and 74

Temporal and spatial components of risk characterization are not, but should be, addressed.

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Initial Response: Accept. Temporal and spatial components of risk characterization will be addressed in the text.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The text referred to in this section is discussed in Section 3.4 (e.g. 3.4.2.2).

EPA 21. Section 3.4, page 68, fourth paragraph; page 73, first paragraph

The text presents a discussion on environmental hazard quotients. A reference should be provided for this discussion.

Initial Response: Accept. The authors introduced the Environmental Hazard Quotient (EHQ) term. The text will be modified to indicate so with additional explanation.

June 9, 1992 Status: Closed. Provide additional explanation and reference, if possible.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The text referred to in this section is now discussed in Section 3.4.1.1.

EPA 22. Figure 3-4, page 69

The term "potential" in the title should be changed to "primary" because the figure illustrates the pathways of most significant exposure but does not address all potential exposure pathways.

Phytoplankton are assessed as the sole primary producer in the ecosystem. Macrophytes should also be included as primary producers.

Bio-uptake and ambient contact should be included as primary pathways for aquatic flora.

Respiration and ambient contact should be included as primary pathways for aquatic fauna.

The term "hyporheon" in the figure is not clearly represented. The hyporheon is the interstitial space between surface water and groundwater and is usually found in cobblestone or gravel streams. The type of migration from the hyporheon (chemical/physical, biotic, or both) should be identified and the corresponding pathways should be assessed.

Initial Response: Accept in part. The first four comments are accepted and new text will be added to explain Figures 3-4 and 4-4. The fifth comment is rejected.

June 9, 1992 Status: Closed. A footnote has been provided to give a definition for "hyporheon."

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Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to EPA comment #9. The figure referred to in this section is now Figure 3-5.

EPA 23. Figure 3-5, page 70

The term "potential" in the title should be changed to "primary" because the figure illustrates the pathways of most significant exposure but does not address all potential exposure pathways.

The term "absorption" should be replaced with "bio-uptake".

Surface water should be addressed as a matrix of the riparian community.

Initial Response: Accept in part. The term "potential" will be changed to "primary." The term "absorption" will be replaced with "sorption", and surface water will be added in the figure as a matrix to riparian and terrestrial communities.

June 9, 1992 Status: Closed.

Final Response: The figure has been modified on indicated in the initial response and is now Figure 3-6.

EPA 24. Figure 3-6, page 71

The term "potential" in the title should be changed to "primary" because the figure illustrates the pathways of most significant exposure but does not address all potential exposure pathways.

The term "absorption" in the figure should be replaced by "bio-uptake".

Initial Response: Accept in part. The term "potential" will be changed to "primary", and the term "absorption" will be changed to "sorption."

June 9, 1992 Status: Closed.

Final Response: The figure has been modified as indicated in the initial response and is now Figure 3-7.

EPA 25. Section 4.2, page 79, second paragraph

The text suggests that acceptable exposure levels in a medium for an individual substance would be based on a hazard quotient of 0.3. While 0.3 may be applicable to industrial scenarios where three principle pathways exist (soil ingestion, water ingestion, and air inhalation), the text should clearly state that for other exposure scenarios, 0.3 may not be acceptable. The determination of a target hazard quotient is more appropriately addressed case-by-case.

Initial Response: DISCUSS. The authors recommend reducing the scope of the discussion on the qualitative risk assessment. The authors agree that modification of the discussion on the use of a 0.3 hazard quotient (HQ) for application to other scenarios is required. The authors also agree that an HQ of 0.3 should be the initial target when evaluating the

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more-or-less equal three pathways (soil ingestion, water ingestion, and air inhalation). The HQ departure from 0.3 should be evaluated on a case-by-case basis.

June 9, 1992 Status: Closed. The risk assessment committee will meet at 9AM on July 7, 1992, in the EPA conference room to develop a qualititative risk assessment methodology.

Final Response: The discussion of qualitative risk assessments in Section 4.2 has been revised to a general overview. Based on discussions between the Tri-Party members of the RAC, Appendix C has been added to Revision 2 of the HSBRAM. This new appendix provides a discussion and methodology for preparing qualitative risk assessments at the Hanford Site. The paragraph referred to in the comment has been deleted in Revision 2 of the HSBRAM.

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REFERENCES
For EPA Comments

EPA 1989a. Risk Assessment Guidance for Superfund, Volume 1. Human Health Evaluation Manual, Part A. Interim Final. EPA/540/1-89/002. U.S. Environmental Protection Agency. December 1989.

EPA 1989b. Risk Assessment Guidance for Superfund, Volume 2. Environmental Evaluation Manual. Interim Final. EPA 540/1-89/001. U.S. Environmental Protection Agency. March 1989.

EPA 1989c. Technical Appendix: Exposure Analysis of Ecological Receptors. For inclusion in Superfund Exposure Assessment Manual. Office of Emergency and Remedial Response, U.S. Environmental Protection Agency. December 1989.

EPA 1989d. Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. EPA/600/3-89/013. Office of Research and Development. U.S. Environmental Protection Agency. March 1989.

EPA 1991. Human Health Evaluation Manual, Part B: Development of Risk-based Preliminary Remediation Goals. Publication 9285.7-01B. U.S. Environmental Protection Agency. December 1991.

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EPA AND ECOLOGY
RECOMMENDED FORMAT
ENVIRONMENTAL EVALUATION METHODOLOGY REPORT

1. Introduction

2. Scope of the Environmental Evaluation

- 2.1 Objectives
- 2.2 Site characterization
  - 2.2.1 Physical setting
  - 2.2.2 Nature and extent of contamination
  - 2.2.3 Ecosystems
    - 2.2.3.1 Regional
    - 2.2.3.2 Site-specific
    - 2.3.3.3 Food webs
  - 2.2.4 Existing information on ecological effects
- 2.3 Problem definition
  - 2.3.1 Contaminant identification and screening
  - 2.3.2 Sources of nonchemical stress
  - 2.3.3. Habitats of potential concern
  - 2.3.4 Endpoints
    - 2.3.4.1 Assessment
    - 2.3.4.2 Measurement
  - 2.3.5 Conceptual site model

3. Exposure Assessment

- 3.1 Potential receptors
- 3.2 Potential pathways
- 3.3 Endpoint evaluation
  - 3.3.1 Quantitative analysis
  - 3.3.2 Qualitative analysis
- 3.4 Land use
- 3.5 Uncertainty analysis
- 3.6 Summary of exposure assessment

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4. **Toxicity Assessment**

4.1 Parameter-specific dose-response data

4.2 In-situ dose-response data

4.3 Field studies

4.4 Endpoint evaluation

4.4.1 Quantitative analysis

4.4.2 Qualitative analysis

4.5 Uncertainty analysis

4.6 Summary of toxicity assessment

5. **Risk Characterization**

5.1 Quantitative endpoint evaluation

5.2 Qualitative endpoint evaluation

5.3 Uncertainty analysis

5.4 Summary of risk characterization

5.4.1 Evidence of environmental impact

5.4.2 Evaluation of observed impact

5.4.3 Potential future impact

6. **Summary of Environmental Evaluation**

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Enclosure #3

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DISPOSITIONS TO ECOLOGY COMMENTS ON THE HANFORD SITE
BASELINE RISK ASSESSMENT METHODOLOGY,
DOE/RL-91-45, Revision 1, March 1992

Comments by the Washington Department of Ecology, S. F. Cross, Ecology, to E. D. Goller, RL, "Hanford Site Baseline Risk Assessment Methodology, Revision 1," dated May 19, 1992.

Ecology 1. Preface, page i

Deficiency: The preface states USDOE position on four areas. The positions are incompatible with a tri-party risk assessment methodology, the TPA, and current activities (such as the Future Site Use Working Group). They are incompatible with a document to which Ecology is a party. Brief responses are as follows:

- To not use the four scenarios must be justified on a case by case basis. USDOE may not reserve a right to pollute groundwaters of the State through a claim of use or ownership.

- The three parties do not need to wait for a ROD to accept MTCA as an ARAR.

- The point of compliance for groundwater is below the waste site. The operable unit boundaries are not appropriate as points of compliance for air contaminants. The cleanup should result in the dissolution of operable units. See WAC 173-340-700(6) and -720.

- Institutional control as part of a remedial alternative will only be allowed when specifically justified case by case. See NCP 300.430(a)(1)(iii).

Even if the preface is deleted from this document, USDOE advocacy of these positions foreshadows disagreements incompatible with USDOE's declared mission of remediating the Hanford site.

Recommendation: These issues must be resolved to the satisfaction of Ecology prior to the next draft of the *Methodology*.

Initial Response: Discuss. The issues will be addressed prior to the next draft of the Hanford Site Baseline Risk Assessment Methodology (HSBRAM).

June 9, 1992 Status: Closed.

Final Response: The Department of Energy, Richland (DOE-RL) has agreed to remove the preface from the HSBRAM. Based on discussions at meetings of the Inter-Agency Working Group for Risk Assessment (Risk Assessment Committee or RAC), the scenarios to be evaluated for each risk assessment will be determined on a site-specific basis. See response to Ecology Comment 26 for additional text clarification.

The remaining issues identified by Ecology will be addressed by the parties at appropriate times during the CERCLA process, such as part of the Record of Decision (ROD) for an operable unit.

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Ecology 2. Section 1.3, bottom paragraph of page 2

Deficiency: An important reference is not included.

Recommendation: Include *Guidance for Data Useability in Risk Assessment*, EPA/540/G-90/008, 1990.

Initial Response: Accept. The text will be revised to include the reference as a source of information for conducting baseline risk assessments.

June 9, 1992 Status: Closed.

Final Response: The text has been revised to include the recently published final guidance document rather than the reference indicated above. The *Guidance for Data Useability in Risk Assessment (Part A)*, OSWER Directive 9285.7-09A, June 2, 1992, is cited.

Ecology 3. Section 1.5.2, first full paragraph of page 5, first sentence

Deficiency: The text incorrectly states that the overall goal of the ecological evaluation is "to determine cleanup levels." That conclusion does not follow from the excerpt of the NCP section 300.430(d)(4). Developing remedial alternatives is not synonymous with determining cleanup levels. See also section 3.1.

Recommendation: Delete the last four words of the sentence.

Initial Response: Accept. The last four words of the sentence will be deleted.

June 9, 1992 Status: Closed.

Final Response: Text has been modified as indicated above.

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Ecology 4. Section 1.5.2, page 5, second full paragraph of page, second sentence

Deficiency: The text is presumptuous in stating that satisfying NCP requirements will necessarily meet the general requirements of RCRA and the state. This has not been demonstrated.

Recommendation: Change the word "will" to "may".

Initial Response: Accept. The word "will" will be changed to "may".

June 9, 1992 Status: Closed.

Final Response: Text has been modified as indicated above.

Ecology 5. Section 1.5.2, page 5, last paragraph, last sentence

Deficiency: The term "ecology" is incorrectly applied to domestic animals in the context of the environmental evaluation of the risk assessment.

Recommendation: Point out that the ecological evaluation applies neither to humans nor domestic animals.

Initial Response: Accept. The focus of ecological evaluation will be clarified to note that it does not include domestic animals or humans.

June 9, 1992 Status: Closed.

Final Response: Text has been modified as indicated above.

Ecology 6. Section 2.0, page 7

Deficiency: The data evaluation element is incorrectly labeled as "identification of contaminants of potential concern." The text incorrectly states that RAGS (EPA/540/1-89/002) exhibit 9-1 is a suggested outline for a baseline risk assessment, when it is actually an outline for a baseline risk assessment report.

Recommendation: Use RAGS terminology and procedure in the *Methodology*. Delete the first sentence of the third paragraph.

Initial Response: DISCUSS: See Ecology Comment #10.

June 9, 1992 Status: Open. The first part of section 2 will be revised to emphasize Hanford site specific nature of the four bullets. The titles of the four elements will remain the same. Section 2.1 will be revised to address the nine steps. The nine steps are conducted as part of the data evaluation process that occurs for a Remedial Investigation (RI) report and may be addressed in sections of the RI report other than the baseline risk assessment. The risk assessor, however, should be aware of the nine steps and how they have been conducted for the specific RI report and baseline risk assessment. The risk assessor should discuss the quality of data in the Uncertainty Section of the risk assessment. Reference and discussion of TICs will be added to the Methodology. The nine steps are to be covered in the compromise.

Final Response: Revised text was provided to the RAC for review. Based on a telephone discussion [Steve Cross, Ecology, and Lonie Swenson, Golder Associates Inc., (August 20, 1992)] the status of this comment has been closed. The text provided below is the text that has been negotiated for inclusion in Revision 2 of the HSBRAM.

2.0 HUMAN HEALTH EVALUATION METHODOLOGY

The following section presents a detailed discussion on the four elements of risk assessment relative to the Hanford Site baseline risk assessment methodology. The human health evaluation for Hanford Site risk assessments consists of four elements. These elements are:

- Identification of contaminants of potential concern,

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- Exposure assessment,
- Toxicity assessment, and
- Risk characterization

Section 2.1 discusses the identification of contaminants of potential concern and the preliminary risk-based screening process. The exposure assessment and Hanford Site-specific details are provided in Section 2.2 and a discussion of the toxicity assessment is provided in Section 2.3. The integration of exposure information and toxicity information to develop the risk characterization is discussed in Section 2.4. A summary of the human health evaluation is provided in Section 2.5.

The risk assessor is referred to Exhibit 9-1 of RAGs (EPA 1989a) for a suggested outline of the baseline risk assessment report based on the four elements above. The first element listed above has been modified from the outline by the replacement of the term "chemical" with the term "contaminant". Potential contamination at the Hanford Site is not limited to chemicals, but also includes radionuclides. Therefore, the more generic term is used. The outline is provided as a guide and should be modified appropriately for use at the Hanford Site. The baseline risk assessment at the Hanford Site is usually part of a more complex investigation and report (e.g., the RI/FS) and some information may be addressed in other portions of such a report.

The CERCLA RI/FS process at the Hanford Site encourages active discussion by Tri-Party unit managers throughout the development of the work plan, site investigation, and preparation of risk assessments for RI/FS reports. Discussions on the status of the human health evaluation should be appropriately integrated into these activities, without compromising schedule constraints, to keep all parties informed of issues related to the four elements of the baseline risk assessment.

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2.1 IDENTIFICATION OF CONTAMINANTS OF POTENTIAL CONCERN

This section discusses the process for using data that has been collected and evaluated as part of the site characterization process to identify contaminants of potential concern at a site. EPA (1989a) identifies nine steps that address the organization of data for the baseline risk assessment and that should be conducted prior to the baseline risk assessment. These steps are:

1. gather all data available from the site investigation and sort by medium;
2. evaluate the analytical methods used;
3. evaluate the quality of data with respect to sample quantitation limits;
4. evaluate the quality of data with respect to qualifiers and codes;
5. evaluate the quality of data with respect to blanks;
6. evaluate tentatively identified compounds (TICs);
7. compare potential site-related contamination with background;
8. develop a set of data for use in the risk assessment;
9. if appropriate, further limit the number of contaminants to be carried through the risk assessment

At the Hanford Site, baseline risk assessments are usually part of the RI report for a specific site. Consequently, many of these nine steps are conducted as part of the overall data evaluation process that occurs for an RI report and may be addressed and

documented in sections of the RI report other than within the baseline risk assessment (e.g., step 2-5 as part of data validation).

Section 2.1 focuses on steps 7, 8, and 9 to provide specific procedures for Hanford Site baseline risk assessments. The risk assessor, however, should be aware of all nine steps provided above and how they have been conducted for a specific RI report and the baseline risk assessment that they have prepared as part of that RI report. The quality of the data and confidence in the data based on these nine steps should be addressed in the uncertainty discussion for the baseline risk assessment as indicated in subsection 2.4.3.1.

Ecology 7. Section 2.1.1, page 7

Deficiency: The text inappropriately applies the Pareto principle in support of reducing the number of chemicals of potential concern. Wadsworth (1990) does not support the use of the principle in the CERCLA risk assessment context. No citation is provided to document the use of the Pareto principle by the EPA. Ecology is concerned at the Hanford site with more than the "dominant" risk drivers, as there may be "subordinate" risk drivers that are significant.

Recommendation: Do not use the Pareto principle to support the practice of reducing the number of contaminants of potential concern. This practice may be justified by reference to RAGS (EPA/540/1-89/002) and EPA Region 10 guidance. Both RAGS and MTCA require that "screening" be justified prior to use on either a operable unit specific or a Hanford site basis. Also remove the last two sentences of the first paragraph of section 2.1.4 on page 13 and the second paragraph of page 17, section 2.1.5.

Initial Response: Reject. The discussion on the Pareto principle is appropriate and should be retained in the HSBRAM. This principle is recognized in the scientific community. The concept that a large proportion of site-attributable risks may be caused by only a few hazardous substances is an excellent example of the Pareto principle.

The text will be reviewed for possible modification to include the additional references as noted by Ecology to RAGS and EPA Region 10 in addition to the Pareto principle. Recommendations from the reviewers on such modification would be welcome.

June 9, 1992 Status: Open. Text is under review for modification or provision of additional references. The preliminary risk-based screening process provided in the HSBRAM is not based on dominance (a term EPA applies to the flawed process presented in RAGS). The Hanford/EPA-10 process is based on magnitude relative to a *de minimus* (or less) level of risk; one of the results of this process is that the dominant risk drivers will be retained.

Final Response: Revised text was provided for review. Based on a telephone discussion [Steve Cross, Ecology, and Lonie Swenson, Golder Associates Inc. (August 20, 1992)], the inclusion of the Pareto principle is unresolved, but text should be left as presented with no additional discussion required. The text provided below is the text that has been negotiated for inclusion in Revision 2 of the HSBRAM.

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2.1.1 Pareto Principle

At any hazardous substance release site there is the potential that a large number of hazardous substances are present, as thousands of chemical products have been and are being produced and used in the United States. It is not feasible to analyze for all these substances at any given site; fortunately, it is not necessary to do so. Multivariate data sets (e.g., data sets consisting of multiple hazardous substance parameters) typically exhibit a phenomenon described by the Pareto principle (Wadsworth 1990). The Pareto principle states that a relatively large number of problems (e.g., a large proportion of site-attributable risk) in any given situation will found to be caused by only a few factors (e.g., only a few hazardous substances).

The EPA applied the concept behind this principle when it developed lists of approximately 150 hazardous substances that have been most commonly encountered in the course of implementing the nation's clean water, clean air, and hazardous substances programs. The substances in these lists — which are referred to as the target analyte list (TAL) and the target compound list (TCL), and which consist of inorganic and organic substances, respectively — are among those that were manufactured and used in the greatest amounts and that are the most toxic.

The TAL/TCL typically forms the initial set of hazardous substances considered during Hanford site investigations. With appropriate information on the history or site operations and previous environmental investigation data, the initial set can be tailored to site conditions by adding site-specific hazardous substances and indicator parameters that may prove to be of interest and deleting those TAL/TCL parameters that are likely to be absent in any significant quantities. Given the need to augment the TAL/TCL with radiological parameters to take specific operations into account, it is thus easy to see that most remedial, facility, or limited field investigations at the Hanford Site will generate data sets consisting of 100 to 200 hazardous substance parameters.

Once such a data set is validated and provided to the risk assessor, he or she must capitalize on the Pareto principal further to focus the set on a manageable number of parameters to carry through the detailed baseline risk assessment. The need of this step in the baseline risk assessment process is well documented in Section 5.9 of RAGS (EPA 1989a) and in EPA regional guidance (EPA-10 1991). This step of the process is especially critical at the Hanford Site given the complexities of the Site and the need to economize time and cost in order to meet Tri-Party Agreement milestones.

Ecology 8. Section 2.1.1, second full paragraph of page 8, second sentence

Deficiency: a) This quoted material is incomplete. b) The parenthetical added to the quoted material is inappropriate. c) There is no specific reference to the page or section of RAGS from which the quotation was excerpted. d) MTCACR, WAC 173-340-708, includes provisions for the selection of "indicator hazardous substances," which are not mentioned in the *Methodology*.

Recommendation: a) Add a quotation of the second paragraph in RAGS section 5.9. b) Remove the added parenthetical, "[releases from]", from the already quoted material. c) Add a specific page or section reference to the RAGS citation. d) The goal of the

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Methodology to satisfy MTCA as well as CERCLA requirements can only be met by providing for the specific requirements of WAC 173-340-708(2).

Initial Response: DISCUSS: The authors consider the quoted material adequate and the parenthetical statement appropriate. Additional references can be added.

June 9, 1992 Status: Close. Refer the EPA Region 10 guidance as being appropriate with backup of RAGS section 5.9 (which is not to be followed). Delete the quote from RAGS section 5.9 and provide the references.

Final Response: The text has been revised and discussed with EPA and Ecology at a meeting of the RAC on August 13, 1992. The revised paragraph is provided in Comment 7 above.

Ecology 9. Section 2.1.1, page 8, last paragraph of section, last sentence

Deficiency: Reevaluation of EPA guidance is not the within the scope of this methodology.

Recommendation: Delete this sentence.

Initial Response: Accept.

June 9, 1992 Status: Close.

Final Response: Text has been revised as indicated above.

Ecology 10. Section 2.1.2, top paragraph on page 9, second from last sentence.

Deficiency: The text does not recognize the distinction between the data evaluation steps of a risk assessment and the distinct data processing steps that are part of an RI. The risk assessor should not assume that the data evaluation for risk assessment criteria has been completed in the RI/FS as is indicated by this paragraph.

The risk assessor should not assume that the risk assessment type of data evaluation has been completed in the RI/FS, as is stated in this paragraph.

RAGS (EPA/540/1-89/002) chapter 5 specifies nine data evaluation steps "that should be followed to organize the data into a form appropriate for a baseline risk assessment." RAGS emphasizes that "prior to conducting any of these steps, the EPA [or Ecology] remedial project manager (RPM) should be consulted to determine if certain steps should be modified, added, or deleted as a result of site-specific conditions." It is inappropriate for the Hanford methodology to categorically eliminate any of the nine steps without EPA and Ecology agreement that such steps are not appropriate to the Hanford-specific conditions. EPA and Ecology have made no such determination.

"The outcome of the data evaluation is (1) the identification of a set of chemicals that are likely to be site-related and (2) reported concentrations that are of acceptable quality for use

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in the qualitative risk assessment." It is inappropriate to treat the whole data evaluation component of risk assessment as the outcome of its nine steps.

Recommendation: The Hanford risk assessment methodology must expressly provide for each of the nine steps. Each step must be completed unless the Ecology and EPA RPMs agree that such steps are inappropriate. State that it is the responsibility of the risk assessor to confirm that all steps recommended in RAGS have been satisfied.

Initial Response: DISCUSS: The authors recommend this item be discussed at the meeting scheduled for June 9, 1992, and will provide a listing of the nine steps as a basis for the discussion.

June 9, 1992 Status: Open. Refer to Ecology comment #6. See text provided above for Ecology Comment #6.

Final Response: Based on a telephone discussion [Steve Cross, Ecology, and Lonie Swenson, Golder Associates Inc. (August 20, 1992), the following sentence will be added to Subsection 2.1.2 prior to the penultimate sentence of the final paragraph of Subsection 2.1.2:

> "It is the risk assessor's responsibility to confirm that all steps in the data evaluation have been performed."

The text for Section 2.1.2 is provided in the final response to Ecology comment #12.

Ecology 11. Section 2.1.3.1, page 9-11

Deficiency: This section exemplifies the surfeit of rationalization that permeates the *Methodology*.

Recommendation: The paragraph should be shortened.

Initial Response: DISCUSS: Only a few sentences of "rationalization" can be deleted without removing important explanations (e.g., we could remove part of the last paragraph on page 9, "If such an error..." through the end of the paragraph). In addition, Ecology comment #12 seeks to <u>introduce</u> text which is very similar to that already in section 2.1.3.1.

June 9, 1992 Status: Open. Text will be submitted for review by EPA and Ecology.

Final Response: Revised text provided below for Ecology comment #12.

Ecology 12. Section 2.1.3.1, page 9-11.

Deficiency: The text suggests use of "project-specific" background and disparages the use of site-wide background. This is counter to the goal of the M-28 background study. The standard to use is natural background, rather than local background. Contamination from other sites at Hanford can not be applied to increase background levels.

The proposed selection process for control data could result in underestimation of the risk. The *Methodology* allows for use of site-specific control or background data that are different

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from the background data currently being compiled under Tri-Party Agreement Milestone M-28. This process could result in the selection of "control" or background data from locations impacted by the Hanford facility. Control data are used to identify contaminants to be included in the risk characterization. Use of control data from an area impacted by the Hanford facility will result in lower risk estimates by eliminating contaminants of concern for that site.

Recommendations: Explain that site-wide background values will be used as soon as available and to the fullest extent applicable. Use the natural background standard rather than the local background standard.

Insert the following after the last sentence in the first paragraph:

> "Background conditions are currently being compiled for the Hanford Site as a whole under Tri-Party Agreement Milestone M-28. These data should adequately describe widespread anthropogenic sources, and will serve as basis for control data."

Insert the following at the beginning of the second paragraph.

> "There are two considerations that may be used to identify the need for project-specific control data:
>
> - the potential presence of contaminants from a facility outside the Hanford facility which is upwind, upgradient, or upstream of the Hanford facility which may have impacted areas not included in data for Milestone M-28. The facilities currently or historically in the vicinity of the Hanford facility to be considered include: . . . (include a list of such facilities and a figure showing their locations).
>
> - the potential presence of localized differences in soil characteristics that would result in the levels of naturally occurring inorganics elevated above the concentrations identified in Milestone M-28.
>
> The risk assessment should include a clear rationale and justification for the selection of project-specific control data based on these two considerations."

Initial Response: DISCUSS: The authors recommend this item be discussed at the meeting scheduled for June 9, 1992.

June 9, 1992 Status: Open. Text will be submitted for review by EPA and Ecology.

Revised Response: The intent of this section is to use appropriate background for a site. There is no such thing as natural background, as indicated in the comment; there is only background. The definition of background depends on one's perspective, and perspective, in the case of environmental studies, is defined on a project-specific basis.

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EPA published final exposure assessment guidelines in May (FR 22888 - 22938, Paragraph 3.5.2.4) that state:

> Background presence may be due to natural or anthropogenic sources. At some sites, it is significant and must be accounted for. The exposure assessor should try to determine local background concentrations by gathering data from nearby locations clearly unaffected by the site under investigation.

The Ecology comment indicates that the effect of using project-specific control data will be to "increase background levels." This may or may not occur. Soil upper tolerance limits reported for constituents in *Hanford Site Soil Background* (DOE/RL-92-34) ranged from 13 - 770% greater than the operable-unit-specific tolerances limits presented in the 1100-EM-1 Phase I RI report; due to ground-water contamination emanating from the Siemens facility, the Horn-Rapids-Landfill-specific background range is understandably higher than the operable-unit-specific range presented in the same report.

The issue is not what may happen as a result of using appropriate background data, but that appropriate background data must be used. The use of appropriate data will help ensure that proper decisions will be made on the basis of a holistic perspective of the Site. Therefore, changes in text, as recommended in the Ecology comment, are not incorporated in the revised text provided below for the August 13, 1992 meeting.

Final Response: Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC.

2.1.2 Contaminant-of-Potential-Concern Identification Process Overview

The contaminant-of-potential-concern identification process is defensible (based on science and statutory requirements), effective (focused without sacrificing conservatism), and easy to employ (saves time and resources); it also incorporates recent modifications employed by EPA regional risk assessment personnel (EPA-10 1991). The process involves two phases:

- control (Hanford Site or project-specific background) screening (i.e., determination of which of the initial set of hazardous substances and indicator parameters are actual contaminants, or, more simply, definition of contaminants); and

- preliminary risk screening (i.e., determination of which of the substances shown to be actual contaminants in the first step are the

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potential dominant risk-drivers, or, more simply, definition of contaminants of potential concern).

The overall process is graphically depicted in Figure 2-1A and 2-1B, and is described in subsections 2.1.3 and 2.1.4, respectively. A summary of the process is provided in 2.1.5. According to Figure 2-1A, validated investigation data are required to initiate the contaminant-of-potential-concern identification process. Data validation procedures used at the Hanford Site, that have been adapted from EPA protocols, are documented by and available from Westinghouse Hanford Company. Other data evaluation steps, as recommended in Section 5 of RAGS (EPA 1989a) are conducted as part of the RI/FS or RFI/CMS tasks implemented during the site investigation and characterization process. The risk assessor is referred to subsection 2.4.3.1 for additional discussion. It is the risk assessor's responsibility to confirm that all steps in the data evaluation have been performed.

2.1.3 Definition of Contaminants

A contaminant is defined in the following process as any hazardous substance or indicator parameter that exceeds its control distribution. In order to determine which substances are contaminants, the appropriate controls and control distributions must be determined. This stage of the process is statistically based in order to maintain objectiveness in the identification of contaminants. The selection of controls and the selection of control distributions, including detected and non-detected parameters and the handling of non-detected parameters and tentatively identified compounds (TICs) are discussed in the following subsections.

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2.1.3.1 Selection of Controls. The risk assessor must ensure that proper controls or background data sets are employed in the contaminant identification process. Since many substances defined as hazardous by regulation are naturally occurring, failure to consider control data could lead, for example, to the error of attributing risks to a given site when the risks are, in fact, of natural origin. The purpose of a baseline risk assessment is to characterize the risks posed by the release of hazardous substances from a facility.

Control conditions do not refer to pristine or pre-industrial conditions because such conditions no longer exist. As stated by EPA in the final exposure assessment guidelines published in May (FR 22888 - 22938, Paragraph 3.5.2.4):

> Background presence may be due to natural or anthropogenic sources. At some sites, it is significant and must be accounted for. The exposure assessor should try to determine local background concentrations by gathering data from nearby locations clearly unaffected by the site under investigation.

Furthermore, federal and state hazardous substance and waste statutes apply only to releases from specific sites as indicated above, not to wide-spread anthropogenic sources.

Background conditions are being compiled for the Hanford Site under Tri-Party Agreement Milestone M-28. Currently, background reports are available for the soil background for nonradioactive analytes (DOE-RL 1993) and the groundwater background

(DOE-RL 1992). The Hanford Site background data will generally be used to identify contaminants at a waste site, as discussed below in subsection 2.1.3.2.

Site investigation data should also include a characterization of control conditions for each parameter in the initial site-tailored data set in order to define control conditions on a project-specific basis. Appropriate project-specific control data for mobile environmental media (e.g., air, ground water, surface water) are especially important to ensure that site characterization, evaluation and remediation efforts are directed to the waste units actually releasing a given hazardous substance. Contamination can incorrectly be attributed to a waste unit, when the release is actually occurring from an upwind, upgradient, or upstream facility. Such data are necessary for the successful implementation of the IRM strategy which is focused on priority waste sites.

In the absence of appropriate Hanford Site background data or project-specific data, control data available from another project in a similar environmental setting — or those available from a regional, national, or global basis — may be used, with documented caution. Acceptable types of background data would be data from locations one can be reasonably certain are not associated with contamination and are representative of Site, regional, national, or global conditions. Generally, the further a control or background station is from the project area, the less likely the data from that station are representative of project-specific control or background conditions. The selection of control data and the rationale for selection of that data as the control data should be provided in the risk assessment.

2.1.3.2 Definition of Control Distributions and Use of the Hanford Site Background Data. When the compilation of background conditions are finalized for the Hanford Site under Tri-Party Agreement Milestone M-28, these documents should provide a framework for evaluating sampling data for the baseline risk assessments. The Hanford Site background data will generally be used for determining which parameters detected at a site are contaminants. Figure 2-1A provides an overview of the process. For the baseline risk assessment, it is recommended that validated sampling data for a waste site be compared to the Hanford Site 95% upper tolerance limit (UTL) for each parameter, based on the lognormal distribution. If the maximum concentration of a detected parameter is outside the tolerance interval of the Hanford background control distribution, then the parameter should be considered a contaminant and evaluated in the preliminary risk-based screening. The application of the Site-wide background control distributions should be evaluated on a parameter-by-parameter basis. Contaminants that exceed the 95% UTL of their respective lognormal distribution and fail the risk-based screening should be evaluated for potential elimination from the baseline risk assessment based on frequency of detection, as discussed in RAGS, Section 5.9.3 (EPA 1989a).

Hanford Site background data are not currently available for all potential parameters that are detected during project sampling. These parameters should be evaluated by performing the preliminary risk-based screening using the maximum detected concentration of that parameter. A determination of background levels of radionuclides for the Hanford site is expected to be agreed upon in the future. It is not appropriate to screen organics using background (Hanford Site or project-specific). Organics should only be screened using risk-based benchmark concentrations.

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In addition, the Hanford Site background report should be reviewed to ensure that it is appropriate for the project. Hanford Site background would not be used if:

- No Hanford site background data are available, or

- The site-wide background information is too general for a specific natural condition of the project.

  For example, the Hanford Site background data report has identified three terrestrial ecosystems that show distinctly higher concentrations for many analytes. These three soil association types are: (1) highly alkaline soils of playa and ephemeral drainages, (2) riparian ecosystem soils, and (3) the grassy soils on Rattlesnake Mountain (DOE-RL 1993).

2.1.3.3 Project-Specific Background Data.

Project-specific control distributions, if used for screening contaminants, will require review of the intended application by operable unit mangagers prior to use in the risk assessment process. Project-specific control distributions may also may provide information for site characterization and site evaluation to ensure remedial efforts are directed to the source of the contamination. The procedures presented below are recommended for use in calculating project-specific control distributions from sampling data.

<u>Detected Parameters</u>

Given a data set, control conditions for each parameter are defined by means of a tolerance interval. The null hypothesis is that on-site contamination concentrations are not higher than the control data. In virtually all instances, where one is concerned only about elevated concentrations of a substance in the environment, a one-sided upper tolerance limit is calculated; the 95th percentile of the control distribution is estimated at the default confidence rate of 95% (i.e., Type I error rate or false positive error rate, $\alpha = 0.05$). In the case of pH, where one is concerned about both elevated and depressed values, the 2.5th and 97.5th percentiles are estimated (also with $\alpha = 0.05$). The method for the calculation of an upper tolerance limit and one-sided tolerance factors are provided in EPA (1989d); two-sided tolerance factors are tabulated in Hines and Montgomery (1980).

The tolerance limit (or limits) statistically defines the normal range within which one could expect to find the substance occurring 95% of the time (with 95% certainty) under control conditions. Any departure from this range is interpreted as evidence of contamination attributable to the waste unit (or operable unit or aggregate area) in question. As any control data set used at the Hanford Site will be multivariate (i.e., contain perhaps 100 to 200 single parameter variables), the experiment-wise false positive error rate will be much higher than 0.05. The actual error rate will be:

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$$\alpha = 1-(0.95)^n$$

where n is the number of variables in the data set. Using the same control data set repeatedly will have a similar effect on increasing the error rate (Green 1979). As a result, many more substances will be defined as contaminants. For the sake of conservatism and simplicity, however, this bias, even though substantial, can be ignored.

Implicit in this tolerance interval approach is the assumption that the parameters are distributed normally under the control conditions. This assumption, as it is being applied to the distribution of a parameter, as opposed to the distribution of the mean of a parameter distribution (where the Central Limit Theorem supports a normal assumption), is not always met.

An up-front assumption of normality, however, is objective, and, for all practical purposes, sufficiently conservative and robust to justify its use in contaminant identification. [Conservative because virtually all environmental contaminant distributions are skewed to the right and are often best characterized by a lognormal distribution (Hahn and Meeker 1991)]. In addition, the project-specific control data sets are not anticipated to be large enough to conduct a meaningful test for normality; furthermore, the control data sets are expected to be far below the numbers necessary to conduct a non-parametric, or distribution-free, tolerance interval evaluation. However, if a data set is sufficiently large, the assumption of normality should be tested; if the assumption of normality is invalid, the data set should be appropriately transformed to approximate normal conditions (Green 1979; Hahn and Meeker 1991).

Care should be taken in combining data sets, when defining control distribution. When practicable, statistical screening should be employed to ensure that data from more than one distribution are not inadvertently combined into a single distribution. Examples include: differences in surface-soil quality and subsurface soil quality; differences in soil quality between pedons; differences in ground-water quality between aquifers; and differences in ground-water quality data from different time frames in situations where control conditions are temporally variable (e.g., where an upgradient contaminant plume, unrelated to the facility, operable unit, or site in question, is impacting a project-specific control location). An example of an appropriate statistical screening procedure for these situations is an analysis of variance (ANOVA); the reader is advised to consult a statistical methods reference for the specifics on this and other potentially appropriate procedures.

<u>Non-Detected Parameters</u>

When measurements less than the level of detection are reported as non-detected, the data are referred to as censored. In censored data sets, the number of non-detects is known. As contaminant data sets contain considerable amounts of censored data, a process must be established for estimating tolerance limits when a given parameter is never detected or only sometimes detected in the control data set. Computerized methods, such as iterative maximum likelihood calculations, are available for estimating the true means and variances of censored data sets. However, none of these methods are of use if the data set contains no detections of a given parameter, and in a typical control data set of 100 to 200 parameters, this situation arises frequently.

Therefore, for the sake of consistency, objectivity, and simplicity, one-half the sample quantitation limit (SQL) reported whenever a parameter is not detected will be used as a surrogate value in the calculation of the tolerance limit. For example:

Reported Validated Value	Surrogate Value
10 U (i.e., <10) mg/kg	5 mg/kg

Substituting one-half of SQL in such cases does bias the variance estimate of the parameter, but it does not bias the estimate of the mean. Consistent use of this procedure is objective, quick, and simple, does not require special equipment, and allows calculations to be easily duplicated and checked. It will not work, however, in those cases where a given parameter is never, not even once, detected in the control data set. In these cases, use of 0.5 SQL gives an unbiased estimate of the mean, but the variance estimate is entirely artificial.

Therefore, when a parameter is never detected in the control data set the highest reported SQL for that parameter is used as a surrogate upper tolerance limit to define the control distribution. This simple procedure objectively interprets the validated data. For example, one can not distinguish 10 U mg/kg from 6 mg/kg, and this procedure acknowledges this fact. It must be noted that 10 mg/kg is greater than 10 U mg/kg, as 10 U denotes <10. Therefore, a concentration equivalent to a surrogate tolerance limit would be regarded as evidence of contamination, whereas for a calculated tolerance limit, a concentration must first lie outside that limit to qualify as evidence of contamination.

Tentatively Identified Compound

Sample analysis for organic compounds may indicate the presence of additional organic compounds not on the TCL. Both the identity and the concentration of such compounds is highly uncertain. In many cases, only the class of compounds is reported for a tentatively identified compound (TIC). TICs should be reviewed by the risk assessor and discussed qualitatively in the uncertainty section of the risk assessment, as appropriate. Quantitative assessment of TICs in the risk assessment is generally not feasible because there is limited availability of toxicity factors such as slope factors or RfDs for chemicals that are not on the TCL. Further evaluation of TICs may be necessary as part of the site investigation if site information suggests that many TICs are present relative to the TAL and TCL compounds, the TICs are highly toxic, or, they are chemicals that are likely to be at the site based on site information.

Ecology 13. Section 2.1.3.2, page 11, first paragraph of section, sentence

Deficiency: The explanation of confidence intervals and error would be clarified by stating the null hypothesis. The null hypothesis is that on-site contamination concentrations are not higher than background. A type I error would be a conclusion that a contaminant is present, when it is not.

Recommendation: State the null hypothesis.

Initial Response: Accept. The null hypothesis will be added to the text.

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June 9, 1992 Status: Closed.

Final Response: Text has been revised as indicated in final response to Ecology comment #12.

Ecology 14. Section 2.1.3.2, second full paragraph of page 12, second sentence

Deficiency: The text presumes that funding and schedule constraints are such that the control data sets are not anticipated to be large enough to conduct a meaningful test for normality. The text also states that the control data sets will be insufficient to conduct a nonparametric or distribution-free tolerance interval evaluation. Ecology has not agreed to either assumption.

Recommendation: Delete this sentence.

Initial Response: Accept in part. It is extremely unlikely that control data sets will be large enough to prove normality [at least 50 samples would be required - MTCACR (173-340-708(11)(d) requires a minimum of 10 or 20 samples, an insufficient number to prove normality]. Instead of deleting sentences in question, an additional sentence will be added: "However, if the control data sets are sufficiently large, the assumption of normality may be satisfied and should be tested."

June 9, 1992 Status: Closed.

Final Response: Discussion of funding and schedule constraints has been deleted and reference to technical justifications is provided, as agreed to in comment resolution meetings. Final text for this section is provided in the response to Ecology comment #12.

Ecology 15. Section 2.1.3.2, second from the bottom paragraph on page 12, first sentence

Deficiency: The "censored data" terminology may be confusing to nonstatisticians. The common meaning of the word would be disturbing in this context.

Recommendation: Explain or define the term "censored data."

Initial Response: Accept. The term "censored data" will be defined as appropriate.

June 9, 1992 Status: Closed.

Final Response: The text referred to in this comment has been revised and the term "censored data" is no longer used. Revised text for this section (presented in the response to Ecology comment #12) was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of

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the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC.

Ecology 16. Section 2.1.4.2, page 14, first paragraph of section, third sentence

Deficiency: This is not an acceptable statement of the "foreseeable future." It is contrary to current efforts, such as the work of the Future Site Use Project Working Group. The issue was raised in the preface, and may best be resolved in that context.

Recommendation: Remove the second clause of this sentence.

Initial Response: Accept. The second clause of the sentence in question will be removed.

June 9, 1992 Status: Closed.

Final Response: Text has been revised as indicated above.

Ecology 17. Section 2.1.4.2, page 14, fifth full paragraph

Deficiency: Guidance documents do not designate pathways as driving risks at sites. Although these pathways are considered basic to any risk assessment, they are not identified as risk drivers.

Any selection of pathways as risk-drivers must be accompanied by documentation. However, recent research has shown that in addition to the standard pathways such as ingestion of water, there are pathways that can results in equal or greater exposure than the pathways called risk drivers in the *Methodology*. For example, inhalation of indoor air and dermal contact with tap water can result in exposures equal or greater to that from ingestion of water alone. The dose from inhalation of indoor air has been shown to 1.5 to 6.0 times as great as the dose from ingestion. Human Exposure to Volatile Organic Compounds in Household Tap Water: The Indoor Inhalation Pathway, Thomas E. McKone, Environmental Science and Technology, 1987, Vol. 21, No. 12, pages 1194-1201. For dermal exposure, studies have predicted that the average adult during a 20 minute shower may be exposed to the same amount of chemical as from ingestion of 1.4 liters of water a day (Dermal Uptake of Dilute Aqueous Trichloroethylene by Hairless Guinea Pigs, K.T. Bogen et al, AAMRL-TR-90-078, Environmental Sciences Division, Lawrence Livermore National Laboratory, University of California, Livermore, California, June 1990).

Recommendation: Delete this paragraph.

Initial Response: Accept in part. Text will be revised to remove reference of the three pathways as being risk drivers. However, other rationale for their use (that they occur at most sites, are basic to any risk assessment, and development of default parameters are largely geared toward these pathways) will be retained to justify their use in calculating risk-based benchmark concentrations.

June 9, 1992 Status: Closed. Text will be provided for review by EPA and Ecology.

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Final Response: The text provided below is the text agreed to for inclusion in Revision 2 of the HSBRAM:

> One or more of three general exposure pathways — soil ingestion, water ingestion, and air inhalation — occur at most sites and are generally basic to any risk assessment. As a result, the preliminary risk screening will utilize all three of these pathways.

Ecology 18. Section 2.2.1, page 18, fourth paragraph

Deficiency: The evapotranspiration rate is given as 18 cm (7 in). More current information is available. The Consultation Draft *Site Characterization Plan*, DOE/RW-0164, page 5.1-19, makes notable observations.

Recommendation: Include the following statements from the *Site Characterization Plan*: that "evapotranspiration levels can vary greatly with location at Hanford," that the evapotranspiration levels "were from five to nine times the mean annual precipitation," and that "during significant precipitation events, water can move below the vegetative root zone and escape evapotranspiration processes."

Initial Response: Accept. The reference cited by Ecology has been obtained and will be reviewed prior to incorporation of the recommended text.

June 9, 1992 Status: Closed.

Final Response: The text has been revised to incorporate the following paragraph:

> The estimated annual rate of actual evapotranspiration is approximately 18 cm (7 in) USWB and USDOA 1962). However, evapotranspiration levels can vary greatly with location at the Hanford Site due to differences in soil properties and the type and density of local vegetation. A study by Wallace in 1977 calculated evapotranspiration levels of from five to nine times the mean annual precipitation (DOE 1988a). Preliminary work has indicated that during significant precipitation events, water can move below the vegetation root zone and escape evapotranspiration.

Ecology 19. Section 2.2.1, last sentence of top paragraph of page 20

Comment: The uniqueness of the Hanford Reach is not correctly characterized. The Columbia River below Bonneville Dam is not impounded by a dam.

Initial Response: Accept. The sentence will be modified to correctly characterize the uniqueness of the Hanford Reach.

June 9, 1992 Status: Closed.

Final Response: Text has been revised as indicated above.

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Ecology 20. Section 2.2.1, second full paragraph of page 20, last sentence

Deficiency: The text implies that ponds and ditches are only found in the 200 area.

Recommendation: Point out that there are also ditches and ponds in the 100 and 300 areas.

Initial Response: Accept. The text will be added to indicate that there are ditches and ponds in the 100 and 300 areas.

June 9, 1992 Status: Closed.

Final Response: Text has been revised as indicated above.

Ecology 21. Section 2.2.2, page 20, first paragraph of section

Deficiency: a) The first sentence defeats much of the purpose of the *Methodology* by suggesting that populations be determined on a site-specific basis. b) This paragraph only discusses current populations. Current Hanford land use involves the use of pervasive institutional controls. Reliance on institutional controls in a risk assessment is contrary to NCP 300.430(a)(1) and RAGS (EPA/540/1-89/002).

Recommendation: a) The Methodology should characterize populations as broadly as possible, at the aggregate area level for instance. b) The characterization of potentially exposed populations must include future populations based on the four standard scenarios.

Initial Response: Accept in part. Text will be added to make a distinction between current and future receptor populations, and that four standard scenarios will serve as the basis for characterizing possible future receptor populations.

June 9, 1992 Status: Open. Ecology continues to express concern about the text. EPA and RL consider the text adequate.

Ecology Clarification, August 4, 1992:

Comment 21A

This comment remains unresolved. Populations for the four future land use scenarios should be described with as much specificity as possible in the Methodology. To describe populations in each of the dozens of risk assessments that will be conducted would be redundant, inefficient, and potentially disruptive.

Comment 21 B

This comment may be resolved by the authors' partial response. Ecology will review the text to be provided by the authors before making a final determination. There will have to be significant additions to the Section, because it presently describes only current populations.

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Revised Response: The authors have reviewed the comment and comment clarification provided by Ecology. The text in the first paragraph of this section is intended to provide the general description of the land use of the Hanford Site and the surrounding areas as it exists today. This information is provided as general background information. The comments provided by Ecology are addressed in the revised text provided for Ecology Comment #26 and revisions to Section 2.2.2.

Final Response: Based on a telephone discussion [Steve Cross, Ecology, and Lonie Swenson, Golder Associates Inc. (August 20, 1992), the text for Section 2.2.2 is presented below. Comment status: closed.

2.2.2 Characterization of Potentially Exposed Populations

Current on-site receptors are primarily Hanford Site workers. Approximately 12,000 people were employed in DOE activities on the Hanford Site in 1989. The greatest number of these people (about 5,200 or 43%) worked within or immediately adjacent to the Richland city limits in the 700, 1100, and 3000 Areas. The 200 and 300 Areas employed about 3,500 (29%) and 1,900 (15%), respectively. Another 750 (6%) were located in the 100 Area with the remaining individuals (about 7%) working in other areas. Washington Public Power Supply System employed about 1,400 people. A number of other work areas exist on the Hanford Site, such as the Solid Waste Landfill, the Fast Flux Facility, and U.S. Ecology.

The population in the area surrounding the Hanford Site is predominantly rural, with the exception of the cities of Kennewick, Pasco, and Richland. Using the Hanford Meteorological Station tower as a reference point that is approximately in the center of the site and 1980 census data, the total population 80 km (50 mi) from the tower was 340,943 in 1980. The number who resided in incorporated cities was 210,999 (Jaquish and Bruce 1990).

Recreational activities associated with the Columbia River include hunting, fishing, boating, water skiing, and swimming. Agricultural activities near the Hanford Site include irrigated and dryland farming, and livestock grazing. About one-third of the crop acreage is irrigated, one third in dryland production, and the remaining third is idle or in summer fallow (Watson et al. 1991).

The Hanford Site is located in lands ceded to the United States in 1855 under treaties with the Yakima Indian Nation and the Confederated Tribes of the Umatilla Indian Reservation. Under both treaties the Native American signatories retained the right to fish at usual and accustomed places, and retained the privileges of pasturing horses, hunting and gathering roots and berries on open and unclaimed lands within the ceded areas. The protection of these resources for potential future use by the Native Americans, if areas of the Hanford Site were to become open and unclaimed, has been an issue in connection with activities at the Hanford Site.

For the baseline risk assessment, the receptor populations for a site are selected based on both the location and activities of current populations, as discussed above, and populations associated with potential future land use. Section 6.2.2 of RAGS (EPA 1989a) provides information on identifying potentially exposed populations. Specific current and future scenarios for Hanford Site baseline risk assessments are discussed in subsection 2.2.4.

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Ecology 22. Section 2.2.3.2, page 25

Deficiency: The lists of pathways are not complete. OSWER Directive 9285.6-03, section 6.0 includes two more routine pathways. The EPA Region 10 Supplemental RAGS, table III, also includes several more pathways, and does not distinguish primary and secondary pathways.

The *Methodology* makes an unsubstantiated distinction between pathways. The OSWER Directive makes no distinction between primary and secondary pathways.

The statement that secondary pathways should only be qualitatively evaluated, but may be qualitatively evaluated is unsubstantiated and unacceptable. The text neglects to mention that both quantitative and qualitative assessments of risk should be evaluated in an uncertainty analysis. However, no uncertainty estimate is possible in a qualitative assessment of risk, so the uncertainty analysis would be relatively meaningless. *Guidance for Data Useability in Risk Assessment*, EPA/540/G-90/008.

The bullets are not consistent with figure 2-4.

Recommendation: Include the all pathways relevant to Hanford site risk assessments. Substantiate or remove the primary/secondary pathway concept. Explain whether the bulleted items on page 25 are intended to be consistent with the EPA guidance or with figure 2-4.

Initial Response: DISCUSS: The list of pathways is not inconsistent with OSWER Directive 9285.6-03 or EPA Region 10 Supplemental RAGS (Table III). The sixth paragraph on page 25 clearly describes the biota pathways that have also been selected as primary exposure pathways. There is also no inconsistency between the text and Table 2-4. Discuss with Ecology the possibility of replacing "primary/secondary" terminology.

June 9, 1992 Status: Open. Comment will be reconsidered by S. F. Cross of Ecology.

Ecology Clarification, August 4, 1992:

The reference EPA 1991a lists pathways that are "evaluated on a routine basis" for appropriate scenarios. These pathways are:

Ingestion of Potable Water
Ingestion of Soil and Dust
Inhalation of Contaminants
Consumption of Homegrown Produce
Consumption of Locally Caught Fish

The set of three bullets of HSBRAM, page 25, does not include:

Ingestion of Dust
Consumption of Homegrown Produce
Consumption of Locally Caught Fish

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These three pathways must be added to the list to coincide with the explanation of the second sentence of the second paragraph of Section 2.2.3.2.

The reference EPA-10 1991, Table 4-1, lists ten pathways for appropriate scenarios. There are:

Ingestion of Water
Inhalation of Volatiles
Dermal Contact with Water
Consumption of Fish/Seafood
Ingestion of Sediment
Dermal Contact with Sediment
Soil Ingestion
Dermal Contact with Soil
Inhalation of Particulates/volatiles From Soil
Consumption of Produce, Meat, Milk

The set of three bullets of HSBRAM, page 25, does not include:

Dermal Contact with Water
Consumption of Fish/Seafood
Ingestion of Sediment
Dermal Contact with Sediment
Dermal Contact with Soil
Consumption of Produce, Meat, Milk

These six pathways must be added to the list to coincide with the explanation of the second sentence of the second paragraph of Section 2.2.3.2.

The reference EPA-10 1991, Table III, lists five pathways for appropriate scenarios. These are:

Water Ingestion
Soil & Dust Ingestion
Inhalation
Dermal Contact with Soil
Dermal Contact with Water

The set of three bullets on HSBRAM, page 25, does not include:

Dust Ingestion
Dermal Contact with Soil
Dermal Contact with Water

These three pathways must be added to the list to coincide with the explanation of the second sentence of the second paragraph of Section 2.2.3.2.

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In summary, the following pathways must be added to the list to coincide with the explanation of the second sentence of the second paragraph of Section 2.2.3.2.

Ingestion of Dust
Consumption of Homegrown Produce
Consumption of Locally Caught Fish
Dermal Contact with Water
Consumption of Fish/Seafood
Ingestion of Sediment
Dermal Contact with Sediment
Dermal Contact with Soil
Consumption of Produce, Meat, Milk

The discrepancies must be corrected. Each of the Pathways must be expressly addressed. The "in addition" and "also selected" pathways do not fill the list and are out of context with the explanation on the second paragraph of the Section. The use of "include" in the introduction of the three pathways does not circumvent its incompleteness. Please provide a complete and coherent list of pathways that coincides with the reference cited.

Final Response: The information requested by Ecology is already presented in Section 2.2.3.2 and in Figure 2-4. All pathways indicated by Ecology that are provided in Table 4-1 (EPA 1991a), Table III (EPA-10 1991) and EPA 1991a are provided in Figure 2-4. Discussion on these pathways for Hanford Site risk assessment is provided in Section 2.2.3.2. Based on the clarification of the Ecology comment, the text has been revised as indicated below to provide bullets of the requested information in addition to the material already presented in the text and figures. Please note that:

- "and dust" has been added to the bullet for ingestion of soil; dust ingestion is routinely assumed to ba a part of the soil ingestion pathway and as indicated by EPA (1991a), the amount of dust ingested is considered part of the default intake parameter provided for the ingestion of dust (EPA 1991a); consequently, dust ingestion is not always considered a specific entity;

- consumption of produce, meat, and milk are addressed individually; therefore, consumption of homegrown produce and consumption of produce are considered the same; and

- the consumption of locally caught fish and consumption of fish/seafood are the same pathway for Hanford Site exposures.

The authors would also like to acknowledge that the clarification to the comment also indicates that Table 4-1 (EPA-10 1991) lists ten pathways for appropriate scenarios. This table provides a "General Approach for Selection of Exposure Pathways". As indicated in the text and Table 4-1 of EPA-10 (1991), site-specific and contaminant-specific decisions for evaluation of each pathway are also necessary. The HSBRAM provides for such decisions by acknowledging the primary and secondary pathways that are evaluated at a site.

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Revised text was provided for review. Based on a telephone discussion [Steve Cross, Ecology, and Lonie Swenson, Golder Associates Inc. (August 20, 1992)], the following text has been included in Revision 2 of the HSBRAM and the status of this comment is closed. Additional discussion (paragraphs 4 and 5 of Section 2.2.3.2) on the external exposure pathway has been added to the text since the August conversation.

2.2.3.2 Exposure Pathways. As noted above, the conceptual model (Figure 2-4) summarizes pathways that are likely to contribute significantly to overall risks and that can be assessed with relatively well-defined parameters. These pathways are considered either primary or secondary pathways for Hanford Site risk assessments as discussed below.

Primary pathways are presented in the conceptual model as those pathways, exposure media, and routes that should be quantitatively evaluated for a specific scenario if contaminants are present in a medium. The primary pathways listed below include many of those evaluated in risk assessments at most hazardous waste sites (EPA-10 1991 and EPA 1991a) and frequently are risk-driving pathways at hazardous waste sites (see Figure 2-4). These pathways should be evaluated for all scenarios and include:

- Ingestion of soil and dust,
- Inhalation of fugitive dust and/or volatiles,
- Ingestion of water (surface water or groundwater),
- Dermal contact with soil contaminants, and
- External exposure from radionuclides in soil.

External exposure to radionuclides is added as a Hanford Site-specific pathway because of radionuclide use and production at the site. Soil contaminated by photo-emitters is the only exposure media that should be routinely evaluated for the external exposure pathway.

If radioactive contaminants are covered by clean soil, the soil may provide sufficient shielding to effectively eliminate the external exposure pathway. This shielding effect is a function of shielding thickness, photon energy, and source activity. However, it may be generally assumed that all low energy (<100 keV) photons are effectively shielded if the source is covered by at least 1 meter of soil (Kocher and Sjoreen 1985). Three meters of soil will eliminate external exposure to all but the highest energy photon emitters (>1 MeV).

Depending on land use, excavation may occur, thereby reducing or eliminating the clean soil cover. The effect of shielding on the reduction or elimination of external exposures should therefore be based on the thickness of clean soil cover assumed to exist following excavation.

Several biota pathways have also been selected as primary exposure pathways for specific scenarios. Again, because of the residential and agricultural areas in the vicinity of the Hanford Site, the specific concern with radionuclides, the location of the Columbia River and the potential for contaminated groundwater to reach the river, and the recreational hunting that occurs, biota pathways have been selected as primary pathways for the recreational, residential, and agricultural scenarios, as appropriate. The biota pathways are:

- Consumption of dairy products (milk),
- Consumption of beef,

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- Consumption of game (e.g., venison, upland game birds, waterfowl, etc.)
- Consumption of Columbia River fish, and
- Consumption of homegrown produce.

Secondary pathways are pathways that should be qualitatively evaluated, at a minimum, but may be quantitatively evaluated based on site characterization, contaminant characteristics, contaminant migration, and availability of pathway-specific toxicity information. All pathways qualitatively evaluated should be discussed in the uncertainty sections of the exposure assessment and the risk characterization. Secondary pathways are indicated in the conceptual model presented in Figure 2-4. These pathways are:

- Ingestion of sediment,
- Dermal contact with sediment,
- Inhalation of volatiles from water, and
- Dermal contact with water.

Pathways have been selected as secondary pathways because they represent exposure routes that depend on contaminant-specific parameters, frequency or duration of exposures, or likelihood of occurrence. These secondary pathways may also contribute less to the overall risk or may require qualitative evaluation because of limited availability of contaminant-specific information.

A sediment exposure pathway in the river is an example of a pathway selected as a secondary pathway because the frequency of contact is limited by such factors as the weather and receptor activity patterns (e.g., hunters normally wear clothing that protects from such exposures, water skiers have little, if any, direct contact with sediment, swimmers and people wading represent a population much smaller than those drinking the water and exposures occur on a less regular basis at the same exact location). In addition, the size of the Hanford Site may preclude the impacts to sediments from many sites that are located away from the river and for which groundwater transport would be the only mechanism of transport for contaminants.

Dermal exposures to water are also considered a secondary pathway because significant exposures may rely on chemical-specific factors such as dermal permeability. The faster penetrating contaminants (dermal permeability constant >0.1 cm/hr) may also pose a hazard similar to direct consumption, but environmental contaminants in this range appear to be a minority (EPA 1992c). Dermal uptake is generally not an important role for radionuclides, most of which have small dermal permeability constants. However, there may be exceptions at the Hanford Site, such as tritium, that may have high dermal permeabilities and these radionuclides should be evaluated on a case-by-case basis.

Two potential air exposure routes are not presented in the conceptual model and are not recommended for quantitative evaluation under any scenario. These pathways are:

- Ingestion of contaminated particulates or volatiles secondary to inhalation of contaminated air, and
- dermal exposure to airborne contaminants.

Ingestion of contaminants is adequately evaluated by the soil ingestion pathway, especially for children who are considered to have the same potential ingestion intake

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during the entire year from either playing outside in contaminated soil or inside on dirty/dusty floors. Ingestion of radioactive contaminants secondary to inhalation is already accounted for by the EPA inhalation dosimetry model (EPA 1989e). Dermal exposures to airborne chemicals and radionuclides are considered to be lower than inhalation intakes and are generally not considered in Superfund Risk Assessments as noted in sections 6.3 and 10.5.5 of RAGS (EPA 1989a). Qualitative discussion of such pathways may be appropriate in the uncertainty section of the risk assessment.

Three pathways associated with external exposure to radionuclides are also not recommended for quantitative or qualitative evaluation unless site-specific information suggests the need to consider these pathways. The pathways are:

- Air immersion pathway,
- External radiation exposure from sediment, and
- Water submersion.

Exclusion of the air immersion pathway is suggested due to the transient nature of such exposures and the current lack of contaminant waste streams (e.g., the production of gaseous effluents) that would provide an air immersion exposure. External radiation exposure from contaminants in sediment or due to water submersion may also be excluded from evaluation. As stated in Section 10.5.5 of RAGS (EPA 1989a), the shielding effects of water and the generally short durations of water submersion exposures typically make this a pathway of lesser significance.

If site-specific information suggests that these may be important pathways, radiation doses and risks incurred during such events may be evaluated as follows. This first step is to use dose rate conversion factors (DRFs), combined with estimates of exposure duration, to calculate committed effective doses due to radioactively contaminated media. Current sources of DRFs include DOE 1988 and EPA 1988b. The resulting dose (in units of rems) can then be multiplied by a cancer incidence risk factor to yield a cancer risk estimate. For the purposes of this methodology, a cancer induction risk factor of 6.2E-04/rem should be used, as this is the factor currently employed by EPA (1989e) to calculate radionuclide slope factors. Such an evaluation should be performed by health physicists familiar with dosimetric concepts. Justification for such an evaluation may include the detection of external radiation fields with field survey instruments, or the presence of high-energy gamma emitters in media of concern (e.g., water and sediment).

Although the conceptual model and scenarios presented in this risk methodology have indicated primary and secondary pathways for evaluation in risk assessments, this does not preclude the evaluation of other pathways. The risk assessor, lead regulatory unit manager, or the DOE unit manager may identify contaminants or pathways at a specific site that warrant additional evaluation. Pathways that are not quantitatively evaluated should be addressed with respect to their contributions to uncertainty in exposure assessment and risk characterization, focusing on their potential impacts on overall risk.

Ecology 23. Section 2.2.3.2, first sentence of first paragraph of page 26.

Deficiency: This sentence is incorrect in stating that there is a connection between contaminant-specific parameters and risk for a particular pathway. The risks for exposure

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pathways with contaminant-specific parameters can be equal to or greater than pathways without such parameters.

Recommendation: Remove this portion of the sentence.

Initial Response: DISCUSS: Replace first sentence of paragraph with:

> "Several pathways have been selected as secondary pathways because they represent exposure routes that depend on contaminant-specific factors, frequency or duration of exposures, or likelihood of occurrence. These secondary pathways may also contribute less to the overall risk or may require qualitative evaluation because of limited availability of contaminant-specific information."

June 9, 1992 Status: Open. Comment will be reconsidered by S. F. Cross of Ecology.

Ecology Clarification, August 4, 1991:

The language suggested in USDOE's Response acceptably addresses the concern expressed in the comment.

Final Response: The status of this comment is closed. Text has been changed as indicated above.

Ecology 24. Section 2.2.3.2, second paragraph of page 26, last sentence.

Deficiency: The text states that most radionuclides have a small permeability constant, but does not specify the minority of radionuclides that do not.

Recommendation: Specify what is "low" for a permeability constant, and explain how low is low. Specify which radionuclides do not have a "low" permeability constant.

Initial Response: DISCUSS: The sentence in question is nearly a direct quote from RAGS (10.5.5). Discuss whether citing RAGS would be adequate, or if text should provide more detail.

June 9, 1992 Status: Closed. Text will be inserted regarding the radionuclides at Hanford, such as tritium, that may have high permeabilities.

Final Response: The following sentence has been added to the indicated paragraph: "However, there may be exceptions at the Hanford Site, such as tritium, that may have high dermal permeabilities and these radionuclides should be evaluated on a case-by-case basis."

Ecology 25. Section 2.2.3.2, first sentence of second full paragraph of page 27

Deficiency: The text states that the risk assessor may consider other pathways.

Recommendation: Point out the lead regulatory or USDOE unit manager may also require evaluation of other pathways.

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Initial Response: Accept. The text will be revised to include general reference to the risk assessor, lead regulatory unit manager or USDOE unit manager who may identify the need to evaluate additional pathways.

June 9, 1992 Status: Closed.

Final Response: Text has been revised as follows:

Although the conceptual model and scenarios presented in this risk methodology have indicated primary and secondary pathways for evaluation in risk assessments, this does not preclude the evaluation of other pathways. The risk assessor, lead regulatory unit manager, or the DOE unit manager may identify contaminants or pathways at a specific site that warrant additional evaluation. Pathways that are not quantitatively evaluated should be addressed with respect to their contributions to uncertainty in exposure assessment and risk characterization, focusing on their potential impacts on overall risk.

Ecology 26. Section 2.2.4, page 27, *et seq*

26A. **Deficiency:** The bottom paragraph on page 27 indicates that application of the four scenarios would have to be justified on a site-by-site basis for each risk assessment. This defeats the purpose of the *Methodology* to provide uniform guidance for the Hanford site. At present, all four scenarios must be applied in all risk assessments. Over time, the parties will reach understandings about certain areas where some of the scenarios will not be applicable.

Recommendation: Revise the thrust of the paragraph to explain that it is assumed that all four scenarios will be applied in every risk assessment, unless site-specific conditions justify otherwise.

Initial Response: DISCUSS: The scenarios for a baseline risk assessment should be determined on a site-specific basis as discussed in Section 6.2.2 of RAGS (EPA 1989) and WAC 173-340-708.

June 9, 1992 Status: Open. Provide text to say that a decision will be made by the Unit Managers or the issue will be elevated in the procedure for Tri-Party Agreement issues resolution.

Ecology Clarification, August 4, 1992:

The point of departure for the application of future land use scenario is that all four be applied at each site. To <u>not</u> use one or more scenarios would then have to be justified on a site-by-site basis, with the agreement of the operable unit managers. It may be possible for the Risk Assessment Working Group to agree on some aggregate area limitations on the scenario, pending the conclusions of the land use stake-holders group.

Revised Response: The application of all four recommended scenarios without evaluation of site-specific conditions is inappropriate. As indicated in the clarification to the comment by Ecology, it may be possible for the Risk Assessment Group to agree on some limitations on the scenarios. We recommend that this be discussed within the group. If agreement can be reached on this topic, then the text provided below would be modified to

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incorporate the scenario information. If agreement cannot be reached, then the dispute resolution process should be initiated on this issue.

Final Response: The text referred to in this comment has been revised and is presented after Ecology comment #26C. Revised text for the discussion on the recreational scenario, residential scenario, and agricultural scenario was negotiated at the August 13, 1992, meeting of the inter-Agency Risk Assessment Committee. Revised text for the remainder of this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC.

26B. **Deficiency:** The second full paragraph on page 28 calls for the creation of a site-specific commercial/industrial scenario. This methodology should be establishing a generic scenario.

Recommendation: Explain that only in exceptional cases, on agreement of the operable unit managers, will a site-specific scenario be developed.

Initial Response: Accept. The text will be modified to clarify that only in exceptional cases, and on agreement with unit managers, will site-specific scenarios be developed.

June 9, 1992 Status: Closed.

Final Response: The text referred to in this comment has been revised and is presented after Ecology comment #26C. Revised text for the discussion on the recreational scenario, residential scenario, and agricultural scenario was negotiated at the August 13, 1992, meeting of the inter-Agency Risk Assessment Committee. Revised text for the remainder of this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC.

26C. **Deficiency:** The third full paragraph of page 28 distinguishes the use of the four Hanford-wide scenarios as future scenarios from the use of site-specific current scenarios. The site-specific current use scenario would be, essentially, a fifth land use scenario. This

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current/future land use timeframe is introduced in the Preface to this draft of the *Methodology*.

Recommendation: Use just the four Hanford-wide future-use scenarios.

Initial Response: DISCUSS: How to address current land use (which is slightly different than the future industrial scenario). Discuss whether this represents a "fifth" land use, or if it is simply the standard industrial scenario modified with site-specific information.

June 9, 1992 Status: Open. Refer to Ecology comment #21.

Ecology Clarification, August 4, 1992

The current industrial land use scenario would be distinct from the future industrial land use scenario. The current situation is not truly a "scenario", since it represents actual conditions of worker access to and exclusion from potential exposure pathways. Institutional control is a remedial alternative, not a land use. Because current conditions depend on institutional controls, continuation of the current land use would actually be a remedial alternative. If the current land use is industrial, then the assessment of that scenario must assume the collapse of institutional controls, and the appearance of "civilian" industrial uses. Although USDOE may wish to conduct a risk assessment of current institutional conditions, such an analysis would not substitute for the future land use of scenarios subject of Comment 26A.

Revised Response: The clarification to this comment incorrectly notes that institutional control, as part of current land use is a remedial alternative. Current exposures are based on current conditions. If institutional control exists at a site, then the baseline conditions for that site include institutional control.

Final Response: The text referred to in this comment has been revised and is presented after Ecology comment #26C. Revised text for the discussion on the recreational scenario, residential scenario, and agricultural scenario was negotiated at the August 13, 1992, meeting of the inter-Agency Risk Assessment Committee. Revised text for the remainder of this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC.

2.2.4 Exposure Scenarios

The Hanford Site information found in subsection 2.2.1, the current receptor information discussed in 2.2.2, and the pathway information and conceptual model presented in 2.2.3 are integrated to develop current and potential future exposure scenarios for use in assessing risk at a site. Both current and potential future exposures are

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considered in accordance with 40 CFR 300.430(d)(4) and WAC 173-340-708. Current exposure estimates are used to determine the risk based on existing exposure conditions at the site. Future exposure estimates provide decision-makers with an understanding of likely future risks.

Four scenarios have been developed for the methodology. These scenarios are a commercial/industrial scenario, a recreational scenario, a residential scenario, and an agricultural scenario. For the commercial/industrial scenario two variations are provided, limited action and no action. The limited action scenario is provided in the HSBRAM because of recent DOE guidance on "Use of Institutional Controls in a CERCLA Baseline Risk Assessment" (DOE 1992). As indicated in subsection 2.2.2, almost all current use of the Hanford Site, except for that described under the recreational scenario, is commercial/industrial. The recreational scenario has been developed because of the location of the Columbia River adjacent to the Hanford Site. The Columbia River is an important recreational area for fishing and other water sports, including use of the river bank along the Hanford Site up to the high water mark for waterfowl hunting. Residential and agricultural land use also currently occur near the Hanford Site.

The application of a specific scenario in the risk assessment should be based on site-specific information and characterization of exposed populations as discussed in Section 6.2.2 of RAGS (EPA 1989a). This is also in accordance with WAC 173-340-708. The inclusion or exclusion of any of the four scenarios and evaluation of the limited action alternative should be determined in a timely manner by the regulatory and DOE unit managers with support from technical and risk assessment personnel. The rationale for inclusion or exclusion of current and future scenarios should be well documented. In addition to on-site scenarios, other receptors, such as recreational populations or those that may be located off-site, should also be determined based on the location of a specific site, contaminants detected at a site, the potential for contaminant transport off-site, and other relevant factors. It is important to note that off-site receptors may not always be the closest receptors based on physical location. For example, for some sites downwind receptors may be more distant than upwind receptors, but because of the potential for contaminant transport the downwind receptors would be a more likely exposed population.

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The scenarios are briefly discussed below. The risk assessor is referred to Appendix A for more extensive information in each scenario including exposure parameters that should be used for preparing baseline risk assessments.

Limited Action - Commercial/Industrial Scenario: Because the current use of the Hanford Site is commercial/industrial, this scenario will be assessed at most sites. After analyzing the required RME, additional exposure scenarios could be developed wherein the benefits of maintaining existing institutional controls or newly proposed controls are accounted for in a limited action - commercial/industrial scenario. A site-specific limited action commercial/industrial scenario may be developed on a case-by-case basis for use as a current scenario if industrial activities are currently conducted at a site. Site-specific exposure parameters related to type of activities (e.g., office workers, maintenance workers, etc.), frequency and duration of activities (e.g., daily, monthly, etc.), and media contact during the activities (e.g., drinking water, soil, etc.) should be applied. Development of a site-specific scenario will generally be the exception and will require agreement of the operable unit managers. All site-specific data and values must be justified and documented in the risk assessment report as recommended by EPA (1991a).

Commercial/Industrial Scenario: The commercial/industrial scenario is presented in Appendix A. The baseline risk assessment should assume no action and this scenario may be used, as appropriate, for evaluating current exposures when site-specific activities are similar to those represented by this scenario. It may also be used for evaluating future commercial/industrial scenarios. The commercial/industrial scenario represents exposures that may occur to a person working at a site whose job is primarily indoors, but who would have some outside activities that could result in exposure to the soil sufficient to incur soil ingestion and dermal contact exposures. In addition, the scenario considers other commercial/industrial exposures (e.g., ingestion of potable water and inhalation of contaminated air) generally used to assess exposures associated with commercial/industrial land use, as recommended by EPA (1991a), and exposures specific to the Hanford Site and its contaminants (e.g., external exposure to radionuclides). Specific exposure parameters and factors are summarized in Tables A-1, A-2, and A-3 of Appendix A.

Recreational Scenario: Recreational activities associated with the Columbia River could potentially result in exposure to hazardous substances released from the Hanford Site. As discussed above, these recreational activities include hunting, fishing, boating, water skiing, and swimming. The recreational scenario presented in Appendix A considers these current activities and incorporates additional activities, as appropriate, for a future recreational scenario. Specific exposure parameters and factors are summarized in Tables A-4 and A-5, and A-6 of Appendix A.

Revisions in the recreational scenario may be required when options under consideration for the Hanford Reach are finalized. The Draft Comprehensive River Conservation Study and Environmental Impact Statement for the Hanford Reach of the Columbia River (National Park Service (NPS) 1992) has proposed that land along the Hanford Reach be designated a National Wildlife Refuge with Wild and Scenic River overlay.

Residential Scenario: As discussed above, there is not current on-site residential use of Hanford Site land. However, residents are located in areas adjacent to, downwind, and down river from the site. A residential scenario is provided in Appendix A for evaluating residential populations. Specific exposure parameters and factors for the residential scenario are summarized in Tables A-7, A-8, and A-9.

Agricultural Scenario: An agricultural scenario is also provided in Appendix A. As discussed in subsection 2.2.2, agricultural land use occurs in the vicinity of the Hanford Site. The agricultural scenario includes a farm residence. Specific exposure parameters and factors for the agricultural scenario are summarized in Tables A-10, A-11, and A-12.

Ecology 27. Section 2.2.5, page 29, first sentence of section

Deficiency: The text states that "exposure is defined as . . ." without reference.

Recommendation: Reference where this definition is derived or delete "defined as."

Initial Response: Accept. The words "define as" will be deleted.

June 9, 1992 Status: Closed.

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Final Response: The text has been revised as indicated above.

Ecology 28. Section 2.2.5.4, second from bottom paragraph of page 33

Deficiency: This discussion of the shielding effect of soil does not consider that the soil may be disturbed. Disturbances of up to fifteen feet deep may be expected under the four land-use scenarios, and should be considered. Deeper disturbances and mixing may occur during remediation; for example, as in the macroengineering report. There may be instances where unacceptable risk will justify or require cleaning up deeper than fifteen feet.

Recommendation: Add a discussion that exposures to soils up to fifteen feet deep may occur under the four land-use scenarios if the soil is disturbed, and that remediation may affect deeper soils.

Initial Response: Accept in part. Discussion will be added to address exposures to soils up to fifteen feet deep as a result of the four land-use scenarios. However, the effect of remediation shall not be considered as this is a baseline risk assessment methodology.

June 9, 1992 Status: Closed. Also see EPA comment #3.

Final Response: Text of Section 2.2.5.4 has been revised overall. Discussion of external exposures has also been added to Section 2.2.3.2 to address the concerns identified in this comment. See final response to Ecology comment #22.

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Ecology 29. Section 3

Deficiencies: The Environmental Evaluation methodology will not identify all sources of environmental impact because the scope and focus are limited in the following areas:

- Identification of habitats of potential concern
- Identification of contaminants of potential concern
- Selection of assessment and measurement endpoints
- Toxicity assessment
- Risk characterization
- Critical aspects that are not clearly discussed

The focus of the proposed environmental evaluation methodology is too narrow.

Recommendations: As described in the following comments, the scope and focus of each of these sections needs to be expanded to incorporate the concepts for Environmental Evaluation endorsed in RAGS, Vol 2.

Initial Response: Reject. The focus of the environmental evaluation is limited to the areas mentioned in the text in order to provide a systematic approach to conducting the environmental evaluation within the context of the NCP requirements for the baseline risk assessment.

June 9, 1992 Status: Closed. Defer to following comments.

Final Response: Closed by revision of Chapter 3 to incorporate the key concepts of the EPA Framework (EPA 1992). During the course of comment resolutions on "Chapter 3 Environmental Evaluation", the recently released EPA document "Framework for Ecological Risk Assessment" EPA/630/R-92/001 was reviewed by members of the RAC. At a meeting of the RAC held on August 28, 1992, it was agreed that Chapter 3 would be revised in format and content to incorporate the key concepts of the framework with modifications made to address the CERCLA-specific and Hanford-specific aspects of ecological risk assessment. At subsequent meetings, the revisions to Chapter 3 to incorporate the framework have been reviewed by the RAC, additional informal comments have been made and discussion of those comments has occurred. The text of Chapter 3 has been revised to reflect the negotiations made regarding the language in the text. Therefore, Chapter 3, as prepared in Revision 2 of the HSBRAM, reflects final resolution of all comments on Chapter 3.

The comments and initial response provided below for Ecology comments #29 through #50 all refer to Revision 1 of the HSBRAM. They are included because they are part of the initial phase of the comment resolutions for Revision 1 of the HSBRAM. Major format modifications have been made to Chapter 3. Consequently, the comments no longer refer to the same sections, paragraphs, or lines in Revision 2. Please note that the Revision 2 text incorporates the initial responses indicated for Ecology Comments #29 through #50 if they are appropriate for the revised text and if the language was agreed upon in negotiations on the text.

Ecology 30. Section 3.1, page 49, first paragraph of section

Deficiency: The purpose of the environmental evaluation is incorrectly stated. See also section 1.5.2.

Recommendation: The appropriate concept is that "the results of the baseline risk assessment will help establish acceptable exposure levels for use in developing remedial alternatives." NCP 300.430(d)(4).

Initial Response: Accept. The text will be modified to include the appropriate concept as indicated.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 and Section 3.1 have been revised as discussed above in the final response to Ecology comment #29. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. The text for Section 3.1 that has been negotiated is provided below.

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3.1 FRAMEWORK FOR CONDUCTING BASELINE ENVIRONMENTAL EVALUATIONS

The regulatory goal for the environmental evaluation component of a baseline risk assessment, as presented in subsection 1.5.2, is to characterize current and likely future ecological risks attributable to releases of contaminants from the site under investigation. The NCP specifies that [40 CFR § 300.430 (e)(2)(i)(G)]:

> Environmental evaluation shall be performed to assess threats to the environment, especially sensitive habitats and critical habitats of species protected under the Endangered Species Act (ESA).

The results of the environmental evaluation are used to help establish acceptable exposure levels for use in developing remedial alternatives [40 CFR § 300.430 (d)(4)].

In addition, the EPA framework is written generally enough to encompass both baseline and remedial action alternative evaluations. However, the application of the environmental evaluation component of the Hanford Site baseline risk assessment methodology presented herein is much more focused. Per the NCP, the methodology addresses only the releases (and subsequent fate and transport) of site contaminants (including indirect effects) within the context of the general framework and evaluates only the baseline condition(s) (see subsection 1.5.2).

Under CERCLA and related statutes, contaminants derived from a site release are the only relevant stressors from a baseline perspective. This is acknowledged by EPA (1992g) which states that ecological effects assessment links concentrations of contaminants to adverse effects in receptors. A commitment has been made by DOE-RL to develop a guidance document, in fiscal year 1993, for conducting risk assessments to support remedial alternatives evaluations performed under such statutes as CERCLA and the National Environmental Policy Act (NEPA) (S.H. Wisness, DOE-RL [letter to P.T. Day, EPA-10 and D.B. Jansen, Ecology] March 31,1992). The upcoming document will need to adopt the broad-range stressor concept set forth in EPA (1992b).

Human health and environmental evaluation processes are compared in subsection 3.1.1, the integration of ecological knowledge and goals is addressed in subsection 3.1.2, the relationship between environmental evaluations and natural resource damage assessments is discussed in subsection 3.1.3, and qualifications for ecological risk assessors are presented in subsection 3.1.4.

3.1.1 Comparison of Human Health and Environmental Evaluation

Although the analogy to the human health evaluation process is evident in Figure 3-1, the environmental evaluation process has some significant differences. The first step, problem formulation, includes contaminant identification, which forms the initial step of the human health evaluation process. The terminology is broader for the environmental process as there is a need to identify, in addition to contaminants of potential concern, habitats of potential concern (e.g., sensitive or critical habitats) and biological species of potential concern (e.g., endangered or threatened, or structurally or functionally important, species) within such habitats. To date, there exists little guidance for the identification of environmental contaminants of potential concern. The preliminary risk-based screening procedure presented in Figure 2-1a and 2-1b is recommended for all baseline environmental

evaluations. Comparison of contaminants with aquatic water quality criteria is expected as a minimum effort for scenarios involving aquatic life. Screening of contaminants using agreed upon environmental scenario(s) and risk levels is a possibility once sufficient ecotoxicological]], data are available for a given contaminant and a process has been agreed to by the Tri-Parties.

While human health evaluations focus on sensitive individuals within a single species, environmental evaluations are more complex. During the problem formulation phase, the ecological risk assessor is faced with a site at which there are numerous individuals of many species, the populations of which are organized into communities, which are the living parts of the ecosystem. The initial challenge to the ecological risk assessor is to focus, in a logical manner, the scope of the environmental evaluation to a manageable and meaningful level of effort. The appropriate focus is usually not on individuals, but on populations or higher levels of ecological organization (Barnthouse et al. 1986a).

A second departure from the human health evaluation process entails grouping the exposure and toxicity assessment into a single phase of analysis. This is done because the two assessments are often inseparable in many environmental evaluations. While biological effects on species or assemblages of species are the ultimate assessment endpoints of most baseline environmental evaluations conducted at sites with hazardous substance releases, it is often more efficient to assess these species indirectly. In conducting such indirect assessments, the boundaries of exposure and toxicity often become blurred.

An example of the indirect assessment that is quite applicable to the Hanford Site is evaluating the risk to the species comprising the freshwater aquatic community of the Hanford Reach of the Columbia River. A partial approach for such an evaluation could entail the comparison of documented, or projected, contaminant levels in the water column to water-quality criteria and standards established by the EPA (EPA 1986b) and Ecology to provide for the protection of some freshwater aquatic life. (No similar criteria for terrestrial organisms exist.)

Another significant difference between environmental and human health evaluations is that the analysis phase of the environmental evaluation process must take potential indirect effects into account. It is possible to have a significant adverse effect attributable to a release of a hazardous substance on a species of potential concern without a direct exposure or direct toxic effect on that species. An example, applicable to the Hanford Site, is the elimination of a migratory predator's prey species due to the toxic effects of a spill occurring during the predator's season of absence from the site.

Finally, a distinction needs to be made between the environmental evaluation and the biotic pathways component of the human health evaluation. These evaluations, while having the potential to share significant portions of data and much of the same methods of analysis, are separate. The species forming a major portion of the human food chain would be considered of interest from the perspective of the biotic pathways component of the human health evaluation, but may not necessarily be of interest from the perspective of the environmental evaluation. The environmental evaluation addresses ecological concerns which have been defined as those that exclude the concerns involving human ecology. These latter concerns are properly addressed within the context of the human health evaluation.

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Ecology 31. Section 3.1, page 49, third and fourth paragraphs of section

Deficiency: There is no explanation of the purported advantages of departing from the Fava, et al., framework. Although Fava, et al., was a preliminary document, the *Framework* will soon be formally issued by EPA.

Recommendation: Departing from the *Framework* should be justified to the satisfaction of all three parties, in light of the impending release of the guidance.

Initial Response: Reject. The Fava et.al. document is a summary report only and justification for departing from this document is unnecessary. The EPA document, entitled "Framework for Ecological Risk Assessment" (EPA 630/R-92/001) which has just been released and will be reviewed to see if it is applicable to the baseline risk assessment and the HSBRAM.

June 9, 1992 Status: Open. Readdress issue upon all parties reviewing the "Framework for Ecological Risk Assessment," EPA/630/R-92/001, February 1992.

Ecology Clarification, August 4, 1992:

The comment was originally written in reference to the report on the draft Framework. Since then, the final Framework has been promulgated. The overall conceptual process, Figure 1, has not changed. Some of the components have been refined, most significantly the problem definition. Validity of the comment has not diminished. If it is suggested that the Methodology depart from the Framework, then the advantages of that departure must be explained and justified. See the discussion of Comments 32 and 37 below.

Final Response: See final response to Ecology comment #30.

Ecology 32. Section 3.1, page 50, first full paragraph

Deficiency: "Habitat of potential concern" and "biological species of potential concern" are restrictive concepts. This appears to be screening procedure that could improperly eliminate significant risk.

Recommendation: See section 3.2.2.1.

Initial Response: Reject. The "habitat of potential concern" and "biological species of potential concern" are general discussion concepts. They are not meant to be screening procedures to eliminate significant risk.

June 9, 1992 Status: Open. Comment to be reviewed by S. F. Cross of Ecology.

Ecology Clarification, August 4, 1992 of Comments 32 and 37:

These two comments would be resolved by adding a clarifying explanation after the first sentence of the first paragraph of Section 3.2. State that:

> This explanation of the problem definition process is based on the Framework for Ecological Risk Assessment, which should be examined for a full understanding of the process.

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The reference to the draft Framework of Fava, et al., in the first sentence would require updating.

Revised Response: The concepts are provided as a focus that is mandated in the NCP. For example, there are provisions to evaluate, as appropriate, indirect effects and indicator species. These provisions eliminate the concern regarding potential restrictions.

Final Response: See final response to Ecology comment #30.

Ecology 33. Section 3.1, second full paragraph of page 50, last sentence

Deficiency: It is not appropriate to state that the focus of ecological importance is usually not on individuals, but populations. Such a conclusion, if appropriate, properly belongs under the determination of endpoints.

Recommendation: Delete this sentence.

Initial Response: Reject. The Ecological Assessment of Hazardous Waste Sites (EPA/600/3-89/013) states that the principal ecological effects are on the population- and community-levels, not on individuals.

June 9, 1992 Status: Closed. Reference to section 2.4.1 of the document cited in the response will be added to the text.

Final Response: See final response to Ecology comment #30.

Ecology 34. Section 3.1, fourth full paragraph of page 52, sentence

Comment: NPL site and aggregate area are not the same. List aggregate area as a separate item.

Initial Response: Accept. Aggregate area will be separated from NPL sites and will be listed as a separate item.

June 9, 1992 Status: Closed.

Final Response: See final response to Ecology comment #30.

Ecology 35. Section 3.2.1, page 54, first paragraph of section, first sentence

Deficiency: The level of ecological study at the Hanford site relative to most NPL sites is not documented.

Recommendation: Delete the first clause.

Initial Response: Reject. There are documented ecological studies for the Hanford area. For example, a public document entitled "Fiscal 1991 - 100 Areas CERCLA Ecological Investigations," WHC-EP-0448, contains a wealth of ecological information for the area.

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June 9, 1992 Status: Closed. Cite examples in text if possible.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.1.2.

Ecology 36. Section 3.2.1, bottom paragraph of page 54, second and third sentence

Deficiency: The U.S. Dept. of Interior has determined that significant natural resource concerns have the potential to be affected by releases from the sites at Hanford. A natural resource damage assessment conducted by any of the natural resource trustees would be based on injuries to natural resources remaining after cleanup. There is a critical need to involve the trustees in the ecological evaluation.

Recommendation: Revise the paragraph so that, instead of indicating that natural resource trustees will have little interest or involvement in Hanford cleanup, there are commitments to solicit trustee involvement in the ecological evaluations and cleanup decisions.

Initial Response: Accept. The text will be revised to indicate that there are commitments to solicit natural resource trustee involvement in Hanford ecological evaluation and clean up decisions.

June 9, 1992 Status: Open. Text will be provided to EPA and Ecology for review.

The following sentence will be added to the end of the paragraph:

Therefore, DOE-RL, with the assistance of EPA-10 and Ecology, are soliciting the involvement on the part of federal, state, and tribal natural resource trustees in the overall Hanford restoration process.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.1.3.

Ecology 37. Section 3.2.2.1, page 55

Deficiency: This process is restrictive. There may be habitats that do not meet the ESA regulatory definition that will nonetheless be addressed in the environmental evaluation. There may be species outside of "critical habitats" that will be addressed in the ecological evaluation. This section does not recognize the use of biomarkers, which may be measured in "unimportant" species. Notwithstanding the above, the definitions of habitats of potential concern in the context of this *Methodology* should not be restricted to those used in the ESA regulations. The definition of habitat of potential concern would have to include any habitats identified in the conceptual model as potentially exposed to contaminants.

Recommendation: Do not use the concepts of habitat of potential concern and species of potential concern.

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Initial Response: Reject. The "habitat of potential concern" and "biological species of potential concern" are general concepts.

June 9, 1992 Status: Open. Comment is to be reviewed by S. F. Cross of Ecology.

Ecology Clarification, August 4, 1992: See clarification for Comment 32.

Revised Response: The first sentence of Paragraph 3.2.2.1 refers to both critical and sensitive habitats. The remainder of p. 55 discusses critical habitats, but most of p. 58 and all of Tables 3-2 are devoted to a discussion of sensitive habitats. As sensitive habit is quite broadly defined, and provisions are included to evaluate, as appropriate, indirect effects and indicator species, Ecology's concern is addressed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.2.2.2.

Ecology 38. Section 3.2.2.2, page 58-60

Deficiency: The selection of contaminants of potential concern does not include consideration of those without ARARs that could accumulate in the food chain. The assumption that the human health methodology is also protective of the environmental is unsubstantiated, and has recently been brought into question. See *Superfund Report*, May 6, 1992, page 21.

Recommendation: Include provisions for identifying contaminants without ARARs for terrestrial and aquatic food chain effects. Remove statements linking human health and environmental evaluation.

Initial Response: DISCUSS: In addition to the screening process discussed in the document, a recommendation and discussion for the use of "best professional judgement" to evaluate additional contaminants of potential concern can be added to this section.

June 9, 1992 Status: Open. See EPA comment #16.

Ecology Clarification, August 4, 1992:

State the qualifications present in the Ecology and EPA comments. Make the technical references. Allowing for "best professional judgement" is fine, but more methodological specificity is needed. State that this subject may be further developed in the future as site specific information becomes developed.

Revised Response: The only article on environmental evaluation we found in the May 6, 1992, *Superfund Report* (Minnesota Launches Ecological Risk Assessment to Fill Guidance Vacuum, p. 21) says nothing about bioaccumulation. The major point we get out of the piece is that Hanford is a year ahead of the State of Minnesota on the subject of how to perform environmental evaluations.

We cannot remove the linkage between human health and environmental protection in the contaminant identification screening procedure. The procedure has been

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thoroughly presented, discussed, and evaluated, and no one on the RAC (or any other reviewing entity) has offered an alternative (let alone a viable alternative). In fact, the procedure has been praised by an independent group of ecological risk assessors from Oak Ridge National Laboratory.

It is interesting to note that the State of Minnesota anticipates that their guidelines will not be "terribly prescriptive" because the science for risks to ecosystems is not as well developed as that for human health effects..." The HSBRAM makes this point, as well. In order to compensate for the relative lack of knowledge in this arena, we can add language about the potential need to take best professional judgement into account for the ecotoxicity of certain substances. This can also encompass contaminant characteristics such as bioaccumulation.

Insert the following at the end of Paragraph 3.2.2.2:

> The above points provide strong arguments for the application of the human-health oriented preliminary risk-based screening procedure to environmental receptors. Given the importance of this assumption, however, best professional judgement can be used to add certain contaminants that are known, for example, to be relatively highly toxic to non-humans or to be highly concentrated in the food chain of one or more of the species of concern.
>
> Copper in aquatic habitats is an example of a substance that is not very toxic to humans, but that is highly toxic to a variety of aquatic biota. In this instance, however, a chronic ambient water quality criterion (promulgated as a standard under state regulations) exists which is factored into the preliminary risk-based screening procedure. Dichlorodiphenyltrichloroethane (DDT) and its degradation products can pose significant risks to various species, primarily because of its bioaccumulation potential. In this instance, however, DDT is considered to be a human carcinogen, and past practice has shown the preliminary risk-based screening procedure to be protective of environmental receptors.
>
> While best professional judgement can be used to expand the list of environmental contaminants of potential concern, its indiscriminant use should be avoided. One must remember that the vast majority of toxicological data developed for the protection of human health are based on bioassays carried out on environmental receptors, and that these data are almost invariably adjusted to more conservative levels to adjust for the uncertainty associated with interspecies extrapolation. In short, the preliminary risk-based screening procedures has demonstrated itself to be protective of the environment in the past, and is expected to continue to do so.

Final Response: Chapter 3 has been reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.2.2.1. Section 3.2.2.1 is provided below. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree

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DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. On March 17, 1993, clarifications to the revised text for Revision 2 of the HSBRAM were discussed and agreed upon in telephone conversations between Steve Cross of the Washington Department of Ecology, Larry Gadbois, EPA, and Nancy Lane and Steve Clark of WHC.

3.2.2.1 Stressor Characteristics. The characterization of stressors begins with the identification of chemical, radionuclide or physical stressors. Chemical stressors include inorganic and organic substances. Physical stressors include extremes of natural conditions such as temperature change, habitat alteration or destruction. In accordance with the NCP, the baseline risk assessment addresses the release of contaminants from a site and the direct and indirect effects associated with the contaminant release. Therefore, the characterization of stressors for Hanford Site baseline environmental evaluations focuses on the identification of contaminants of potential concern, as discussed below.

The preliminary risk-based screening procedure has elements specifically intended to include any contaminant which could be of concern. These include risk-based calculations and comparison to potential ARARs for human health and comparison to potential ARARs and consideration of best professional judgement for environmental health. While judgement can be used to expand the list of environmental contaminants of potential concern, indiscriminant expansion of the list should be avoided. As noted in Figures 2-1A and 2-1B, best professional judgement is significant in ecotoxicologic hazard evaluation of those contaminants of potential concern that do not exceed the specific ARARs. It is assumed that this process will be protective of both human health and ecological exposures.

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Ecology 39. Section 3.2.2.3, page 61, second paragraph

Deficiency: The definition of measurement endpoint is inadequate. The definition of measurement endpoint from the top of page 42 of RAGS Vol. II (EPA/540/1-89/001) provides a sentence that clarifies the relation of assessment to measurement endpoints.

Recommendation: Insert: "Measurement endpoints are those used in the field to approximate, represent, or lead to the assessment endpoint."

Initial Response: Accept. The "measurement endpoints are those used in the field to approximate, represent, or lead to the assessment endpoint" will be inserted in the text.

June 9, 1992 Status: Closed.

Revised Response: We recommend changing the response indicated. Measurement endpoints are not necessarily field tools. We use them on the desk top all the time.

We recommend deleting "field" from the response. The response would read "measurement endpoints are those used to approximate, represent, or lead to an assessment endpoint."

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.2.3.

Ecology 40. Section 3.2.2.3, page 61-62

Deficiency: Indicator species are the only example of measurement endpoints included.

Recommendation: Expand the examples of assessment and measurement endpoints to include those listed in tables 2-3 and 2-4 of *Ecological Assessment of Hazardous Waste Sites,* EPA/600/3-89/013.

Initial Response: Accept. The examples of assessment and measurement endpoints will include those listed in tables 2-3 and 1-4 of Ecological Assessment of Hazardous Waste Sites, EPA/600/3-89/013.

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.2.3.

Ecology 41. Section 3.2.2.3, page 61, third paragraph

Deficiency: It is not clear of what this paragraph is an example.

Recommendation: Specify the concept that this paragraph on indicator species exemplifies.

Initial Response: DISCUSS: The authors request clarification on the concern expressed in the comment.

June 9, 1992 Status: Closed. An editorial review of the second and third paragraphs will be performed to clarify the concepts.

Revised Response: Modify the third paragraph of Paragraph 3.2.2.3 as follows:

> For example, two general types of indicators species could potentially be used for measurement endpoints. "Indicator species" is a general term referring, in this document, to a species that is the focus of the evaluation, but that is not necessarily an endangered, threatened, or sensitive species.
>
> The first type of indicator species includes those species or groups of species...

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.2.3.

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Ecology 42. Section 3.2.2.3, second paragraph of page 62, second sentence

Deficiency: The last part of this sentence is unrelated to the first part. Biology itself is not an exact science. The methodology will not address budget and schedule restraints.

Recommendation: Delete ", but the actual selection is far from an exact science, and most projects are highly constrained by schedule and budget".

Initial Response: Accept in part. The paragraph will be clarified and revised to state:

> "Endpoint selections are highly site-specific. Two EPA documents, "*Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference*" (EPA 1989h) and "*Selection and Ranking of Endpoints for Ecological Risk Assessment*" (EPA 1989d) provide useful guidance on the selection of appropriate endpoints. The actual selection, however, is far from an exact science. Table 3-3 and 3-4 provide examples of good assessment and measurement endpoints. Table 3-5 provides some characteristics of assessment and measurement endpoints."

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.2.3.

Ecology 43. Section 3.2.2.3, page 63, table 3-3

Deficiency: Several of the items were changed from the EPA guidance with no explanation and resulting improvement in clarity or content. The list itself is vague without the EPA text.

Recommendation: Change "easily measured" back to "readily measured". Delete "cost-effectively measured". Explain that the items are explained in the EPA guidance, and provide a specific page or section reference.

Initial Response: Accept in part. The specific reference will be cited and the word "easily" will be changed to "readily".

June 9, 1992 Status: Closed.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Table 3-5.

Ecology 44. Section 3.3, page 64, second full paragraph

Deficiency: The cause and effect relationship of the first sentence is not explained. It is not explained why reasonable maximum exposure concepts entail the use of mean values.

Recommendation: Provide explanations.

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Initial Response: Accept. The text will be revised to clarify the maximum exposure concepts and more specific cross-references to Chapter 2 will be added, as appropriate.

June 9, 1992 Status: Open. Text will be provided for review by EPA and Ecology.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.3.

Ecology 45. Section 3.3.1, page 64, second paragraph of section, second sentence.

Deficiency: This paragraph could be improved, and the *Methodology* enhanced by providing more detailed guidance. The fact that there is less standardized ecotoxicological data than human health toxicological data creates a need for the *Methodology* to address or develop site-specific information. Because there are a limited number of habitats covering extensive areas of the Hanford site, this should be manageable. It may require a follow-up effort to supplement this Methodology.

Recommendation: The Methodology should provide for the development of site-specific ecological information.

Initial Response: DISCUSS: In the authors opinion, the methodology provides for the development of site-specific ecological information. Additional discussion on the subject is welcome.

June 9, 1992 Status: Open. Comment to be reviewed by S. F. Cross of Ecology.

Ecology Clarification, August 4, 1992:

The response does not provide a point for further discussion.

The authors may point out precisely where the Methodology "provides for the development of site-specific ecological information." The authors may reconcile the Methodology statement that "it is not possible to provide detailed guidance" with the Response that "the methodology provides for the development of site-specific ecological information." The authors may look to the Framework for Ecological Risk Assessment, Section 3.2.3, for support.

This comment reflects issues familiar to those of Comment 46. Comment 46 was accepted by USDOE. We expect to see a comprehensive list of potential site-specific ecotoxicological tests provided in the Methodology. This will help address the concerns expressed in Comment 45.

Revised Response: Ecology's follow-up comment is too vague to be readily understood (it appears they may be confusing "Site" with "site); however, it seems that they are deferring their concern to the acceptance of Comment #46. Therefore, no further action on this comment is required.

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Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.3.3.2.

Ecology 46. Section 3.3.1 and 3.3.2, pages 64-67.

Deficiency: The text only discusses ecotoxicological data that is available in the scientific literature. Ecotoxicological data from in-situ test or field studies are not included. There are many instances when data on certain contaminants or types of exposure will not be available in the literature. If the impact of these chemicals is to be considered, then Hanford-specific toxicity tests will need to be conducted, and ecological data compiled from special studies.

Recommendation: Expand the discussions in both sections to include in-situ toxicological tests and ecological field studies.

Initial Response: Accept. The discussion will be expanded to include in-situ toxicological tests and ecological field studies, as appropriate.

June 9, 1992 Status: Open. Text will be provided for review by EPA and Ecology.

Revised Response: Modify the third paragraph of Subsection 3.3.1 as follows:

> Potential sources of existing ecotoxicity information that may be useful...

Insert the following before the penultimate paragraph of Subsection 3.3.1:

> If existing ecotoxicological data are not available, it may be necessary to undertake field or laboratory studies to provide for an appropriate toxicological assessment. An impact assessment could be undertaken to determine whether or not any significant adverse impact to a sensitive or indicator community has occurred. Further information on the design and implementation of such studies is provided in Green (1979). Bioassays, conducted in either *in situ* or in the laboratory, could be undertaken to develop site-specific ecotoxicological information. Further information on the design and implementation of bioassays is provided in EPA (1989h) and EPA (1991e).

The literature cited in the above insert consists of:

R.H. Green. 1979. Sampling Design and Statistical Methods for Environmental Biologists. John Wiley and Sons, Inc. Toronto.

EPA 1991e, Technical Support Document for Water Quality-based Toxics Control, EPA/505/2-90-001, U.S. EPA, Office of Water, Washington, D.C.

EPA 1989h, Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference, EPA/600/3-89/013 U.S. EPA, Environmental Research Laboratory, Corvallis, Oregon.

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Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.3.2.2.

Ecology 47. Section 3.4, page 68, second paragraph of section

Deficiency: What does "integrated by comparison" mean? How are the results extrapolated? How does one profile exceed another?

Recommendation: Answer these questions in the text.

Initial Response: Accept. The sentence will be modified to clarify "integrated by comparison".

June 9, 1992 Status: Open. Text will be provided for review by EPA and Ecology.

Revised Response: The term "integrated by comparison" will be changed to the word "compared."

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.4.1.1.

Ecology 48. Section 3.4, page 68, fourth and fifth paragraphs of section

Deficiency: No reference is provided for the use of a procedure such as the environmental hazard quotient (EHQ) ratio, the exposure profile:dose-response ratio, and the environmental hazard index (EHI).

Recommendation: Provide a reference that justifies the use of such a procedure, and explains or demonstrates how it is conducted.

Initial Response: Accept. The text will be revised to provide an explanation of EHQ.

June 9, 1992 Status: Closed. Refer to EPA comment #21.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.4.1.1.

Ecology 49. Section 3.4, page 73, second full paragraph

Deficiency: What is a "subjective probabilistic" evaluation.

Recommendation: Explain this concept.

Initial Response: Accept. A reference or short explanation will be provided.

June 9, 1992 Status: Closed. Text will be provided for review by EPA and Ecology.

Revised Response: Change the parenthetic to:

(e.g., in the form of an evaluation employing probabilistic modeling).

Subjective probability assessment (which is a tool used in probabilistic modeling that will be explained in the Probabilistic Baseline Risk Assessment Demonstration) is the process of assigning a numeric probability distribution to a parameter that is consistent with one's subjective beliefs.

Final Response: Chapter 3 has been revised and reformatted as discussed in the final response to Ecology comment #29. The text referred to in this section is now discussed in Section 3.4.1.2. Revised text for this section was discussed and agreed to at a meeting of the inter-Agency Risk Assessment Committee on March 10, 1993. Those in attendance were Steve Cross of the Washington Department of Ecology, Audree DeAngeles, Neil Morton, and Harry Ellis of Planning Research Corporation (PRC) [representing Larry Gadbois and Dave Einan of the U. S. Environmental Protection Agency (EPA)], Karen Jones of Dames and Moore, Steve Clark and Nancy Lane of Westinghouse Hanford Company (WHC), Lonie Swenson of Golder Associates Inc., and by telephone, Eric Goller of the U.S. Department of Energy Richland Field Office. The revised text is provided below.

3.4.1.2 Uncertainty. An important element of the risk characterization process is the uncertainty analysis. This is particularly true for environmental evaluations where methods and data bases are not standardized to the extent of the human health evaluation methods and data bases. The uncertainty assessment for an environmental evaluation can range from a purely uncertainty qualitative assessment, based on best professional judgement, to a detailed uncertainty quantitative assessment (e.g., in the form of an evaluation employing probabilistic [simulation] modeling). The type of uncertainty assessment best suited for a particular environmental evaluation depends on the degree of detail and the outcome of the evaluation itself.

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The EPA (1992b) points out four categories of uncertainty that may be relevant to an environmental risk assessment:

- Conceptual model formulation — incorrect assumptions made during conceptual model development;
- Information and data — incompleteness of data or information;
- Stochasticity (natural variability) — inherent in stressors characteristics, ecological component and factors that influence their distribution; and,
- Error — introduced through experimental design or the sampling/measurement procedures.

The EPA (1989b) recommends that biotic pathway assessments (within the context of both the human health and the environmental evaluation) be regarded, at best, as semiquantitative due to a current lack of understanding of the general theoretical relationships among contaminants, ecosystems, and biological species. The EPA also notes

that biotic pathway assessment errors of up to three-to-four orders of magnitude should be anticipated. Two approaches are suggested for uncertainty analysis. The first would be a simple qualitative approach that provides an overall general statement of the degree of uncertainty based upon an evaluation by the risk assessors performing the environmental assessment. The second would consist of an entirely independent analysis using available quantitative and qualitative information relevant to the four categories of uncertainty pointed out by the EPA (1992b), above, following the problem formulation phase of the methodology. It is suggested that if the two independent analyses agree with one another sufficiently, the overall evaluation would be deemed to have an acceptably low degree of uncertainty.

The EPA (1989b) recommends that the uncertainty assessment include the following:

- Variance estimates for all statistics;
- Assumptions underlying use of statistics, indices, and models;
- The range of conditions under which models or indices are applicable; and
- Narrative explanations of other sources of potential error in the data.

In addition to the above, any data-quality deficiencies that are known to be associated with the data sets and any faulty assumptions employed in the evaluation should also be documented and addressed in the uncertainty assessment.

The uncertainty analysis discussed above is a limited approach. The alternative is to conduct a probabilistic risk assessment from the start of the evaluation. In this manner, the resulting risk distribution curve not only provides variance information, it also provides for a much more reasonable estimate of risk or likely future risk. For most environmental evaluations at the Hanford Site, however, a semi-quantitative uncertainty assessment is currently the most feasible approach.

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Ecology 50. Section 3.4, page 74, last two paragraphs of section

Deficiency: Several critical components of environmental evaluations are not included as section headings. No outline for the report is included.

Recommendation: Use the attached outline and include a discussion of any headings currently missing from section 3.

Initial Response: DISCUSS: The outline provided will be discussed.

June 9, 1992 Status: Open.

Final Response: The ecological evaluation is being reviewed in terms of the "Framework for Ecological Risk Assessment," EPA/630/R-92/001, February 1992. Use of the outline presented will be determined in terms of the framework and the deliverable required for the Remedial Investigation Phase 1 reports for CERCLA investigations. The reference to an outline is now provided in the introductory paragraphs of Chapter 3.0.

Ecology 51. Section 4.1, page 76-77, third paragraph of section

Deficiency: Ecology commented on this paragraph in the prior draft. The five criteria are presented out of context, and are beyond the scope of this methodology.

Recommendation: Refer to Ecology comments 50 and 51 on the prior draft of the *Methodology*.

Initial Response: Reject. The HSBRAM should be discussed within the context of the MTCACR. It identifies constraints under which the results of the risk assessment may be evaluated and helps put into perspective how the HSBRAM meets these constraints.

June 9, 1992 Status: Open. To be discussed internally by RL.

Final Response: Text has been revised to delete the specific mention of the five criteria.

Ecology 52. Section 4.1, first and third full paragraphs of page 77

Deficiency: These paragraphs do not recognize that carcinogenic risks for individual substances may not exceed 10^{-6} under Method B, or 10^{-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 10^{-5}. Individual substances may not pose a risk greater than 10^{-6} under Method B.

Recommendation: Revise this paragraph to provide for individual substance cleanup levels. This comment also applies to section 4.2, page 78, last sentence.

Initial Response: Accept. Text will be revised as recommended.

June 9, 1992 Status: Open. To be discussed internally by RL.

Final Response: The individual substance cleanup levels are presented in this paragraph. The text has been revised to clarify the information.

Ecology 53. Section 4.2, page 78, first paragraph, second to last sentence

Deficiency: It is not correct to state that the qualitative risk assessment includes "other site information." The qualitative risk assessment is one set of information which will be considered along with other site information in determining whether an IRM is appropriate.

Recommendation: State that the qualitative risk assessment provides the characterization of site risks that TPA representatives will evaluate with other site information to determine whether an IRM is appropriate.

Initial Response: Accept. The sentence will be revised to state "Thus, the qualitative risk assessment will provide the characterization of site risks that TPA representative will evaluate with other site information to determine whether an IRM is appropriate."

June 9, 1992 Status: Closed.

Final Response: Text has been revised as indicated above.

Ecology 54. Section 4.2, page 78, third paragraph

Deficiency: This paragraph neglects to explain the role of ARARs.

Recommendation: Explain that the cleanup requirements of ARARs can also justify an IRM.

Initial Response: Accept. Add final sentence to third paragraph stating "In addition to a risk-based trigger, an IRM may also be initiated by an ARAR trigger as discussed in DOE-RL (1991)."

June 9, 1992 Status: Closed.

Final Response: The discussion of qualitative risk assessments in Section 4.2 has been revised to a general overview. Based on discussions between the Tri-Party members of the RAC, Appendix C has been added to Revision 2 of the HSBRAM. This new appendix provides a discussion and methodology for preparing qualitative risk assessments at the Hanford Site. The paragraph referred to in the comment has been deleted in Revision 2 of the HSBRAM.

Ecology 55. Section 4.2, page 78, fifth paragraph

Deficiency: Even if the industrial/commercial scenario is used for screening purposes, it may not therefor be used for establishing acceptable exposure levels. The goal of IRMs is to achieve final cleanup levels, and avoid the expensive "second pass." The land use statements in this paragraph are unacceptable to Ecology. Use of the other scenarios will not screen fewer sites, because the qualitative risks of the sites may be ranked under any scenario.

Recommendation: A qualitative risk assessment in support of an IRM may not rely on the Hanford Site Development Plan, or scenarios based on institutional control of the site. The process of screening sites for conducting IRMs must not be confused with the determination of cleanup levels. It is feasible to use other scenarios for screening in a ranking framework rather than a threshold framework.

Initial Response: DISCUSS: Recommend reducing the scope of the discussion on the qualitative risk assessment in this document.

June 9, 1992 Status: Closed. Defer to the Risk Assessment Methodology Committee meeting scheduled for July 7, 1992, at 9 AM in the EPA Hanford Office conference room.

Final Response: The discussion of qualitative risk assessments in Section 4.2 has been revised to a general overview. Based on discussions between the Tri-Party members of the RAC, Appendix C has been added to Revision 2 of the HSBRAM. This new appendix provides a discussion and methodology for preparing qualitative risk assessments at the

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Hanford Site. The paragraph referred to in the comment has been deleted in Revision 2 of the HSBRAM.

Ecology 56. Section 4.2, third paragraph on page 79

Deficiency: IRM cleanup goals should be to meet final cleanup levels, and to avoid "second passes." Cleanup must remove all "unacceptable" risk, not just most risk.

Recommendation: Delete this paragraph.

Initial Response: DISCUSS: Recommend reducing the scope of the discussion on the qualitative risk assessment in this document.

June 9, 1992 Status: Closed. Defer to the Risk Assessment Methodology Committee meeting scheduled for July 7, 1992, at 9 AM in the EPA Hanford Office conference room.

Final Response: The discussion of qualitative risk assessments in Section 4.2 has been revised to a general overview. Based on discussions between the Tri-Party members of the RAC, Appendix C has been added to Revision 2 of the HSBRAM. This new appendix provides a discussion and methodology for preparing qualitative risk assessments at the Hanford Site. The paragraph referred to in the comment has been deleted in Revision 2 of the HSBRAM.

Ecology 57. Appendix A, tables

Deficiency: Different age groups are used to represent different pathways for the same media.

Recommendation: Explain that the numbers in the tables are default parameters available from the EPA and Ecology, and do not necessarily dictate pathway/age group relationships. The methodology should clearly state that both children and adult age groups should be used consistently for all pathways, unless documentation eliminates one.

Initial Response: DISCUSS: The authors request clarification on the comment in order to address the concerns of Ecology.

June 9, 1992 Status: Open. Comment to be reviewed by S. F. Cross of Ecology.

Ecology Clarification, August 4, 1992:

In Appendix A, age groups are not used consistently across a pathway. For example, the following table illustrates the information currently available for the residential scenario for noncarcinogens.

Pathway		Age Group Exposure Factors
Soil	-ingestion	children
	-dermal	children and adults

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Air	-inhalation	children
Groundwater	-ingestion	children
	-inhalation	adults
	-dermal	adults
Surface Water	-ingestion	children
	-inhalation	adults
	-dermal	adults
Sediment	-ingestion	children
	-dermal	children and adults
Biota	-game	adults
	-fish	adults

A literal interpretation of the above table suggests that children drink tap water, but somehow avoid taking baths, showers, or breathing the air. Likewise, these children drink surface water without getting wet or breathing the air around the river. Also, they do not eat fish from the river or fruits/vegetables from their gardens. This type of illogical situation is present on many of the tables. A consistent and conservative approach for noncarcinogens is to assume child exposure to all pathways, at a minimum, and children and adults for every pathways.

The carcinogenic Tables have similar inconsistencies. We recommend that the 30-year exposure period be divided into 6-years as children, and 24-years as adults as a standard for all carcinogenic calculations, regardless of pathway.

Revised Response: As indicated by Ecology, the age groups are not consistent among pathways for a specific scenario. The use of different age groups, however, is consistent with currently recommended risk assessment guidance and practice. The guidance used in the development of the HSBRAM all recommend a blend of age groups for evaluating the reasonable maximum exposure for multiple pathways in a scenario. These guidance documents include the "Supplemental Risk Assessment Guidance for Superfund Sites" (EPA-10 1991), "Standard Default Exposure Parameters OSWER Directive 9285.6-03" (EPA 1991a), and "Risk Assessment Guidance for Superfund: Volume 1, Human Health Evaluation Manual, Part B: Development of Risk-Based Remediation Goals, OSWER 9285.7-01B (EPA 1991d). The Model Toxics Control Act also uses different age groups to determine soil cleanup levels for different exposure pathways.

Therefore, although a literal interpretation as indicated in the clarification by Ecology is accurate, it does not consider the overall end product of the evaluation of multiple pathways for a scenario. The purpose of this overall evaluation is an estimate of exposure that is reasonable and not necessarily, the highest or most conservative. Use of the recommendations provided in the clarifications would be contrary to current national, regional, and state documents consulted in preparation of the HSBRAM.

Final Response: Based on a telephone discussion [Steve Cross, Ecology, and Lonie Swenson, Golder Associates Inc. (August 20, 1992)], the status of this comment is closed. It should be noted that the tables provided in Appendix A have been revised for Revision 2 of the HSBRAM to improve the presentation of the material.

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