

HSWA LANL G/P 98



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**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

April 2, 1998

Mr. Theodore Taylor, Program Manager  
Los Alamos Area Office  
Department of Energy  
528 35<sup>th</sup> Street  
Los Alamos, New Mexico 87544

Dr. John C. Browne, Director  
Los Alamos National Laboratory  
P. O. Box 1663, Mail Stop A100  
Los Alamos, New Mexico 87545

**RE: Request for Supplemental Information: Risk-Based Corrective Action Process, Revision 1, dated August 20, 1997, the Environmental Restoration Projects at Los Alamos National Laboratory and Sandia National Laboratories**

Dear Mr. Taylor and Dr. Browne:

The RCRA Permits Management Program (RPMP) of the New Mexico Environment Department has reviewed the Risk-Based Corrective Action Process (LA-UR-97-2811), Revision 1, dated August 20, 1997, and requests supplemental information detailed in the attachment.

LANL must respond to the request for supplemental information within thirty (30) days of the receipt of this letter. If LANL does not submit a complete response to this request within thirty (30) calendar days, LANL should be advised that a Notice of Deficiency will be issued.



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Mr. Taylor and Dr. Browne  
April 2, 1998  
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Should you have any questions regarding this letter, please contact me or Mr. John Kieling, RPMP's LANL Facility Manager at (505) 827-1558.

Sincerely,



Robert S. ("Stu") Dinwiddie, PH. D., Manager  
RCRA Permits Management Program

RSD:bt

attachment

cc w/ attachment:

J. Canepa, LANL EM/ER, MS M992  
J. Davis, NMED SWQB  
B. Garcia, NMED HRMB  
M. Johansen, DOE LAAO, MS A316  
J. Kieling, NMED HRMB  
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S. Yanicak, NMED DOE OB, MS J993  
File: Reading  
File: HSWA LANL G/P '98  
Track: LANL, 4/2/98, NA, DOE/LANL, HRMB/Dinwiddie, RE, file

## ATTACHMENT

### Request for Supplemental Information Risk-Based Corrective Action Process, Revision 1, dated August 20, 1997

#### GENERAL COMMENTS

*Because human health and ecological risk assessment methodologies have not been approved the risk-based corrective action process described in this document cannot adhere to or be consistent and logical with an integrated approach to the RCRA corrective action process.*

1. The Document of Understanding (DOU) is not a regulatory document, therefore, all references to this document are irrelevant and as such should be removed.
2. Introduction section should show how this Risk-Based Corrective Action Process (RBCAP) fits into the RCRA corrective action program.
3. LANL-SNL/NM should work with the AA to identify and incorporate the appropriate technical policy decisions, that are critical to risk management process, into the corrective action process (e.g., defining data quality objectives, determining target risk or radiation dose rate level, or addressing resource protection) prior to beginning that process.
4. LANL-SNL/NM should focus on the basic R-BCA process and discuss that any deviation from this process will be addressed, following AA approval, on a case-by-case basis.
5. This document describes a phased or tiered risk-based approach to the corrective action process, that integrates site assessment and response action with human health and ecological risk assessment to determine the need for remedial action and adapt appropriate corrective action activities to site-specific conditions and risks. The process should begin with a simple analysis (i.e., screening assessment) and evolve to more complex evaluations (i.e., a risk assessment) at the higher phase/tier of site investigations. Data collected during the site characterization/investigation, such as that leading to a RFI or the equivalent (including historical data and new data collected during site investigation), should be adequate in quantity and in quality to answer the questions posed at each phase/tier of investigation, which support the decisions made at the conclusion of each phase/tier evaluation. Note, that actions taken during the risk-based decision process should be protective of human health and the environment.

As more information and/or new data become available, this approach allows the degree of uncertainty associated with the assessment to be reduced at each higher phase/tier, resulting in modified or relaxed assumptions and/or parameter values. However, these

practices are NOT always the case with the proposed RBCAP by LANL and SNL/NM. Therefore, LANL-SNL/NM should review and revise their RBCAP to incorporate additional information/data collection requirement as the prerequisite to beginning the next phase/tier of that process.

6. Each phase/tier of the RBCA process should include an uncertainty assessment/analysis that qualitatively and/or quantitatively (if Monte Carlo or other numerical analysis techniques are employed at more complex phases of investigation) addresses potential impacts of screening or risk assessment assumptions and parameters on their estimated numerical results at each phase/tier of the assessment. As a result, the level of confidence in numerical risk and/or cleanup goals estimates can be determined for a site. The quantitative estimates of environmental risks are conditional estimates given a considerable number of assumptions about exposure and toxicity. Uncertainty about the numerical results is generally large (i.e., on the range of at least an order of magnitude or greater). Consequently, it is important to fully specify the assumptions and uncertainties inherent in the screening and risk assessment to place the risk estimates in proper perspective. Another use of uncertainty assessment/analysis can be to identify areas where a moderate amount of additional data might considerably improve the basis for selection of a remedy. Therefore, it is critical that this analysis identifies the key site-related variables and assumptions that contribute most to the uncertainty.

There are several categories or sources of uncertainties associated with site screening and risk assessments and consequently, risk-based cleanup goals/levels. One is the initial selection of constituents used to estimate exposures and risk on the basis of the sampling data and toxicity information. Other sources of uncertainty are inherent in the toxicity values for each constituent used to estimate risk. Additional uncertainties are inherent in the exposure assessment for individual constituents and individual exposures. These uncertainties are usually driven by uncertainty in the constituent monitoring data (e.g., by using laboratory or otherwise qualified data or lack of quantitation in the chemical/radiochemical analyses) and the models (e.g., environmental fate and transport models) used to estimate exposure concentrations in the absence of monitoring data, but can also be driven by population intake parameters and their assumed values. The likelihood of exposure pathways and land uses actually occurring is the other uncertainty that may result from the definition of a site physical setting. Finally, additional uncertainties are incorporated in the screening or risk assessment due to uncertainty associated with toxicity values for each constituent used to estimate risk and multiple substance/constituent and multiple pathway exposure assumptions. All these categories or sources must be evaluated and their combined impact on the risk and risk-based cleanup goal/level estimates must be addressed.

Therefore, LANL-SNL/NM should review and revise the proposed RBCAP to include uncertainty analysis, as discussed above. The results of uncertainty analysis should indicate the potential impact of each key assumption on estimated risk and risk-based

cleanup goal/level values with respect to both direction (e.g., may under- or over-estimate risk) and magnitude (e.g., order of magnitude) of the impact. Those impacts should be considered at the conclusion of each phase/tier evaluation.

7. All applicable ecological and human health-based criteria and their role in the risk-based corrective action process (RBCAP) should be clearly defined at each phase/tier of the investigation.
8. A relation, if any, between the introduction section and the subsequent sections/chapters of this document should clearly be identified.
9. No ecological/environmental health-based criteria have been identified nor applied in the proposed RBCAP, therefore, a "no further action" (NFA) proposal is an invalid risk management option. This is because without ecological impacts evaluation, it cannot be determined whether or not human health-based decisions will be protective of the environment.
10. LANL-SNL/NM have failed to discuss the development of the site conceptual model prior to beginning the screening assessment and risk assessment. A preliminary site conceptual model should be developed prior to beginning site investigation and it should be updated as new data/information becomes available (i.e., at each higher phase/tier of the RBCAP).
11. LANL-SNL/NM have failed to address the data requirements at the screening and risk assessment phase/tier levels of the proposed process. Therefore, LANL-SNL/NM should review and revise that process to include the data requirement characterizations.
12. LANL-SNL/NM have failed to address the potential ground water and surface water concerns. Therefore, both facilities should propose the approach to address the risk-based corrective action process applicable to those sites where adverse impacts to ground and surface water quality are likely.
13. LANL-SNL/NM have failed to address the potential environmental fate and transport processes and mechanisms. This document should propose the approach to address environmental fate and transport mechanisms for contaminants at the sites, e.g., bioaccumulation/biomagnification, surface runoff, etc.
14. These review comments do not address technical quality of related documents that discuss statistical analysis methods used for the Environmental Restoration Project at LANL (e.g., such as Ryti et al. (1996) or Project Consistency Team). These documents will be addressed under separate review process.

15. Screening assessment has failed to consider potential risks to ecological receptors. Therefore, LANL-SNL/NM should review and revise their approach to include ecological screening assessment into their RBCAP.
16. Site screening decisions should be made based on background comparisons of inorganic constituents and risk-based screening assessment. The risk-based screening tools applied at this phase/tier of the risk-based corrective action process should consider both potential risk to human health and the environment and use conservative, i.e., protective, non-site-specific (i.e., generic) health-based criteria. As more site-specific data and information become available, thus, reducing the level of uncertainty, more relaxed technical assumptions may be used at more complex phases/tiers of the investigation.
17. Adequate analytical methods must be selected to conduct site characterization, i.e., to delineate the nature and extent of site contamination. These investigations must occur prior to background comparison of inorganic chemicals and risk-based screening. Screening assessment should not be performed at sites where the nature and extent of contamination are undefined. Therefore, the discussion of analytical methods and any relevant QA/QC issues should be moved to page 3 and incorporated into Section i (General Assumptions).
18. The multiple chemicals evaluation employed during the screening assessment, as proposed, does not ensure adequate protection of human health from potential exposure to multiple noncarcinogenic contaminants. Therefore, this multiple chemicals evaluation should be reviewed and revised for consistency with the screening process described in the draft HRMB position paper entitled "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached).
19. As discussed in Comment #6, the uncertainty analysis component should be included into both screening and risk assessment result interpretations and used to support risk management decisions.

## SPECIFIC COMMENTS

### 1. Introduction

20. Page 1, 2nd paragraph: "Many of the assumptions that follow in the *Risk-Based Corrective Action Process* (RBCAP) are agreed upon in the Document of Understanding (DOU) ... the DOU have information relative to RBCAP assumptions. As LANL and SNL/NM regulators concur with additional RBCAP assumptions, the agreed-upon assumptions will be formalized in future annexes of the DOU or in facility-specific documents, as necessary."

**Comment:** The Document of Understanding (DOU) is not a regulatory document, therefore, the reference to this document is irrelevant and should be removed. LANL-SNL/NM should identify any technical assumptions or criteria that have been agreed upon or approved by the AA and document these agreements or approvals.

21. Page 1, 4th paragraph, 5th sentence: "Following initial identification of a solid waste management unit (SWMU) or an area of concern (AOC), archival information is reviewed to determine if existing data will support NFA."

**Comment:** LANL-SNL/NM should:

- 1) identify and define any type of information referred to as "existing data";
- 2) revise this sentence to include "proposal for" in front of "NFA", to read: "Following initial identification of a solid waste management unit (SWMU) or an area of concern (AOC), archival information is reviewed to determine if existing data and information will support proposal for NFA." Please use the same qualifier each time the NFA is mentioned.

22. Page 1, 4th para, 6th sentence: "If not, sampling and analysis plans are developed and implemented."

**Comment:** LANL-SNL/NM should review and revise this sentence to assure that sampling and analysis plans are approved by the AA prior to their implementation.

23. Page 1, 5th para. A reference is made to Figure A-1 in Appendix A.

**Comment:** LANL-SNL/NM should:

- 1) explain the role of "approvals" or "reviews" in the corrective action process or remove these legend items and revise the diagram for \*R designation. The legend to this diagram is unclear in that no documented attempt has been made to explain the role of identified items, such as "DOE approval" or "NMED review", in the corrective action process. Item noted "\*R" could not be located in the diagram;
- 2) remove note located under this diagram: "Explanatory text for this diagram can be found in a future annex (nearly completed) of the Document of Understanding (NMED et al., 1995)" because it text refers to the future annex. Explanatory text should be included within the Appendix to explain the diagram.

24. Page 2, Figure 1 showing LANL-SNL/NM Decision Framework for the RCRA Corrective Action

- Comments:
- 1) The decision framework should address both human and ecological health criteria;
  - 2) LANL-SNL/NM should revise the figure to acknowledge that the nature and full extent of environmental media contamination are delineated prior to the site screening;
  - 3) The 4th box ( "Site Screening Decision") should include the following steps:
    - a) comparison of the maximum constituent concentrations to background levels of inorganics (and radionuclides) to answer whether or not constituent concentrations are greater than their respective background concentrations. If no, propose for NFA. If yes, move to the next step.
    - b) comparison of the maximum constituent concentrations to generic human and ecological health-based criteria, i.e., applicable standards, if available or human health screening action levels (HHSALs) and ecological health screening action levels (EHSALs). These comparisons should answer whether or not constituent concentrations are greater than standards or HHSALs and EHSALs. If the answer is "NO" to both questions, proposal for NFA may be warranted. If the answer is "YES" to any of these two questions, move to the next (5th) box, which should call for collection of additional information or site-specific data to support corrective action decision.
  - 4) The 5th box "Facility may perform preliminary risk assessment" implies that there is another option than a preliminary risk assessment option at this stage of the RCRA corrective action process. If another option is considered at this stage, please identify this option. If the sole option is that of a preliminary risk assessment, please identify how a preliminary risk assessment differs from the screening assessment. It is recommended that no risk assessment be performed (either preliminary or not) prior to collecting additional site-specific data and/or information and updating the site conceptual model.
  - 5) LANL-SNL/NM should identify the accelerated cleanup verification or confirmation procedure in this figure.
  - 6) The Decision Framework shows that if a site does not qualify for accelerated cleanup, a corrective measures study (CMS) is required (see box 8th). The 8th box calls for preliminary remediation goals to be discussed or re-evaluated at this point. However, these preliminary remediation goals have

been mentioned for the first time in the 8th box. Therefore, it is unclear when and how they are proposed to be developed.

## II. Site Screening Decision Assumptions

### i. General Assumptions

26. Page 3, 1st para, 1st sentence identifies that sites can be proposed for NFA when "sufficient archival data/information exist(s), site characterization data is complete, or cleanup confirmation data is complete".

Comment: LANL-SNL/NM should:

- 1) identify source(s) of "archival data/information";
- 2) revise this sentence to read "Sites can be proposed for NFA under the HSWA Module when .... site contamination is fully characterized (i.e., the nature and extent of contamination has been delineated) or cleanup is verified/confirmed and NFA criteria (listed below) are met".

27. Page 3, assumption 1, 1st para, 3rd sentence refers to the DOU as a source of NFA criteria.

Comment: Remove any reference to the DOU (see also Comment #1).

28. Page 3, assumption 1, last bullet, NFA Criterion 5, 1st sentence states that the PRS can be proposed for NFA if it has been characterized or remediated in accordance with current applicable state or federal regulations, and the available data indicate that contaminants pose an acceptable level risk under current and projected future land use.

Comment: LANL-SNL/NM should revise this sentence to read: "The PRS has been characterized or remediated in accordance with current applicable state or federal regulations (whichever is more stringent), and the available data indicate that contaminants pose an acceptable risk level under current and projected future land use."

29. Page 3, assumption 2., 1st sentence refers to "historical process knowledge and screening samples" as the information sources utilized to focus sampling and analysis plans.

Comment: 1) Since decisions about analyte lists must be based on reliable information sources, LANL-SNL/NM should indicate how the historical process knowledge will be documented to assure its reliability.

2) LANL-SNL/NM should describe how "screening samples" are obtained .

30. Page 3, assumption 2., 2nd sentence states that when any degree of uncertainty is involved, then a full-scan analysis may be necessary.

Comment: LANL-SNL/NM should define a "full-scale analysis" .

31. Page 3, assumption 2. This assumption states that professional judgment and/or results from field survey techniques can be used to bias the location and the number of samples needed for site characterization.

Comment: LANL-SNL/NM should not base the RCRA corrective action decisions solely on a professional judgment. Defensible technical documentation must be available to make these decisions. However, professional judgment can be used in conjunction with results of the surveys using appropriate field survey techniques and instruments. Therefore, LANL-SNL/NM should revise this paragraph to read: "Results from field surveys using adequate techniques and instruments can be used to bias the location of and the number of samples needed for site characterization in order to increase the probability of detecting contaminants relative to purely random sampling approaches."

## ii. Background Comparison Assumptions

32. Pages 3 and 4, assumption 4.

Comment: 1) LANL-SNL/NM should define the natural (unaffected) background and state that this concept applies to naturally occurring inorganic chemicals only, including those radioactive (see the draft HRMB position paper entitled "*Application of Background Concentrations in the Risk Assessment Process*" [attached] for the definition of stable inorganic chemicals).

2) LANL-SNL/NM should review and revise assumption 4 to assure its consistency with the procedure described in the draft HRMB position paper entitled "*Application of Background Concentrations in the Risk Assessment Process*" (attached). Any deviation from this procedure must obtain the AA approval on a case-by-case basis, prior to its implementation.

3) LANL-SNL/NM should review and revise the 1st paragraph on page 4 to ensure that the selection of statistical methods for background comparisons will consider the shapes of the distributions of constituent concentrations .

4) Discussion of background values development appears to be unnecessary in this document. Most of SNL/NM's background soil values have already been

approved by the AA and these approved values should be used to select contaminants of potential concern for soil at SNL/NM sites. LANL's background soil values have not yet been approved by the AA, however, they are subject of a separate review process. Only constituent concentration values that will be approved as those representing natural background for LANL can be used in the background comparison process.

5) Although values representing natural background constituent levels may and will likely differ for both LANL and SNL/NM due to the difference of geological systems and mineralogy at both laboratories, data analyses assumptions and the assumptions affecting the use of background as a contaminant screening tool should be similar for both facilities. Therefore, LANL and SNL/NM should review and revise the appropriate text on page 4 to address consistent use of statistical tools at both facilities. Graphical comparisons of data (data plots), including background and PRS data, are always valuable methods helping understand the shape of the examined data and, therefore, select appropriate statistical methods or tests of their analyses.

6) SNL/NM should review and revise the shaded text in box on page 4 to exclude the comparison of the lead concentrations to the EPA guidance screening values, because it is irrelevant to this section, i.e., the background comparison assumptions.

### iii. Screening Assumptions

33. Page 5, screening assumptions.

Comment: 1) The title of this chapter should be revised to read: "Human Health Risk-Based Screening Process and Assumptions" since LANL-SNL/NM address only the screening process using human health risk-based criteria;

2) LANL-SNL/NM have failed to present a preliminary site conceptual model;

3) LANL-SNL/NM should propose the screening approach consistent with that outlined in the draft HRMB position paper entitled "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached).

34. Page 5, assumption 5, 1st paragraph, 1st sentence states that a screening assessment is performed to evaluate potential soil contaminants.

Comment: LANL-SNL/NM should discuss the process leading to selection of soil as the only environmental medium to be evaluated.

35. Page 5, assumption 5, 1st paragraph, 4th sentence informs that the screening process has been completed at SNL/NM because it has fewer potential release sites.

Comment: 1) SNL/NM has failed to state whether or not the AA has approved the screening methodology prior to its implementation by the facility;

2) This sentence disagrees with information in the shaded box on page 6 implying that no screening assessment has been performed at SNL/NM sites. Instead, SNL/NM has performed an obscure preliminary risk evaluation using probabilistic techniques. The latter could not be addressed by this review because SNL/NM has failed to present and discuss the evaluation criteria, their technical basis, and data requirements. SNL/NM must decide whether or not it has completed a screening assessment at the ER Project sites. The screening process must be consistent with that described in the draft HRMB position paper entitled "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached). If the screening process has been completed at all SNL/NM ER Project sites, its technical basis and results should become available to the AA. One possible use of these results could be to guide any further investigation at those sites that have failed the screening, e.g., to conduct a preliminary risk evaluation.

Therefore, SNL/NM should review and revise this information to propose a step-by-step approach to conducting a preliminary risk evaluation. Again, a preliminary risk evaluation is applicable to those SNL/NM sites that have failed a screening level assessment, assuming that the latter is consistent with the process described in the draft HRMB position paper entitled "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached).

36. Page 5, assumption 5, bullets 1 through 5. These bullets identify SALs as the tools used to identify chemicals of potential concern (COPCs) and determine the need for further investigation.

Comment: LANL-SNL/NM should:

1) define SAL's, identify their technical basis, and

2) review and revise these bullets to include the definition of SALs consistent with that provided in the draft HRMB position paper entitled "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached).

37. Page 5, assumption 5, 4th bullet refers to a target dose used to derive SALs for radionuclides and the use of RESRAD code to calculate SALs for these constituents.

- Comment: 1) LANL-SNL/NM should define the target dose of radionuclides and the risk level this target dose is associated with;
- 2) LANL-SNL/NM's dose and risk calculation model should include radiation exposure from dermal contact with high energy beta-emitters or the omission of this potential exposure pathway should be justified;
- 3) Exposure parameter values adopted by the RESRAD computer code may differ from those considered as "standard EPA-recommended" residential exposure parameter values. LANL-SNL/NM should develop an attachment containing proposed exposure parameter values for the use as RESRAD input parameters and have them approved by the AA prior to their use;
- 4) Because the RESRAD code models environmental fate and transport of radioactive contaminants at the site, it is important that LANL-SNL/NM have the site-specific input parameter values approved prior to their use.

38. Page 5, assumption 5, 5th bullet, 1st sentence: "In general, the maximum observed concentration, rather than an average of several observations, is compared with SALs/ALs in order to identify COPCs. "

Comment: The RPMP technical policy is that the maximum observed constituent concentrations are used to screen COPCs (see the draft HRMB position paper entitled "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" [attached]). Therefore, LANL-SNL/NM should revise this sentence to read: "The maximum observed constituent concentrations are compared with SALs/ALs in order to identify COPCs."

39. Page 5, assumption 5, 5th bullet, 3rd sentence: "In some cases (with prior approval from regulators), observations made on composite samples, or averages of closely related samples such as field duplicates, may be compared with SALs/ALs to identify COPCs."

Comment: The RPMP technical policy is that only observations made on discrete samples and the maximum observed constituent concentrations are used to screen COPCs (see the HRMB position paper entitled "*Compositing of Soil Samples during Site Characterization*"). Therefore, LANL-SNL/NM should remove the sentence.

40. Page 5, assumption 5, 5th bullet, last sentence states that SALs are based on exposure to contaminants in surface soils.

Comment: LANL-SNL/NM should justify the use of surface soil contamination as the sole basis of SALs development and develop an approach addressing subsurface contamination.

41. Page 5, assumption 5, shaded box, 1st bullet, 2nd sentence: "Analytes that exceed background require further action if they also exceed SALs or if the analyte contributes significantly to the multiple chemical evaluation (MCE)."

Comment: LANL-SNL/NM must review and revise this sentence to reflect the RPMP technical policy regarding application of SALs that is outlined in the draft HRMB position paper entitled: "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached).

42. Page 5, assumption 5, shaded box, bullets 1 and 2 discuss the source and use of SALs at LANL.

Comment: LANL-SNL/NM must review and revise these bullets to reflect the RPMP technical policy decisions regarding SALs's development and application that are presented in the draft HRMB position paper entitled: "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached).

43. Page 5, assumption 5, shaded box, 2nd bullet, 3rd sentence: "As required and when sufficient toxicity data are available in the peer-reviewed literature, LANL ER Decision Support Council personnel will calculate SALs for chemicals not included in the Region IX database."

Comment: 1) LANL must review and revise this sentence to read: "As required and when sufficient toxicity data are available in the peer-reviewed literature, LANL ER Decision Support Council personnel will calculate SALs for chemicals not included in the most recent EPA Region VI, IX, or III tables. These SALs will be calculated using methodology outlined in the HRMB position paper entitled: "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" and submitted for the AA approval prior to their use."

2) SNL/NM must develop the procedure to calculate SALs for chemicals not included in the most recent EPA Region VI, IX, or III tables. The SALs shall be calculated using methodology outlined in the draft HRMB position paper entitled: "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached) and submitted for the AA approval prior to their use.

44. Page 5, assumption 5, shaded box, 2nd bullet, 6th sentence states that when toxicity data are not available, surrogate chemicals will be chosen to evaluate toxicity.

Comment: LANL-SNL/NM should review and revise this sentence to read: "Constituents without toxicity data available will be carried through to a baseline risk assessment."

45. Page 5, assumption 5, shaded box, 2nd bullet, 7th and 8th sentences: "For PCBs, a SAL of 1ppm will be used for field screening at industrial sites (EPA 1994: Section [a][3][ii]). A SAL of 0.1 ppm will be used at residential sites."

Comment: LANL-SNL/NM should explain what kind of "field screening" they intend to perform at industrial and residential site. If the purpose of this "field screening" is to delineate the extent of PCB contamination prior to selecting the type of exposure scenario to be evaluated and a SAL value to be used (i.e., industrial or residential), the PCBs fate and transport mechanisms must be evaluated. In addition, LANL-SNL/NM should revise and correct reference for PCBs SALs (PCBs SALs could not be located in the EPA's document (i.e., EPA, 1994) referenced).

46. Page 5, assumption 5, shaded box, 3rd bullet identifies the target radiation dose level to calculate SALs at 10 mrem/yr.

Comment: Assuming that the target radiation dose rate level is consistent with the RPMP technical policies, it is unclear how this target dose rate will be applied to generate SALs for individual radionuclides. Therefore, LANL-SNL/NM should discuss a step-by-step process of developing those SALs.

47. Page 5, footnote 1 defines radiation dose as the effective dose equivalent resulting from external and internal radiation doses acquired through inhalation or ingestion of radionuclides.

Comment: Both inhalation AND ingestion routes of exposure to radionuclides will result in internal exposure dose. In addition, dermal contact with high energy beta-emitters, which is not considered here, can result in substantial radiation dose to an individual. Therefore, LANL-SNL/NM should revise the footnote to read: "Dose is defined as the effective dose equivalent as incurred by exposure of an individual to external and internal radiation from inhalation and ingestion of and dermal contact with radionuclides."

48. Page 6, shaded box identifies a preliminary risk evaluation, "additional assessment activities", and "another risk evaluation" as tools in the process leading to NFA proposal or a cleanup action.

**Comment:** This discussion appears to be irrelevant to the screening assessment process. In addition, it is hard to follow the logic, if any, of discussion presented in this box. Therefore, SNL/NM should review and revise the appropriate text in the shaded box to assure consistency with the screening assessment process outlined in the draft HRMB position paper entitled: "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached) OR delete this text and work with the AA to adequately describe a risk assessment process.

49. Pages 6 and 7, assumption 6 describes the multiple contaminant evaluation process at LANL and SNL/NM.

**Comment:** The technical assumptions applied to the multiple contaminant evaluation process deviate substantially from the RPMP technical policy decisions presented in the draft HRMB position paper entitled: "*Human Health Risk-Based Screening Action Levels and Screening-Level Assessment*" (attached). Therefore, LANL-SNL/NM should review and revise the process of multiple contaminants evaluation during the screening level assessment to ensure consistency with the RPMP position.

50. Pages 7 and 8, assumption 7 addresses the choice of analytical methods to detect constituents in the site media and measure their concentrations.

**Comment:** Adequate analytical methods must be selected to conduct site characterization, i.e., delineate the nature and extent of the site contamination. This occurs prior to background comparison of inorganic chemicals and risk-based screening. Therefore, LANL-SNL/NM should move assumption 7 to page 3 incorporating it into Section i (General Assumptions).

51. Page 7, assumption 7, 1st bullet states: "SW 846 methods (when available) are used for fixed analytical laboratories unless other methods are justified."

**Comment:** LANL-SNL/NM should review and revise this sentence to read: "SW 846 methods (when available) or approved equivalent methods are used for fixed analytical laboratories."

52. Page 8, 1st bullet addresses the use of field analytical methods to detect constituents and measure their concentrations in the site environmental media.

**Comment:** LANL-SNL/NM should review and revise this bullet to ensure consistency with the RPMP technical policy presented in the HRMB position paper entitled: "*Field Screening/Field Analytical Technologies*".

53. Page 8, 3rd bullet (in shaded box) suggests the use of statistical tools to verify correlation between field and fixed analytical laboratory results to support site decisions.

Comment: Use of statistical tools to determine or verify any correlation between field and fixed analytical laboratory results can easily lead to meaningless conclusions. Therefore, LANL-SNL/NM should revise this bullet to assure that only fixed analytical laboratory results and those field techniques identified as appropriate in the HRMB position paper entitled: "*Field Screening/Field Analytical Technologies*" will be used to support RCRA corrective action decisions OR delete this bullet.

54. Pages 8 and 9, assumption 8 addresses corrective action decision criteria for those sites that failed the risk-based screening assessment stage.

Comment: The risk-based screening assessment and the criteria addressed in assumption 8 do not consider potential ecological impacts evaluation. Therefore, NFA proposal cannot be an option for these sites. Thus, LANL-SNL/NM should revise assumption 8 to address ecological health risk-based concerns.

55. Page 8, assumption 8, 1st bullet: Further Evaluation implies "More in-depth analysis of available data, e.g., using site-specific exposure assumptions, or collection of additional data following screening."

Comment: Exposure assumptions can be modified or relaxed only if additional, e.g., site-specific information, becomes available. This may occur after completion of the screening being a non-site-specific process that triggers collection of additional information and/or site-specific data if a site has failed it. Therefore, LANL-SNL/NM should revise this statement to clarify that further site evaluation may occur only in the presence of additional site-specific information or data.

56. Page 8, assumption 8, 1st bullet: Risk Assessment discussion.

Comment: This discussion is unclear and appears to confuse the data requirements for different phases of the risk-based corrective action process. Therefore, LANL-SNL/NM should revise this bullet to assure that:

- 1) the screening (i.e., comparison of the maximum constituent concentrations with background levels of inorganics and SALs/ALs), as a non-site-specific assessment, uses existing data and information; and

2) following the screening, additional information (e.g., resulting from the research of scientific literature) or collection of additional site-specific data are necessary for those sites where active clean-up is not an option.

57. Page 8, assumption 8, 1st bullet: Risk Assessment, 2nd sentence states that "Preliminary risk can be assessed using conservative assumptions and existing data."

Comment: In this sentence, the preliminary risk assessment process appears to be synonymous with the screening assessment. If in fact, it is synonymous, LANL-SNL/NM should state that preliminary risk assessment is a non-site-specific assessment; if it is not - LANL-SNL/NM should revise this sentence by identifying preliminary risk assessment information and/or data requirements.

58. Page 8, assumption 8, 1st bullet: Risk Assessment, 3rd sentence: "Additional data may be required for the baseline risk assessment if the current data are not adequate to support risk assessment decision (see assumptions 10 -17)."

Comment: LANL-SNL/NM should revise this sentence to read: "Additional information and site-specific data may be required for the baseline risk assessment if the current data are not adequate to support risk management decision." In addition, assumptions 10 through 17 **do not belong** to this section and thus, the reference to them should be removed.

59. Page 8, assumption 8, 1st bullet: Accelerated Cleanup, 4th condition under which accelerated cleanup can proceed for sites that failed the risk-based screening without further evaluation if there is acceptable knowledge available to adequately identify COPCs.

Comment: LANL-SNL/NM should define the acceptable knowledge and then, revise the bullet to read: "acceptable knowledge is available to adequately identify and quantify COPCs, ... ."

60. Page 8, assumption 8, 1st bullet: Accelerated Cleanup, 6th condition states that "the remedy is not worse for the ecosystem, worker safety, or public health than the problem;"

Comment: LANL-SNL/NM should describe the criteria used to determine whether or not "the remedy is worse for the ecosystem".

61. Page 8, assumption 8, 1st bullet: Accelerated Cleanup, 7th condition reads: "uncertainties can be handled by contingencies in the accelerated cleanup plan, and stopping criteria are defined;"

Comment: LANL-SNL/NM should:

- 1) identify those contingencies and the nature and role of stopping criteria;
- 2) propose an approach to address cleanup verification/confirmation.

62. Page 8, assumption 8, 1st bullet:, paragraph before the last, 1st sentence implies that risk-based screening can be performed in the case where extent of contamination in not adequately defined.

Comment: RPMP technical policy prevents from performing a risk-based screening assessment, either human health or ecological, prior to characterizing the nature and extent of site contamination. In addition, this sentence appears to be contrary to the first sentence of assumption 8 stating that identification of COPCs (i.e., screening) proceeds any decision about further action at the site. Please, clarify this inconsistency.

63. Page 9, assumption 8, 1st bullet: Stabilization.

Comment: Please clarify whether in place on-site or off-site stabilization is of concern.

64. Page 9, assumption 8, 1st bullet: Stabilization, 3rd condition states that sites may be considered for stabilization if appropriate technologies are available to deal with the known contaminants.

Comment: Please clarify whether treatment technologies are of concern here and revise the sentence to read: "appropriate [treatment ?] technologies are available to deal with the contaminants."

65. Page 9, assumption 8, 1st bullet: Stabilization, 5th condition states that sites may be considered for stabilization if the stabilization is not worse than the problem for the ecosystem, worker safety, or public health .

Comment: LANL-SNL/NM should describe the criteria used to determine when "the stabilization is worse than the problem for the ecosystem".

66. Page 9, assumption 8, shaded box, 2nd bullet, last sentence: "However, the risk related to the PAHs will be presented as part of the background risk characterization."

Comment: LANL-SNL/NM should revise this bullet to read: "However, the risk related to the PAHs will be presented as part of the baseline or anthropogenic background risk characterization."

67. Page 9, assumption 9 identifies that approaches for ecological screening and risk assessment will be consistent with guidance in the EPA *Framework for Ecological Assessment* as further detailed in the draft *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*.

Comment: An approach to ecological screening assessment should be presented in this section and the results of this screening should be used in conjunction with the results from the human health screening (discussed in this section) to make risk management decisions. This approach should be similar to that developed for human health screening assessment (see above).

LANL-SNL/NM should update the principal reference documents to include: *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*; Interim Final, June 5, 1997.

The approach to ecological screening assessment should be consistent with that identified as Step I (Screening-Level Problem Formulation and Ecological Effects Evaluation) and Step II (Screening-Level Exposure Estimate) in the EPA document entitled: *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*; Interim Final, June 5, 1997. Any deviation from this approach must be approved by the AA prior to its implementation.

LANL-SNL/NM should outline the ecological screening approach prior to assumption 7.

### III. Risk-Based Decision Assumptions

68. Page 9, risk-based decision assumptions.

Comment: LANL-SNL/NM should revise this title to distinguish between these risk-based decision assumptions and those discussed in Section II of this document.

69. Page 9, assumption 10, 1st bullet states that individual sites will be aggregated, as necessary, for appropriate risk evaluation.

Comment: This approach seems to be reasonable and justified, especially if hazardous waste released at one site has been transported to another site or if cumulative risks are of concern (e.g., for ecological assessments). However, if more than one site is included into an aggregate subjected to risk evaluation (either human or ecological health-based), then risks associated with each individual site should also be evaluated separately. This risk information may be used to determine the degree to which any individual site contributes to the

total risk estimated for an aggregate (in order e.g., to prioritize the contributing sites for the need of further action) and to make any RCRA corrective action decision for an individual site.

Therefore, LANL-SNL/NM should revise this bullet to address these concerns.

70. Page 9, assumption 11, 1st bullet, 1st sentence: "Decisions made after comparison of individual observations to a SAL/AL are based on generic, conservative assumptions."

Comment: LANL-SNL/NM should revise this sentence to read: "Decisions made after comparison of the maximum observed constituent concentrations to a SAL/AL are based on generic, conservative assumptions."

71. Page 9, assumption 11, 1st bullet, 2nd sentence states that appropriate site-specific risk assessments may differ from screening conclusions because the exposure assumptions underlying the SAL/AL calculation are not site-specific, and also because risk depends on the extent and distribution of contamination rather than the maximum observed concentration.

Comment: Screening level assessment is usually performed when there is little site-specific information available, thus, the high degree of uncertainty is associated with it's conclusions. Screening assessment is designed to identify these data/information gaps to be addressed following the screening for those sites that have failed the screening. The use of the maximum observed constituent concentrations is not the only example of site-specific data limitations. Therefore, following the screening, more site-specific information is usually acquired and additional data may be collected, thus, reducing the level of the uncertainty. This latter may allow for modifications of original or non-site-specific exposure assumptions and parameter values which, in turn, may lead to less stringent risk estimates and conclusions. LANL-SNL/NM should review and revise the sentence to address these concerns and remove the statement implying that "... risk depends on the extent and distribution of contamination rather than the maximum observed concentration."

72. Page 10, assumption 11, 1st bullet states that chemicals with the detection limits exceeding the SALs/ALs may be evaluated qualitatively and eliminated from further consideration if, based on process knowledge, they are not expected to be present at a site.

Comment: This issue should be discussed earlier in Section II among QA/QC issues. Analytical methods used to support this risk-based RCRA corrective action process decisions should be sufficiently sensitive to achieve the detection limits well below the levels of human or ecological health concern. Whether or not an analyzed constituent is unrelated to the site activities should be determined

prior to the risk-based screening process. Therefore, LANL-SNL/NM should delete the bullet or revise it to state that chemicals identified as COPCs because the detection limit was greater than their respective SALs/ALs will be carried through to a risk assessment.

73. Page 10, assumption 11, 2nd bullet states that if a chemical having a detection limit greater than SAL is expected to be present, it will be included in the risk assessment calculations with the assumption that it is present at a concentration equal to one-half the detection limit.

Comment: Again, this issue should be discussed earlier in Section II among QA/QC issues. Analytical methods used to support this risk-based RCRA corrective action process decisions should be sufficiently sensitive to achieve the detection limits well below the levels of human or ecological health concern. Whether or not an analyzed constituent is unrelated to the site activities should be determined prior to the risk-based screening process. Although this approach might generally be acceptable it may not be sufficiently protective in the cases of substances with the high toxic potency. Therefore, LANL-SNL/NM should revise this bullet to ensure that chemicals having high detection limits will be carried through to a risk assessment.

#### **i. Human-Health Risk Assessment**

74. Page 10, assumption 12 identifies the basis for the determination of land-use scenarios to be evaluated.

Comment: Current and potential future land use determination should be made for a site prior to beginning the screening assessment and ideally, this information should be used to base the exposure assumptions and scenarios upon during the screening level evaluation. This comment is somehow consistent with PCBs' discussion presented in the shaded box on page 5 (Section iii. entitled "Screening Assumptions", assumption 5). Therefore, LANL-SNL/NM may consider relocating this assumption to Section II.

75. Page 10, assumption 12, 2nd bullet, 1st sentence: "Conceptual models for specific sites consider all exposure pathways appropriate for the site and all populations potentially exposed in a specific scenario."

Comment: Risk-based decisions must be protective of the most sensitive groups of human population, therefore, LANL-SNL/NM should revise this sentence to read: "Conceptual models for specific sites consider all exposure pathways appropriate for the site and all populations potentially exposed in a specific scenario, including sensitive groups of population, such as children ."

76. Page 10, assumption 12, 4th bullet in the 2nd shaded box refers to the future land use designation at SNL/NM, which is recreational or industrial. These future land use designations are consistent with those approved by the Citizen's Advisory Board.

Comment: NMED is currently considering the appropriate land use designations for SNL/NM.

77. Page 10, assumption 13, 1st sentence states: "Estimation of risks to human health is based on reasonable and site-specific exposure assumptions."

Comment: 1) The RPMP technical policy is that potential risk to human health is evaluated using reasonable maximum exposure (RME) assumptions and exposure parameter values. LANL-SNL/NM should apply the RME assumptions and exposure parameter values in the absence of the documented and technically defensible site-specific data. A facility may elect, but is not required, to additionally evaluate an average exposure of an individual (or "central tendency exposure") or other exposure situations (e.g., using probabilistic techniques) to support risk management decisions. Therefore, LANL-SNL/NM should revise this sentence to read: "Estimation of risks to human health is based on reasonable maximum exposure (RME) of an individual and site-specific exposure assumptions and parameter values." In addition, LANL-SNL/NM should propose an approach to be used in the absence of the documented and technically defensible site-specific exposure assumptions and parameter values.

2) Based on a site conceptual model, LANL-SNL/NM should identify the principal exposure pathways and receptors to be evaluated.

78. Page 10, assumption 14 states that water exposure pathway is selected when data indicate that water resources may be impacted. Surface water pathways are also considered, as appropriate.

Comment: LANL-SNL/NM should:

1) clarify whether or not "water resources" are synonymous with "ground water resources" and revise this assumption accordingly;

2) specify the criteria used to determine whether or not ground water resources may be impacted by a site contaminated media and when it is appropriate to consider surface water exposure pathways for risk evaluation;

3) work with the AA to identify ground water and surface water exposure pathways for routine evaluation under different exposure scenarios.

79. Page 10, assumption 14, 1st shaded box, 1st bullet states that the potential contaminant migration to ground water may be modeled when the potential for transport to ground water exists.

Comment LANL-SNL/NM should propose an approach to determine the potential for contaminant transport to ground water. Please, identify and discuss the methods or specific models used to predict the potential contaminant migration to ground water. Note, that these models must be calibrated and validated prior to their use.

80. Page 11, assumption 15 identifies a baseline risk assessment as a tool to provide a basis for NFA at sites where COPCs have been identified.

Comment: LANL-SNL/NM should discuss the data requirements for this baseline risk assessment.

81. Page 11, assumption 15, 2nd bullet states "If the total carcinogenic risk posed by a PRS is within the  $10^{-4}$  -  $10^{-6}$  risk range (or lower), and the non-carcinogenic risk threshold has not been exceeded, the site may be proposed for NFA."

Comment: Please define the non-carcinogenic risk threshold.

82. Page 11, assumption 15, 4th bullet discusses use of the RESRAD code to calculate radionuclide cleanup levels and identifies a target dose limit of 15 mrem/yr above background as a basis for these calculations.

Comment: LANL-SNL/NM should:

1) clarify that a target dose limit of 15 mrem/yr represents the total dose received from all site-derived radionuclides;

2) describe the process of calculating individual radionuclide cleanup levels using the RESRAD code and this total dose limit of 15 mrem/yr;

3) discuss the difference, if any, between these cleanup levels and the radiological SALs/ALs (see Comment number 37);

4) address the concerns identified in comments number 37. 2), 3), and 4).

83. Page 11, assumption 15, 4th bullet, 3rd sentence states that: for volumetric radiological contamination (soil, rubble, etc.), cleanup levels are proposed on a site-specific basis for each nuclide present and are generally calculated using the RESRAD computer code.

Comment: If cleanup levels for some nuclides will be calculated using means other than the RESRAD computer code LANL-SNL/NM should identify those other methods.

84. Page 11, assumption 15, 5th bullet, the first two sentences state: "In most cases, radionuclide health assessments are presented in terms of dose (the DOE and EPA measure for limiting risk associated with radionuclides). In those cases for which the risk associated with radionuclides influences decisions associated with other COPCs at the site, the radionuclide risk may also be presented in terms of carcinogenic risk (for qualitative comparison only)."

Comment: LANL-SNL/NM should review and revise these two sentences to ensure that slope factors for radionuclides are used to estimate excess cancer risk from radionuclide exposure to compare with EPA's target risk range of 1 in 10,000 to 1 in 1,000,000 lifetime excess cancer risk for cleanup. For comparison with radiation protection standards and dose limits, dose conversion factors (DCFs) should be used to estimate radiation dose equivalent resulting from site-related exposures.

85. Page 11, assumption 16, 1st bullet, last sentence states that when appropriate, alternative statistical models will provide estimates of reasonable maximum exposure.

Comment: LANL-SNL/NM should state the criteria or conditions appropriate to apply alternative statistical models and define those models. Note, that any alternative statistical model must be approved by the AA prior to its use.

86. Page 11, assumption 16, 2nd bullet states that the exposure areas/volumes are established through the DQO process using appropriate land use assumptions and in general, these exposure areas/volumes will be consistent with the selected exposure scenario. The smallest area or volume to which a receptor would be exposed over the entire exposure period determined by that scenario will be used.

Comment: LANL-SNL/NM should discuss the defensible approach to delineate the exposure areas and volumes. Please, provide the technical justification for applying the assumption of "the smallest area or volume" to estimate a receptor exposure and address the protection of human health under this assumption.

## **ii. Ecological Risk Assessment**

87. Page 12, assumption 17 discusses the approach to conduct ecological risk evaluation.

Comment: LANL-SNL/NM should revise this assumption to ensure consistency with the AA-approved ecological screening/risk assessment methodologies for both facilities.

#### **IV. REMEDY SELECTION AND IMPLEMENTATION ASSUMPTIONS**

88. Page 12, assumption 18 states: "Site-specific land-use assumptions and exposure scenarios (Assumptions 12 and 13) are considered in establishing preliminary remediation goals and media cleanup standards, and also in risk assessments to estimate the reduction of risk realized by a potential corrective action."

Comment: LANL-SNL/NM should explain the difference in the way preliminary remediation goals (PRGs) and media cleanup standards or levels (MCLs) are generated and applied. Assumption 18 implies that PRGs and MCLs are products of processes other than risk-based. Please, define both concepts focusing on the data requirement and assumptions used to develop them.

89. Page 12, assumption 19 states that target risk and dose levels will be set following EPA, NMED, and DOE guidance.

Comment: RPMP has determined the target risk level for the Group A and B carcinogens at  $10^{-6}$  and for Group C carcinogens -  $10^{-5}$ .

90. Page 12, assumption 19, 2nd bullet states that for volumetric radiological contamination (soil, rubble, etc.), cleanup levels are proposed on a site-specific and ALARA basis for each radionuclide present. For unrestricted release of residential sites, a target level of 15 mrem/yr above background is used.

Comment: LANL-SNL/NM should revise this bullet to state that a target level of 15 mrem/yr applies to the total radiation dose rate from all radionuclides present at the site (see also Comment number 82).

91. Page 12, assumption 19, 3rd bullet states that risk due to background inorganics will be calculated and presented to regulators for consideration in the establishment of appropriate cleanup level decisions.

Comment: Although it is not required by the AA, the background inorganic risk estimate may be used in support of the risk management decisions.

92. Page 13, assumption 21, 2nd bullet, 4th condition states that ALARA considerations may lead to selection of a goal above the dose-based goal (up to 100 mrem/yr) if conditions make the ultimate goal unachievable.

Comment: LANL-SNL/NM should revise the bullet to ensure that if this occurs, institutional controls will be implemented to protect public health and the environment.

93. Page 13, assumption 21, 3rd bullet states that elements of subjectivity remain in any ALARA decision.

Comment: Although this statement is generally truthful it may be irrelevant in the context of the RCRA corrective action process that requires corrective action decisions be documented and technically defensible. Thus, LANL-SNL/NM should remove the bullet.

94. Page 13, assumption 21, 5th bullet states that the principle of ALARA is consistent with the CERCLA process for remedy selection.

Comment: LANL-SNL/NM should remove this bullet as irrelevant or revise it to address the RCRA corrective action process for remedy selection.

95. Page 13, assumption 22, 1st bullet: "Verification sampling plans based on nature and extent will be designed to collect the appropriate number of samples to calculate a 95% UCL to compare to cleanup levels."

Comment: LANL-SNL/NM should revise this sentence to read: "Verification sampling plans based on nature and extent of contamination will be designed to collect the appropriate number of samples to calculate a 95% UCL of the mean contaminant concentration to compare to cleanup levels."

96. Page 13, assumption 22, 2nd bullet, 2nd sentence states that for radionuclides, identification of hot spots and evaluation of non-uniform radiological contamination will follow RESRAD and other applicable DOE guidance.

Comment: The attainment of cleanup levels for radionuclides as described above is unclear and should be revised to ensure its technical defensibility. For instance, it is unclear how RESRAD, i.e. a computer code developed to estimate radiation dose, risk, and dose-based radionuclide cleanup levels, can serve as DOE guidance for identification of hot spots and evaluation of non-uniform radiological contamination.

97. Page 13, assumption 23 states that if media cleanup levels are unattainable using the selected remedy, an alternative remedy (e.g., conditional) and/or cleanup goals/levels will be negotiated.

Comment: LANL-SNL/NM should:

- 1) define the conditional remedy;

- 2) identify the parties involved in these negotiations and propose negotiation criteria.

## V. Risk-Based Decision Factors and Risk Management Assumptions

98. Page 13, assumption 24, 1st sentence: "The procedures described to this point are used to develop a consistent qualitative or quantitative evaluation of site risks at LANL and SNL/NM."

Comment: Since the procedure of qualitative evaluation of site risks at LANL or SNL/NM has not been described to this point, LANL-SNL/NM should revise this sentence to read: "The procedures described to this point are used to develop a consistent quantitative evaluation of site risks at LANL and SNL/NM."

99. Page 13, assumption 24, bullets 1st through 7th .

Comment: These bullets describe the uncertainties inherent in any risk analysis and identify the elements of a cost-benefit analysis. The uncertainty and cost-benefit analyses should be conducted separately. The uncertainty analysis elements are incomplete, as identified by these bullets (see Comment number 6). Risk management decisions should consider integrated results (expressed either in a qualitative or numerical form or both) of both the uncertainty and cost-benefit analyses. Therefore, LANL-SNL/NM should revise these bullets to ensure that at a minimum, key sources of uncertainties will be addressed.

100. Page 14, continuation of assumption 24 identifies technical policy issues impacting remedy selection decisions.

Comment: LANL-SNL/NM should revise the 24th assumption to ensure that the risk management assumptions are consistent with the AA technical policy decisions for the RCRA corrective action process for remedy selection.

## Appendix B: Dermal Exposure Assessment

101. Pages B-1 and B-2, Figure B-1 presenting the framework to evaluate the importance of dermal exposure decisions.

Comment: LANL-SNL/NM should revise the framework to ensure that:

- 1) actual measured values of dermal permeability coefficient be used for the inorganics, if available in the latest published literature;

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2) the latest dermal permeability constants for organics and inorganics in water and soil be applied, if available in the published literature ;

3) all dermal exposure parameter values are consistent with the RME dermal exposure defaults parameters from the updated EPA Exposure Factors Handbook (1998) and the latest published literature.

**HAZARDOUS AND RADIOACTIVE MATERIALS BUREAU**  
**New Mexico Environment Department**

*Position Paper*



*Position Paper*

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**HUMAN HEALTH RISK-BASED SCREENING ACTION LEVELS AND  
SCREENING-LEVEL ASSESSMENT**

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**The nature, rate and horizontal and vertical extent of contamination MUST be determined PRIOR TO a screening level assessment.**

**1.0 Introduction**

Human Health Screening Action Levels (HHSALs) are non-site-specific, media-specific human health risk-based constituent concentrations that would most likely be protective of human health under residential and industrial/commercial worker exposure scenarios. However, these levels should not be viewed as an alternative of or a substitute for a site-specific risk assessment. They should **not** be used for the following:

1. To determine clean up or "no-action" levels at RCRA Corrective Action sites;
2. To substitute for applicable risk assessment guidance;
3. To determine if a waste exhibits hazardous characteristics (40 CFR 261); or
4. To determine ecological impacts or evaluate ecological concerns.

**Providing that all constraints in Section 3.0 of this paper are met, the facility may use the most recent EPA Region 6 *Human Health Media-Specific Screening Levels* (HMSSLs) table (the "table") as a source for HHSAL values (Attachment 1). **The table addresses stable chemical inorganic and organic constituents; it does not address radioactive constituents.****

All HMSSL values in the table are risk-based with noted exceptions. These values can be applied directly as screening values if only a single contaminant contributes nearly all of the human health risk at the site. The following discussion identifies the

methodology behind the HHMSSL calculations, their limitations, and provides detailed instructions for the recommended uses of the values within the table.

## **2.0 HHMSSL and HHSAL Development**

Chemical-specific HHMSSL values were calculated using the following non-site specific or generic conditions:

- default exposure assumptions, pathways, and parameter values,
- target risk level of  $10^{-6}$  for Class A or B carcinogens and  $10^{-5}$  for Class C carcinogens in a single medium (i.e., water, air, fish muscle tissue, or soil), and
- target risk level with a hazard quotient equal to one for non-carcinogens in a single medium (i.e., water, air, fish muscle tissue, or soil).

Exposure pathways considered for specific land use conditions (i.e., residential or industrial) are ingestion, dermal contact, and inhalation.

The table also contains soil screening levels for the protection of air and ground water. These soil screening levels incorporate the same exposure assumptions as HHMSSLs, along with additional assumptions concerning inter-media transfer or transport of contaminants (EPA's *Draft Soil Screening Level Guidance*). As such, soil screening levels should be distinguished from HHMSSLs.

## **3.0 Constraints on HHMSSL and HHSAL Application**

HHMSSLs have many limitations that must be considered prior to their use. Below are some important limitations of HHMSSLs and instructions for their use:

1. A consultation with the Administrative Authority ~~toxicologist/risk assessor~~ should take place prior to making a final decision in the corrective or remedial action process;
2. The screening level assessment should only be used in the preliminary stages of the site investigation;
3. The screening levels only address human health protection;
4. Food-chain transfer of contaminants, except for consumption of fish caught as a result of recreational fishing; and cumulative risk from multiple contaminants and multiple media are specifically excluded from consideration in the calculation of HHMSSLs;
5. Exposure to chemical mixtures (specifically for non-carcinogens) are not accounted

for because HHMSSLs were developed for a single contaminant in a single medium.

6. If more than one non-carcinogen is identified or expected to be present in the environmental medium at the site, the non-carcinogenic chemical HHMSSL value should be divided by a safety factor of 10 for comparison with the maximum contaminant concentration in that medium;
7. For carcinogens, HHMSSLs account for exposure to multiple contaminants because the non-carcinogenic HHMSSL values correspond to the lower end of the 1E-04 to 1E-06 "risk range";
8. Exceedance of a screening level in the site environmental medium does not indicate that a corrective action is required. It may indicate that a site-specific and more detailed analysis is needed;
9. If future residential land use cannot be definitely ruled out, unrestricted land use (residential) exposure parameter values should be considered for the initial screening of sites or contaminants of potential concern (COPCs);
10. COPCs can be selected using the HHMSSL values once the screening levels for the non-carcinogenic contaminants are divided by a safety factor of 10 to account for exposure to chemical mixtures.

In summary, if more than one contaminant is identified in the site environmental medium, the human health risk-based screening assessment should compare the maximum observed/detected concentration or activity of each contaminant in that medium to the following:

1. A carcinogenic effect HHMSSL or HHSAL, which is a risk-based concentration calculated using a conservative target risk (i.e., based on lower end of the 1E-04 to 1E-06 "risk range") to account for multiple carcinogenic contaminants for carcinogens, and
2. A noncarcinogenic effect HHSAL, which equals 10% of HHMSSL value to account for exposure to chemical mixtures.

Therefore, contaminants can be screened out or eliminated from further evaluation (i.e., from a site-specific human health risk assessment) as COPCs if maximum detected concentrations or activities of contaminants in a given medium are below 1E-06 cancer risk HHMSSL/HHSAL or below a HHSAL hazard quotient of 0.1. Constituents which failed this screening should be carried through to a risk assessment.

In addition, the HHMSSL/HHSAL approach can be utilized by HRMB reviewers to spot-check formal RCRA documents containing screening-level and baseline risk assessments addressing human health risks.

The HHMSSL table compiles information from the following sources:

- draft**
1. EPA Region IX Preliminary Remediation Goal (PRG) values for tap water and direct soil exposure;
  2. EPA Region III Risk-Based Concentration Table values labeled "I" for tap water and soil, and values for ambient air, fish, and soil screening levels;
  3. EPA's Draft Soil Screening Level Guidance values for soil;
  4. EPA Region 6 Current and Proposed National Primary and Secondary Drinking Water Regulations Table (values labeled MCLs for drinking water);
  5. Risk Assessment Guidance for Superfund (RAGS);
  6. Health Effects Assessment Summary Tables (HEAST);
  7. Agency for Toxic Substances and Disease Registry Toxicological Profiles;
  8. EPA Provisional Guidance technical reference documents;
  9. Region 6 Draft Supplemental Guidance to RAGS technical reference documents;
  10. OSWER Directives policy documents (e.g., residential soil lead screening level); and
  11. Elemental Composition of Surficial Materials in the Conterminous United States and OSWER Regional Toxics Coordinators Memorandum titled "Background Metals in Soil" dated March 14, 1989, values for soil regional background.

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New Mexico Environment Department

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**USE OF TOLERANCE INTERVALS TO CALCULATE CONSTITUENT CONCENTRATIONS REPRESENTATIVE OF NATURAL BACKGROUND**

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For adequate review, HRMB must be provided the entire data set (including non-detectable constituent concentrations, background data points on a map indicating all sampling locations) used to perform the statistical analysis and the type of statistical analysis performed. **The use of tolerance intervals is conditional upon review of this data set and approval of this procedure by HRMB.**

The use of tolerance intervals is an alternate approach to the analysis of variance in determining the presence of statistically significant contamination if 50 percent or more of the observations are quantified (i.e., above the detection limits) AND the original data distribution is normal or normally distributed after logarithmic transformation (EPA 1989). For those data sets which do not meet these requirements, HRMB will determine the applicability of the procedure based on careful review of the data sets provided.

A tolerance interval is constructed from data obtained from (uncontaminated) background locations. The site constituent concentrations are then compared with the tolerance interval. If the site constituent concentrations fall outside the tolerance interval, contamination may be present.

Tolerance intervals may be used for determining statistically significant contaminant concentrations if the following criteria are met and documented:

1. Tolerance intervals are appropriate for use at sites that do not exhibit high degrees of spatial variation. The presence of homogeneous soil types must be verified. The tolerance interval approach is appropriate for sites that overlie extensive homogeneous geologic deposits (e.g., thick homogeneous lacustrine clays) that do not naturally display geochemical variations.

- draft
2. The data set must be inspected for outliers (i.e., unusually high or low values) and their identity and source (such as analytical laboratory transcription errors) must be documented.
  3. A normality test must be applied to the data set prior to the selection of the tolerance interval approach.
  4. The tolerance interval must be calculated using an adequate data set (i.e., a minimum of 8 data points).
  5. At a minimum, HRMB requires a ~~minimum~~ coverage<sup>1</sup> of 95 percent. And HRMB requires a tolerance coefficient<sup>2</sup> of percent. This means that when one has a confidence level of 95 percent, the upper 95 percent tolerance limit (UTL) contains at least 95 percent of the distribution of observations from background location data.
  6. Calculated UTLs must be compared to human health and ecological screening values to determine relevance of the UTL values.
  7. Variability within each data set must be defined (i.e., minimum and maximum constituent concentrations, detection limit and frequency of detection, arithmetic average constituent concentration value, and the standard deviation).

## REFERENCES

US EPA, 1989. *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities - Interim Final Guidance*, NTIS PB89-151047.

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- <sup>1</sup> The coverage is defined as a specified proportion (percent) of the population of background observations (i.e., constituent concentrations) that is contained within a tolerance interval with a specified tolerance (or confidence) coefficient.
  - <sup>2</sup> The tolerance coefficient is defined as the probability with which the tolerance interval includes the proportion of the population of background observations.

**HAZARDOUS AND RADIOACTIVE MATERIALS BUREAU**  
**New Mexico Environment Department**

*draft*

*Position Paper*



*Position Paper*

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**APPLICATION OF BACKGROUND CONCENTRATIONS IN THE RISK  
ASSESSMENT PROCESS<sup>1</sup>**

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**Issue:** This paper will attempt to provide a technically defensible application of background values in the risk assessment process and will eliminate the need to include chemicals which are naturally elevated in the environment. Background concentrations, for the purpose of this concept paper, are defined as naturally-occurring inorganic chemical concentrations. These concentrations are relied on by project managers (and risk assessors) to identify areas of release, define nature and extent of contamination, and to determine if a corrective action is required at a site. At times, background concentrations may aid in expediting the corrective action process by providing a fast comparison of detected chemical concentrations to background concentrations to determine if a release has occurred.

There are multiple concerns in deciding if background concentrations should be established. There are even more issues in how to establish background concentrations. This paper does not deal with address those issues. What is assumed by this paper is that background concentrations have been adequately established and that they are considered to be representative of the natural distribution of these chemicals. The question now lies in how to use these representative values in the risk assessment process.

**Proposal:** Unpermitted chemical releases are investigated and cleaned under RCRA. Corrective actions historically have not included the requirement of cleaning down to below naturally-occurring inorganic background levels. Therefore, chemicals with detections (investigative sample concentrations) below background concentrations can be dropped as

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chemicals of concern. This will remove the chemicals from the baseline risk assessment and consequently from being considered in establishing clean up levels.

Chemicals with maximum measured values above naturally-occurring background concentrations should be considered chemicals of concern, after taking into account frequency of detection, relative concentrations and presence/absence of the chemicals in other media matrices. These chemicals should be considered in the baseline risk assessment or in any interim activities. The potential risk for those chemicals should be estimated based on the actual detected values or as representative concentrations (e.g., upper confidence limit). Background concentrations should not be subtracted from actual detected values. However, risk due to background may be calculated for comparison purposes.

**Conclusion:** This approach will provide for a clear use of naturally-occurring background values in the risk assessment process and eliminate the need of including chemicals which are naturally elevated in the environment. Representative site-specific background concentrations or regional background values should be approved by the regulatory authority prior to their use. Regional background values are available in the **Environmental Protection Agency Region 6's Human Health Media-Specific Screening Levels**.

1. This Position Paper developed jointly with Environmental Protection Agency Region 6 and adapted from the concept paper of the same title dated October 9, 1997.

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